**APPENDIX 5**

# 

# Randomized Lifestyle Studies (Priority 1)

**Akgul Gundogdu, N.; Sevig, E. U.; Guler, N.**

**The effect of the solution-focused approach on nutrition-exercise attitudes and behaviours of overweight and obese adolescents: Randomised controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Internal (University) support |  |  |
| Country | Turkey |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| Outcomes other  than BMI | Other Obesity, glucose metabolism, lipids, behaviors |  |  |
| IRB | Approval was obtained from the Ethics Committee of University Clinical Studies. Adolescents and their families were informed and written consent was  obtained. | | |
| Population | | | |
| Inclusion criteria | 12-13 years (14 initially included, but later excluded), no diagnosed metabolic disease, could communicate, did not have any condition (disability, cardiac  reasons, etc) hindering them from performing exercise, overweight or obese (BMI>=85th) | | |
| Exclusion criteria | Could not continue to the end, had a metabolic disease, w ere using metformin, or moved out of the city | |  |
| Group differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Solution-Focused Approach (SFA) Interviews | Usual Care | Overall |
| N enrolled | 16 | 16 | 32 |
| Sex | 62.5% female, 37.5% male | 43.7% female, 56.3% male | NR |
| Age (mean and range) | 12.62 | 12.68 | NR |
| Race | NR | NR | NR |
| BMI-SDS | 2.96 (2.52-3.33) | 3.10 (2.68-3.23) | NR |
| Interventions | |  |  |
|  | Solution-Focused Approach (SFA) Interviews | Usual Care |  |
| Intervention as defined by author | Solution-focused interview s about the adolescents' nutrition and exercise behaviors, their habits they w anted to change, and how to  do it. | The control group received no intervention. The adolescents in the control group continued to receive monthly and three-monthly routine care in the polyclinic. In polyclinic care, routine diagnostic examinations of the adolescents were conducted and their treatments were given  by their doctors. |  |
| Intervention Type | Lifestyle | Usual Care |  |
| Intervention  Length | 6 months | 6 months |  |
| Intensity as  described by authors | Eight interview s, 30-45 minutes, every two weeks | The adolescents in the control group continued to receive monthly and three-monthly routine care in the polyclinic |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |
| Provider type | Subspecialist, other | Subspecialist |  |
| Clinic setting | Specialty clinic | Specialty clinic |  |
| Components | Nutrition counseling, activity counseling, motivational interviewing | Usual care only |  |

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| --- |
| Outcomes |
| BMI |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1  month |  |  |  |  | 6  months |  |  |  |  |
|  | median | IQR (low er  bound) | IQR (upper  bound) | p (w ithin  group) | p (betw een  groups) | median | IQR (low er  bound) | IQR (upper  bound) | p (w ithin  group) | p (betw een  groups) |
| Solution-Focused Approach  (SFA) Interview s | 30.85 | 27.99 | 33.92 | - | - | 27.68 | 24.8 | 30.27 | <0.001 | <0.001 |
| Usual Care | 30.87 | 28.07 | 33.69 | - | - | 32.16 | 30.2 | 35.12 | 0.02 | - |
| BMI-SDS |  |  |  |  |  |  |  |  |  |  |
|  | 1  month |  |  |  |  | 6  months |  |  |  |  |
|  | median | IQR (low er bound) | IQR (upper bound) | p (w ithin group) | p (betw een groups) | median | IQR (low er bound) | IQR (upper bound) | p (w ithin group) | p (betw een groups) |
| Solution-Focused Approach  (SFA) Interview s | 2.96 | 2.52 | 3.33 | <0.001 | - | 2.42 | 1.73 | 2.74 | <0.001 | <0.001 |
| Usual Care | 3.1 | 2.68 | 3.23 | - | - | 3.1 | 2.74 | 3.35 | 0.338 | - |

**Anderson, Yc; Wynter, Le; Grant, Cc; Cave, Tl; Derraik, Jgb; Cutfield, Ws; Hofman, Pl**

**A Novel Home-Based Intervention for Child and Adolescent Obesity: the Results of the Whanau Pakari Randomized Controlled Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported by grants from the Health Research Council of New Zealand, the Royal Australasian College of Physicians, the Maurice and Phyllis  Paykel Trust, the Taranaki Medical Foundation, and Lotteries Health Research Committee. | | |
| Country | New Zealand |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethics approval w as granted by the Central Health and Disability Ethics Committee (New Zealand) (CEN/11/09/ 054). Written and verbal inf ormed consents w ere  obtained from all participants or their guardians. | | |
| Outcomes other than  BMI | Other obesity, Glucose metabolism, Psychosocial, Mental Health, Behaviors |  |  |
| Population | | | |
| Inclusion  criteria | Eligible participants (recruited January 2012-August 2014) w ere aged 5 to 16 years and had BMI>98th percentile or>91st percentile w ith w eight-related  comorbidities. | |  |
| Exclusion  criteria | Exclusion criteria included significant medical or psychological conditions leading to an inability to undertake physical activity or participate in group sessions, a  lack of “readiness” to make lifestyle changes based on a quantitative and qualitative assessment, and the absence of a committed family member | | |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Whanau Pakari Intervention | Control ("Minimal Treatment") | Overall |
| N | 69 | 69 | 138 |
| Sex | 49% f, 51% m | 58% f, 42% m | NR |
| Age | 10.7 (3.0) | 10.3 (3.2) | NR |
| Race | 45% Maori, 41% New Zealand European, 14% other | 42% Maori, 48% New Zealand European, 10% Other | NR |
| BMI SDS | 3.08 (0.58) | 3.05 (0.57) | NR |
| Interventions | |  |  |
|  | Whanau Pakari Intervention | Control ("Minimal Treatment") |  |
| Intervention as defined by author | Received 6-month follow -up w ith home visits and assessments w ith advice, as w ell as a multidisciplinary team meeting review w ith pediatrician oversight to address any identified w eight-related comorbidities. Those in the intensive intervention group also participated in a 12-month multi- disciplinary program w ith w eekly group sessions delivered by a physical  activity coordinator, dietitian, and psychologist. | Both groups received 6-month follow -up w ith home visits and assessments w ith advice, as w ell as a multidisciplinary team meeting review w ith pediatrician oversight to address any identified w eight-related comorbidities. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  Length | 12 months | 12 months |  |
| Intensity as  described by authors | 12-month multi-disciplinary program w ith w eekly group session | Participants in both groups receiving comprehensive assessments and advice at each 6-month follow -up for 2 years. |  |
| Assigned  intensity | >=52 hours | <5 hours |  |
| Provider  types | Primary care, nutrition provider, mental health, exercise | Primary care, nutrition |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training,  mental health, community recreation center | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Whanau Pakari  Intervention | 78 | -0.13 | -0.19 | -0.06 | NS | 69 | -0.1 | -0.19 | -0.02 | NS |
| Control ("Minimal Treatment") | 72 | -0.08 | -0.15 | -0.02 | - | 69 | -0.12 | -0.2 | -0.03 | - |

**Arauz, Boudreau Ad; Kurowski, Ds; Gonzalez, Wi; Dimond, Ma; Oreskovic, Nm Latino families, primary care, and childhood obesity: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Robert Wood Johnson Foundation, Massachusetts General Hospital Multicultural Affairs Career Development Aw ard |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the Partners IRB. |  |  |
| Outcomes other  than obesity | Other labs, lipids, glucose metabolism, psychosocial, behaviors |  |  |
| Population | | | |
| Inclusion criteria | Eligible participants w ere 1) Latino children 2) ages 9–12 years w ho w ere 3) overw eight or obese (age- and gender-specifıc BMI in the 85th–94th and95th  percentile, respectively) w ho received primary care at a single community health center | | |
| Exclusion criteria | Children w ith chronic diseases other than asthma w ere excluded. |  |  |
| Group differences | Randomized |  |  |
| Special  populations | Latino |  |  |
|  | Pow er Up (Intervention) | Waitlist control | Overall |
| N | 14 | 12 | 26 |
| Sex | 35.7% male, 64.3% female | 41.7% male, 58.3%  female | NR |
| Age (mean and range) | 10.2 | 10.4 | NR |
| Race | Hispanic (64.3% 1st immigrant generation) | Hispanic (41.7% 1st immigrant  generation) | 100%  Latino |
| BMI-SDS | 2 | 2.2 | NR |
| Interventions | |  |  |
|  | Pow er Up (Intervention) | Waitlist control |  |
| Intervention as defined by author | The intervention consisted of tw o components: (1) Pow er Up classes that educated children and caregivers about healthy  behav-iors surrounding nutrition, activity, and stress management and(2) culturally sensitive coaching to empow er families to incorporate learned behaviors and address both family and social barriers to lifestyle changes. | Usual care |  |
| Intervention type | Lifestyle | NA |  |
| Intervention  Length | 6 months | NA |  |
| Intensity as described by authors | Pow er Up is a 1.5-hour interactive curriculum for overw eight/obese children and their caregivers of -fered at an urban community health center during early evening hours. Classes w ere conducted in fıve consecutive w eekly sessions, w ith a sixth 3 months later. + All families met w ith the coach in person at least once, follow ed by periodic in-person or phone meetings during the 6 months after enrollment. Home visits w ere offered and families w ere encouraged to have contact  w ith the coach at least monthly; how ever, each family’s pref erences and needs dictated the setting and timing of meetings | NA |  |
| Assigned intensity | 5-25 hours | NA |  |
| Provider types | Primary care, nutrition provider, exercise, other (health educator) | NA |  |
| Components | Nutrition counseling, activity counseling, activity training, motivational interview ing, community health center | Usual care only |  |

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| --- | --- | --- | --- |
| Outcomes |  | | |
| BMI SDS |  |  |  |
|  | 6 months  N | Mean | SD p (w ithin group) p (betw een groups) |
| Pow er Up (Intervention) | 13 | -0.03 | 0.14 0.05 1 |
| Waitlist control | 10 | -0.05 | 0.08 0.13 |

**Armstrong, S.; Mendelsohn, A.; Bennett, G.; Taveras, E. M.; Kimberg, A.; Kemper, A. R.**

**Texting Motivational Interviewing: A Randomized Controlled Trial of Motivational Interviewing Text Messages Designed to Augment Childhood Obesity Treatment**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Duke MedicalCenter Institutional Review Board approved all procedures(Pro00050555) and w e registered the trial on Clinical-trials.gov  (NCT01989065). | | |
| Outcomes other  than BMI | Behaviors, other |  |  |
| Population | | | |
| Inclusion criteria | Eligibility criteria included age 5–12 years and BMI>=95th percentile adjusted for age and sex. | |  |
| Exclusion criteria | We excluded participants w ith an underlying medical condition leading to obesity (endocrine or genetic disorder, or currently on a medication know n to cause  w eight gain), w hose parents or guardians did not have access to or ow n a cell phone, or w ho w ere unable to read and w rite in English. | | |
| Group differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Intervention (Texting + Healthy Lifestyles) | Control (Healthy Lifestyles only) | Overall |
| N | 47 | 54 | 101 |
| Sex | 36.2% male | 40.7% male | 38.6% male |
| Age (mean and  range) | 10.7 | 9.4 | 9.9 |
| Race | 53.2% black, 23.4% w hite, 23.4% other; 17.0% Hispanic | 42.6% black, 35.2% w hite, 21.4% other; 20.4% Hispanic | 47.5% black, 29.7% w hite, 22.8% other;  18.8% Hispanic |
| BMI (no z  reported) | 29.1 | 28.9 | 30.5 |
| Interventions | |  |  |
|  | Intervention (Texting + Healthy Lifestyles) | Control (Healthy Lifestyles only) |  |
| Intervention as defined by author | Parent participants randomized to the intervention group received usual care plus daily ( Monday–Friday) text messages on their designated mobile device for 12  w eeks. | Control group received standard care, w hich included monthly  lifestyle counseling visits by a physician and dietician. Standard care participants received text message reminders for the 3-month study outcomes visit. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  Length | 12 w eeks | 12 w eeks |  |
| Intensity as  described by authors | Usual care + daily ( Monday–Friday) text messages on their designated mobile device for 12 w eeks | Monthly lifestyle counseling visits, text message reminders for the 3- month study outcomes visit |  |
| Assigned  Intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider | Primary care, nutrition provider |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |  |
| Components | Nutrition counseling, activity counseling, other (texting) | Nutrition counseling, activity counseling |  |

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| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Median | IQR (low er bound) | IQR (upper bound) | p (betw een groups) |
| Intervention (Texting + Healthy Lifestyles) | 47 | 0.1 | 0 | 0.2 | 0.2 |
| Control (Healthy Lifestyles only) | 54 | 0 | -0.1 | 0.1 | - |

**Baan-Slootweg, O; Benninga, Ma; Beelen, A; Palen, J; Tamminga-Smeulders, C; Tijssen, Jg; Aalderen, Wm Inpatient treatment of children and adolescents with severe obesity in the Netherlands: a randomized clinicaltrial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed |  |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocol w as approved by the Medical Ethics Committee of the Academic Medical Center of the University of Amsterdam. Assent and w ritten  inf ormed consent w ere obtained from the parents or the legal representatives of participants and from adolescents (aged 12-18 years). Parents and/or caregivers gave additional w ritten consent to participate in their children’s treatment and educational regimens | | |
| Outcomes  other than BMI | Other obesity, blood pressure, lipids, other labs, glucose metabolism, other (CV fitness) | |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere 8 to 18 years of age and a BMI z score of at least 2.3, corresponding to the 98.9th percentile, according to the grow th curves based on the fourth Dutch National Grow th Study of 1997 (calculated via [http://groeiw](http://groeiw/) eb.pgdata.n /calculator.asp), w ith obesity-related comorbidity (eg, obstructive sleep apnea syndrome, elevated insulin levels, type 2 diabetes mellitus, liver function disorders, hypertension, dyslipidemia, joint problems) or a BMI z score of at  least 3.0 (corresponding to the 99.9th percentile). | | |
| Exclusion criteria | Exclusion criteria consisted of severe psychiatric disorder, intellectual dis-ability, obesity caused by endocrine disorders (eTable in the Supplement), use of medication that could cause significant w eight gain or w eight loss, and/or participation in a concomitant w eight management program | | |
| Group  differences | Randomized |  |  |
| Special  populations | Severe obesity |  |  |
|  | Ambulatory Treatment | Inpatient Treatment | Overall |
| N | 45 | 45 | 90 |
| Sex | 58% female, 42% male | 58% female, 42% male | 58%  female, 42%  male |
| Age (mean and  range) | 13.9 | 13.8 | NR |
| Race | 71% Netherlands, 29% other | 49% Netherlands, 51% other | NR |
| BMI SDS | 3.35 | 3.35 | NR |
| Interventions | |  |  |
|  | Ambulatory Treatment | Inpatient Treatment |  |
| Intervention as defined by author | Patients randomized to the ambulatory treatment pro-gram and their caregivers attended the program for 12 visits at increasing time intervals for a 6-month period. After w eighing, the children exercised for an hour (sw imming and gymnastics). Children and parents w ere also encouraged to exercise at home on 3 additional days per w eek and to reduce sedentary behaviors. After physical exercise, the children at-tended an educational program for 1 hour and a nutritional educational session for half an hour. | Patients randomized to the inpatienttreatment program w ere hospitalized for 26 w eeks. They fol-low ed a program during w eekdays and returned home for the w eekends w ith homew ork assignments. The program consisted of an exercise schedule 4 days per w eek (30 to 60 minutes each day, w ith a mean duration of 45 minutes for each exercise session) and nutrition/behavior modification once per w eek (60 minutes for each session). Patients and caregivers received comparable inf ormation about nutrition and behavior, but the 1-hour lessons w ere held separately, at 3  times during the treatment period |  |
| Intervention  type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  Length | 6 months | 6 months |
| Intensity as described by authors | 12 visits, including 1-hour activity + 1 hour nutrition education | exercise schedule 4 days per w eek (30 to 60 minutes each day, w ith a mean duration of 45 minutes for each exercise session) and nutrition/behavior modification once per w eek (60 minutes for each  session). |
| Assigned Intensity | 5-25 hours | >=52 hours |
| Provider types | Primary care, nutrition provider, mental health, exercise | Primary care, nutrition provider, mental health, pyschosocial support,  exercise |
| Clinic Setting | Primary care | Inpatient |
| Components | Nutrition counseling, activity counseling, activity training, nutrition  training, mental health, community recreation center | Nutrition counseling, activity counseling, activity training, CBT,  psychosocial ref errals |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 6 months |  |  |  | 30 months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Ambulatory Treatment | 38 | 3 | 0.83 | 0.001 | 0.04 | 28 | 3.3 | 1.17 | 0.99 | 0.33 |
| Inpatient Treatment | 41 | 2.74 | 0.8 | 0.001 | - | 31 | 3.13 | 1.1 | 0.38 | - |

**Banks, J; Sharp, Dj; Hunt, Lp; Shield, Jp**

**Evaluating the transferability of a hospital-based childhood obesity clinic to primary care: a randomised controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | National Institute for Health Research |  |  |
| Country | United Kingdom |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Willing participants gave verbal consent over the phone and w ere randomized. Written consent w as collected at the first appointment. Ethical approval granted  by Southmead Research Ethics Committee. | | |
| Outcomes other  than BMI | Psychosocial |  |  |
| Population | | | |
| Inclusion criteria | 5-16 years old w ith a BMI >= 98th centile and ref erred from the Care Of Childhood Obesity Clinic. | |  |
| Exclusion  criteria | NR directly, but clinical comorbidities and parental type 2 diabetes (although these children w ere later allow ed in to the program) | |  |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Hospital Based (BRHC) | Primary Care (PCC) | Overall |
| N | 26 | 42 | 68 |
| Sex | 42% male | 36% male | 38%  male |
| Age (mean and  range) | 11.5 | 11.4 (5.7-17.0) | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.86 | 3.17 | NR |
| Interventions | |  |  |
|  | Hospital Based (BRHC) | Primary Care (PCC) |  |
| Intervention as defined by author  Intervention type | Initial consultation w ith the COCO consultant. They w ere offered a further 4 COCO appointments over a 1-year period at 3-monthly intervals, w here they w ould also see a dietician and/or exercise specialist as directed by the consultant  Lifestyle | PCC patients w ere offered 5 appointments over 12 months; at each appointment the family saw the practice nurse w ho w eighed and measured the child, plotting the data on grow th charts. The nurse discussed overall progress, focusing on factors that  facilitated or inhibited w eight reduction. The family then saw the dietician and exercise consultant for specialist advice  Lifestyle |  |
| Intervention Length | 12 months | 12 months |  |
| Intensity as  described by authors | Four COCO appointments over 1 year | 5 appointments over 12 months |  |
| Assigned Intensity | 5-25 hours | 5-25 hours |  |
| Provider types | Nutrition provider, Exercise, subspecialist | Primary care, nutrition provider, exercise |  |
| Clinic setting | Multidisciplinary w eight management clinic | Primary care |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 12 months | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Hospital Based (BRHC) | 23 | -0.15 | 0.25 | NS |
| Primary Care (PCC) | 29 | -0.17 | 0.26 | - |

**Bathrellou, E; Yannakoulia, M; Papanikolaou, K; Pehlivanidis, A; Pervanidou, P; Kanaka-Gantenbein, C; Tokou, I; Tsiantis, J; Chrousos, Gp; Sidossis, Ls Parental involvement does not augment the effectiveness of an intense behavioral program for the treatment of childhood obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | No conflict of interest to declare. The study w as funded in part by the Department of Nutrition and Dietetics Graduate Program | |  |
| Country | Greece |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | in Athens, Greece. Approval to conduct the study w as obtained from both the Ethics Committee of Harokopio University and the Ethics Committee of “Agia  Sophia” Children’s Hospital, and all parents provided their w ritten consent. | | |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Overw eight or obese children, aged betw een 7 and 12 years |  |  |
| Exclusion criteria | Any chronic physical or men-tal illness |  |  |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Child alone | Child and parent | Ove rall |
| N | 19 | 23 | 42 |
| Sex | NR | NR | NR |
| Age (mean and  range) | 9.1 | 9.4 | NR |
| Race | NR | NR | NR |
| BMI-based percent  overw eight | 42.5 | 37.5 | NR |
| Interventions | |  |  |
|  | Child alone | Child and parent |  |
| Intervention as defined by author | Multidisciplinary program involving many CBT principles and some novelties as regards the dietetic practice, such as supervision of the dieticians by the psychiatrists and implementation w ith booster sessions after the intensive program. In the Child-alone group, sessions w ere conducted w ithout any parental involvement and parental help was not required unless the child requested it. | Multidisciplinary program involving many CBT principles and some novelties as regards the dietetic practice, such as supervision of the dieticians by the psychiatrists and implementation w ith booster sessions after the intensive program . In the Child-and-parent group, parents w ere asked to act as helpers: apart from attending tw o individual sessions w ith the dietician, they also participated in the last 10 minutes of each session, w hile their cooperation w as actively requested in sup-porting their  child to implement the goals set. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  Length | 12 w eeks plus 6 monthly booster sessions | 12 w eeks plus 6 monthly booster sessions |  |
| Intensity as  described by authors | The intensive program consisted of 12 w eekly sessions, each lasting 1 hour and  conducted individually. Follow ed by booster sessions after the intensive program (6 monthly sessions from 3 to 9 months and one final session at 5 months. | The intensive program consisted of 12 w eekly sessions,  each lasting 1 hour and conducted individually. Follow ed by booster sessions after the intensive program (6 monthly |  |

|  |  |  |
| --- | --- | --- |
|  |  | sessions from 3 to 9 months and one final session at 5  months. |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Dietitian, mental health | Dietitian, mental health |
| Clinic setting | multidisciplinary WMP | multidisciplinary WMP |
| Components | Nutrition counseling, activity counseling, mental health | Nutrition counseling, activity counseling, mental health |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI-based Percent Overw eight | | | | | | |
|  | 3 months |  | 18 months | |  |  |
|  | N | Mean | p (betw een groups) | N | Mean | p (betw een groups) |
| Child alone | 18 | NR | NR | 16 | NR | 0.311 |
| Child and parent | 18 | NR |  | 16 | NR |  |

**Berkowitz, Ri; Rukstalis, Mr; Bishop-Gilyard, Ct; Moore, Rh; Gehrman, Ca; Xanthopoulos, Ms; Cochran, Wj; Louden, D; Wadden, Ta Treatment of adolescent obesity comparing self-guided and group lifestyle modification programs: a potential model for primary care**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as supported by grants SAP4100033130 (RIB)from the Pennsylvania Department of Health and K24-DK065018 (TAW) from the National  Institutes of Health and grant UL1RR024134 from the National Center forResearch Resources. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the institutional review boards at the tw o sites (ClinicalTrials.Gov Identifier: NCT0107321 5). | |  |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Participants w ere 12–16-year-old males and postmena-rcheal females w ith a BMI28 kg/m2. | |  |
| Exclusion criteria | Candidates underw ent a medical screening to rule out contraindications to treatment. These included cardio-vascular disease (including arrhythmias), type 1 or 2 dia-betes mellitus, psychiatric disorders (such as major depressive disorder and behavioral disorders), pregnancy, use of a w eight-loss medication or  a w eight loss of 5kg in the prior 6 months, use of medications promoting w eight gain (e.g., oral steroids), or cigarette smoking | | |
| Group  differences | Randomized |  |  |
| Special populations | Rural |  |  |
|  | Group LMP (Lifestyle Modification Program) | Self-guided LMP (Lifestyle Modification Program) | Overall |
| N | 81 | 88 | 169 |
| Sex | NR | NR | 76.9% female |
| Age (mean and  range) | NR | NR | 14.6 |
| Race | NR | NR | 46.7& w hite, 46.7% African-American, 0.6% Native  American, 1.2%  unknow n, 4.7% multi race, 2.4% Hispanic |
| BMI-SDS | NR | NR | 2.3 |
| Interventions | |  |  |
|  | Group LMP (Lifestyle Modification Program) | Self-guided LMP (Lifestyle Modification Program) |  |
| Intervention as defined by authors | Adolescents in both treatment conditions received the same 12-month comprehensive family-based LMP curricu-lum. The LMP w as delivered  follow ing detailed treatment manuals provided to adolescents and parents (or guardians) (Wadden & Berkow itz, 2001), w hich w ere w rit-ten at a fifth-grade reading level. All adolescents w ere asked to consume a nutritionally balanced diet of 1300– 1500 kcal/day, according to the United States Department of Agriculture (USDA) MyPyramid guidelines (USDA, 2009) to increase physical activity to 60 min or 10,000 steps daily, and to decrease sedentary behaviors to few er than 2 hr daily . Parents and teens in the Group LMP w ere provided 17 additional in-clinic group visits at w hich they review ed their progress in completing the lessons from the treatment manual, had interactive discussions around eating and  physical activity topics, and received peer support. | Adolescents in both treatment conditions received the same 12-month comprehensive family-based LMP curricu-lum. The LMP w as delivered follow ing detailed treatment manuals provided to adolescents  and parents (or guardians) (Wadden & Berkow itz, 2001), w hich w ere w rit-ten at a fifth-grade reading level. All adolescents w ere asked to consume a nutritionally balanced diet of 1300–1500 kcal/day, according to the United States Department  of Agriculture (USDA) MyPyramid guidelines (USDA, 2009) to increase physical activity to 60 min or 10,000 steps daily, and to decrease  sedentary behaviors to few er than 2 hr daily . |  |

|  |  |  |
| --- | --- | --- |
| Intervention  type | Lifestyle | Lifestyle |
| Intervention  Length | 12 months | 12 months |
| Intensity as  described by authors | Both Group and Self -Guided LMP participants had six scheduled clinic  visits (45 min each). Group LMP w ere provided 17 additional in-clinic group visits . | Both Group and Self -Guided LMP participants had six scheduled clinic visits (45 min each). |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider type | Primary care, Nutrition, Mental Health | Primary care, Nutrition, Mental Health |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, mental health | Nutrition counseling, activity counseling, mental health |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |
| 6 months |  |  | 12 months | |  |  |  |
| N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Group LMP (Lifestyle Modification Program) | -0.94 | 0.24 | NS | 61 | -0.45 | 0.35 | 0.88 |
| Self-guided LMP (Lifestyle Modification Program) | -0.77 | 0.25 | - | 53 | -0.38 | 0.36 | - |
| BMI SDS | | | | | | | |
| 6 months |  |  | 12 months | |  |  |  |
| N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Group LMP (Lifestyle Modification Program) | -0.11 | 0.02 |  | 61 | -0.12 | 0.03 | 0.91 |
| Self-guided LMP (Lifestyle Modification Program) | -0.09 | 0.02 | - | 53 | -0.12 | 0.03 | - |

**Berkowitz, Ri; Wadden, Ta; Gehrman, Ca; Bishop-Gilyard, Ct; Moore, Rh; Womble, Lg; Cronquist, Jl; Trumpikas, Nl; Levitt, Katz Le; Xanthopoulos, Ms Meal replacements in the treatment of adolescent obesity: a randomized controlled trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This study w as supported by grants DK054713 and K24-DK065018 from the National Institutes of Health and grant UL1RR024134 from the National Center for  Research Resources. Unilever provided SlimFast for the study | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | This study w as approved by the institutional review boards of the Children’s Hospital of Philadelphia and of the University of Pennsylvania (ClinicalTrials.Gov  Identifier: NCT0021217). | | | |
| Outcomes other than  BMI | Other obesity, blood pressure, lipids, glucose metabolism, mental health | |  |  |
| Population | | | | |
| Inclusion  criteria | 13–17-year-old males and postmenarcheal females w ho had a BMI of 28–50kg/m2 | |  |  |
| Exclusion  criteria | Cardiovascular disease (including arrhythmias); types 1 or 2 diabetes mellitus; major psychiatric disorders; pregnancy; use of a w eight-loss medication  or a w eight loss of 5kg or more in the prior 6 months; use of medications promoting w eight gain (e.g., oral ster-oids); or cigarette smoking. | | | |
| Group  differences | Randomized |  |  |  |
| Special  populations | None |  |  |  |
|  | Conventional Diet | Meal Replacement | Meal Replacement follow ed by conventional diet | Overall |
| N | 42 | 71 | NR | 113 |
| Sex | 79% female | 82% female | NR | 81% female |
| Age (mean  and range) | 15.2 | 14.9 | NR | 15.0 (13-17) |
| Race | 26% w hite, 64% African American, 10% other | 26 w hite, 61% African American, 13% other | NR | 26% w hite,  62% African American, 12% other |
| BMI SDS | 2.4 | 2.3 | NR | 2.3 |
| Interventions | |  |  |  |
|  | Conventional Diet | Meal Replacement | Meal Replacement follow ed by  conventional diet |  |
| Intervention as defined by author | Adolescents in all treatment conditions received the same comprehensive family based LMP. Participants w ho consumed the CD w ere instructed to consume a diet consistent w ith recommendations of the US Dietary guidelines (12). Participants w ere encouraged to consume ≤30% of kcal/day from fat, ~15% from protein, and the remainder from carbohydrates. | Adolescents in all treatment conditions received the same comprehensive family based LMP. The daily MR plan consisted of three SlimFast shakes that w ere provided free of charge (Unilever, Englew ood, NJ), combined w ith one prepackaged meal of the adolescents’ choice,  tw o servings of fruit, and three servings of  vegetables (all purchased by participants). Prepackaged meals w ere selected from a list of frozen food entrées, all of w hich provided | Meal replacement for first 4 months, follow ed by transition to conventional diet (as described). |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | about 225–300 kcal per serving, w ith 20–25g  of protein. |  |
| Intervention  type | Lifestyle | Specif ic Diet | Dieting + Lifestyle |
| Intervention  Length | 12 months | 12 months | 12 months |
| Intensity as described by authors | Phase 1: w eekly group LMP meetings (assume 90 min?). After 2 w eeks of orientation, for the next 14 w eeks adolescents w ere prescribed a 1300–1500kcal/day CD diet. Phase 2 = From months 5–7, all participants received tw ice monthly group LMP meetings, follow ed by monthly group meetings from months 8 to 12. | Phase 1: w eekly group LMP meetings (assume 90 min?) After 2 w eeks of orientation, for the next 14 w eeks adolescents w ere prescribed a 1300– 1500kcal/day isocaloric diet. Phase 2 = From months 5–7, all participants received tw ice monthly group LMP meetings, follow ed by monthly group meetings from months 8 to 12. | Adolescents and their parents attended w eekly group LMP meetings. After 2 w eeks of orientation and learning how to self -monitor dietary intake, for the next 14 w eeks ado- lescents w ere prescribed a 1,300– 1,500kcal/day CD, comprised of con- ventional foods, or an isocaloric MR  diet. |
| Assigned  intensity | 5-25 hours | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider, mental health | Primary care, nutrition provider, mental health | Primary care, nutrition provider, mental  health |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program | Multidisciplinary w eight management  program |
| Components | Nutrition counseling, activity counseling,  CBT/therapy | Nutrition counseling, activity counseling,  CBT/therapy | Nutrition counseling, activity  counseling, CBT/therapy |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
|  | 4 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Conventional Diet | 37 | -1.3 | 0.3 | 0.007 | 26 | -0.96 | 0.5 | NS |
| Meal Replacement | 65 | -2.3 | 0.2 |  | 26 | -1.3 | 0.5 |  |
| Meal Replacement follow ed by conventional diet |  |  |  |  | 23 | -1.3 | 0.5 | - |
| BMI SDS | | | | | | | | |
|  | 4 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Conventional Diet | 37 | -0.1 | 0.02 | 0.07 | 26 | -0.09 | 0.04 | NS |
| Meal Replacement | 65 | -0.2 | 0.02 | - | 26 | -0.1 | 0.04 | - |
| Meal Replacement follow ed by conventional diet |  |  |  |  | 23 | -0.11 | 0.04 | - |

**Bocca, G; Corpeleijn, E; Heuvel, Er; Stolk, Rp; Sauer, Pj**

**Three-year follow-up of 3-year-old to 5-year-old children after participation in a multidisciplinary or a usual-care obesity treatment program**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The study w as sponsored w ith an unrestricted grant by Hutchison Whampoa Limited, 22/F Hutchison House, 10 Harcourt Road, Hong Kong. | |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by theMedical Ethics Committee of the University Medical CenterGroningen |  |  |
| Outcomes other  than BMI | other obesity, behaviors |  |  |
| Population | | | |
| Inclusion criteria | Children aged 3-5 years w ere ref erredto the outpatient clinic if they had a BMI-z>1.1. |  |  |
| Exclusion criteria | Medical causes for obesity, eating disorders, mental retardation and behavioral problems |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | Preschoolers |  |  |
|  | Multidisciplinary Intervention | Usual Care | Overall |
| N | 40 | 35 | 75 |
| Sex | 70.0% female | 74.3% female | 28%  male |
| Age (mean and range) | 4.6 | 4.7 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.7 | 2.7 | NR |
| Interventions | |  |  |
| Intervention as | Multidisciplinary Intervention  The multidisciplinary lifestyle intervention program included dietary advice for children and parents (6 sessions of 30 min each),physical activity sessions for children (12 sessions of 60 min each)and psychological counselling for parents only (6 sessions of 120 min each). Dietary advice | Usual Care  In the usual-care group, children and parents w ere follow ed up by a pediatrician (3 sessions |  |
| defined by  authors  Intervention Type | w as given by a dietician and aimed at improving eating behavior by using personal goals. Physical activity sessions under guidance by a physiotherapist mimicked elementary school exercise.  Lifestyle | of 30-60 min each)w ho advised on healthy eating and an active lifestyle.  Lifestyle |  |
| Intervention  Length | 16 w eeks | 16 w eeks |  |
| Intensity as described by authors | The multidisciplinary lifestyle intervention program included dietary advice for children and parents (6 sessions of 30 min each), physical activity sessions for children (12 sessions of 60 min each) and psychological counselling for parents only (6 sessions of 120 min each). | In the usual-care group, children and parents w ere follow ed up by a pediatrician (3 sessions of 30-60 min each) w ho advised on healthy  eating and an active lifestyle. |  |
| Assigned Intensity | 26-51 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, mental health, exercise | Primary care |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management clinic |  |
| Components | Nutrition counseling, activity counseling, activity training, CBT/therapy, other (parent training) | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 36 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Multidisciplinary Intervention | 17 | 0.394 | -0.002 | 0.79 | NS |
| Usual Care | 12 |  |  |  |  |

**Bocca, G; Corpeleijn, E; Stolk, Rp; Sauer, Pj**

**Results of a multidisciplinary treatment program in 3-year-old to 5-year-old overweight or obese children: a randomized controlled clinical trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The study w as sponsored by an un-restricted grant from Hutchison Whampoa Limited, HongKong. | |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the medical ethics committee of the University Medical Center Groningen. Written inf ormed consent from the parents or legal  caretakers w as obtained. | | |
| Outcomes other  than BMI | Other obesity, behaviors |  |  |
| Population | | | |
| Inclusion criteria | Aged 3 to 5 years; Overw eight or obese children, as defined by the International Obesity Task Force | |  |
| Exclusion  criteria | Children w ith mental retardation, severe behavioral problems, or other criteria interfering w ith participation w ere excluded. Also, children w ho w ere over-w eight  or obese ow ing to know n medical conditions or eating disorders, according to the Dutch Eating Behavior Questionnaire, w ere excluded from the study. | | |
| Group  differences | Randomized |  |  |
| Special populations | Preschoolers |  |  |
|  | Multidisciplinary Intervention | Usual Care | Overall |
| N | 40 | 35 | 75 |
| Sex | 30% male | 25.7% male | NR |
| Age (mean and  range) | 4.6 | 4.6 | 4.7 |
| Race | NR | NR | NR |
| BMI SDS | 2.7 | 2.7 | 2.7 |
| Interventions | |  |  |
|  | Multidisciplinary Intervention | Usual Care |  |
| Intervention as described by authors | Children and parents in the multidisciplinary intervention pro-gram received dietary advice, physical activity sessions and, for parents only, psychologic counseling. Dietary advice consisted of 6 sessions of 30 minutes each, guided by a dietician. The physical activity sessions consisted of 12 group sessions of 60 minutes each and w ere supervised by a physio-therapist. Behavioral therapy for parents comprised 6 group sessions of 120 minutes  each that w ere guided by a psychologist. | Children and parents in the usual-care group w ere follow ed up by a pediatrician, also during a period of 16 w eeks. Children and parents in the usual-care group w ere follow ed up by a pediatrician, also dur- ing a period of 16 w eeks. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  Length | 16 w eeks | 16 w eeks |  |
| Intensity as described by authors | In total, the multidisciplinaryintervention program consisted of 25 sessions, together ap- proximately 30 hours in 16 w eeks. | Children and parents in the usual-care group w ere  follow ed up by a pediatrician, also during a period of 16 w eeks. In this period, they w ere seen 3 times for 30 to 60 minutes each time. |  |
| Assigned intensity  Provider types | 26-51 hours  primary care, nutrition provider, mental health, exercise | <5 hours Primary care |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |  |

Components nutrition counseling, activity counseling, activity training, mental health Nutrition counseling, activity counseling

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
| 16 w eeks | |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Multidisciplinary Intervention | 33 | -1.2 | 1 | <0.05 | 32 | -1 | 1.4 | 0.03 |
| Usual Care | 29 | -0.6 | 1.1 | - | 25 | 0 | 1.6 | - |
| BMI SDS | | | | | | | | |
| 16 w eeks | |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Multidisciplinary Intervention | 33 | -0.5 | 0.4 | <0.05 | 32 | -0.6 | 0.5 | 0.02 |
| Usual Care | 29 | -0.3 | 0.4 | - | 25 | -0.3 | 0.5 | - |

**Bocca, G; Kuitert, Mw; Sauer, Pj; Stolk, Rp; Flapper, Bc; Corpeleijn, E**

**A multidisciplinary intervention programme has positive effects on quality of life in overweight and obese preschool children**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The study w as sponsored by an unrestricted grant from Hutchison Whampoa Limited, Hong Kong. |  |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Medical Ethics Committee of the University Medical Center Groningen, and inf ormed consent w as obtained from the  children’s parents or legal caretakers. The procedures follow ed w ere in accordance w ith the 1975 Declaration of Helsinki, as revised in 1983. | |  |
| Outcomes other  than BMI | Other obesity, psychosocial |  |  |
| Population | | | |
| Inclusion criteria | obese children from 3- to 5-years-old. We included childrenin the study if they w ere overw eight or obese according tothe International Obesity Task Force  definitions, w ith aBMIz-score of more than 1.1 for overw eight children andmore than 2.3 for obese children. | | |
| Exclusion criteria | Children w ith obesity caused by medical problems, and w ith mental retardation or behavioural problems, w ere excluded from the study | |  |
| Group  differences | Randomized |  |  |
| Special populations | Young children (age 3-5) |  |  |
|  | Multidisciplinary intervention | Standard Care | Overall |
| N | 40 | 35 | 75 |
| Sex | 30% male | 25.7% male | NR |
| Age (mean and  range) | 4.6 | 4.7 | 4.7 |
| Race | NR | NR | NR |
| BMI SDS | 2.7 | 2.7 | NR |
| Interventions | |  |  |
|  | Multidisciplinary intervention | Standard Care |  |
| Intervention as defined by author | The children and parents in the intervention group received dietary advice from a dietician during 6, 30-min sessions. In addition, the children took part in 12, 60-min physical activity group sessions, conducted by a physiotherapist, w hich mimicked elementary school exercises and aimed to improve the child’s w ell-being.Parents in the intervention group also received six psychological counselling sessions, each lasting 2 h, w hich encouraged them to provide a healthy role model  and to change their family’s attitudes tow ards healthy eating and physical activity | Children and parents in the standard care group received advice on a healthy lifestyle from a resident in paediatrics, during three sessions lasting betw een 30 min and 1 h. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  Length | 16 w eeks | 16 w eeks |  |
| Intensity as  described by authors | 6 30-min dietary sessions, 12 60-min PA sessions, six 2-hour counseling | 3 30 min to 1 hr sessions |  |
| Assigned intensity | 26-51 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, mental health, exercise | Primary care |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, activity training, motivational interview ing, mental health | Nutrition counseling, Activity counseling |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 16 w eeks | |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Multidisciplinary intervention | 31 | -0.5 | 0.4 | NR | 20 | -0.6 | 0.5 | NR |
| Standard Care | 28 | -0.3 | 0.4 | - | 20 | -0.3 | 0.5 | - |

**Bohlin, A; Hagman, E; Klaesson, S; Danielsson, P**

**Childhood obesity treatment: telephone coaching is as good as usual care in maintaining weight loss - a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by the Stockholm County Council. |  |  |
| Country | Sw eden |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Stockholm Regional Ethical Committee (2006/1291-31/4) and is registered: Clinical-Trials.gov: NCT 02794090. | | |
| Outcomes  other than BMI | None |  |  |
| Population | | | |
| Inclusion  criteria | All families w ith chil-dren aged 5–14 years w ere invited to participate in the ran-domized study of individual treatment after the parents had attended at least  four out of seven meetings in the ini-tial group treatment. | | |
| Exclusion  criteria | Exclusion criteria w ere obesity-related syndromes (Laurence Moon Bardet Biedl and Prader Willi)and non-Sw edish-speaking parents | | |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Telephone Coaching | Usual Care | Overall |
| N | 18 | 19 | 37 |
| Sex | 47.4% female | 22.2% female | NR |
| Age (mean and  range) | 9.8 | 9.3 | NR |
| Race | 26.3% non-Scandinavian parent | 38.9% non-Scandinavian parent | Turkey 7, Iraq 4, Syria 3,  Phillippines 1, Morocco 1, Spain  1 |
| BMI SDS | 2.97 | 2.91 | NR |
| Interventions | |  |  |
|  | Telephone Coaching | Usual Care |  |
| Intervention as described by authors | Weight maintenance. In the TC group, the goal w as to stay in contact everymonth, excluding the summer vacation. During each TCsession, the treating nurse spoke w ith one of the parents,and the timing of the next TC session w as agreed uponat the end of each conversation. amilies in the TC group used astructured questionnaire w ithfive categories as a guide dur-ing TC contact w ith the nurse. The questionnaire raisedissues such as current w eight, w hat w orks w ell and lessw ell regarding eating habits, physical activity, sedentaryactivities, the process of change and potential conflictsaround this. The inf ormation from the questionnaire  w asused by the nurse from a problem-solving perspective. After 18 months, children had a study-endfinal visit w here the w eight and  height w as checked. | Weight maintenance. The number of visits in the UC group follow ed the UC (15)model, and the sessions w ere led by the treating nurse. |  |
| Intervention  type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  Length | 18 months | 18 months |
| Intensity as described by authors | Monthly, <15 minutes | 0-min programme for parents once a w eek for 7  w eeks, In parallel w ith the parental programme, the children partici-pated in an educational and physical activity group. Afterthis initial group treatment programme, treatment w asindividualized for each patient and involved visits to amedical doctor (normally 1–2 times/year), a nurse (1–8 times/year) and, if necessary, a dietician and physiotherapist. As treatment w as individualized, the frequency of visits  varied by patient. Follow up visits 45 min duration |
| Assigned  intensity | <5 hours | 5-25 hrs |
| Provider types | Group leader, unspecified, nurse | Group leader, unspecified. Primary care, nutrition  provider, physiotherapist |
| Clinic setting | Multidisciplinary w eight management | Multidisciplinary w eight management |
| Components | Nutrition counseling, activity counseling | Usual care, activity training, nutrition provider,  exercise |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI-SDS |  |  |  |  |  |  |  |  |  |  |
| 18 Months | |  |  |  | 36 Months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Telephone Coaching | 15 | -0.16 | 0.39 | 0.1 | >0.8 | 15 | -0.42 |  |  | 0.6 |
| Usual Care | 18 | -0.12 | 0.43 | 0.4 | - | 19 | -0.52 |  |  | - |

**Boutelle, Kn; Norman, Gj; Rock, Cl; Rhee, Ke; Crow, Sj Guided self-help for the treatment of pediatric obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by the National Institutes of Health (NIH) DK080266. Dr Crow e has research grants from Shire, Alkermes, and Novartis; the other authors indicated  they have nofinancial relationshipsrelevant to this article to disclose. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the University of California, San Diego, Institutional Review Board |  |  |
| Outcomes other  than BMI | Behaviors, other (parent BMI) |  |  |
| Population | | | |
| Inclusion  criteria | Children aged 8 to 12 years w ho w ere overw eight or obese (BMI percentile:85th to 98th) and their parents |  |  |
| Exclusion  criteria | Families w ere excluded if either the child or parent w as currently involved in any other psychological or w eight-loss treatment, w as using medications that  affected appetite or w eight, had a psy-chiatric condition, or did not speak English | | |
| Group  differences | Randomized |  |  |
| Special Populations | None |  |  |
|  | Immediate Guided Self -Help | Delayed Guided Self Help | Overall |
| N | 25 | 25 | 50 |
| Sex | 60% female | 64% female | NR |
| Age (mean and  range) | 10.3 | 10.5 | NR |
| Race | 4% Asian, 8% African American, 4% NH/PI, 12% Hispanic, 72% w hite | 12% Asian 4% African American,  0% NH/PI, 16% Hispanic, 68% w hite | NR |
| BMI SDS | 1.71 | 1.71 | NR |
| Interventions | |  |  |
|  | Immediate Guided Self -Help | Delayed Guided Self Help |  |
| Intervention as defined by authors | Families received a parentmanual, a child manual, and an activi-ties manual. The activities manualw as designed to provide activities andgames that parents and childrencould do together to enhance programlearning at home. Families w ere told to readthe assigned chapter in the parent andchild manuals betw een visits, apply theskills, and complete any activities fromthe activities manual that w ere of in-terest to  their family. Meetings w ith the interventionistsw ereamaximumof 20minutes inlength,w iththe exception of session 2, w hich w asdesigned to be 1 hour to allow fortime to discuss the dietary recom-mendations. Visits w ere  focused onmonitoring w eight of parent and child,reflectingonchildandparentbehaviorsthat led to any w eight changes (to im-prove self-regulation), answ ering anyquestions regarding program material,and problem solving any barriers toimplementing program recommenda-tions. Parents and children w ere givenself -monitoring  booklets and w ere toldto w rite dow n their food intake andphysical activity daily in as much detailas possible. | The delayed treatment group did nothave any contact w ith the project teamduring the 5-month delay, and they re-ceived the GSH-PO intervention startingat T2. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 5 months | 5 months |  |

|  |  |  |
| --- | --- | --- |
| Intensity as described by authors | 11 visits, 20 minutes each; 1 visit 1 hour | The delayed treatment group did not have any contact w ith the project team during the 5-month delay, and they received the GSH-  PO intervention starting at T2. |
| Assigned  intensity | 5-25 hours | NA |
| Provider types | Research, "graduate students in clinical psychology" | NA |
| Clinic setting | Primary care | NA |
| Components | Nutrition counseling, activity counseling, mental health | NA |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| Child BMI |  |  |  |  |  |  |  |  |  |  |  |  |
| T1 (Baseline) | |  | T2 (5 months) | |  | T3 (11 months) | |  | T4 (17 months) | |  |  |
|  | mean | SD | N | mean | SD | N | mean | SD | N | mean | SD | N |
| Immediate Guided Self -Help | 24.07 | 1.92 | 25 | 23.34 | 2.11 | 22 | 24.03 | 2.64 | 22 |  |  |  |
| Delayed Guided Self Help | 24.4 | 2.55 | 25 | 25.17 | 2.79 | 25 | 24.48 | 3.01 | 22 | 25.01 | 3.23 | 22 |
| Child BMI SDS | | | | | | | | | | | | |
| T1 (Baseline) | |  | T2 (5 months) | |  | T3 (11 months) | |  | T4 (17 months) | |  |  |
|  | mean | SD | N | mean | SD | N | mean | SD | N | mean | SD | N |
| Immediate Guided Self -Help | 1.71 | 0.25 | 25 | 1.49 | 0.32 | 22 | 1.5 | 0.37 | 22 |  |  |  |
| Delayed Guided Self Help | 1.71 | 0.28 | 25 | 1.74 | 0.3 | 25 | 1.56 | 0.34 | 22 | 1.55 | 0.39 | 22 |

**Broccoli, S; Davoli, Am; Bonvicini, L; Fabbri, A; Ferrari, E; Montagna, G; Panza, C; Pinotti, M; Storani, S; Tamelli, M; Candela, S; Bellocchio, E; Giorgi, Rossi P Motivational Interviewing to Treat Overweight Children: 24-Month Follow-Up of a Randomized Controlled Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | No external funding |  |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | NR |  |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Eligible participants w ere all overw eight children (BMI percentile ≥85th and <95th)20 aged betw een 4 and 7 years, resident in the province of Reggio Emilia,  and under the care of said pediatrician for ≥12 months. | | |
| Exclusion criteria | Exclusion criteria w ere metabolic pathologic conditions and all pathologic conditions related to obesity and being overw eight. Moreover, those families w ho did not consider their children being overw eight to be an issue and w ere not interested in the negative consequences or advice on how to lose w eight (families in  the “precontemplation stage”) w ere also excluded. | | |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Motivational Interview ing (MI) | control | Overall |
| Sex | Male: 40.1%; Female: 59.9% | Male: 36.8%; Female:63.2% | NR |
| Age in years (mean and  range) | 6.7 | 6.5 | NR |
| Race | NR | NR | NR |
| BMI-SDS/ BMI-z-  score | 1.35 | 1.35 | NR |
| BMI | 18.27 | 18.21 | NR |
| N | 187 | 185 | 372 |
| Interventions | |  |  |
|  | Motivational Interview ing (MI) | control |  |
| Intervention as defined by author | The intervention consisted of 5 Motivational interview ing (MIs) delivered at 1, 4, 7, and 12 months after the baseline visit. First session: To negotiate 2 objectives: changes in diet and PA habits, respectively; second session To assess the degree of achievement of the negotiated objectives and to reinf orce or to redefine them; third session: To reinf orce or to redefine negotiated objectives and to redefine negotiated objectives; Fourth session: To reinf orce or to redefine negotiated objectives and To redefine negotiated objectives; Fifth  session: BMI, PA, and dietary habits assessment; final strength of objectives | They received a booklet w ith the main inf ormation on obesity prevention (eg, opportunistic healthy diet recommendations if the pediatrician w as seeing the child for other reasons). |  |
| Intervention type | Lifestyle | Usual Care |  |
| Target person | - | - |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as  described by authors | Session 1: 45/60 min; session 2:45/60 min; session 3: 30 min and 45/60 min; session 4: 30 min and 45/60 min; session 5: 45 min | 45min |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity hours | <5 hours | < 5 hours |
| Provider type | Pediatrician | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Motivational Interview ing | Usual care |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |
|  | 12 months |  |  | 24 months |  |  |
| Change in BMI | | 95% CI Low er Bounds | 95% CI Upper Bounds | Change in BMI | 95% CI Low er Bounds | 95% CI Upper Bounds |
| Motivational Interview ing (MI) | 0.46 | 0.27 | 0.65 | 1.52 | 1.29 | 1.75 |
| control | 0.78 | 0.61 | 0.96 | 1.56 | 1.33 | 1.79 |
| BMI z-score | | | | | | |
|  | 12 months |  |  | 24 months |  |  |
| Change in BMI | | 95% CI Low er Bounds | 95% CI Upper Bounds | Change in BMI | 95% CI Low er Bounds | 95% CI Upper Bounds |
| Motivational Interview ing (MI) | -0.12 | -0.17 | -0.06 | -0.05 | -0.12 | 0.01 |
| control | -0.01 | -0.06 | 0.04 | -0.03 | -0.09 | 0.02 |

**Butte, Nf; Hoelscher, Dm; Barlow, Se; Pont, S; Durand, C; Vandewater, Ea; Liu, Y; Adolph, Al; PÃ©rez, A; Wilson, Ta; Gonzalez, A; Puyau, Mr; Sharma, Sv; Byrd-Williams, C; Oluyomi, A; Huang, T; Finkelstein, Ea; Sacher, Pm; Kelder, Sh**

**Efficacy of a Community- Versus Primary Care-Centered Program for Childhood Obesity: TX CORD RCT**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |  |  |  |
| Sponsorship  source | This research w as supported by cooperative agreement RFA-DP-11-007 from the Centers for Disease Control and Prevention. Additional support w as provided  by the Michael and Susan Dell Foundation through the Michael & Susan Dell Center for Healthy Living. | | | | | | |
| Country | USA |  |  |  |  |  |  |
| Setting | - |  |  |  |  |  |  |
| Comments | - |  |  |  |  |  |  |
| Authors  name | - |  |  |  |  |  |  |
| Institution | - |  |  |  |  |  |  |
| Email | - |  |  |  |  |  |  |
| Address | - |  |  |  |  |  |  |
| Methods | | | | | | | |
| Design | Randomized  controlled trial |  |  |  |  |  |  |
| Group | Parallel group |  |  |  |  |  |  |
| IRB | Institutional Review Boards for Human Subject Research for University of Texas Health Science Center, Baylor College of Medicine, and Seton Healthcare Family approved all protocols. Inf ormed consent covering parent and child participation w as obtained from at least one parent or primary  caretaker, and w ritten assent w as obtained from children aged 6 to 12 years. | | | | | | |
| Outcomes  other than BMI | Other obesity, blood pressure, psychosocial | |  |  |  |  |  |
| Population | | | | | | | |
| Inclusion  criteria | Inclusion criteria for the children w ere ages 2 to 12 years and BMI>/=85th percentile | | | |  |  |  |
| Exclusion  criteria | Exclusion criteria w ere complications of obesity that w ould interfere w ith exercise (e.g., orthopedic problems);  obesity-related conditions, such as systematic steroid use or | | | | |  |  |
| Group  differences | Randomized |  |  |  |  |  |  |
| Special  populations | Low income,  ethnically diverse |  |  |  |  |  |  |
|  | Next Steps Ages 2-5 y Comparison | MEND Ages 2-5 y Intervention | Next Steps Ages 6- 8 y Comparison | MEND/ CA TCH Ages 6-  8 y Intervention | Next Steps Ages 9- 12 y Comparison | MEND/ CA TCH Ages 9-  12 y Intervention | Overall |
| N enrolled | 60 | 100 | 68 | 113 | 106 | 102 | 549 |
| Sex | NR | NR | NR | NR | NR | NR | 49.5%  male, 50.5  female |
| Age in years | NR | NR | NR | NR | NR | NR | NR |
| Race | NR | NR | NR | NR | NR | NR | 86%  Hispanic, 12%  Black |
| BMI % 95th | 110.2 | 113 | 116.8 | 120 | 117.2 | 117.5 | NR |
| Interventions |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Next Steps Ages 2-5  y Comparison | MEND Ages 2-5 y  Intervention | Next Steps Ages 6-  8 y Comparison | MEND/ CA TCH Ages 6-  8 y Intervention | Next Steps Ages 9-  12 y Comparison | MEND/ CA TCH Ages 9-  12 y Intervention |
| Intervention as defined by author | The comparison w as a 12-month clinic-based program, Next Steps(16), w hich  w as conducted at  12 primary care clinics and entailedthe  follow ing: electronic health record changes including BMIscreening; an alert for BMI85th percentile; diagnosis codes, labo-ratory tests, and ref errals common in obesity management; NextSteps brief counseling materials for primary care providers; and Next Steps activity booklets for parents and children to  w ork onnutrition and physical activity targets in a self-  directed manner | The intervention conducted at YMCA entailed the follow ing:   1. a 3-month Intensive Phase, w hich included MEND 2-5 for children aged 2-5 years and MEND/ CA TCH6-12 for children aged 6-12 years and their parents/caretakers, and 2. a 9-month Transition Phase, in w hich   reinf orcement sessions w ere offered monthly for the children and parents/caretakers, and YMCA sports (basketball, flag football, soccer, sw imming,  fitness) w ere offered  tw ice w eekly for school- aged children.  MEND/ CA TCH6-12 w as  administered separately for children aged 6-8 and 9-12. | The comparison (Next Step) w as a 12-month clinic- based program. It entailed the  follow ing: electronic health record changes including BMI screening; an alert for BMI  85th percentile; diagnosis codes, laboratory tests, and ref errals common in obesity manage | The intervention conducted at YMCA entailed the follow ing:   1. a 3-month Intensive Phase, w hich included MEND 2-5 for children aged 2-5 years and MEND/ CA TCH6-12 for children aged 6-12 years and their parents/caretakers, and 2. a 9-month Transition Phase, in w hich   reinf orcement sessions w ere offered monthly for the children and parents/caretakers, and YMCA sports (basketball, flag football, soccer, sw imming,  fitness) w ere offered  tw ice w eekly for school- aged children.  MEND/ CA TCH6-12 w as  administered separately for children aged 6-8 and 9-12. | The comparison (Next Step) w as a 12-month clinic- based program. It entailed the  follow ing: electronic health record changes including BMI screening; an alert for BMI  85th percentile; diagnosis codes, laboratory tests, and ref errals common in obesity management; | The intervention conducted at YMCA entailed the follow ing:   1. a 3-month Intensive Phase, w hich included MEND 2-5 for children aged 2-5 years and MEND/ CA TCH6-12 for children aged 6-12 years and their parents/caretakers, and 2. a 9-month Transition Phase, in w hich   reinf orcement sessions w ere offered monthly for the children and parents/caretakers, and YMCA sports (basketball, flag football, soccer, sw imming,  fitness) w ere offered  tw ice w eekly for school- aged children.  MEND/ CA TCH6-12 w as  administered separately for children aged 6-8 and 9-12. |
| Intervention  type (choose one) | Lifestyle | Lifestyle | Lifestyle | Lifestyle | Lifestyle | Lifestyle |
| Intervention length | 12 months | 12 months | 12 months | 12 months | 12 months | 18 tw ice-w eekly sessions (120minutes) w ith monthly boosters in  transition phase |
| Intensity as described by authors | Families  w ereencouraged to seek follow -up clinic visits to address childhood obe-sity for an estimated 8 hours of contact | MEND2-5 offered 27 hours of contact | Families  w ereencouraged to seek follow -up clinic visits to address childhood obe-sity  for an estimated 8  hours of contact | MEND/ CA TCH6-  12provided 49.5 hours plus 72 hours of YMCA sports | Families  w ereencouraged to seek follow -up clinic visits to address childhood obe-sity  for an estimated 8  hours of contact | MEND/ CA TCH6-  12provided 49.5 hours plus 72 hours of YMCA sports |
| Assigned  Intensity | 5-25 hours | 26-51 hours | 5-25 hours | >=52 hours | 5-25 hours | >=52 hours |
| Provider type (select  all) | Primary Care | Nutrition providers, other (community health  w orkers) | Primary care | Nutrition providers, other (community health  w orkers) | Primary care | Nutrition providers, other (community health  w orkers) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Clinic setting (choose one—  probably) | Primary Care | YMCA | Primary Care | YMCA | Primary Care | YMCA |
| Components (choose all) | Nutrition counseling, activity counseling, motivational interview ing | Nutrition counseling, activity counseling, nutrition training, activity training, community  recreation center | Nutrition counseling, activity counseling, motivational  interview ing | Nutrition counseling, activity counseling, nutrition training, activity training, community  recreation center | Nutrition counseling, activity counseling, motivational  interview ing | Nutrition counseling, activity counseling, nutrition training, activity training, community  recreation center |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| %-BMIp95 |  |  |  |  |  |  |  |  |  |  |
|  | 3 mo vs.  baseline |  |  |  |  | 12 mo vs. 3  mo |  |  |  |  |
|  | N | Mean | SE | p (w ithin  group) | p (betw een  groups) | N | Mean | SE | p (w ithin  group) | p (betw een  groups) |
| Next Steps Ages 2-5 y Comparison | 60 | -0.58 | 0.82 | NS | NS | 60 | 1.92 | 0.94 | <0.05 | NS |
| MEND Ages 2-5 y Intervention | 100 | -1.29 | 0.62 | <0.05 |  | 100 | 1.77 | 0.74 | <0.05 |  |
| Next Steps Ages 6-8 y Comparison | 68 | -0.39 | 0.8 | NS | <0.05 | 100 | 1.15 | 0.88 | NS | NS |
| MEND/ CA TCH Ages 6-8 y  Intervention | 113 | -2.32 | 0.6 | <0.05 |  | 113 | 1.74 | 0.7 | <0.05 |  |
| Next Steps Ages 9-12 y Comparison  MEND/ CA TCH Ages 9-12 y | 106  102 | -1.21  -2.59 | 0.55  0.55 | <0.05  <0.05 | NS | 106  102 | 0.96  0.6 | 0.61  0.68 | NS  NS | NS |
| Intervention  BMI (kg/m2) | | | | | | | | | | |
|  | 3 mo vs.  baseline |  |  |  |  | 12 mo vs. 3  mo |  |  |  |  |
|  | N | Mean | SE | p (w ithin  group) | p (betw een  groups) | N | Mean | SE | p (w ithin  group) | p (betw een  groups) |
| Next Steps Ages 2-5 y Comparison | 60 | -0.1 | 0.16 | NS | NS | 60 | 0.5 | 0.18 | <0.05 | NS |
| MEND Ages 2-5 y Intervention | 100 | -0.19 | 0.13 | NS |  | 100 | 0.6 | 0.15 | <0.05 |  |
| Next Steps Ages 6-8 y Comparison | 68 | 0.17 | 0.16 | NS | <0.05 | 68 | 1.12 | 0.17 | <0.05 | NS |
| MEND/ CA TCH Ages 6-8 y  Intervention | 113 | -0.25 | 0.12 | <0.05 |  | 113 | 1.26 | 0.14 | <0.05 |  |
| Next Steps Ages 9-12 y  Comparison | 106 | -0.01 | 0.14 | NS | NS | 106 | 1.19 | 0.14 | <0.05 | NS |
| MEND/ CA TCH Ages 9-12 y  Intervention | 102 | -0.29 | 0.13 | <0.05 |  | 102 | 1.2 | 0.15 | <0.05 |  |

**Casazza, K; Cardel, M; Dulin-Keita, A; Hanks, Lj; Gower, Ba; Newton, Al; Wallace, S**

**Reduced carbohydrate diet to improve metabolic outcomes and decrease adiposity in obese peripubertal African American girls**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The present study w as funded by grant NIH K99 DK083333, ThrasherResearch Fund, University of Alabama Center for Women’s Reproduc-tive Health  P/F Grant, CA-47888, NIH P60DK07962 6, P30 DK056336 | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The protocol w asapproved by the institutional review board for human subjects atthe University of Alabama at Birmingham (UAB). | |  |
| Outcome other  than BMI | Other obesity, Lipids, Glucose metabolism |  |  |
| Population | | | |
| Inclusion criteria | overw eight/obese (ranging from 92ndbody mass index [BMI] percentile and above) AA girls ages 9 to14 years.; pubertal stage II to V | |  |
| Exclusion criteria | Exclusion criteria w ere medical diagnoses and/or taking medications know n to affect body composition, metabolism, cardiac function, and the like. | |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | STAN (standard carbohydrate) | SPEC (reduced carbohydrate) | Overall |
| N | 14 | 12 | 26 |
| Sex | 100% female | 100% female | 100%  female |
| Age | 12.5 | 12.4 | 12.4 |
| Race | 100% black | 100% black | 100%  black |
| BMI SDS | 2.5 | 2.2 | 2.4 |
| Interventions | |  |  |
|  | STAN (standard carbohydrate) | SPEC (reduced carbohydrate) |  |
| Intervention as described by authors | The 16-w eek intervention included 2 phases: a 5-w eek eucaloric (w eight stable) phase and an 11-w eek hypocaloric (w eight loss,  approximately 1000-calorie reduction) phase. All food w as provided for both phases of the study, w ith overall energy amount determined according to resting energy requirements. The STAN comprised 55% of  energy from CHO and 27% of energy from fat | The 16-w eek intervention included 2 phases: a5-w eek eucaloric (w eight stable) phase and an 11-w eek hypocaloric(w eight loss, approximately 1000-calorie reduction) phase. All foodw as provided  for both phases of the study. The SPEC comprised 42% of energy from CHOand 40% of energy from fat. |  |
| Intervention type | Specific diet | Specific diet |  |
| Intervention  length | 16 w eeks | 16 w eeks |  |
| Intensity as described by  authors | At baseline, participants attended 2 visits. Participants w ere w eighed tw ice per w eekto ensure compliance w ith the diet. | At baseline, participants attended 2 visits. Participants w ere w eighed tw ice per w eekto ensure compliance w ith the diet. |  |
| Assigned  intensity | 5-25 hours | 5-25 hours |  |
| Provider types | Nutrition provider | Nutrition provider |  |
| Clinic setting | Research | Research |  |
| Components | Nutrition counseling, activity counseling, other (specific diet) | Nutrition counseling, activity counseling, other (specific diet) |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| Weight, kg |  |  |  |  |  |
| 16 w eeks | | | | | |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| STAN (standard carbohydrate) | 14 | -4.5 | 1 | <0.01 | 0.09 |
| SPEC (reduced carbohydrate) | 12 | -5 | 0.9 | <0.001 | - |

**Chen, J. L.; Guedes, C. M.; Cooper, B. A.; Lung, A. E.**

**Short-Term Efficacy of an Innovative Mobile Phone Technology-Based Intervention for Weight Management for Overweight and Obese Adolescents: Pilot Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by the American Nurses Foundation Research Grant and the National Center for Advancing Translational Sciences, National Institutes of Health,  through UCSF-CTSI UL1TR00187 2. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| Outcomes  other than BMI | Other obesity, blood pressure, behaviors, self -efficacy |  |  |
| IRB | The studyw as approved by the Committee on Human Research at theUniversity of California, San Francisco (#12-09686) | |  |
| Population | | | |
| Inclusion criteria | To be eligible to participate in the study, an adolescent had to(1) be aged betw een 13 and 18 years, (2) have a BMI greaterthan or equal to 85th percentile (as indicated by the CDC grow thchart), (3) ow n a mobile phone, (4) have access to a computerw ith Internet access, (5) be able to speak and read English, and(6) be a patient at one of the clinics participating in the study.Eligible adolescents also had to be in good health, be free ofacute or life-threatening disease, and be  able to engage inactivities of daily living such as attending school | | |
| Exclusion  criteria | See inclusion criteria. |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | May be Chinese immigrants but they had to speak English? |  |  |
|  | Intervention (iStart Smart) | Control | Overall |
| N | 23 | 17 | 40 |
| Sex | 58% male | 53% male | 58% (I think this is a reporting  error) |
| Age (mean and  range) | 15 | 14.77 | 14.9 |
| Race | NR | NR | 90%  Chinese- American |
| BMI SDS | 1.6 | 1.54 | NR |
| Interventions | |  |  |
|  | Intervention (iStart Smart) | Control |  |
| Intervention as defined by author | The fmobile phone-based intervention had three components:use of the Fitbit Flex (6 months), participation in the iStart Smartfor Teens online educational program (3 months), and receiptof biw eekly text messages during the maintenance phase (3months; see Figure 1). Theeight- module iStart Smart for Teens educational program usedan online  format consisting of short videos and animationnarratives; the modules  w ere accessible via both mobile phoneand computer. In addition, the | Control groupparticipants w ere given an Omron HJ-105 pedometer and ablank food-and-activity diary and w ere asked to use thepedometer and diary for 3 months. Participants w ere asked torecord and track physical activity, sedentary activity, and foodintake in the diary. They also accessed an online program thatconsisted of eight modules related to general adolescent healthissues, such as |  |

|  |  |  |
| --- | --- | --- |
|  | mobile phone-based interventionparticipants received instructions regarding topically relevantactivities via mobile phone or computer; supplementary general inf ormation and tips w ere presented via app messages. 3-month maintenance phase. During thismaintenance phase, participants received biw eekly text messages that encouraged  and stabilized positive behavior changes. | diet and nutrition, dental care, saf ety, commondermatology care, and risk-taking behaviors. |
| Intervention type | Lifestyle | Lifestyle |
| Intervention  Length | 6 months (3 month intervention, plus 3 months maintenance period w ith  biw eekly texts) | 3 months |
| Intensity as described by  authors | 8 10-minute modules, text messages, fitbit | "8 modules" |
| Assigned  Intensity | <5 hours | <5 hours |
| Provider types | Other--trained research assistant | Other--trained research assistant |
| Clinic setting | Primary care (recruitment); other (online content) | Primary care (recruitment); other (online content) |
| Components | Nutrition counseling, activity counseling, other (online content) | General health counseling |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |
|  | Baseline |  |  | 3 months |  |  | 6 months |  |  |
|  | mean | SD | N | mean | SD | N | mean | SD | N |
| Intervention (iStart Smart) | 27.37 | 3.26 | 23 | 26.91 | 3.25 | 23 | 26.93 | 3.43 |  |
| Control | 28.35 | 4.36 | 17 | 28.81 | 4.43 | 17 | 29.18 | 3.88 |  |
| BMI SDS | | | | | | | | | |
|  | Baseline |  |  | 3 months |  |  | 6 months |  |  |
|  | mean | SD | N | mean | SD | N | mean | SD | N |
| Intervention (iStart Smart) | 1.6 | 0.5 | 23 |  |  |  | 1.42 | 0.38 |  |
| Control | 1.54 | 0.42 | 17 |  |  |  | 1.8 | 0.5 |  |

**Crabtree, V. M.; Moore, J. B.; Jacks, D. E.; Cerrito, P.; Topp, R. V.**

**A transtheoretical, case management approach to the treatment of pediatric obesity**

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| Study Identification |  |  |  |
| Sponsorship source | This study w as supported by a University of Louisville School of Medicine Grant-in-Aid. |  |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the Institutional Review Board at the University of Louisville, and inf ormed consent/assent w as obtained for all participants | | |
| Outcomes other  than BMI | Physical Activity |  |  |
| Population |  |  |  |
| Inclusion criteria | Nineteen obese (BMI ≥ 95th percentile for age and sex) AA children ages 8-12 years w ere recruited during office visits at 2 urban pediatric clinics. | |  |
| Exclusion criteria | NR |  |  |
| Group differences | Randomized |  |  |
|  | Case Management Intervention | Usual care | Overall |
| N enrolled | 10 | 9 | 19 |
| Sex | Male 3, female 6 | 66% f, 33% m | 19 |
| Age in years | 10.9 | 11.2 | NR |
| Race | 10 AA | 9 AA | 19 AA |
| BMI | 31.1 (5.0) | 30.8 (3.0) | NR |
| BMI percentile by  age | 98.4 (1.9) | 98.9 (0.7) | NR |
| Weight (kg) | 71.7 ± 16.6 | 73.6 ± 15.3 | NR |
| Interventions | |  |  |
|  | Case Management Intervention | Usual care |  |
| Intervention as defined by author | Depending on the stage of change for the parent and child, an intervention w as designed that w as either cognitive or behavioral in nature. Cognitive interventions w ere selected for families in the precontemplation and contemplation stages,  w hereas behavioral interventions w ere used for those in the action or maintenance stages. 3 The case manager delivered the module during a w eekly phone call and assisted the parent and child in identifying barriers to completing the activity,  and then modified the activity or selected a new activity to be performed during the subse-quent w eek. | The control group received usual care |  |
| Intervention type  (choose one) | Lifestyle | Usual care |  |
| Intervention length | 12 w eeks | Usual care |  |
| Intensity as described by authors | The case manager delivered the module during a w eekly phone call and assisted the parent and child in identifying barriers to completing the activity, and then modified the activity or selected a new activity to be performed during the subsequent w eek. After each 4-w eek period, the case manager met w ith the family, collected all of the w eekly compliance records,  and administered the modified URICA to both the parent and child. Based on the results of the assessment, the next 4-w eek  intervention w as designed. | Usual care |  |
| Assigned Intensity | 5-25 hours | <5 hours |  |
| Provider type  (select all) | Primary care, Psychosocial support | Primary care |  |
| Clinic setting  (choose one— probably) | Primary care | Primary care |  |
| Components  (choose all) | Motivational interview ing, nutrition counseling, activity counseling | Usual care only |  |

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| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Change in BMI percentile |  |  |  |  |
|  | Baseline |  | 12 w eeks |  |
|  | Mean | SD | Mean | SD |
| Case Management Intervention | 98.4 | 1.9 | 96.9 | 6.5 |
| Usual care | 98.9 | 0.7 | 98.6 | 0.8 |
| BMI | | | | |
|  | Baseline |  | 12 w eeks |  |
|  | Mean | SD | Mean | SD |
| Case Management Intervention | 31.1 | 5 | 30.8 | 5.4 |
| Usual care | 30.8 | 3 | 30.7 | 3.4 |

**Croker, H; Viner, Rm; Nicholls, D; Haroun, D; Chadwick, P; Edwards, C; Wells, Jc; Wardle, J**

**Family-based behavioural treatment of childhood obesity in a UK National Health Service setting: randomized controlled trial**

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| Study  Identification |  |  |  |
| Sponsorship  source | The trial w as funded by Cancer Research UK, Great Ormond Street Hospital and Weight Concern. |  |  |
| Country | UK |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval w as obtained from the Research Ethics Committee at Great Ormond Street/Institute of Child Health(registration number 03BS18). Written inf ormed consent w as obtained from all children and  parents/guardians. |  |  |
| Outcomes other  than BMI | BMI, other obesity, blood pressure, psychosocial, mental health. |  |  |
| Population | | | |
| Inclusion criteria | Children w ere eligible to participate if they w ere 8–12 years of age; overw eight or obese according to the International Obesity Task Force (IOTF) definition; had at least one parent or guardian w illing to participate in treatment; and parent and child had sufficient command of English to participate in groups and understand the  programme materials. |  |  |
| Exclusion criteria | Exclusion criteria w ere an identified medical cause for obesity (for example, hypothyroidism, Prada Willi syndrome, single-gene def ects), type-2 diabetes, taking obesity medication, undergoing obesity treatment,  significant learning difficulties, significant mental health problems in child or parent, or currently receiving psychological or psychiatric treatment, including psychotrophic medication. |  |  |
| Group differences | Randomized |  |  |
|  | Family Based Behavioral Treatment | Wait-list control | Overall |
| N | 37 | 35 | 72 |
| Sex | 29.7% male | 31.4% male | 30.6% male |
| Age | 10.8 | 9.8 | 10.3 |
| Race | 67.6% w hite, 18.9% black, 10.8% Asian, 2.7% other | 45.7% w hite,  20.0% black,  17.1% asian,  17.1% other | 56.9% w hite,  19.4% black,  13.9% asian,  9.7% other |
| BMI SDS | 3.1 | 3.3 | 3.2 |
| Interventions | |  |  |
|  | Family Based Behavioral Treatment | Wait-list control |  |
| Intervention as defined by author | FBBT is a structured intervention comprising advice on w hole-family lifestyle change, w ith a behavioural w eight control programme for the overw eight child. Children w ere required to attend w ith one parent or carer, w ith a maximumof 8–10 families per group. The aims w ere to reduce fat and energy intake, increase physical activity  and change parent–child interactions. | Waitlist control |  |
| Intervention Type | Lifestyle | NA |  |
| Intervention  length | 6 months | NA |  |
| Intensity as  described by authors | The intervention theref ore comprised 15 sessions over 6 months(10 w eekly, 3 fortnightly, 2 monthly). Sessions took place in the late afternoon (after the school day) and lasted for approximately 1.5 h | NA |  |

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| --- | --- | --- |
| Assigned  intensity | 5-25 hours | NA |
| Provider types | Primary care (ref erral), nutrition provider, mental health, other (research) | NA |
| Clinic setting | Primary care | NA |
| Components | Nutrition counseling, activity counseling, mental health | Usual care only |

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| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Family Based Behavioral Treatment | 33 | -0.11 | 0.16 | <0.01 | NS |
| Wait-list control | 30 | -0.1 | 0.16 | <0.01 | - |

**DÃ-az, Rg; Esparza-Romero, J; Moya-Camarena, Sy; Robles-SardÃ-n, Ae; Valencia, Me**

**Lifestyle intervention in primary care settings improves obesity parametersamong Mexican youth**

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| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported by a grant from the International Atomic Energy Agency (ARCAL 6/059) and CONACyT (R/182996). | |  |
| Country | Mexico |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the CIAD Institutional Review Board. |  |  |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose |  |  |
| Population | | | |
| Inclusion criteria | Criteria for participation included age betw een 9 and 17 years, BMI >95th percentile based on the Centers for Disease Control and Prevention grow th chart  (15) or BMI >90th percentile w ith w aist circumference >90th percentile (16), caregivers interested in w eight control, and w illingness to attend the group educational sessions. | | |
| Exclusion criteria | Exclusion criteria included glucose intolerance or type 2 diabetes, psychiatric disorders, any medical condition that w ould preclude participation in the study, the use of medication that affected w eight, or involvement in a w eight loss program or structured physical activity. Participants w ho had lost w eight during the  4 months bef ore the study w ere also excluded. | | |
| Group differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Lifestyle | Control | Overall |
| N | 21 | 22 | 43 |
| Sex | 48% male | 50% male | NR |
| Age | 11.6 | 11.7 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.12 | 2.07 | NR |
| Interventions | |  |  |
|  | Lifestyle | Control |  |
| Intervention as described by  authors | Participants randomized to lifestyle intervention attended a family-centered program consisting of 12 sessions of behavioral curriculum, dietary advice from a registered dietitian (w eekly for the  first 3 months and monthly thereafter), and monthly consultations w ith a primary care physician | Control group participants attended monthly consultations w ith a primary care physician  w ho received a brief training on obesity |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 12 months | 12 months |  |
| Intensity as described by authors | The program consisted of 12 consecutive, w eekly,2-hour group sessions in the clinic. Participants and their parents attendedw eekly consultations w ith the RD during the first 12consecutive w eeks of the study and monthly thereafter. Participants and their parents  hadmonthly consultations of 10 to 15 minutes w ith a primarycare physician. | Participants in the control group and their parents at-tended monthly consultations of  10 to 15 minutes inlength w ith a primary  care physician. |  |
| Assigned intensity | 26-51 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider | Primary care |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI SDS |  |
| 6 months | 12 months |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Lifestyle | 21 | -0.31 | 0.2 | <0.05 | <0.05 | 21 | -0.29 | 0.24 | <0.05 | <0.05 |
| Control | 22 | -0.07 | 0.12 | <0.05 |  | 22 | -0.09 | 0.23 | NS |  |

**Davis, Am; James, Rl; Boles, Re; Goetz, Jr; Belmont, J; Malone, B**

**The use of TeleMedicine in the treatment of paediatric obesity: feasibility and acceptability**

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| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This research w as supported by grants from The Sun-flow er Foundation: Healthcare for Kansans, and by the National Institute of Diabetes and Digestive and  Kidney Diseases (K23 DK068221). | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Institutional Review Board approval w as obtained, and signed consent/assent forms w ere returned to research personnel via school personnel. | | |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | 5th grade children, The nurses targeted families of children w ho w ere overw eight or obese (BMI85th percentile for age and gender). | |  |
| Exclusion criteria | Major developmental difficulties that w ould interfere w ith participation in a group programme | |  |
| Group  differences | Randomized |  |  |
| Special  populations | Rural population |  |  |
|  | Telemedicine | Physician Visit | Overall |
| N | NR | NR | 17 |
| Sex | NR | NR | 58.8% female |
| Age | NR | NR | 9.9 |
| Race | NR | NR | 47.1% w hite,  47.1% African  American, 5.9% Hispanic |
| BMI Percentile | 95.3 | 95.7 | NR |
| Interventions | |  |  |
|  | Telemedicine | Physician Visit |  |
| Intervention as described by authors | The TeleMedicine intervention w as composed of four 1-h long group sessions delivered over an 8-w eek period. Parents and children attended each session, along w ith the school nurse. Groups w ere led by a PhD level psychologist via TeleMedicine from a tertiary care medical centre. At the end of each meeting, the children returned to the TeleMedicine room and w orked  w ith parents and the psychologist to set goals for the upcoming w eek | The physician visit intervention w as composed of a single visit w ith the child’s primary care physician. To standardize visits and assure the visit took place, a list of topics w as sent to each child’s physician suggesting w hat they may w ant to discuss during the visit. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 2 months | 1 visit |  |
| Intensity as  described by authors | 4 1-hour group session | 1 visit |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider types | Mental health, other (school nurse) | Primary care |  |
| Clinic setting | School based health center | Primary care |  |
| Components | Nutrition counseling, Activity counseling, mental health, other (telemedicine) | Nutrition counseling, activity counseling |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI Percentile |  |
|  | 12 months |
|  | Text summary |
| Telemedicine | 14/17 follow ed-up, "no differences" |
| Physician Visit | No changes w ere seen at follow up |

**Davis, Am; Sampilo, M; Gallagher, Ks; Dean, K; Saroja, Mb; Yu, Q; He, J; Sporn, N**

**Treating rural paediatric obesity through telemedicine vs. telephone: outcomes from a cluster randomized controlled trial**

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| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The author(s) disclosed receipt of the follow ing financial supportfor the research, authorship, and/or publication of this article:funding from the National  Institutes of Health (NIDDK08101 6). | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | All study procedures w ere approved by the relevant Institutional Review Board. | |  |
| Outcomes other  than BMI | BMI, Behaviors, other |  |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere: children w ith BMI of > 85th for age/gender, family living in a rural area (city and/or county population < 20,000), child attending a school  w ith phone and Internet capabilities, and the family having access to a phone. | | |
| Exclusion criteria | Exclusion criteria w ere family moving to a non-rural area, child having physical limitation or receiving an injury w hich significantly limited physical mobility, child having a significant medical issue, or child and parents having significant developmental delay or cognitive impairment that w as know n to the school. No  children w ho met the inclusion criteria had to be excluded | | |
| Group  differences | Randomized |  |  |
|  | Telemedicine | Telephone | Overall |
| N enrolled | 42 | 61 | 103 |
| Sex | 17% m | 29% m | 46% m |
| Age in years | 9.39 | 8.97 | 9.14 |
| Race | 38% w | 52% w | 90% w |
| Child BMIz | 1.66 | 1.78 | 1.73 |
| Child BMI%ile | 94.02 | 94.49 | 94.3 |
| Parent BMI M | 33.43 | 30.88 | 31.81 |
| Interventions | |  |  |
| Intervention as | Telemedicine  The intervention w as based upon cognitive behavior family based,covering behavioral, nutrition and phys Topics included Goal Setting, Stop-Light Diet,16Sede Praising and Ignoring, Calorie Counting, Portion Siz anddressing tips for the large body types, among ot Each group session had specific objectives outlined manual and began w ith a short introduction and rev | Telephone  al theory and w as The intervention w as based upon cognitive behavioral theory and w as ical activity topics. family based,covering behavioral, nutrition and physical activity topics. ntary Activity, Topics included Goal Setting, Stop-Light Diet,16Sedentary Activity,  e, Self -Esteem, Praising and Ignoring, Calorie Counting, Portion Size, Self-Esteem, hers (see table 1). anddressing tips for the large body types, among others (see table 1). in a treatment Each group session had specific objectives outlined in a treatment  iew of w eekly goals manual and began w ith a short introduction and review of w eekly goals |  |
| defined by  author  Intervention type (choose one) | and progress led by both the off -site leader and the  representative. Then, the off -site leader (a clinician research team) met w ith the parents via the random (telemedi- cine, telephone), and simultaneously the representative met w ith the children in the next room manualized topics. All group meetings lasted approx The parent and child groups covered the same topic group w as more didactic and the child group more ac  Lifestyle | on-site school and progress led by both the off -site leader and the on-site school  member of the representative. Then, the off -site leader (a clinician member of the ized modality research team) met w ith the parents via the randomized modality on-site school (telemedi- cine, telephone), and simultaneously the on-site school  to cover their representative met w ith the children in the next room to cover their imately one hour. manualized topics. All group meetings lasted approximately one hour. s, but the parent The parent and child groups covered the same topics, but the parent tivity-based. group w as more didactic and the child group more activity-based.  Lifestyle |  |

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| --- | --- | --- |
| Intervention  length | 8 months | 8 months |
| Intensity as  described by authors | The intervention consisted of eight w eekly meetings follow ed by six  monthly meetings, for a total intervention period of eight months, w hich w as Davis et al. 87 designed to coincide w ith a typical school year. | The intervention consisted of eight w eekly meetings follow ed by six  monthly meetings, for a total intervention period of eight months, w hich w as Davis et al. 87 designed to coincide w ith a typical school year. |
| Assigned  Intensity | 5-25 hours | 5-25 hours |
| Provider type  (select all) | Other (school personnel- nurse, gym teacher, computer teacher) and  member of clinical research team | Other (school personnel- nurse, gym teacher, computer teacher) and  member of clinical research team |
| Clinic setting  (choose one— probably) | Other- School setting | Other- School setting |
| Components  (choose all) | Nutrition counseling, activity counseling, mental health | Nutrition counseling, activity counseling, mental health |

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| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| Changes in Child BMIz |  |  |  |  |  |  |
|  | Baseline |  | 8 w eeks |  | 8 months |  |
|  | Mean | SD | Mean | SD | Mean | SD |
| Telemedicine | 1.68 | 0.39 | -0.01 | 0.16 | 0 | 0.22 |
| Telephone | 1.77 | 0.51 | -0.07 | 0.19 | 0 | 0.18 |

**Davis, Am; Sampilo, M; Gallagher, Ks; Landrum, Y; Malone, B**

**Treating rural pediatric obesity through telemedicine: outcomes from a small randomized controlled trial**

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| Study  Identification |  |  |  |
| Sponsorship  source | National Institutes of Health (DK068221 to A.M.D.). |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | All study procedures w ere approved by the relevant institutional  review board. |  |  |
| Outcomes other than  BMI | Behaviors, Psychosocial |  |  |
| Population | | | |
| Inclusion criteria | School: Criteria for school participation included having rural designation (in a tow n or county w ith a population <20,000) and telemedicine capabilities (common in rural districts for distance learning).  Students: Inclusion criteria included living in a rural area and attending elementary school, BMI percentile 85th for age/gender, and parent’s ability to speak  English | | |
| Exclusion criteria | School: Schools that did meet the inclusion criteria  Students: Exclusion criteria included having a developmental disability that w ould prevent the child from participating in the group, or being immobile, w hich w ould  prevent them from increasing exercise. Parents and children w ho chose to participate gave inf ormed consent and assent, respectively. | | |
| Group  differences | Randomized |  |  |
| Special  Populations | Rural |  |  |
|  | Telemedicine group (intervention) | Physician visit group (comparison) | Overall |
| N enrolled | 31 | 27 | 58 |
| Sex n(%) | Male 70.69 (41) | Male 70.97 (22) | 41 (71%) male |
| Age in years  M(SD) | 8.48 (1.73) | 8.69 (1.78) | 8.55 (1.74) |
| Race | 30 (97%) Caucasian | 22(81%) Caucasian | Caucasian (89.66%)three w ere Native American (5.17%), and three (5.17%) did not indicate  their race/ethnicity |
| Child BMI percentile M  (SD) | 94.69 (4.13) | 93.78 (4.35) | 94.18 (4.27) |
| Maternal BMI M (SD) | 30.47 (8.93) | 31.25 (9.88) | 30.83 (9.30) |
| Interventions | |  |  |
|  | Telemedicine group (intervention) | Physician visit group (comparison) |  |
| Intervention as defined by author | Children and families  participated in 8 w eekly psychoeducational groups over telemedicine led by trained PHD-level psychologists or trained graduate students/postdoctoral fellow s, follow ed  by 6 monthly meetings. Topics that w ere covered included: 1  Overview of program and expectations; goal setting | Children and families randomized to the physician visit group agreed to meet w ith their primary care physician to discuss a standardized list of topics. Topics that w ere covered included the causes of obesity and the relationship betw een diet, exercise, and body mass index; the  importance of eating a balanced diet; and current exercise |  |

|  |  |  |
| --- | --- | --- |
|  | 2 Use of goal charts; reinf orcement and incentives 3 Stop-light diet and nutrition recommendations   1. Screen time and sedentary activity; the importance of tracking; activity monitor results: your child’s data 2. Praising and ignoring: role play and homew ork 3. Diet recall results: your child’s data; calorie counting; healthy substitutions 4. Portion sizes: lesson, demonstration, and quiz 5. Self-esteem; dressing for larger body sizes; adult modeling: w hat I like about myself 6. Reading food labels and vitamins/minerals 10 The concept of nutrient density   11 Potlucks, BBQs, and other events: how to be smart 12 Exercising as a family   1. The application of energy balance 2. The use of privileges and maintenance | and  sedentary behavior recommendations for children. |
| Intervention  length | 8 months | 1 visit |
| Intensity as described by authors | Children and families randomized to the TM intervention participated in 8 w eekly psychoeducational groups over telemedicine led by trained PHD-level psychologists or trained graduate students/postdoctoral fellow s, follow ed  by 6 monthly meetings. | Children and families randomized to the physician visit group agreed to meet w ith their primary care physicianto discuss a standardized list of topics. |
| Assigned  Intensity | 5-25 hours | <5 hours |
| Provider type (select  all) | Mental health, Other (School representative ) | Primary care |
| Clinic setting (choose one—  probably) | Telemedicine | Primary care |
| Components  (choose all) | Nutrition counseling and activity counseling, self esteem | Nutrition counseling and activity counseling |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| Child BMIz Change |  |  |  |  |  |  |  |  |  |  |
|  | Pretreatment\_month  1 |  |  |  | Posttreatment\_ Month  8 | |  |  |  |  |
|  | Mean | SD | Change in  Mean | t-  statistics | p-  value | Mean | SD | Change in  Mean | t-  statistics | p-  value |
| Telemedicine group (intervention) | 1.88 | 0.52 |  |  |  | 1.76 | 0.52 | -0.12 | 3.018 | 0.007 |
| Physician visit group  (comparison) | 1.7 | 0.45 |  |  |  | 1.55 | 0.59 | -0.15 | 2.684 | 0.014 |

**Davoli, Am; Broccoli, S; Bonvicini, L; Fabbri, A; Ferrari, E; D'Angelo, S; Buono, A; Montagna, G; Panza, C; Pinotti, M; Romani, G; Storani, S; Tamelli, M; Candela, S; Giorgi, Rossi P**

**Pediatrician-led motivational interviewing to treat overweight children: an RCT**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | No external funding. |  |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | parents signedthe inf ormed consent form |  |  |
| Outcomes  other than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion  criteria | Eligible partic-ipants w ere all overw eight children (85th$BMI percentile$95th)34betw een 4 and7 years old resident in the RE Provinceand assisted by that  pediatrician for atleast 12 months. | | |
| Exclusion criteria | Exclusion criteria w eremetabolic pathologic conditions and allpathologic conditions related to obesityand overw eight. Moreover, those familiesw ho did not consider childhood over-w eight a problem and w ere not in-terested in the negative consequences orin advice on how to lose w eight (familiesin  the“precontemplation stage”)w erealso excluded. | |  |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Intervention | Usual Care | Overall |
| N | 187 | 185 | 372 |
| Sex | 40.1% male | 36.8% male | NR |
| Age | 6.7 | 6.5 | NR |
| Race | NR | NR | NR |
| BMI SDS | 1.35 | 1.35 | 1.35 |
| Interventions | |  |  |
|  | Intervention | Usual Care |  |
| Intervention as defined by author | A family pediatrician–led MI w as offeredto children assigned to the interventiongroup consisting of 5 individual meet-ings based on the transtheoreticalmodel of addiction and behavior change(Table 1).37The child and parents alw ayshad to leave the meeting having agreedon 2 objectives (1 concerning food and 1concerning PA  improvements) thatw ere clearly defined and achievable. | children w how ere randomly assigned to the controlgroup received a booklet w ith the maininf ormation on obesity prevention.During the year of intervention, theyreceived the usual care currently of -fered by pediatricians to  overw eightchildren (ie, opportunistic advice if thepediatricianisseeingthechildf orotherreasons). |  |
| Intervention  type | Lifestyle | Usual care |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as described by  authors | 1st Baseline MI=45-60 min; 2nd, after 1 month=45-60; 3rd, after 3 months=30 mins; 4th, after 3 months=30 mins; 5th, 1 yr after  baseline=45 | Usual care |  |
| Assigned  intensity | <5 hours | <5 hours |  |
| Provider types | Primary care | Primary care |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 12 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Intervention | 176 | -0.11 | -0.17 | -0.05 | NS |
| Usual Care | 179 | 0.01 | -0.06 | 0.05 |  |
| BMI | | | | | |
|  | 12 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Intervention | 176 | 0.49 | 0.29 | 0.68 | 0.007 |
| Usual Care | 179 | 0.79 | 0.61 | 0.97 |  |

**de Ferranti, S. D.; Milliren, C. E.; Denhoff, E. R.; Quinn, N.; Osganian, S. K.; Feldman, H. A.; Ebbeling, C. B.; Ludwig, D. S. Providing food to treat adolescents at risk for cardiovascular disease**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | Dr. de Ferranti w as supported by a National Institutes of Health Grant K23 HL 085308, by a Career Development Aw ard from Boston Children’s Hospital, by the Farb Family Fund, and by the Kostin Family Innovation Fund. Erica Rose Denhoff w as supported by the Boston Children’s Heart Foundation. Dr.  Feldman,Car ly Milliren, and Nicolle Quinn w ere supported by Harvard Catalyst, The Harvard Clinical and Translational Science Center (National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health Aw ard #UL1 RR 025758, and financial contributions from Harvard University and its affiliated academic health care centers). Dr. Ebbeling w as supported by the New Balance Foundation. Dr. Ludw ig  w as supported by a career aw ard from NIDDK (K24DK082730) | | |
| Country | USA |  |  |
| Setting | - |  |  |
| Comments | - |  |  |
| Authors name | - |  |  |
| Institution | - |  |  |
| Email | - |  |  |
| Address | - |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Written inf ormed consent w as obtained from participants or parents. The study w as approved by the BCH Institutional Review Board (clinicaltrials.gov  registrationNCT01 0803 39). | | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other labs, behaviors | |  |
| Population | | | |
| Inclusion  criteria | Indi-viduals aged 8-21 years w ere eligible to participate if they had ele-vated body mass index (BMI)85th percentile using CDC ref erencepopulation (20), a  fasting insulin10mU/ ml, and at least tw o addi-tional CV risk factors. | | |
| Exclusion criteria | Exclusioncriteria included w eight>275 lbs (125 kg) due to concerns aboutvenous access, current or anticipated pregnancy, major medical illnessor medications that might significantly affect CV risk factors or w eight(e.g., thyroid disorders), alcohol, tobacco, or other drug use, seriousfood allergy, or abnormalities at screening that indicated a need forpharmacotherapy. For this pilot study, w e also excluded participantsw hom w e anticipated w ould have significant difficulty  follow ing thestudy protocol (e.g., behavioral issues, major food restrictions, or aver-sions) or w ho lived outside a reasonable driving distance | | |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Low fat diet (LF) | Low glycemic load diet (LGL) | Overall |
| N | 12 | 15 | 27 |
| Sex | NR | NR | 33% male |
| Age | NR | NR | 13.2 |
| Race | NR | NR | 48% w hite,  19% black,  33% other,  26% Hispanic |
| BMI SDS | 1.99 | 2.09 | 2 |
| Interventions | |  |  |
|  | Low fat diet (LF) | Low glycemic load diet (LGL) |  |
| Intervention as  described by author | During the Intensive Phase all participants received 3 customized  meals and 1 snack per day prepared according to their assigned diets (LF orLGL) for 6 out of 7 days per w eek. On the 7th day participants | During the Intensive Phase all participants received 3 customized  meals and 1 snack per day prepared according to their assigned diets (LF orLGL) for 6 out of 7 days per w eek. On the 7th day |  |

|  |  |  |
| --- | --- | --- |
|  | w ere instructed to eat along the assigned dietary strategy. Dietary change w as rein-forced by w eekly in-person home nutrition counseling and w eekly phone calls covering topics consistent w ith the participant’s group assignment using an adapted nutrition curriculum . During the Maintenance Phase, participants w ere asked to follow theirassigned dietary strategy w ith no provision of food or in-person con-tact. The study dietitians continued to provide behavioral support byphone at regular intervals (w eeks 10, 12, 16, and 20). The LF diet w as basedon contemporary dietary guidelines (20% total fat of w hich 7% w ere saturated fat). | participants w ere instructed to eat along the assigned dietary strategy. Dietary change w as rein-forced by w eekly in-person home nutrition counseling and w eekly phone calls covering topics consistent w ith the participant’s group assignment using an adapted nutrition curriculum . During the Maintenance Phase, participants  w ere asked to follow theirassigned dietary strategy w ith no provision of food or in-person con-tact. The study dietitians continued to provide behavioral support byphone at regular intervals (w eeks 10, 12, 16, and 20). The LGL diet targeted aglycemic index of 50% for each meal, calculated as product of theglycemic index of a food and the amount of carbohydrate in thatfood using glucose as the  ref erence. |
| Intervention  type | Dieting | Dieting |
| Intervention  length | 2 months, 4 months maintenance | 2 months, 4 months maintenance |
| Intensity as described by  authors | 2 month intensive: Weekly in-person home nutrition counseling, w eekly hone calls; 4 additional contacts in maintenance phase | 2 month intensive: Weekly in-person home nutrition counseling, w eekly hone calls; 4 additional contacts in maintenance phase |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Nutrition provider | Nutrition provider |
| Clinic setting | Research unit | Research unit |
| Components | Nutrition counseling, activity counseling, nutrition training | Nutrition counseling, activity counseling, nutrition training |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI |  |  |  |
|  | 6 months |  |  |
|  | mean | SE | N |
| Low fat diet (LF) | 27.8 | 0.59 | 12 |
| Low glycemic load diet (LGL) | 30 | 1.27 | 15 |
| BMI SDS | | | |
|  | 6 months |  |  |
|  | mean | SE | N |
| Low fat diet (LF) | 1.84 | 0.06 | 12 |
| Low glycemic load diet (LGL) | 1.98 | 0.08 | 15 |

**de Niet, J.; Timman, R.; Bauer, S.; van den Akker, E.; Buijks, H.; de Klerk, C.; Kordy, H.; Passchier, J.**

**The effect of a short message service maintenance treatment on body mass index and psychological well-being in overweight and obese children: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Support for this study w asreceived from Vodaf one, the Netherlands. Grantsw ere received from the Erasmus University MedicalCentre Rotterdam – MRACE  (Medical ResearchAdvice Committee) grant no. 2006-26 and Innova-tion Fund Insurances (Innovatief onds Verzekeringen)grant no. 06–334. | | |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocol w as approved by theMedical Ethics Committee of the Erasmus MC Uni- versity Medical Centre Rotterdam and by the medicalethics committees of the participating  hospitals. |  |  |
| Outcomes other  than BMI | Psychosocial |  |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere being overw eight or obese, parent participation in the BFC and a sufficient know ledge of the Dutch language. | |  |
| Exclusion criteria | Exclusion criteria for overw eight and obese children participating in the BFC programme included behavioural problems defined as a score >70 on the Child  Behaviour Checklist (CBCL) (14) and any disease causing overw eight that could be treated w ith drugs and mental retardation. Furthermore, parents and child had to be both sufficiently fluent in the Dutch language and show sufficient motivation to actively participate in the programme. | | |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | SMSMT+ | Control group | Overall |
| N | 73 | 68 | 141 |
| Sex | 38% male | 34% male | 36%  male |
| Age | 10 | 9.8 | 9.9 |
| Race | Dutch- 78% | Dutch- 71% | Dutch-  75% |
| BMI SDS | 2.63 | 2.54 | 2.59 |
| Interventions | |  |  |
|  | SMSMT+ | Control group |  |
| Intervention as defined by author | Maintenance after 3 months of PWMP. Participants in the SMSMT group received a mobilephone for the period of the SMSMT intervention. The children w ere requested tosend  w eekly self-monitoring data on a five-point Likertscale via SMS. Next, the program suggested a feed-back message w ith a 160-character limitation out of alarge pool of pre-formulated statements, w hich w as tailored to the child's individual pattern of change inbehaviour. The  feedback w as checked for plausibilityby a researcher w ho tailored the feedback messagew hen  needed. | Usual care (in the PWMP) |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 9 months (maintenance) | 9 months (maintenance) |  |
| Intensity as described by authors | Weekly texting contact; follow -up group sessions forchildren and parents and individual appointments areorganized at 6, 9, and 12 months after the start ofthe programme. (90 min + 1 hour) | Follow -up group sessions forchildren and parents and individual appointments areorganized at 6, 9, and 12 months after the  start ofthe programme. (90 min + 1 hour) |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider, mental health, exercise | Primary care, nutrition provider, mental health,  exercise |
| Clinic setting | Multidisciplinary w eight management | Multidisciplinary w eight management |
| Components | Nutrition counseling, activity counseling, motivational interview ing, mental health, activity training, other (texting) | Nutrition counseling, activity counseling,  motivational interview ing, mental health, activity training |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| SMSMT+ | 73 | 2.4 | 0.59 | 0.34 | 73 | 2.38 | 0.59 | 0.76 |
| Control group | 68 | 2.3 | 0.56 | - | 68 | 2.34 | 0.57 | - |

**DeBar, Ll; Stevens, Vj; Perrin, N; Wu, P; Pearson, J; Yarborough, Bj; Dickerson, J; Lynch, F**

**A primary care-based, multicomponentlifestyle intervention for overweight adolescent females**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Funded by the National Institutes of Health (NIH). |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The HMO Human Subjects Pro-tection Committee approved and mon-itored all study procedures. Parents orguardians provided inf ormed consent,and  adolescents provided assent. | | |
| Outcomes other than  BMI | Psychosocial, mental health, behaviors, glucose metabolism, lipids |  |  |
| Population | | | |
| Inclusion  criteria | Eligibility w as limited to female healthplan members aged 12 to 17 years w ith an age-and gender-adjusted BMI>=90th percentile | |  |
| Exclusion  criteria | Exclusion criteria included: significant cognitiveimpair ment or psychosis, severe obe-sity (BMI.45), use of medicationsknow n to affect body w eight,  andpregnancy. | |  |
| Group  differences | Randomized |  |  |
| Special  populations | Adolescent females |  |  |
|  | Intervention | Control | Overall |
| N | 105 | 103 | 208 |
| Sex | 100% female | 100% female | 100% female |
| Age | 14.12 | 14.03 | 14.1 |
| Race | 71.43% w hite | 72.82% w hite | NR |
| BMI SDS | 2 | 2 | 2 |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as defined by author | The multicomponent intervention included the follow ing: (1) change in dietary intake and eating patterns; (2) increasing physical ac-tivity by using developmentally tailored forms of exercise (eg, exergaming); (3) addressing issues associated w ith obesity in adolescent girls (eg, de-pression, disordered eating patterns, poor body image); and (4) training participants’ PCPs to support behavioral w eight management goals collaboratively. Over the intervention’s first 3 months, parents w ere invited to separate, w eekly group meetings, during w hich staff explained the nutritional and physical activity principles the teens w ould learn so that parents could help support their daughters and reduce potential barriers to success. | Usual care participants received a packet of materials, including outlines of evidence-based approaches to w eight management for youth and adults, a parents’ guide to help adolescents make healthy lifestyle changes, local resources for w eight management and healthy activity, and suggested books and online materials on healthy lifestyle change. Usual care participants also met w ith their PCPs at the study onset to encourage healthy  lifestyle changes, although PCPs w ere not given the tai-lored patient assessment summaries described earlier in the intervention arm  for use in their visit nor w ere usual care  participants scheduled for a 6-month study-related session w ith their PCPs. |  |
| Intervention  type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 5 months | 6 months |
| Intensity as described by authors | The teen intervention compromised 90-minute group meetings conducted over5 months. Groups met 16 times, w eekly for 3 months and biw eekly during months 4 and 5. At each session, teens w ere w eighed and review ed dietary and physical activity self-monitoring re-cords. If unable to attend a particular session, teens w ere offered telephone sessions. Baseline and 6 month PCP visit. | Usual care participants also met w ith their PCPs at the study onset to encourage healthy lifestyle changes, although PCPs w ere not given the tailored patient assessment summaries described earlier in the intervention arm for use in their visit nor w ere usual care participants scheduled for a 6-month  study-related session w ith their PCPs. |
| Assigned  intensity | 5-25 hours | <5 hours |
| Provider  types | Primary care, nutrition provider, mental health | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training, mental health,  motivational interview ing, Other- Parent education, Other- PCP education | Usual care |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention | 100 | 1.88 | 0.41 | NR | 90 | 1.85 | 0.46 | 0.012 |
| Control | 95 | 1.94 | 0.38 | - | 83 | 1.92 | 0.39 | - |

**Deforche, B; Bourdeaudhuij, I; Tanghe, A; Debode, P; Hills, Ap; Bouckaert, J**

**Post-treatment phone contact: a weight maintenance strategy in obese youngsters**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None |  |  |
| Country | Belgium |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Written inf ormed consent w as obtained fromall participants and parents. |  |  |
| Outcomes other  than obesity | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Obese youngsters (16.372.6 y, 11.3–18.3 y) w hocompleted a 10-month residential treatment programm |  |  |
| Exclusion criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Experimental | Control | Overall |
| N | 10 | 10 |  |
| Sex | 50% female | 50% female | 50%  female |
| Age | NR | NR | 16.3 |
| Race | NR | NR | NR |
| ABMI% | NR | NR | NR |
| Interventions | |  |  |
| Intervention as | Experimental  After initial treatment, both experimental and controlgroups w ere invited to the residential centre for 3- monthlycheck-ups. In addition, the experimental group follow ed a5-month w eight-loss maintenance programme. The mainte-nance programme started 1.5 months after initial treatmentbecause of the summer holidays.  During the maintenanceprogramme, there w ere w eekly contacts betw een a therapist(specialist in promoting | Control  Checkup every 3 months |  |
| defined by author  Intervention type | physical activity) and the patients,either by mail or phone. The patients recorded their physicaland sedentary activities in a diary (self-monitoring, self -control) and sent their diary to the therapist each w eek. Inturn, the therapist phoned them biw eekly to discuss briefly(5–10 min) their activity behaviour.  Lifestyle | Lifestyle |  |
| Intervention  length | 5 months | 5 months |  |
| Intensity as described by  authors | The administration (letters,incentive system, preparing phone calls) took about 20 minper 2 w eeks per patient. In the first 15 w eeks, patients w erecalled biw eekly, and during the last 6 w eeks, phone contactsw ere cut back to one  call every 3 w eeks. | Checkup every 3 months |  |
| Assigned  intensity | 5-25 hours | <5 hours |  |
| Provider types | Mental health | Usual care |  |
| Clinic setting | Multidisciplinary w eight management program, (post inpatient discharge) | Multidisciplinary w eight management program, (post  inpatient discharge) |  |
| Components | Nutrition counseling, activity counseling, other (incentives) | Usual care |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| Adjusted BMI Percent |  |  |  |  |  |
| Post (5 months) | | | | | |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Experimental | 10 |  | Trajectory: increase in OW during maintenance phase (p<0.05) | | NR |
| Control | 10 |  | Trajectory: increase in OW slow ed dow n during maintenance (NS) | | NR |

**Demol, S; Yackobovitch-Gavan, M; Shalitin, S; Nagelberg, N; Gillon-Keren, M; Phillip, M**

**Low-carbohydrate (low & high-fat) versus high-carbohydrate low-fat diets in the treatment of obesity in adolescents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | None listed. |  |  |  |
| Country | Israel |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the local Ethics Committee for Research in Humans of the Israel Ministry of Health. Writ-ten inf ormed consent w as obtained from  each participant and his or her legal guardian. | | | |
| Outcomes other than  BMI | Other obesity, glucose metabolism, lipids |  |  |  |
| Population | | | | |
| Inclusion criteria | The study sample consisted of 55 obese patients aged 12–18 years (mean 14.4±1.7) ref erred to the Obesity Clinicof the Institute for Endocrinology and Diabetes at Schneider Children’s Medical Center of Israel betw een January and March 2005. All patients w ere Tanner stage 4–5, and all had a body mass index (BMI)  greater than the 95th percentile for age and gender according to the grow th charts of the Cen-ters for Disease Control and Prevention. | | | |
| Exclusion criteria | Subjects w ith a chronic disease (such as diabetes, renal, heart or liver dis-eases, thyroid function disorder or diagnosed psychologicaldisorder), subjects  receiving w eight–loss-inducing medica-tion and subjects w ho had participated in another w eight–loss study or slimming diet w ithin 2 months prior to thepresent study w ere excluded. | | | |
| Group  differences | Randomized |  |  |  |
| Special  populations | None |  |  |  |
|  | Low carb/low fat | Low carb/high fat | High carb/low fat | Overall |
| N | 18 | 20 | 17 | 55 |
| Sex | 38.9% male | 50% male | 23.5% male | 38.2%  male |
| Age | 14 | 14.3 | 14.9 | NR |
| Race | NR | NR | NR | NR |
| BMI SDS | 3.4 | 3.1 | 3.3 | 3.3 |
| Interventions | |  |  |  |
|  | Low carb/low fat | Low carb/high fat | High carb/low fat |  |
| Intervention as described by authors | All participant received menus and detailed instructionaccording to their diet group. In order to increase the com-pliance to the diet regiment, once a month during the threemonths of intervention all participants received three  new different detailed menus according to their diet group.  Low -carbohydrate, low -fat, protein-rich diet con-taining 1200–1500 kcal a day: 60 g carbohydrates(up to 20%), 30% fats and 50% proteins. As part of theintervention, participants attended w eekly sessions w ith adietitian and a  psychologist. At the end of the intervention pe- riod (w eek 12), the participants w ere given new | All participant received menus and detailed instructionaccording to their diet group. In order to increase the com-pliance to the diet regiment, once a month during the threemonths of intervention all participants received three  new different detailed menus according to their diet group. Low -carbohydrate, high-fat diet containing1200–1500 kcal a day: 60 g carbohydrates (up to20%), 60% fats and 20% proteins. As part of theintervention, participants attended w eekly sessions w ith adietitian and a psychologist. At the end of the intervention pe- riod (w eek 12), the participants w ere given new  instructionsand menus for a high-carbohydrate | All participant received menus and detailed instructionaccording to their diet group. In order to increase the com-pliance to the diet regiment, once a month during the threemonths of intervention all participants received three  new different detailed menus according to their diet group. High-carbohydrate, low -fat diet containing 1200–1500 kcal a day: 50–60% carbohydrates, 30% fatsand 20% proteins. As part of theintervention, participants attended  w eekly sessions w ith adietitian and a psychologist. At the end of the intervention pe- riod (w eek 12), the participants w ere given new  instructionsand menus for a high-carbohydrate |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | instructionsand menus for a high-carbohydrate low -fat maintenance dietand scheduled for  follow -up visits every 3 months for thef ollow ing  9 months. | low -fat maintenance dietand scheduled for  follow -up visits every 3 months for thef ollow ing 9 months. | low -fat maintenance dietand scheduled for  follow -up visits every 3 months for thef ollow ing 9 months. |
| Intervention  type | Specific diet | Specific diet | Specific diet |
| Intervention length | 12 w eeks | 12 w eeks | 12 w eeks |
| Intensity as described by  authors | 12 w eekly sessions | 12 w eekly sessions | 12 w eekly sessions |
| Assigned  intensity | 5-25 hours | 5-25 hours | 5-25 hours |
| Provider types | Specialist, nutrition provider, mental health | Specialist, nutrition provider, mental health | Specialist, nutrition provider, mental health |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program | Multidisciplinary w eight management program |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 12 w eeks | |  |  | 52 w eeks | |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Low carb/low fat | 18 | 2.8 | 0.3 | NS | 18 | 2.7 | 0.3 | NS |
| Low carb/high fat | 17 | 2.7 | 0.3 |  | 17 | 2.7 | 0.4 |  |
| High carb/low fat | 20 | 2.9 | 0.3 |  | 20 | 2.5 | 0.3 |  |
| BMI | | | | | | | | |
| 12 w eeks | |  |  | 52 w eeks | |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Low carb/low fat | 18 | 32.5 | 1.6 | NS | 18 | 32.4 | 1.6 | NS |
| Low carb/high fat | 17 | 31.7 | 1.6 |  | 17 | 32.6 | 1.7 |  |
| High carb/low fat | 20 | 32 | 1.5 |  | 20 | 31.1 | 1.6 |  |

**Ebbeling, Cb; Leidig, Mm; Sinclair, Kb; Hangen, Jp; Ludwig, Ds**

**A reduced-glycemic load diet in the treatment of adolescent obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | This study w as supported by grants 1R01DK59240 and1K01DK62237, from the National Insitute of Diabetes andDigestive Kidney Diseases (Bethesda, Md); the Charles H.Hood Foundation (Boston, Mass); pilot and feasibility projectgrant DK46200 from the Boston Obesity and Nutrition Re-search Center (Boston); and grant M01 RR02172 aw ardedby the National Institutes of Health (Bethesda) to supportthe General Clinical Research Center at Children’s Hospi-tal Boston, Boston. Nutrition bars w ere offered to sub-jects in the experimental (Balance Bar; kindly provided by KraftFoods, Inc, Northfield, Ill) and conventional  groups (NatureValley Granola Bar; General Mills, Inc, Minneapolis, Minn) foroccasional use as snacks. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The protocol w as approved by the Institutional Review Boardat Children’s Hospital Boston. Written inf ormed consent w asobtained from subjects 18 years or  older and from the parentsof minors; assent w as obtained from minors. | | |
| Outcomes other  than BMI | Other obesity, glucose metabolism |  |  |
| Population | | | |
| Inclusion  criteria | Obese patients 13-21 years |  |  |
| Exclusion criteria | Allsubjects w ere free of major medical illness, as assessed bymeans of physical examination and screening laboratory tests(measurement of kidney and liver enzymes, thyrotropin, gly-cosylated hemoglobin, and fasting plasma glucose levels andurinalysis). | | |
| Group  differences | Randomized |  |  |
| Special  populations | Adolescents |  |  |
|  | Experimental (Reduced GL) | Conventional (Reduced Fat) | Overall |
| N | 7 | 7 | 14 |
| Sex | NR | NR | NR |
| Age | 16.9 | 15.3 | NR |
| Race | NR | NR | NR |
| BMI | 34.9 | 37.1 | NR |
| Interventions | |  |  |
|  | Experimental (Reduced GL) | Conventional (Reduced Fat) |  |
| Intervention as described by authors | The reduced-GL prescription emphasized selection of carbo- hydrate-containing foods (eg, nonstarchy vegetables, fruits, le- gumes, nuts, and dairy) that are characterized by a low to mod- erate GI.14Patients w ere instructed to balance consumption  ofcarbohydrates w ith protein and fat at every meal and snack.The prescription w as not energy restricted. Rather, subjects  w ereadvised to eat to satiety and to snack w hen hungry. The tar- geted proportion of energy from carbohydrate and fat w ere 45%to 50% and 30% to 35%, respectively, w ith the remainder  fromprotein. Social cognitive theory provided a conceptual  framew ork forthe educational and behavioral components of  treatment thatw as consistent betw een intervention groups. | The reduced-fat prescription w as based on current rec-ommendations for  w eight loss and diabetes prevention,25,26w ithemphasis on limiting dietary fat intake and increasing the in-take of grains, vegetables, and fruits. Meal plans  w ere de-signed to elicit a negative energy balance of 250 to 500 kcal/d. ubjects w ere counseled toobtain 55% to 60% of energy from carbohydrates, 25% to 30%from fat, and the remainder from protein. Social cognitive theory provided a conceptual framew ork forthe educational and behavioral components of treatment thatw as consistent betw een intervention groups. |  |
| Intervention  type | Specific diet | Specific diet |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 12 months | 12 months |
| Intensity as  described by authors | 6-month intensive interven-tion (12 dietary counseling sessions) and a 6-month fol-low -up (2 dietary counseling sessions). | 6-month intensive interven-tion (12 dietary counseling sessions) and a 6- month fol-low -up (2 dietary counseling sessions). |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Nutrition provider, mental health | Nutrition provider, mental health |
| Clinic setting | Research center | Research center |
| Components | Nutrition counseling, activity counseling, mental health | Nutrition counseling, activity counseling, mental health |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 12 months | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Experimental (Reduced GL) | 7 | -1.3 | 0.7 | 0.02 |
| Conventional (Reduced Fat) | 7 | 0.7 | 0.5 |  |

**Fleischman, A; Hourigan, Se; Lyon, Hn; Landry, Mg; Reynolds, J; Steltz, Sk; Robinson, L; Keating, S; Feldman, Ha; Antonelli, Rc; Ludwig, Ds; Ebbeling, Cb Creating an integrated care model for childhood obesity: a randomized pilot study utilizing telehealth in a community primary care setting**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship  source | This study w as funded by New Balance Foundation. DSL w as supported by a career aw ard from the National Insti-tute of Diabetes and Digestive and  Kidney Diseases(DK082730). | | |
| Country | USA |  |  |
| Setting | - |  |  |
| Comments | - |  |  |
| Authors name | - |  |  |
| Institution | - |  |  |
| Email | - |  |  |
| Address | - |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Crossover |  |  |
| IRB | The study w asapproved by the BCH Institutional Review Board. Parentsor guardians (hencef orth ref erred to asparents) providedw ritten inf ormed consent,  and patients provided w rittenassent. | | |
| Outcomes other  than BMI | Other obesity, behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | Inclusion criteria included age betw een 10 and 17 yearsand BMI≥95th percentile for gender and age | |  |
| Exclusion criteria | Exclusion criteria included know n obesity comorbidities requiring medical intervention (e.g. type 2 diabetes); inability to actively participate in treatment (e.g. physical or cognitive limitations); major medical illness; use of medication or supplement know n to af fect body w eight; unstable home environment (homeless, temporary living situation or lack of w orking phone or electricity), w hich w as deemed likely to impede participation in the study; diagnosed eating  disorder; untreated significant depression or anxiety; orself-reported suicidal ideation in the past month. | | |
| Group differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Group 1: PCP + specialist telehealth | Group 2: PCP only | Overall |
| N | 21 | 19 | 40 |
| Sex | NR | NR | 77.5%  female |
| Age | NR | NR | 14.3 |
| Race | NR | NR | 87.5%  w hite |
| BMI SDS | 2.11 | 2.1 | NR |
| Interventions | |  |  |
|  | Group 1: PCP + specialist telehealth | Group 2: PCP only |  |
| Intervention as described by authors | low -glycaemic load diet, For nutrition education and goal setting, PCPs utilized abooklet that w as developed for this pilot study to alignw ith the obesity specialist treatment, The patient and a parent had 12 tele-visits over 6 months,alternating betw een a dietitian and  psychology fellow | low -glycaemic load diet, For nutrition education and goal setting, PCPs utilized abooklet that w as developed for this pilot study to align w ith the obesity  specialist treatment |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as described by authors | PCP every 3 months. 12 tele-visits over 6 months,alternating betw een a dietitian and psychology fellow . Dietitian visits w ere 1 h during a 6-w eek intensivephase (w eekly visits) and 30 min thereafter (less frequent fol-low -up visits). All psychologist visits w ere  1 h. | PCP every 3 months. |  |
| Assigned intensity | 5-25 hours | <5 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider type | Primary care, nutrition provider, mental health | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, mental health, motivational interview ing, other  (telehealth) | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  |  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Group 1: PCP + specialist telehealth | 21 | -0.11 | 0.02 | <0.0001 | 0.049 | 21 | -0.11 | 0.03 | 0.0006 | 0.23 |
| Group 2: PCP only | 19 | -0.05 | 0.02 | 0.04 | - | 19 | -0.06 | 0.03 | 0.08 | - |
| BMI | | | | | | | | | | |
|  | 3 months |  |  |  |  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Group 1: PCP + specialist telehealth | 21 | -1.1 | 0.2 | <0.0001 | 0.1 | 21 | -1.3 | 0.4 | 0.001 | 0.43 |
| Group 2: PCP only | 19 | -0.6 | 0.2 | 0.02 | - | 19 | -0.9 | 0.4 | 0.02 | - |

**Flodmark, Ce; Ohlsson, T; RydÃ©n, O; Sveger, T**

**Prevention of progression to severe obesity in a group of obese schoolchildren treated with family therapy**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This study w as supported by the Goljie Foundation, the Sw edish Medical Association, the Albert Pahlsson Foundation, the Sw edish Society of Medicine, the  Johanna Andersson Foundation, "Forenade Liv" Mutual Life Insurance Company Stockholm, and the Medical Faculty of the University of Lund. | | | |
| Country | Sw eden |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study design w as approved by the Research Ethics Committee of Lund University. | |  |  |
| Outcomes other  than BMI | Other obesity |  |  |  |
| Population | | | | |
| Inclusion criteria | BMI of 23 kg/m2. From children aged 10-11 screen for obesity at school. | |  |  |
| Exclusion criteria | None reported. |  |  |  |
| Group  differences | Randomized (tw o treatment groups--control not randomized). |  |  |  |
| Special  populations | None |  |  |  |
|  | Family therapy | Conventional treatment | Control | Overall |
| N | 24 | 19 | 50 | 93 |
| Sex | 54.2% female | 47.4% female | 62%  female | NR |
| Age | NR | NR | NR | NR |
| Race | NR | NR | NR | NR |
| BMI | 24.7 | 25.5 | 25.1 | NR |
| Interventions | |  |  |  |
|  | Family therapy | Conventional treatment | Control |  |
| Intervention as defined by author | Dietary counseling by a dietitian and regular visits to an experienced pediatrician w ith an interest in w eight problems. Prescribed diet of 1500-1700 calories, advised to reduce far to  30%. Also 6 family therapy sessions over 1 year. | Dietary counseling by a dietitian and regular visits to an experienced pediatrician w ith an interest in w eight problems. Prescribed diet of 1500-1700 calories, advised to reduce far to  30%. | Untreated |  |
| Intervention type | Lifestyle | Lifestyle | NA |  |
| Intervention  length | 14-18 months | 14-18 months | NA |  |
| Intensity as described by authors | Received dietary counseling, medical checkups by another pediatrician, 6 family therapy visits. | Ten families w ere seen by the dietitian once. The remaining families w ere satisfied w ith the counseling given by the  pediatrician, w hom they visited tw ice during the first 6 months  and then every 6 months during the rest of the | NA |  |
| Assigned  intensity | 5-25 hours | <5 hours | NA |  |
| Provider types | Primary care, nutrition provider, mental health | Primary care, nutrition provider | NA |  |
| Clinic setting | Primary care | Primary care | NA |  |
| Components | Nutrition counseling, activity counseling, mental health,  motivational interview ing | Nutrition counseling, activity counseling | Usual  care |  |

Outcomes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BMI |  |  |  |  |  |  |  |  |
| Post treatment | |  |  | One year follow -up | |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Family therapy | 22 | 25 | 0.53 | 0.22 | 20 | 25.8 | 0.73 | 0.15 |
| Conventional treatment | 19 | 26.1 | 0.72 |  | 19 | 27.1 | 0.88 |  |
| Control | 50 |  |  |  | 48 | 27.9 | 0.61 |  |

**Fonseca**

**Effectiveness analysis of an internet-based intervention for overweight adolescents: next steps for researchers and clinicians**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | FundingThis w ork w as funded by Fundação para a Ciência e a Tecnologia (PTDC/ DTP- PIC/07 69/2012 Project). | |  |
| Country | Portugal |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocol w as approved by the EthicsCommittee of the Faculty of Medicine, University of Lisbon. Adolescents and their parents signed  an in-formed consent. | |  |
| Outcomes other than  BMI | Psychosocial |  |  |
| Population |  |  |  |
| Inclusion criteria | Participants w ere required to be overw eight,aged betw een 12 and 18, w illing to participate in the studyand have internet access at least once a w eek. | | |
| Exclusion criteria | Exclusioncriteria w ere the presence of severe psychopathology,pregnancy or having been proposed for bariatric surgery | |  |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Experimental Group | Control Group | Overa ll |
| N | 40 | 40 | 80 |
| Sex | 18/40 male | 21/40 male | 39/80  male |
| Age | 14.48 | 14.52 | NR |
| Race | NR | NR | NR |
| BMI | 30.95 | 31.42 | NR |
| Interventions | |  |  |
|  | Experimental Group | Control Group |  |
| Intervention as  defined by authors | In addition to the standard intervention, the experimentalgroup w as invited to access the e-therapeutic platform,w hich includes a set of resources, such as educationalresources (videos, brochures, menus, w eekly tips, accessto other links), self -monitoring (food, w eight and physicalactivity records), social support (chats, discussion forumsand personalized messages), interactive training andmotivational tools (personal goals planning, treatmentprogression registry, positive reinf orcement | The control group follow ed the clinical standard interven-tion, including individual appointments  w ith the paediatri-cian, dietician and exercise physiologist every 3 months. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 12 w eeks | 12 w eeks |  |
| Intensity as described by authors | individual appointments w ith the paediatri-cian, dietician and exercise physiologist every 3 months. + "case manager" | individual appointments w ith the paediatri-cian, dietician and exercise physiologist every 3  months. |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, exercise provider | Primary care, nutrition provider,  exercise provider |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight  management program |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing, other (e-therapeutic platform) | Nutrition counseling, activity counseling, motivational  interview ing |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI |  |
|  | 12 w eeks |
|  | Text summary |
| Experimental  Group | a non significant main effect ofthe time on the scores of the variables; a non significantmain effect of the groups on the scores of the variables;and a non  significant interaction betw een the time andthe groups on the scores of the variables. |
| Control Group |  |

**Ford, Al; Bergh, C; SÃ¶dersten, P; Sabin, Ma; Hollinghurst, S; Hunt, Lp; Shield, Jp Treatment of childhood obesity by retraining eating behaviour: randomised controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by the BUPA Foundation. TheMandometer devices w ere loaned to the research team at no cost. | |  |
| Country | United Kingdom |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by United Bristol Hospitals Trust research ethics committee (ref 04/Q2006/9) and w ritten inf ormed consent w as given by all  participating families | |  |
| Outcomes  other than BMI | Other obesity, blood pressure, glucose metabolism, lipids, behaviors |  |  |
| Population | | | |
| Inclusion  criteria | Eligibility criteria w ere age 9-<18 at recruit-ment, BMI >95th centile, minimal or no learning dif -ficulties, no underlying medical problem such ashypothyroidism,  and no medication for insulin resis-tance. Participants w ere recruited from new patientsref erred to the obesity clinic. | | |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Standard Care | Mandometer | Overall |
| N | 52 | 54 | 106 |
| Sex | 56% female | 56% female | NR |
| Age | 12.5 | 12.7 | NR |
| Race | NR | NR | NR |
| BMI SDS | 3.21 | 3.29 | NR |
| Interventions | |  |  |
|  | Standard Care | Mandometer |  |
| Intervention as defined by authors | The clinic w as run by a multidisciplinary team com-posed of a clinician, a paediatric dietitian, and an exer-cise specialist, all of w hom consulted w ith each family.Emphasis w as placed on implementing changes toincrease levels of enjoyable physical activity tonational recommended levels (60 minutes of exercisea day) alongside a balanced diet, again based on theeatw ell plate. Families w ere encouraged to set theirow n dietary goals and targets, w ith practical adviceand guidance from the dietitian. In encouraging activ-ity the approach w as one of facilitation rather than pre-scription. Motivational interview ing techniques  w ereused to engage participants and families in the decisionmaking process for lifestyle changes, w hich is consis-tent w ith self determination principles and is morelikely to lead to responsibility for  long term change. Families w ere given further clinic appointments at three monthly intervals. | Those in the Mandometer group saw a research nurse,previously trained in Mandometer technology at the Mandometer Clinic, Stockholm,  Sw eden, initially once a w eek for sixw eeks, every second w eek for a further six w eeks, andonce every sixth w eek thereafter. The research  nurse tel-ephoned the patients to offer support and encourage-ment every  second w eek from w eek 12 onw ards. Dietary advice w as provided by a paediatric dietitiannot involved w ith the standard clinic, based on theFood Standards Agency“eatw ell plate”at w ww.eatw ell.gov.uk. A clin-ician met the participants every four months, emphasis-ing the need to change eating habits and improvephysical activity as advocated in the standard clinic. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 12 months | 12 months |  |

|  |  |  |
| --- | --- | --- |
| Intensity as described by authors | At the first contact about an hour w as spent w ith each family. Families w ere given further clinic appointments at three monthly intervals. | initially once a w eek for six w eeks, every second w eek for a further six w eeks, and once every sixth w eek thereafter. The research nurse  telephoned the patients to offer support and encouragement every second  w eek from w eek 12 onw ards. Clinician every four months. |
| Assigned  intensity | <5 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider, exercise | Primary care, nutrition provider |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, other (Mandometer device) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS (Per protocol) |  |  |  |  |  |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Standard Care | 46 | -0.14 | -0.04 | -0.23 | 0.13 |
| Mandometer | 45 | -0.4 | -0.3 | -0.51 |  |

**Garipağaoğlu 2009, M; Sahip, Y; Darendeliler, F; Akdikmen, O; Kopuz, S; Sut, N**

**Family-based group treatment versus individual treatment in the management of childhood obesity: randomized, prospective clinical trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None reported |  |  |
| Country | Turkey |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by theinstitutional review board of the Hospital of Istanbul,Istanbul Medical Faculty, Istanbul University. Inf ormedconsent w as taken  from the children and families. | | |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Eighty obese self -ref erred children (51% female, 49%male), w hose ages varied from 6 to 14 years (10.1±2.7 years), and their parents | |  |
| Exclusion  criteria | Children w ith an organic cause of obesity andthose w ho received any medication w ere not included in thestudy. | |  |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Individual treatment | Group treatment | Overall |
| N | 40 | 40 | 80 |
| Sex | 47.5% male | 50.0% male | NR |
| Age | 10.3 | 10.3 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.47 | 2.4 | 2.46 |
| Interventions | |  |  |
|  | Individual treatment | Group treatment |  |
| Intervention as described by authors | Children in the individual treatment (standard group)w ere invited to the dietetics department for dietary andbehavioral intervention program w ith their parents and w eremonitored for w eight control. Participants w ere trained inthe same intervals (seven sessions) w ith 30-min sessionsduring the 3-month program. Thirty-nine subjects completedthe 3-month program and 37 of them returned for follow -upvisits 1 year  later. | Children and parents in the grouptreatment (study group) w ere invited together for trainingsessions during the 3-month program. Forty subjectscompleted the program and 39 of them returned forfollow -up visits 1 year later. Training sessions w eredesigned so that there w ere four sub- groups each includingten children and parents. Ninety minutes w as allocated foreach training session and sessions w ere carried out  seventimes |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 3 months | 3 months |  |
| Intensity as described by  authors | Participants w ere trained inthe same intervals (seven sessions) w ith 30- min sessionsduring the 3-month program. | This w as a3-month w eight control program for children that includedseven training sessions at 2-w eek intervals. Ninety minutes w as allocated  foreach training session and sessions w ere carried out seventimes. |  |
| Assigned  intensity | <5 hours | 5-25 hours |  |
| Provider types | Specialist, nutrition provider | Specialist, nutrition provider |  |
| Clinic setting | Multidisciplinary w eight management | Multidisciplinary w eight management |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  | 12 months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Individual treatment | 39 | 2.35 | 0.49 | 0 | 0.041 | 37 | 2.37 | 0.38 | 0.274 | 0.14 |
| Group treatment | 40 | 2.36 | 0.49 | 0 |  | 39 | 2.36 | 0.48 | 0 |  |
| BMI | | | | | | | | | | |
|  | 3 months |  |  |  | 12 months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Individual treatment | 39 | 26.3 | 4.1 | 0 | 0.023 | 37 | 26.8 | 3.9 | 0.575 | 0.267 |
| Group treatment | 40 | 26.5 | 3.5 | 0 |  | 39 | 26.7 | 3.1 | 0 |  |

**Garnett, S. P.; Gow, M.; Ho, M.; Baur, L. A.; Noakes, M.; Woodhead, H. J.; Broderick, C. R.; Burrell, S.; Chisholm, K.; Halim, J.; De, S.; Steinbeck, K.; Srinivasan, S.; Ambler, G. R.; Kohn, M. R.; Cowell, C. T.**

**Optimal macronutrient content of the diet for adolescents with prediabetes; RESIST a randomised control trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported by the BUPA Foundation Australia Pty Limited (2008–2012), the Diabetes Australia Research Trust 2008, and the Heart Foundation,  Australia (Grant G08S3758) (2009–2010). | | |
| Country | Australia |  |  |
| Methods | | | |
| Design | Randomized Controlled Trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by The Children’s Hospital at West-mead Human Research Ethics Committee (07/CHW/12); Syd-ney South West Area Health, Western Zone (08/LPOOL/195); andSydneySouthWestAreaHealthService, RoyalPrinceAlfred Hospital (08/RPAH/455). Written inf ormed consent from par-  ents and assent from the young people w as sought prior to their enrollment in the study. | | |
| Outcomes  other than BMI | other obesity, glucose metabolism, lipids, blood pressure |  |  |
| Population | | | |
| Inclusion  criteria | Ten- to 17-year-old adolescents w ho w ere overw eight or obese, w ith either pre-type 2 diabetes as defined by the American Diabetes Association and/or clinical  features of insulin re-sistance w ere included in the study. | | |
| Exclusion criteria | Type 1 or type 2 diabetes, contraindications to metformin therapy, secondary causes of obesity, psychiatric disturbance, significant mental illness, inability to take part in physical ac-tivity, w eight loss medications or medications know n to cause w eight gain, and w eight greater than 120 kg. Adolescents taking  metformin prior to commencement of the study w ere required to have a 3-month w ashout period. | | |
| Group  differences | Randomized |  |  |
| Special  Population | None |  |  |
|  | Moderate-Carbohydrate Increased Protein Diet | High-carbohydrate, Low -Fat Diet | Overall |
| Age | 13.0 [10.1–16.5] | 13.2 [10.2–17.4] | NR |
| Sex | 34 girls (60.7%) | 32 girls (58.2%) | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.39 +/- 0.25 | 2.33 +/-0.32 | NR |
| Interventions | |  |  |
|  | Moderate-Carbohydrate Increased Protein Diet | High-carbohydrate, Low -Fat Diet |  |
| Intervention as defined by author | Metformin (Diabex) w as provided at no cost to all participants for the duration of the study. The initial dose w as 250 mg tw ice a day. After the first 2 w eeks, this w as increased to a final dose of 500 mg tw ice daily.The intervention consisted of 3 phases: 1) phase 1 (0 to 3 months), intensive structured dietary intervention; 2) phase 2 (4–6 months), intensive exercise program plus ongoing dietary sup-port; and  3) phase 3 (7–12 months), maintenance. Diet 2 w as a moderate-carbohydrate, increased-protein diet, w hich is 40%–45% of total energy as carbohydrate (moderate glycemic load), 30% fat (10% saturated fat), and 25%–30% protein. Consistent w ith our clinical practice, both diets w ere prescriptive, and 2 different energy levels w ere prescribed, depending on age: 6000–7000 kJ (10–14 years old) or 7000–8000 kJ (15–17 years old). In brief, in phase I the participants and at least 1 parent/care giver attended 4 face-to-face meetings (baseline and 2, 6, and 12 w eeks) w ith the dietitian. In addition to the face to face contact, the dietitian also made contact w ith the participant using phone,  e-mail, or text message, depending on the pref erence of the par-ticipant at 4 and 9  w eeks. Food consistent w ith the prescribed diet plans and equating to approximately | Metformin (Diabex) w as provided at no cost to all participants for the duration of the study. The initial dose w as 250 mg  tw ice a day. After the first 2 w eeks, this w as increased to a final  dose of 500 mg tw ice daily.The intervention consisted of 3 phases: 1) phase 1 (0 to 3 months), intensive structured  dietary intervention; 2) phase 2 (4–6 months), intensive exercise program plus ongoing dietary support; and 3) phase 3 (7–12 months), maintenance. Diet 1 w as a high- carbohydrate, low -fat diet, w hich is 55%-60% of total energy as carbohydrate (moderate glycemic load), 30% fat (10% saturated fat), and 15% protein. Consis-tent w ith our clinical practice, both diets w ere prescriptive, and 2 different energy levels w ere prescribed, depending on age: 6000–7000 kJ (10–14 years old) or 7000–8000 kJ (15–17 years old). In  brief, in phase I the participants and at least 1 parent/care |  |

|  |  |  |
| --- | --- | --- |
|  | 25% of the partici-pants energy requirements w as provided to the families. During phase II the dietitian gave nutritional support [phone, e-mail, or short message service (SMS)] to the participant every 4 w eeks, w ith a face-to-face visit at w eek 26.During phase II, all participants received a supervised exercise program for 45 minutes to 1 hour, tw ice a w eek for 12 w eeks in a commercial  gym,includingFitnessFirst,oralocalparkinthe geographic area in w hich they lived. Participants w ere given free access to the gyms. The exercise program consisted of a circuit training program w ith an age-appropriate mix of resistance exercises and aerobic stations conducted by a qualified fitness trainer, blinded to the treatment arm. In addition to the gym program, participants w ere encouraged to exercise at least once a w eek at home. | giver attended 4 face-to-face meetings (baseline and 2, 6, and 12 w eeks) w ith the dietitian. In addition to the face to face contact, the dietitian also made contact w ith the  participant using phone, e-mail, or text message, depending on the pref erence of the par-ticipant at 4 and 9 w eeks. Food consistent w ith the prescribed diet plans and equating to approximately 25% of the participants energy requirements w as provided to the families. During phase II the dietitian gave nutritional support [phone, e-mail, or short message service (SMS)] to the participant every 4 w eeks, w ith a face- to-face visit at w eek 26During phase II, all participants received a supervised exercise program for 45 minutes to 1 hour, tw ice a w eek for 12 w eeks in a commercial gym, includingFitness First, or a local park in the geographic area  in w hich they lived. Participants w ere given free access to the gyms. The exercise program consisted of a circuit training program w ith an age-appropriate mix of resistance exercises and aerobic stations conducted by a qualified fitness trainer, blinded to the treatment arm. In addition to the gym program, participants w ere encouraged to exercise at least once a  w eek at home. |
| Intervention type | Specif ic Diet | Specif ic Diet |
| Intervention  length | 12 months | 12 months |
| Intensity as described by authors | In brief, in phase I the participants and at least 1 parent/care giver attended 4 face-to- face meetings (baseline and 2, 6, and 12 w eeks) w ith the dietitian. In addition to the  face to face contact, the dietitian also made contact w ith the participant using phone, e-mail, or text message, depending on the pref erence of the participant at 4 and 9  w eeks | In brief, in phase I the participants and at least 1 parent/care giver attended 4 face-to-face meetings (baseline and 2, 6, and 12 w eeks) w ith the dietitian. In addition to the face to  face contact, the dietitian also made contact w ith the  participant using phone, e-mail, or text message, depending on the pref erence of the participant at 4 and 9 w eeks |
| Assigned  intensity | <5 hours | <5 hours |
| Provider types | primary care (or study physician); nutrition provider, exercise | primary care (or study physician); nutrition provider, exercise |
| Clinic setting | research unit | research unit |
| Components | medication, prescription diet; nutrition counseling, activity counseling, activity training | medication, prescription diet; nutrition counseling, activity  counseling, activity training |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI 95th percentile |  |  |  |  |  |  |  |  |  |  |  |  |
|  | baseline |  |  |  | 3 month |  |  |  | 6 Month |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value | N | Mean | SD | P Value |
| Moderate-Carbohydrate Increased Protein Diet | 56 | 133 | 19 | NA |  |  |  | 0.001 |  |  |  | 0.009 |
| High-carbohydrate, Low -Fat Diet | 55 | 132 | 23 | NA |  |  |  | 0.001 |  |  |  | 0.009 |

**Garnett, S. P.; Gow, M.; Ho, M.; Baur, L. A.; Noakes, M.; Woodhead, H. J.; Broderick, C. R.; Chisholm, K.; Briody, J.; De, S.; Steinbeck, K.; Srinivasan, S.; Ambler,**

**G. R.; Cowell, C. T.**

**Improved insulin sensitivity and body composition, irrespective of macronutrientintake, after a 12 month intervention in adolescents with pre-diabetes; RESIST a randomised control trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | The project w as funded by BUPA Foundation Australia Pty Limited (2008 to 2012), Diabetes Australia Research Trust (DART) 2008 and Heart Foundation, Australia (#G08S3758) 2009 to 2010. SPG w as supported by a National Health and Medical Research Council Australian (NHMRC) Clinical Research Fellow ship  (#457225) 2007 to 2010 and an Early Career Research Fellow ship, Cancer Institute NSW 2011 to 2013. | | |
| Country | Australia |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as conducted according to the guidelines laid dow n in the Declaration of Helsinki and w as approved by CHW Human Research Ethics Committee (07/CHW/12) and Sydney South West Area Health, Western Zone (08/LPOOL/195). Written informed consent from parents and assent from the adolescents w as  sought prior to enrolment. | | |
| Outcomes other than  BMI | BMI, glucose metabolism, lipids, blood pressure |  |  |
| Population | | | |
| Inclusion criteria | Ten to 17 year old adolescents w ho w ere overw eight or obese, as defined by the International Obesity TaskForce [14] w ith either pre type 2 diabetes [16] and/or clinical features of insulin resistance. As previously described clinical features of insulin resistance w ere defined as a fasting insulin (pmol/L)/glucose (mmol/L) ratio >20 w ith one or more of the follow ing: acanthosis nigricans, polycystic ovarian syndrome, hypertension, fasting HDL cholesterol <1.03 mmol/L or fasting  triglycerides ≥1.7 mmol/L [12]. | | |
| Exclusion  criteria | Diabetes, contraindications to metformin, secondary causes of obesity, psychiatric disturbance, significant mental illness, inability to take part in physical activity,  w eight loss medications or medications know n to cause w eight gain, and w eight >120 kg. | | |
| Group  differences | Randomized |  |  |
| Special  Population | None |  |  |
|  | Moderate Carbohydrate, Increased Protein | High Carbohydrate, Low fat | Overall |
| Sex | 34 (60.7%) girls; n=56 | 58.2% female | NR |
| Age | 13 (10.1 to 16.5] | 13.2 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.39 (0.25SD) | 2.33 | NR |
| N | 56 | 55 | 111 |
| Interventions | |  |  |
|  | Moderate Carbohydrate, Increased Protein | High Carbohydrate, Low fat |  |
| Intervention as defined by the author | Diet 2 w as a moderate-carbohydrate, increased-protein diet, w ith 40-45% of total energy as carbohydrate (moderate glycaemic load), 30% fat (≤10% saturated fat), 25-30% protein. The intervention consisted of three phases: I (0–3 months): Intensive dietary intervention II (4–6 months): Intensive exercise program plus dietary support III (7–12 months): Participants w ere encouraged to continue w ith their diet/exercise regimens andmetformin. | Diet 1 w as a high-carbohydrate diet, w ith 55-60% of total energy as carbohydrate (moderate glycaemic load), 30% fat (≤10% saturated fat) and 15% protein.The intervention consisted of three phases: I (0–3 months): Intensive dietary intervention II (4–6 months): Intensive exercise program plus dietary support III (7–12 months): Participants  w ere encouraged to continue w ith their diet/exercise regimens and  metformin. |  |
| Intervention  type | Specif ic diet, lifestyle | Specif ic diet, lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 12 months | 12 months |
| Intensity as described by authors | (Description of exercise described) Exercise Phase I Standardised physical activity advice, consistent w ith recommendations for adolescents [17] w as delivered by study dieticians. Phase II Participants received, free of charge, a supervised exercise program, 45–60 minutes, tw ice/w eek for 12 w eeks in a commercial gym, including Fitness First, or a local park in the geographic area in w hich they lived. The program w as designed to be of moderate- tovigorous intensity and consisted of circuit training w ith an age-appropriate mix of resistance and aerobic stations, conducted byqualified fitness trainers, blinded to treatment arm. Participants w ere also encouraged to exercise at least once a w eek at home | (Description of exercise described) Exercise Phase I Standardised physical activity advice, consistent w ith recommendations for adolescents [17] w as delivered by study dieticians. Phase II Participants received, free of charge, a supervised exercise program, 45–60 minutes, tw ice/w eek for 12 w eeks in a commercial gym, including Fitness First, or a local park in the geographic area in w hich they lived. The program w as designed to be of moderate-tovigorous intensity and consisted of circuit training w ith an age-appropriate mix of resistance and aerobic stations, conducted by qualified fitness trainers, blinded to treatment arm.  Participants w ere also encouraged to exercise at least once a w eek at home |
| Assigned  intensity | 26-51 hours | 26-51 hours |
| Provider  type | Primary care, nutrition provider, exercise | Primary care, nutrition provider, exercise |
| Clinic setting | primary care; research center | primary care; research center |
| Components | Nutrition counselling, activity training, Medication | Nutrition counselling, activity training, Medication |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI 95th percentile |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Moderate Carbohydrate,  Increased Protein | 49 |  |  |  | NS | 39 |  |  |  | NS |
| High Carbohydrate, Low fat | 49 |  |  |  |  | 46 |  |  |  |  |

**Gourlan, M; Sarrazin, P; Trouilloud, D**

**Motivational interviewing as a way to promote physical activity in obese adolescents: a randomised-controlled trial using self-determination theory as an explanatory framework**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This research has benefited by the help of the French National Institute of Prevention and HealthEducation (INPES). | |  |
| Country | France |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the researchethics committee of the specific academic institution. Parents provided inf ormedconsent, and adolescents  provided w ritten assent for study participation | |  |
| Outcomes other  than BMI | Behaviors, psychosocial |  |  |
| Population |  |  |  |
| Inclusion criteria | Children ref erred to the w eight loss program by their GP. 11 and 18 years old (Mean age = 13, SD = 1.66), had a BMI over the nineti-eth age and gender  specific percentiles | | |
| Exclusion criteria | unstable or uncontrollable diseases |  |  |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | SWLP + MI | SWLP | Overall |
| N | 28 | 34 | 62 |
| Sex | NR | NR | 41%  female |
| Age | NR | NR | 13 |
| Race | NR | NR | NR |
| BMI | 29.56 | 29.59 | 29.57 |
| Interventions | |  |  |
|  | SWLP + MI | SWLP |  |
| Intervention as described by  authors | In the MI condition, participants received the same intervention by the same healthcare provider plus six MI phone sessions w ith a PA trained  counsellorof 20 min over a six-month period. | In the SWLP group, participants received an intervention consisting of tw o individ-ual face-to-face sessions of 30 min at the hospital w ith  a healthcare provider over athree-month period. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as described by  authors | tw o individ-ual face-to-face sessions of 30 min plus 6 20-min MI phone sessions | tw o individ-ual face-to-face sessions of 30 min |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, exercise | Primary care |  |
| Clinic setting | Weight management program | Weight management program |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Nutrition counseling, activity counseling |  |

Outcomes

BMI

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 3 months |  |  |  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| SWLP + MI | 26 | 28.42 | 4.63 | <0.05 | 26 | 27.95 | 4.53 | 0.17 |
| SWLP | 28 | 29.9 | 5.98 |  | 28 | 29.71 | 5.96 |  |

**Grieken, A; Veldhuis, L; Renders, Cm; Borsboom, Gj; Wouden, Jc; Hirasing, Ra; Raat, H Population-Based Childhood Overweight Prevention: outcomes of the 'Be Active, Eat Right' Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study is funded by a grant from the major funding body ZonMw , the Netherlands Organization for Health Research and Development (50-50110-98-355). | | |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Cluster randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Medical Ethics Committee of the Erasmus UniversityMedical Center Rotterdam approved the study protocol (ref erencenumber MEC-2007-163). | |  |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | 5 year old children attending w ell visit w ith overw eight (not obesity) |  |  |
| Exclusion  criteria | Obesity |  |  |
| Group  differences | Cluster randomized; baseline difference in age w ith control condition significantly older than intervention (p=0.016). | |  |
| Special  populations | None |  |  |
|  | Intervention | Control | Overall |
| N | 349 | 288 | 637 |
| Sex | 38.7% male | 37.5% male | 38.1%  male |
| Age | 5.72 | 5.8 | 5.76 |
| Race | % Dutch 75.8 | % Dutch 80.6 | NR |
| BMI | 18.16 | 18.1 | 18.13 |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as described by authors | The prevention protocol offeredparents inf ormation regarding overw eight prevention and healthylifestyle choices by using a motivational interview ing approach, ifneeded, to motivate the parents to change behavior. The content of an additional counseling session depended onthe stage of behavioral change of the parents [19,21,22]. TheYHC prof essionals assessed the level of motivation of the parentduring the w ell-child visit. The YHC prof essionals needed tocreate  aw areness of the child’s w eight status among the parents.Inf ormation about overw eight and associated consequences couldbe given to parents. Moreover, motivational interview ing tech-niques could be used to further motivate parents to  change healthbehavior. | When a child w ho w as overw eight (not obese) w as detectedw hen visiting a YHC team allocated to the control condition,parents w ere also inf ormed about the overw eight of their child butusual care w as given. Usual care consisted of general inf ormationabout a healthy lifestyle during the w ell- child visit. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 2 years | 2 years |  |
| Intensity as described by authors | Theprevention protocol w as initiated during the w ell-child visit and inaddition up to three structured healthy lifestyle counseling sessionsto promote overw eight- prevention behaviors could be offered,approximately 3, 6 and 12 months after the  w ell-child visit. | Well visit only |  |
| Assigned  intensity | <5 hours | <5 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider types | Primary care | Primary care |
| Clinic setting | Primary care | Primary care, SBHCs |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Intervention | 277 | 1.37 | 1.53 | NS |
| Control | 230 | 1.44 | 1.71 |  |

**Hills, A. P.; Parker, A. W.**

**Obesity management via diet and exercise intervention**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Not reported |  |  |
| Country | Australia |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Procedures employed w ere in accordance w ith the National Health and Medical Research Council's standards for  experimentation w ith human subjects. | | |
| Outcomes  other than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Subjects w ere recruited to an obesity clinic via ref erral from medical practitioners and personalized letters distributed to local primary schools. All subjects w ere classif ied as prepubertal based on the absence of pubic hair in the males and the absence of menarche in the females (Tanner 1962). Verif ication of the above w as provided by the family doctor of each subject in the course of standard medical clearance to embark upon a Obesity management 41 graded exercise programme. Al l obes e subject s w er e abov e th e 95t h percentil e w eigh t fo r ag e (Nationa l Healt h an d Medica l Researc h Counci l 1975 ) an d ha d a Bod y Mas s Inde x (BMI ) tha t exceede d 25. A third group of 15 normal w eight subjects w as  chosen as a normal w eight ref erence group. The latter children w ere matched w ith the obese group in terms of age , school and socioeconomic status. | | |
| Exclusion  criteria | Not provided |  |  |
| Group  differences | Randomly assigned |  |  |
| Special  Populations | NOne |  |  |
|  | Experimental | Control | Normal Weight |
| N Enrolled | 10 | 10 | 15 |
| Sex | NR | NR | NR |
| Age in years | NR | NR | NR |
| Race | NR | NR | NR |
| BMI | 51.6 (2.68 SE) | 50.2 (2.81) | 30.7 (1.81) |
| Interventions | | | |
|  | Experimental | Control | Normal Weight |

Intervention as defined by author

Exercise programme :The exercise programme involved a w eekly supervised session at the clinic and the remainder of the programme w as home based. Fifty minutes of each supervised session involved cardiorespiratory tasks follow ing an appropriate w arm up and preparatory activities. A major aim of the programme w as to provide subjects w ith a w ide variety of movement experiences designed to improve skill level. This involved approximately 20 minutes of gymnastics, dance and motor skill activities on a rotational basis, w ith the remainder of the time incorporating games and games training. Home programme: In

All subjects w ere provided w ith energy balance record sheets to determine food intake and dietary practices. In addition, obese experimental and control subjects had individual consultations w ith a dietitian prior to the commencement of the exercise programme. An initial meeting focused on the results of the completed details described above and revolved around the current dietary practices of subject and family alike. Nutrition education w as the focus, highlighting food selection, appropriate dietary goals and some basic behavioural aspects such as eating slow ly and self -monitoring. Mid-w ay through the exercise programme a second

All subjects w ere provided w ith energy balance record sheets to determine food intake and dietary practices. In addition, obese experimental and control subjects had individual consultations w ith a dietitian prior to the commencement of the exercise programme. An initial meeting focused on the results of the completed details described above and revolved around the current dietary practices of subject and family alike. Nutrition education w as the focus, highlighting food selection, appropriate dietary goals and some basic behavioural aspects such as eating slow ly and self -monitoring. Mid-w ay through the exercise programme a second

|  |  |  |  |
| --- | --- | --- | --- |
|  | addition to the supervised exercise period, experimental subjects w ere encouraged to participate in an aerobic activity of approximately 20 minutes duration, three to four times per w eek.  Record sheets w ere designed enabling parents to oversee involvement of children and verify completion of the home programme.  Reinf orcement, practice of exercises and liaison  w ith parents enabled adherence to the programme. Suggestions regarding the importance of increased habitual physical activity emphasized the necessity for increased daily activity levels and discouragement of sedentary pursuits such as television view ing. Dietary inf ormation: All subjects w ere provided w ith energy balance record sheets to determine food intake and dietary practices. In addition, obese experimental and control subjects had individual consultations w ith a dietitian prior to the commencement of the exercise programme. An initial meeting focused on the results of the completed details described above and revolved around the current dietary practices of subject and family alike. Nutrition education w as the focus, highlighting food selection, appropriate dietary goals and some basic behavioural aspects such as eating slow ly and self -monitoring. Mid-w ay through the exercise programme a second consultation reinf orced and supplemented the  former. The same nutrition inf ormation w as presented to the normal w eight subjects in an attempt to provide all participants w ith as similar as  possible dietary advice. | consultation reinf orced and supplemented the former. The same nutrition inf ormation w as presented to the normal w eight subjects in an  attempt to provide all participants w ith as similar as possible dietary advice. | consultation reinf orced and supplemented the former. The same nutrition inf ormation w as presented to the normal w eight subjects in an  attempt to provide all participants w ith as similar as possible dietary advice. |
| Intervention  type (choose one) | Lifestyle | Lifestyle | Lifestyle |
| Intervention  length | 16 w eeks | 16 w eeks | 16 w eek |
| Intensity as described by authors | The exercise programme involved a w eekly supervised session at the clinic and the remainder of the programme w as home based. Fifty minutes of each supervised session involved cardiorespiratory tasks follow ing an appropriate  w arm up and preparatory activities. In addition to the supervised exercise period, experimental subjects w ere encouraged to participate in an aerobic activity of approximately 20 minutes duration, three to four times per w eek | NA | NA |
| Assigned  Intensity | 5-25 hours | <5 hours | <5 |
| Provider type  (select all) | primary care, exercise, nutrition provider | nutrition provider | NR (nutrition ed given but provider not reported ) |

|  |  |  |  |
| --- | --- | --- | --- |
| Clinic setting  (choose one— probably) | Multidisciplinary w eight management clinic | Multidisciplinary w eight management | school |
| Components (choose all) | activity training, nutrition counseling, activity counseling, parent engagement (invited to attend,  instructed to monitor home PA) | Nutritional counseling | Nutritional counseling |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | Bef ore |  | After |  |
|  | Mea | SE | Mea | SE |
| Experimental | 51.6 | 2.68 | 46.1 | 2.46 |
| Control | 50.2 | 2.81 | 52.8 | 3.02 |
| Normal Weight | 30.7 | 1.81 | 30.6 | 1.75 |

**Hoffman, J.; Frerichs, L.; Story, M.; Jones, J.; Gaskin, K.; Apple, A.; Skinner, A.; Armstrong, S.**

**An Integrated Clinic-Community Partnership for Child Obesity Treatment: A Randomized Pilot Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by the Early Career Aw ard from the Obesity Society, aw arded to Dr Frerichs | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The institutional review boards from Duke University (Pro00066366) and the University of North Carolina at Chapel Hill (15-1867) approved the study protocol. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other (CV fitness) | |  |
| Population | | | |
| Inclusion  criteria | Participants included a consecutive sample of patients aged 5 to 11 w ith a BMI ≥95th percentile, ref erred by their primary care provider to the Healthy  Lifestyles clinic, along w ith each child’s adult primary caregiver (“parent”) aged 18 or older | | |
| Exclusion  criteria | We excluded children w ith a medical cause for obesity (hypothyroidism, Cushing’s syndrome, etc), those w ho lived more than 30 miles from the clinic or  planned to move out of the area, and those w hose parents could not speak or read English or Spanish. | | |
| Group  differences | No differences |  |  |
| Special Population | None |  |  |
|  | Healthy Lifestyles Only | Healthy Lifestyles + Bull City Fit | Overall |
| N Enrolled | 47 | 50 | 97 |
| Sex | male 53% / female 47% | male 42 %/female 58 % | male 47% /  female 53% |
| Age in years | 9.2 (1.8) | 9.1 (1.9) | 9.1 (1.9) |
| Race | White 15%/AA 59%/Hispanic 27%/other 0% | White 9%/AA 45%/Hispanic 40%/other 6 % | White 11% /AA  51%/Hispanic 34%/Other 3% |
| Interventions | |  |  |
|  | Healthy Lifestyles Only | Healthy Lifestyles + Bull City Fit |  |
| Intervention as defined by author | Control participants received standard clinical care at Healthy  Lifestyles, in addition to receiving promotional materials about the local parks and recreation department. Patients w ith obesity and their families meet monthly w ith multidisciplinary team (medical, nutrition, physical therapy, and mental health) to set and monitor  lifestyle behavioral goals and manage health conditions. We invited  control participants to participate in the intervention at the end of the study. | Intervention participants received standard clinical care at Healthy Lifestyles in addition to receiving free, unlimited access to Bull City Fit community-based programming. |  |
| Intervention  type (choose one) | Lifestyle | lifestyle |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as described by authors | Patients w ith obesity and their families meet monthly w ith multidisciplinary team (medical, nutrition, physical therapy, and mental health). Average of 4.4 hrs (range: 2-9, SD: 1.6) | Patients w ith obesity and their families meet monthly w ith multidisciplinary team (medical, nutrition, physical therapy, and mental health). Average 11.7 hrs (range: 2-67.8, SD: 15.3). Bull  City Fit is open 6 days per w eek, 6pm to 8pm on w eekdays and 1 |  |

|  |  |  |
| --- | --- | --- |
|  |  | pm to 3 pmon w eekends (Supplemental Table 4). All members of the immediate household may participate. Activities include structured games and team-building sports (6 days/w eek), cooking classes (1 day/w eek), sw imming lessons (2 days/w eek), and peer support (1 day/w eek). Trained staff supervise and facilitate all  activities. (Average 11.7 hours, but w e base on "possible" hours.) |
| Assigned Intensity | 5-25 hrs (because designed for 6 monthly sessions) | 52+ hours |
| Provider type  (select all) | primary care, nutrition, mental health, exercise | primary care, nutrition, mental health, exercise |
| Clinic setting (choose one—  probably) | pediatric w eight management program | pediatric w eight management program |
| Components  (choose all) | nutrition and activity counseling, motivational interview ing | motivational interview ing, nutrition counseling, nutrition training,  activity counseling, activity training |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMIz |  |  |  |  |  |  |
| Change from Baseline to 3  mo | |  |  | Change from Baseline to 6  mo |  |  |
|  | Change in BMI | 95% CI Low er  Bounds | 95% CI Upper  Bounds | Change in BMI | 95% CI Low er  Bounds | 95% CI Upper  Bounds |
| Healthy Lifestyles Only | 0.04 | -0.05 | 0.06 | 0.04 | -0.06 | 0.13 |
| Healthy Lifestyles + Bull  City Fit | 0.03 | -0.05 | 0.06 | 0.01 | -0.06 | 0.13 |
| BMI 95th percentile | | | | | | |
| Change from Baseline to 3  mo | |  |  | Change from Baseline to 6  mo |  |  |
|  | Change in BMI | 95% CI Low er  Bounds | 95% CI Upper  Bounds | Change in BMI | 95% CI Low er  Bounds | 95% CI Upper  Bounds |
| Healthy Lifestyles Only | -0.66 | -13.3 | 12 | 0.24 | -13.3 | 3.1 |
| Healthy Lifestyles + Bull City Fit | -0.002 | -13.3 | 12 | 5.49 | -13.5 | 3.1 |

**Hofsteenge, Gh; Chinapaw, Mj; Delemarre-van, de Waal Ha; Weijs, Pj**

**Long-term effect of the Go4it group treatment for obese adolescents: a randomised controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study is funded by The Netherlands Organisation for Health Research and Development (ZONMW) (no: 50-50110-98-255). | |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The medical ethical committee for human studies of the VU University Medical Center Amsterdam approved the protocol. Adolescents as w ell as their parents  gave w ritten inf ormed consent | | |
| Outcomes other  than BMI | BMI, other obesity, glucose metabolism, blood pressure, lipids |  |  |
| Population | | | |
| Inclusion criteria | Subjects w ere eligible w hen they met the follow ing inclusion criteria: 1) age betw een 11 and 18 years; 2) overw eight or obesity according to the definition of  Cole et al. | | |
| Exclusion criteria | Exclusion criteria w ere: not Dutch-speaking, obesity as a result of a know n syndrome or organic cause (hypothyroidism), mental retardation, physical  limitations and diagnosed type 2 diabetes mellitus | | |
| Group  differences | Randomized, none |  |  |
| Speical  population | None |  |  |
|  | Intervention group | Control Group | Overall |
| Sex | female 38 (53%) | female 30 (58%) | female 68  (55%) |
| Age | 14.5 | 14.4 | NR |
| Race (ethnicity) | w estern 36 (50%), non w estern 35 (~49%) | w estern 18 (35%), non w estern 35 (65%) | w estern 54  (44%), non  w estern 68  (55%) |
| BMI SDS | 2.93 | 2.93 | NR |
| Interventions | |  |  |
|  | Intervention group | Control Group |  |
| Interention type as defined by author | Go4it is a multidisciplinary group treatment for obese adolescents based on the programs of Braet et al.,9 Epstein et al.,7 and the educational materials of the Dutch Obesity Intervention in Teenagers (DOiT).14 During 7 sessions (duration 90 min) w ith an interval of 2e3 w eeks the adolescents received education on healthy dietary, sedentary and physical activity behaviour. The group sizew as 8e12 adolescents. They received cognitive behavioural therapy in w hich they learned how to improve their lifestyle and how to maintain energy balance. Go4it w as carried out in an outpatient clinic involving a dietician, paediatrician/endocrinologist and psychologist. In addition, tw o separate parallel sessions for parents w ere organised corresponding w ith the first and fourth session of the adolescents.  Four booster group sessions w ere scheduled 6, 14, 26, and 36 w eeks after the 3-months intervention period, in order to encourage the adolescents to maintain or further improve their energy balance behaviour and discuss problems and questions. Throughout the  program the adolescents remained in the same peer group. | The control group received the regular care in the Netherlands (valid for year 2006e2009), consisting of ref erral to a dietician in the home care setting. Adolescents had to make this appointment themselves. |  |
| Intervention type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 3 months | 3 months |
| Intensity as described by authors | During 7 sessions (duration 90 min) w ith an intervalof 2e3 w eeks the adolescents received education on healthy dietary, sedentary and physical activity behaviour.Tw o parent sessions Four booster group sessions w ere scheduled 6, 14, 26,and 36 w eeks after the 3-months  intervention period, | Ref erral to a dietitian in home setting Number of visits unspecified |
| Assigned intensity | 5-25 hours | <5 hours |
| Provider type | primary care, nutrition provider, mental health, subspecialist | Dietician |
| Clinic setting | Speciality Clinic | Specialty Clinic |
| Components | Nutrition counseling,activity counseling, separate parent counseling , cognitive behavioral  therapy | Diet counseling |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  |  |  | 18  months |  |  |  |  |  |  |
|  | n | Mean | SD | Betw een group  difference | Betw een group 95%  CI upper | Betw een group 95%  CI low er | betw een group p  value | n | Mean | SD | Betw een group  difference | Betw een group 95%  CI upper | Betw een group 95%  CI low er | betw een group p  value |
| Intervention  group | 71 | 32.8 | 4.7 | -0.76 | -1.74 | 0.22 |  | 71 | 34.2 | 6.1 | -0.97 | -2.02 | 0.09 |  |
| Control  Group | 51 | 34.2 | 5.3 |  |  |  |  | 51 | 34.9 | 5.6 |  |  |  |  |
| BMI SDS | | | | | | | | | | | | | | |
|  | 6  months |  |  |  |  |  |  | 18  months |  |  |  |  |  |  |
|  | n | Mean | SD | Betw een group  difference | Betw een  group 95% CI upper | Betw een  group 95% CI low er | betw een  group p value | n | Mean | SD | Betw een group  difference | Betw een  group 95% CI upper | Betw een  group 95% CI low er | betw een  group p value |
| Intervention  group | 71 | 2.81 | 0.5 | -0.1 | -0.23 | 0.04 |  | 71 | 2.86 | 0.7 | -0.16 | -0.3 | -0.02 | 0.05 |
| Control  Group | 51 | 2.95 | 0.55 |  |  |  |  | 51 | 2.96 | 0.6 |  |  |  |  |

**Hughes, Ar; Stewart, L; Chapple, J; McColl, Jh; Donaldson, Md; Kelnar, Cj; Zabihollah, M; Ahmed, F; Reilly, Jj**

**Randomized, controlled trial of a best-practice individualized behavioral program for treatment of childhood overweight: scottish Childhood Overweight Treatment Trial (SCOTT)**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported by a grant from the ScottishExecutive Health Department. | |  |
| Country | United Kingdom |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval w as obtained from the research ethicscommittee at each participating site. Written inf ormedconsent w as obtained from all children and  their par-ents/guardians. | | |
| Outcomes other  than BMI | Other obesity, behavior, psychosocial |  |  |
| Population | | | |
| Inclusion criteria | Overw eight children (BMI98th centilerelative to United Kingdom 1990 ref erence data, usuallyref erred to as obesity in the United Kingdom)3,4w how ere aged 5 to 11 years and attending a standard ele-mentary school and had at least 1 parent w ho perceivedthe child’s w eight as a problem and w as w illing to  makelifestyle changes. | | |
| Exclusion  criteria | We excluded children w ho had anunderlying medical cause for their overw eight or seriouscomorbidity that required urgent treatment or w ho had received  treatment for overw eight in the past year. | | |
| Group  differences | Randomized |  |  |
| Special Populations | None |  |  |
|  | Standard Care/Control | Intervention | Overall |
| N | 65 | 69 | 134 |
| Sex | 45% male | 43% male | NR |
| Age | 8.5 | 9.1 | NR |
| Race | NR | NR | NR |
| BMI SDS | 3.3 | 3.2 | NR |
| Interventions | |  |  |
|  | Standard Care/Control | Intervention |  |
| Intervention as defined by authors | Children w ho w ere randomly assigned to the controlgroup received typical dietetic care currently are offeredf or overw eight individuals by hospital and communitydietetic services in Scotland. | Briefly,this is a practical, best-practice behavioral program de-livered by experienced pediatric dietitians w ho aretrained in behavior change counseling8,12on a 1-to-1basis (ie, 1 dietitian saw 1 family). Children w ere encouraged to alter their diet by usinga  modified traffic-light approach [reduce intake of foodshigh in fat and sugar (red), increase intake of fruit andvegetables (green)]5,16increase their physical activity,17and restrict their sedentary behavior (television view ingand playing computer/video games) to no more than  2hours per day or the equivalent of 14 hours per w eek asis w idely recommended.4,6 |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 6 months | 6 months |  |
| Intensity as described by  authors | This involved 3 to 4 outpa-tient appointments delivered by pediatric dietitians dur-ing 6 to 10  months w ith a total patient contact time of 1.5 hours. | The program con-sisted of 8 appointments (7 outpatient visits and 1 homevisit) during 26 w eeks w ith a total patient contact timeof5 hours. |  |
| Assigned intensity | <5 hours | 5-25 hours |  |
| Provider type | Primary care, nutrition provider | Primary care, nutrition provider |  |

|  |  |  |
| --- | --- | --- |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling,  motivational interview ing | Nutrition counseling, activity counseling |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  |  | 12  months |  |  |  |  |  |
|  | N | Median | IQR (low er  bound) | IQR (upper  bound) | p (w ithin  group) | p (betw een  groups) | N | Median | IQR (low er  bound) | IQR (upper  bound) | p (w ithin  group) | p (betw een  groups) |
| Standard  Care/Control | 65 | -0.06 | -0.22 | 0.05 | <0.05 | NS | 65 | -0.19 | -0.31 | 0.02 | <0.05 | NS |
| Intervention | 69 | -0.1 | -0.24 | -0.02 | <0.05 |  | 69 | -0.07 | -0.32 | 0.04 | <0.05 |  |

**Hystad, Ht; Steinsbekk, S; Ã˜degÃ¥rd, R; WichstrÃ¸m, L; Gudbrandsen, Oa**

**A randomised study on the effectiveness of therapist-led v. self-help parental intervention for treating childhood obesity**

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| --- | --- | --- | --- | --- | --- | --- |
| Study  Identification |  | |  | |  | |
| Sponsorship  source | The present study w as supported by the Liaison Committee for Central Norw ay Regional Health Authority; the National Council of Mental Health/Health and  Rehabilitation, NTNU; St Olav University Hospital; the Bergen Medical Research Foundation and the Meltzer Foundation. | | | | | |
| Country | Norw ay | |  | |  | |
| Methods | | | | | | |
| Design | Randomized controlled trial | |  | |  | |
| Group | Parallel group | |  | |  | |
| IRB | The present study w as conducted according to the guidelines laid dow n in the Declaration of Helsinki, and all procedures involving patients w ere approved by  the Regional Ethical Committee for Medical Research. Written inf ormed consent w as obtained from all parents. | | | | | |
| Outcomes other  than BMI | other obesity, behaviors (detailed dietary and energy intake) | |  | |  | |
| Population | | | | | | |
| Inclusion criteria | The inclusion criteria w ere as follow s: age 7–12 years; BMI z-scores >=2; participation of at least one parent; the ability to participate in a group setting. | | | | | |
| Exclusion  criteria | Families w ere excluded if the obese child w as mentally retarded, if there w as an organic cause of obesity or if the child used medication that may interfere w ith  grow th or w eight control. | | | | | |
| Group  differences | randomized | |  | |  | |
| Special Populations | None | |  | |  | |
|  | Therapist -led group | | Self-help group | | Overall | |
| N Enrolled | 39 | | 44 | | 83 | |
| Sex | Male, 23; Female, | 24 | Male, 27; Female, | 25 | Male, 39;  Female, 44 | |
| Age in years | 9.9 (1.5SD) | | 10.5 (1.9SD) | | 10.2 (1.7SD) | |
| Race | NR | | NR | | All but 2 w ere  Caucasian. | |
| BMI z-score | 3.00 (0.51) | | 3.00 (0.36) | | 3.00 | (0.43) |
| BMI | 28.4 (4.5) | | 28.7 (3.5) | | 28.6 | (4.0) |
| Interventions | | |  | |  | |
|  | Therapist -led group | | Self-help group | |  | |
| Intervention as defined by author | The focus of both the TLG and SHG interventions w as to establish regular mealtimes, increase the intake of fruits, vegetables and other high-fibre food, reduce the intake of added sugar and fat, conduct at least 1 h of moderate physical activity per d and reduce sedentary behaviour gradually, tow ards a maximum of 2 h per day | | The focus of both the TLG and SHG interventions w as to establish regular mealtimes, increase the intake of fruits, vegetables and other high-fibre food, reduce the intake of added sugar and fat, conduct at least 1 h of moderate physical activity per d and reduce sedentary behaviour gradually, tow ards a maximum of 2 h per d. The SHG w ere based on the principle of mutual help, derived from the participants’ ow n experiences and know ledge. A health prof essional attended the tw o first and the last meeting to organise the group and facilitate group rules, but did not offer any education or guidance regarding  how to reduce adiposity. | |  | |
| Intervention type (choose  one) | Lifestyle | | Lifestyle | |  | |
| Intervention  length | 24 months | | 24 months | |  | |

|  |  |  |
| --- | --- | --- |
| Intensity as described by authors | The TLG, SHG and children’s groups met simultaneously every second w eek for ten sessions during the first 6 months. During this 6- month period, each family also met monthly for individual counselling. Over the remaining 18 months of the 24-month intervention, the groups met five times at the hospital, and four individual family counselling sessions w ere conducted. Each of the fifteen group  sessions lasted 2 h, w hile each of the ten individual family counselling sessions lasted 30 min. | The TLG, SHG and children’s groups met simultaneously every second w eek for ten sessions during the first 6 months. During this 6- month period, each family also met monthly for individual counselling. Over the remaining 18 months of the 24-month intervention, the groups met five times at the hospital, and four individual family counselling sessions w ere conducted. Each of the fifteen group  sessions lasted 2 h, w hile each of the ten individual family counselling sessions lasted 30 min. |
| Assigned  Intensity | 26-51 hours | 26-51 hours |
| Provider type  (select all) | Psychologists, pediatricians, clinical dietitians and physiotherapists | Health prof essional |
| Clinic setting (choose one—  probably) | Multidisciplinary w eight management | Multidisciplinary w eight management program |
| Components  (choose all) | mental health, nutrition counseling; activity counseling | nutrition counseling; activity counseling; parent peer support; mental  health |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI z-score |  |  |  |  |  |  |
|  | Baseline |  | 6 Months |  | 2 years |  |
|  | Mean | SD | Mean | SD | Mean | SD |
| Therapist -led group | 3 | 0.51 | 2.78 | 0.56 | 2.82 | 0.59 |
| Self-help group | 3 | 0.36 | 2.81 | 0.44 | 2.83 | 0.51 |
| Body Fat % | | | | | | |
|  | Baseline |  | 6 Months |  | 2 years |  |
|  | Mean | SD | Mean | SD | Mean | SD |
| Therapist -led group | 40.4 | 3.8 | 35.7 | 5.6 | 35.6 | 6.3 |
| Self-help group | 40.6 | 4 | 36.2 | 5.6 | 35.6 | 6.4 |

**Kalavainen**

**Clinical efficacy of group-based treatment for childhood obesity compared with routinely given individual counseling**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This w ork w as supported in part by grants from KuopioUniversity Hospital, the Scientific Foundation of FinnishAssociation of Academic Agronomists, Finnish CulturalFoundation of Northern Savo, Juho Vainio Foundation,Ministry of Social Affairs and Health and Social  InsuranceInstitution. | | |
| Country | Finland |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Inf ormed consent w as obtained from the parents, and the study w as approved by the Ethics Committee of Kuopio University and  University Hospital. | |  |
| Outcomes other than  BMI | None |  |  |
| Population |  |  |  |
| Inclusion criteria | Families w ith an obese 7–9-year-old child attendingprimary school w ere inf ormed about the study by schoolnurses and by new spaper  articles. The inclusion criterion w asthe presence of w eight for height from 120 to 200%, | | |
| Exclusion criteria | Exclusion criteria w ere a disease or a medication causingobesity, obvious movement disturbance, major mentalproblems in either children or  parents or a family memberparticipating in an alternative w eight management program | | |
| Group differences | Randomized |  |  |
|  | Routine treatment | Group treatment | Overa ll |
| N | 35 | 35 | 70 |
| Sex | 34% male | 46% male | 28  males |
| Age | 8 | 8.1 | 8.1 |
| Race | NR | NR | NR |
| BMI SDS | 2.5 (0.6) | 2.6 (0.6) | NR |
| Interventions | |  |  |
|  | Routine treatment | Group treatment |  |
| Intervention as described by authors | Routine program w as modified fromcurrent counseling practice for obese children in schoolhealth care in Finland. The program  w as standardized,and all school nurses w ere instructed by the researcher(MPK). The program consisted of booklets for families andtw o individual appointments for each child by schoolnurses. | The program focused on pro-moting a healthy lifestyle and w ell-being of obese childreninstead of w eight management. Group treatment included includedthe same components for example, promoting healthy diet,increasing physical activity and decreasing sedentary life-style w ith the help of behavioral therapy, as used in manyearlier intervention studies.11The recommended mealpattern and quality of the diet w ere in line w ith recommen-dations given for Finnish families.18The parents  w eretargeted as the main agents of change, and they w ereresponsible for  inducing changes at home. Most lifestylechanges w ere intended for the entire family. Overw eightparents w ho desired to lose w eight w ere encouraged. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention Length | 6 months | 6 months |  |
| Intensity as described by authors | Tw o appointments. Theappointments of 30 min in duration w ere held at the end ofthe fall and spring  terms. | The group program consisted of 15 sessions of 90 min in duration held separately for parents and children, except one joint session of making healthy snacks |  |
| Assigned intensity | <5 hours | 5-25 hours |  |
| Provider types | Primary care (school nurse) | Dietician, Other- Researcher |  |
| Clinic setting | School health center | School health center, research |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, nutrition training, activity training |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12 months (6 mo  F/U) |  |  |  |  |
|  | N | Mea  n | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mea  n | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Routine  treatment | 35 | -0.2 | -0.3 | -0.1 | 0.022 | 35 | -0.1 | -0.2 | 0 | 0.081 |
| Group treatment | 35 | -0.3 | -0.4 | -0.3 |  | 34 | -0.2 | -0.3 | -0.1 |  |

**Kalavainen, M; Korppi, M; Nuutinen, O**

**Long-term efficacy of group-based treatment for childhood obesity compared with routinely given individual counselling**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported in part by grants from Kuopio University Hospital, the Scientific Foundation of Finnish Association of Academic Agronomists, Finnish  Cultural Foundation of Northern Savo, Juho Vainio Foundation, Ministry of Social Affairs and Health and Social Insurance Institution. | | |
| Country | Finland |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Ethics Committee of Kuopio University and University Hospital. Inf ormedconsent w as obtained from the parents. | |  |
| Outcome other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | 7-9 year old obese children |  |  |
| Exclusion criteria | The exclusion criteria w ere a disease or a medication causing obesity, obvious movement disturbance, major mental problems in either children or parents or  a family member participating in an alternative w eight management program | | |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Routine | Group | Overall |
| N Enrolled | 35 | 35 | 70 |
| Sex | Boys, 12 (34%); Girl, 23 (66%) | Boys, 16 (46%); Girl, 19 (54%) | 60%  female |
| Age in years | 8.0\* (0.8) | 8.1\* (0.9) | 8.1 |
| Race | NR | NR | NR |
| BMI | 22.9 (2.5) | 23.4 (2.6) | 23.2 |
| BMI-SDS | 2.5 (0.6) | 2.6 (0.6) | 2.6 |
| Interventions | |  |  |
|  | Routine | Group |  |
| Intervention as defined by author | The program consisted of booklets for families and tw o individual appointments for each child by school nurses. The booklets contained inf ormation about w eight he same components for example, promoting healthy diet, increasing physical activity and decreasing sedentary  lifestyle w ith the help of behavioral therapy, as used in many earlier  intervention studies | The program focused on promoting a healthy lifestyle and w ell-being of obese children instead of w eight management. Group treatment included the same components for example, promoting healthy diet, increasing physical activity and decreasing sedentary lifestyle w ith the help of behavioral therapy, as used in many earlier intervention studies |  |
| Intervention type  (choose one) | Lifestyle | Lifestyle |  |
| Intervention  length | 6 months | 6 months |  |
| Intensity as described by  authors | Tw o appointments | 15 sessions of 90 min in duration |  |
| Assigned  Intensity | <5 hours | 5-25 hours |  |
| Provider type  (select all) | Clinical nutrition, researcher | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Clinic setting  (choose one— probably) | SBHC | Primary care |
| Components  (choose all) | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| Change in  BMI |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Post-  intervention |  |  |  | Tw o-year  follow -up |  |  |  | Three-year  follow -up |  |  |  |
|  | Mean | SD | 95%CI low er bound | 95%CI upper bound | Mean | SD | 95%CI low er bound | 95%CI upper bound | Mean | SD | 95%CI low er bound | 95%CI upper bound |
| Routine | 0 | 1.1 | -0.4 | 0.3 | 1.5 | 1.7 | 1 | 2.1 | 2.3 | 2.7 | 1.4 | 3.2 |
| Group | -0.8 | 1 | -1.1 | -0.5 | 1.3 | 1.5 | 0.8 | 1.9 | 2.1 | 1.9 | 1.4 | 2.7 |
| BMI-SDS | | | | | | | | | | | | |
|  | Post-  intervention |  |  |  | Tw o-year  follow -up |  |  |  | Three-year  follow -up |  |  |  |
|  | Mean | SD | 95%CI low er  bound | 95%CI upper  bound | Mean | SD | 95%CI low er  bound | 95%CI upper  bound | Mean | SD | 95%CI low er  bound | 95%CI upper  bound |
| Routine | -0.2 | 0.3 | -0.3 | -0.1 | -0.2 | 0.4 | -0.3 | -0.1 | -0.3 | 0.6 | -0.5 | -0.1 |
| Group | -0.3 | 0.3 | -0.4 | -0.3 | -0.2 | 0.3 | -0.4 | -0.1 | -0.3 | 0.4 | -0.5 | -0.2 |

**Kokkvoll, A.; Grimsgaard, S.; Odegaard, R.; Flaegstad, T.; Njolstad, I.**

**Single versus multiple-family intervention in childhood overweight--Finnmark Activity School: a randomised trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | The trial has been supported by Finnmark Hospital Trust, NorthernNorw ay Regional Health Authority, Norw egian Foundation for Health andRehabilitation and The Norw egian Directorate of Health. Contributions have alsobeen made by the University of Tromsø, the Ministry of Health and Care Services,SpareBank 1 Nord-  Norge and Odd Berg Fund | | |
| Country | Norw ay |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Regional Committee for Medical and Health Research Ethicsapproved the study | |  |
| Outcomes other than  BMI | Other obesity |  |  |
| Population | | | |
| Inclusion  criteria | Inclusion criteria w ere age 6–12 years and BMI corresponding toadult BMI≥27.5 kg/m2. | |  |
| Exclusion  criteria | Exclusion criteriaw ere diseases incompatible w ith ordinary physical activity and psy-chosocial disorders incompatible w ith group interaction | |  |
| Group  differences | No differences |  |  |
| Special  Populations | None |  |  |
|  | SIFI | MUFI | Overall |
| N enrolled | 46 | 45 | 91 |
| Sex | female 22/ male 24 | Female=27; Male=18 | NR |
| Age in years | 10.5+-1.7 | 10.1±1.7 | NR |
| Race | NR | NR | NR |
| BMISDS | 2.81+-0.60 | 2.76+-0.58 | NR |
| Interventions | |  |  |
|  | SIFI | MUFI |  |
| Intervention as defined by author | Families allocated to SIFI met at the hospital outpatient clinic.The children underw ent baseline anthropometric measurements,follow ed by 30-min counselling by a paediatric study nurse. Subsequently, a paediatric consultant performed a clinical inter-view and examination  (30 min) and outlined definite aimstow ards the next consultation. All  families met w ith a nutrition-ist after 1–2 months. They w ere follow ed up by a public healthnurse in their ow n municipality at 1, 2, 5, 8, 10, 15 and18 months from baseline, and at the hospital by a paediatricnurse and a paediatric consultant at 3,12, 24 and 36 months. | Families allocated to MUFI underw ent anthropometric measure-ments and individual counselling identical to those of the SIFI programme. Additional elements w ere: (1) a 3-day inpatient programme at the Paediatric Department focusing on physical activity and healthy food, (2) group sessions w ith other families and a multidisciplinary hospital team (paediatric and psychiatric nurse, paediatric consultant, nutritionist, physiotherapist, coach and clinical educationalist), (3) municipality follow -up including individual (30 min) and group w ise counselling (1 h) w ith a public health nurse, (4) group- based physical activities tw ice w eekly (each session lasting 1 h, organised by  coach and by parents, respectively), (5) family participation in a 4-day camp after 4–6 months. |  |
| Intervention type (choose  one) | Lifestyle | Lifestyle |  |
| Intensity as  described by authors | Defined in table as 8 h in first 12 months; 30-min initial counseling' 30 min interview /examination/aims; clinic visits at 1, 2, 5, 8, 10, 15, and 18 | Defined in table as 36 hrs in first 12 months plus 38 hrs of organized physical  activity in first 12 months; discussed in methods as same as SIFI plus 72 hours inpatient; group sessions not specified duration/frequency; 30-60 min |  |

|  |  |  |
| --- | --- | --- |
|  | months w ith public health nurse; consults at 3, 12, 24, 26 months w ith  pediatric nurse/consultant | counseling not specified duration/frequency; tw ice/w eek PA sessions not  specific total duration; 4-day camp not specified duration |
| Assigned  Intensity | 5-25 hours | >= 52 hours |
| Provider  type (select all) | primary care, nutrition provider | primary care, nutrition provider, exercise, mental health, psychosocial support |
| Clinic setting (choose one—  probably) | Multidisciplinary w eight management program | Inpatient, Multidisciplinary w eight management program |
| Components  (choose all) | nutrition counseling (unclear w hat the other components w ere) | nutrition counseling, activity counseling, activity training, motivaitonal  interview ing |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 3  months |  |  |  |  |  |  | 12  months |  |  |  |  |  |  |
|  | Mean Change | 95% CI  low er bound1 | 95% CI  uper bound2 | Betw een group  difference  Coefficient | 95% CI  low er bound | 95% CI  uper bound | P  value | Mean Change | 95% CI  low er bound1 | 95% CI  uper bound2 | Betw een group  difference  Coefficient | 95% CI  low er bound | 95% CI  uper bound | P  value |
| SIFI | -0.05 | -0.12 | 0.01 | -0.08 | -0.17 | 0.01 | 0.097 | -0.07 | -0.14 | -0.01 | -0.09 | -0.18 | 0.01 | 0.068 |
| MUFI | -0.13 | -0.2 | -0.07 | -0.08 | -0.17 | 0.01 |  | -0.16 | -0.23 | -0.09 | -0.09 | 0.18 | 0.01 |  |

**Kokkvoll, A.; Grimsgaard, S.; Steinsbekk, S.; Flaegstad, T.; Njolstad, I.**

**Health in overweight children: 2-year follow-up of Finnmark Activity School--a randomised trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | The trial has been supported by Finnmark Hospital Trust, NorthernNorw ay Regional Health Authority, Norw egian Foundation for Health andRehabilitation and The Norw egian Directorate of Health. Contributions have alsobeen made by the University of Tromsø, the Ministry of Health and Care  Services,SpareBank 1 Nord-Norge and Odd Berg Fund | | |
| Country | Norw ay |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Regional Committee for Medical and Health Research Ethics,Region North. The families gave w ritten inf ormed consent signed by parents and allchildren≥12  years | | |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Overw eight and obese children aged 6–12 yearsw ith BMI corresponding to>/=27.5 kg/m2in adults (≥the 98centile according to the UK ref erence | |  |
| Exclusion criteria | No additional |  |  |
| Group differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Single Family | Multiple Family | Overall |
| N | 46 | 45 | 91 |
| Sex | 48% female | 60% female | NR |
| Age | 10.5 | 10.1 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.81 | 2.76 | NR |
| Interventions | |  |  |
|  | Single Family | Multiple Family |  |
| Intervention as defined by author | SIFI comprised clinical examination and individual counselling by paediatric nurse, paediatric consultant, nutritionist at the  hospital and follow -up by a local public health nurse. | MUFI comprised a 3-day inpatient programme at the hospital w ith other families and a multidisciplinary team, individual and group-based follow -up visits in their  hometow n, w eekly group- based physical activity and a 4-day family camp |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 24 months | 24 months |  |
| Intensity as described by  authors | 8 hours of contact first 12 months | 36 hours of contact first 12 months; plus 38 hours of organized physical activity |  |
| Assigned intensity | 5-25 hours | 52+ hours |  |
| Provider types | Primary care, nutrition provider, project nurse | Primary care, nutrition provider, exercise provider |  |
| Clinic setting | Multidisciplinary w eight management clinic | Inpatient, multidisciplinary w eight management program |  |
| Components | Nutrition counseling, activity counseling, motivational  interview ing | Nutrition counseling, activity counseling, activity training, motivational  interview ing |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 12 months |  |  |  | 24 months | |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Single Family | 46 | -0.07 | -0.16 | 0.01 | 0.188 | 46 | -0.08 | -0.17 | 0.01 | 0.046 |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Multiple Family | 45 | -0.15 | -0.23 | -0.07 |  | 45 | -0.2 | -0.29 | -0.12 |  |
| BMI |  |  |  |  |  |  |  |  |  |  |
|  | 12 months |  |  |  | 24 months | |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Single Family | 46 | 0.78 | 0.21 | 1.35 | 0.308 | 46 | 2.02 | 1.44 | 2.6 | 0.075 |
| Multiple Family | 45 | 0.37 | -0.18 | 0.91 |  | 45 | 1.29 | 0.74 | 1.84 |  |

**Kong, As; Sussman, Al; Yahne, C; Skipper, Bj; Burge, Mr; Davis, Sm**

**School-based health center intervention improves body mass index in overweight and obese adolescents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship source | This project w as supported in part or in w hole w ith federal funds from the follow ing: National Heart, Lung and Blood Institute of the National Institutes of Health Grant no. R21 HL092533, “Adolescents Committed to Improvement of Nutrition and Physical Activity (ACTION)” and Department of Health and Human Services/National Institutes of Health - National Center for Research Resources Grant no. 8UL1TR000041, and “The University of New Mexico Clinical and  Translational Science Center, CTSC.” | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Cluster randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The protocol w as approved by the University of New Mexico (UNM) Human Research Protections Office and the Research, Development, and Accountability  Department of both high schools. | | | |
| Outcomes  other than BMI | Other obesity, behaviors, blood pressure, lipids, glucose metabolism |  |  |  |
| Population | | | | |
| Inclusion  criteria | Students w ere eligible to participate if they w ere in the 9th to 11th grades and had a BMI ≥85th percentile. | |  |  |
| Exclusion criteria | Exclusion criteria included BMI ≥ 40 kg/m 2 ,previous diagnosis of diabetes, blood pressure in the range of stage 2hypertension[ 12 ], antipsychotic or  corticosteroid medica- tions, or if the adolescent w as not ambulatory. Withdraw al conditions included anorexia nervosa, bulimia nervosa, psy- chosis, suicidal ideation, hospitalization, and pregnancy. | | | |
| Group  differences | No differences |  |  |  |
| Special  Populations | groups w ere 100% R/E minority. |  |  |  |
|  | ACTION | Standard Care Group | Betw een Group  Difference | Overall |
| N Enrolled | 28 | 23 |  | 51 |
| Sex | 17 (61% female) | 13 (57%) female |  | NR |
| Age in years | 15 (1SD) | 14.6 (0.7SD) |  | NR |
| Race | 14% Asian; 75% Hispanic; 0% Native American; 11% multiple | 4% Asian; 61% Hispanic; 13% Native American; 22% multiple |  | NR |
| BMI percentile | 94.5 (4.1SD) | 94.4(4.6SD) |  | NR |
| Interventions | | | | |
|  | ACTION | Standard Care Group | Betw een Group  Difference |  |
| Intervention as defined by author | ACTION, based on the Transtheoretical Model [13], included three primary components: (1) clinical encounters w ith the SBHC clinician every tw o to three w eeks for a total of eight visits over  one academic year, (2) use of motivational interview ing (MI) [14, 15], and (3) obesity risk reduction strategies from a toolkit that w as cocreated w ith a community advisory group made of overw eight and obese adolescents and their parents. The toolkit included a DVD and print materials to provide a “menu of options” during  clinical encounters (Table 1). | The clinician w as trained on the study protocol and procedural materials prior to initiating the trial. Participants in the SCG received one clinic visit at the beginning of the trial that w as similar in content to the first visit of the intervention group except they w ere not given the DVD or DVD player. The AAP “Balance for a Healthy Life” booklet and medical results summary w ith  AAP recommendations [11] w ere also provided to participants. |  |  |
| Intervention  length | 1 year | 1 year |  |  |

|  |  |  |
| --- | --- | --- |
| Intensity as described by authors | 1) clinical encounters w ith the SBHC clinician every tw o to three  w eeks for a total of eight visits over one academic year. After each visit, telephone updates w ere given to the caregiver, during w hich the SBHC clinician used MI to encourage caregivers to adopt the risk reduction strategies.Sessions averaged 47 minutes for the  first session and 24 minutes for subsequent sessions. | Participants in the SCG received one clinic visit at the beginning of the trial that w as similar in content to the first visit of the intervention group except they w ere not given the DVD or DVD player. Sessions averaged for 28 minutes |
| Assigned Intensity | <5 hours | < 5hours |
| Provider type  (select all) | School based health care provider | School based health care provider |
| Clinic setting (choose one—  probably) | SBHCs | SBHCs |
| Components  (choose all) | Motivational Interview ing, nutritional counseling, activity  counseling | Motivational Interview ing |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI median  percentile |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Pre |  |  |  | Post |  |  |  | Difference |  |  |  |
|  | Mean | 95%CI low er  bound | 95%CI Upper  bound | P-  value | Mean | 95%CI low er  bound | 95%CI Upper  bound | P-  value | Mean | 95%CI low er  bound | 95%CI Upper  bound | P-  value |
| ACTION | 97 | 92.8 | 97.4 |  | 96.3 | 92.1 | 97.4 |  | -0.3 | -0.6 | 0.3 |  |
| Standard Care  Group | 96.2 | 91.6 | 97.8 |  | 96.1 | 91.9 | 98.5 |  | 0.2 | -0.1 | 0.8 |  |
| Betw een Group Difference | -0.6 | -1.2 | 0.1 | 0.04 | |  |  |  |  |  |  |  |

**Krebs, Nf; Gao, D; Gralla, J; Collins, Js; Johnson, Sl**

**Efficacy and safety of a high protein, low carbohydrate diet for weight loss in severely obese adolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by the Pediatric Clinical TranslationalResearch Center (RR00069), NIH (K24-RR018357-01, T32 DK07658), and the National Cattlemen’s  Beef Association. | |  |
| Country | USA |  |  |
| Setting | - |  |  |
| Comments | - |  |  |
| Authors name | - |  |  |
| Institution | - |  |  |
| Email | - |  |  |
| Address | - |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocol w as approved by the Colorado Multiple Institutional Review Board (COMIRB) and the Pediatric Clinical Research Center (CRC). All participants provided assent and their parents or guardians gave inf ormed consent.A local Data Saf ety Monitoring Board established through the CRC  review ed study data and progress at quarterly intervals. | |  |
| Outcomes other  than BMI | Other obesity, lipids, glucose metabolism, behaviors |  |  |
| Population | | | |
| Inclusion criteria | In-clusion criteria included primary obesity and a body w eightestimated to be$175% of ideal body w eight. | |  |
| Exclusion criteria | Exclusion criteria in-cluded current diagnosis of Type II Diabetes Mellitus; gallbladder, liver or renal disorders; know n eating disorders; se-vere hypercholesterolemia (total cholesterol >300 mg/dL);endocrine disorders such as hypothyroidism or polycysticovary syndrome; pregnancy; genetic disorder, such asPrader-Willi syndrome; mental retardation; severe depres-sion; or use of any chronic medication that could impact ap-petite. Patients w ith poor family  support that might havepotentially precluded compliance w ith the study require-ments w ere also excluded. | | |
| Group  differences | Randomized |  |  |
| Special  Populations | Adolescents (12-18 years) w ith severe obesity |  |  |
|  | HPLC (High protein, low carbohydrate) | LF (Low fat) | Overall |
| N | 24 | 22 | 46 |
| Sex | 54% female | 55% female | NR |
| Age | 14.2 | 13.7 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.48 | 2.51 | NR |
| Interventions | |  |  |
|  | HPLC (High protein, low carbohydrate) | LF (Low fat) |  |
| Intervention as defined by author | Subjects on the HPLC diet w ere instructed by the CRC bi- onutritionists to aim for a sustained very low carbohydrate intake (less than or equal to 20 g/d) and  for a concomitant high lean protein intake, w hich w as estimated to provide 2.0 to  2.5 g protein/kg ideal body w eight per day. Fat and energy intakes w ere not restricted; the only monitored restriction w as carbohydrate intake. Subjects w ere instructed on appropriate food choices for the diet, and each subject w as  provided a diet education booklet, including a ‘‘food pyramid’’ tailored to the HPLC diet. | The LF diet control group w as instructed on a diet w ith a daily energy intake goal of 70% of resting energy expenditure estimated from the Harris-Benedict equation and w ith less than or equal to 30% of calories from fat. The subjects received a diet education booklet, based on the USDA Food Guide Pyramid |  |
| Intervention  type | Specific diet | Specific diet |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 13 w eeks | 13 w eeks |
| Intensity as described by author | Subjects w ere admitted to the Pediatric Clinical Research Center (CRC) for baseline testing and initiation of the diet, follow ed at 2-w eek intervals in the outpatient CRC clinic, and readmitted for 2 days at w eek 13 for final  assessments. | Subjects w ere admitted to the Pediatric Clinical Research Center (CRC) for baseline testing and initiation of the diet, follow ed at 2- w eek intervals in the outpatient CRC clinic, and readmitted for 2  days at w eek 13 for final assessments. |
| Assigned intensity | 5-25 hours | 5-25 hours |
| Provider types | Research, nutrition provider | Research, nutrition provider |
| Clinic setting | Research, multidisciplinary w eight management | Research, multidisciplinary w eight management |
| Components | Nutrition counseling, activity counseling, specific diet | Nutrition counseling, activity counseling, specific diet |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |
| 13 w eeks | | | | | | | | | | |
|  | N | Mean | SE | p (across groups) |  |  |  |  |  |  |
| HPLC (High protein, low carbohydrate) | 18 | 33.9 | 1.4 | 0.26 |  |  |  |  |  |  |
| LF (Low fat) | 15 | 36.9 | 2.4 |  |  |  |  |  |  |  |
| BMI SDS | | | | | | | | | | |
| 13 w eeks | | | | | | | | | | |
|  | N | Mean | SE | p (across groups) |  |  |  |  |  |  |
| HPLC (High protein, low carbohydrate) | 18 | 2.1 | 0.1 | 0.04 |  |  |  |  |  |  |
| LF (Low fat) | 15 | 2.4 | 0.1 |  |  |  |  |  |  |  |
| BMI SDS (Change from Baseline) | | | | | | | | | | |
| 24 w eeks | |  |  |  | 36 w eeks | |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| HPLC (High protein, low carbohydrate) | 13 | -0.21 | 0.07 | 0.01 | NS | 11 | -0.22 | 0.09 | 0.04 | NS |
| LF (Low fat) | 14 | -0.14 | 0.04 | 0.01 |  | 11 | -0.15 | 0.04 | 0.002 |  |

**Larsen, Lm; Hertel, Nt; MÃ¸lgaard, C; Christensen, Rd; Husby, S; JarbÃ¸l, De**

**Early intervention for childhood overweight: a randomized trial in general practice**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The study w as funded by the health Insurance foundation, rhode’s foundation, the Egmont foun-dation, the Tryg foundation, Institute of Clinical  research, faculty of health Sciences, university of Southern Denmark, and Odense university hospital | |  |
| Country | Denmark |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Approved by the Regional Committee for Ethics and the Danish Data Protection Agency (no mention of consent/assent) | |  |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Overw eight five- to nine-year-old children w ere identified in general practice using the International Obesity Task force (IOTf) criteria | |  |
| Exclusion  criteria | Exclusion criteria w ere: non-Danish-speaking families, previous or current participation in another project concerning overw eight and obesity, mental or  physical disabilities, endocrine causes of obesity, or signs of precocious puberty. | | |
| Group  differences | Randomized (block randomization) |  |  |
| Special  populations | None |  |  |
|  | Model 1 | Model 2 | Overall |
| N | 35 | 45 | 80 |
| Sex | 62.9% female | 66.7% female | NR |
| Age | 6.3 | 6.1 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.79 | 2.88 | NR |
| Interventions | |  |  |
|  | Model 1 | Model 2 |  |
| Intervention as defined by authors | Monthly consultations in general practice during the first study year including focus on lifestyle habits, diet, and physical activity. In the second study year the frequency of consultations w as recommended to be every tw o months, adjusted to the needs of the individual  family. All participants received literature on healthy diet and physical activity. | Intervention as in Model 1, supplemented w ith three educational programmes, each of three hours’ duration, for groups of 2–5 families. The edu-cational sessions in Model 2 w ere intended to take place at study start, after tw o months, and after one year and w ere performed by a dietitian, a physical exercise instructor, and a psychologist w ith the purpose of promoting a healthy lifestyle through know ledge and  inspiration to a healthy diet and enjoyable physical activities. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 2 years | 2 years |  |
| Intensity as  described by authors | Monthly consultations in general practice during the first study year; every tw o months in second year. | Monthly consultations in general practice during the first study year; every tw o months in second year. Plus 3 3-hour programs. |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |
| Provider types | Primary care | Primary care, nutrition provider, exercise, mental health |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Model 1 | 34 | -0.2 | -0.38 | -0.01 | 0.59 |
| Model 2 | 40 | -0.26 | -0.44 | -0.09 |  |

**Lison, Jf; Real-Montes, Jm; Torro, I; Arguisuelas, Md; Alvarez-Pitti, J; Martinez-Gramage, J; Aguilar, F; Lurbe, E**

**Exercise intervention in childhood obesity: a randomized controlled trial comparing hospital-versus home-based groups**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This w ork w as supported by grants from the Comunidad ValencianaGovernment (GV06/227). | |  |  |
| Country | Spain |  |  |  |
| Setting | - |  |  |  |
| Comments | - |  |  |  |
| Authors name | - |  |  |  |
| Institution | - |  |  |  |
| Email | - |  |  |  |
| Address | - |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | In all cases, inf ormed consentw as obtained from parents and participants bef ore random-ization. The study w as approved by the Ethical Committeeof the General Hospital, University of Valencia, Spain. | | |  |
| Outcomes  other than BMI | Other obesity |  |  |  |
| Population | | | | |
| Inclusion  criteria | White OW/OB children and adolescents of both sexes,ranging from 6 to 16 years of age | |  |  |
| Exclusion criteria | Patients w ith secondary obesity syndromes or w ith acute illnesses w ereexcluded from the study. Subjects w ith severe obesity(z score > 2.5) w ere excluded because individuals in thiscategory require specific individualized programs to avoidpotential orthopedic problems. None of the subjects w eretaking regular  medication, nor did they display any clinicalmanifestations of illness. | | | |
| Group  differences | Randomized |  |  |  |
| Special  populations | None |  |  |  |
|  | Control | HOX (Home-Based) | GRX (Hospital Clinic Group-Based) | Overall |
| N | 24 | 41 | 45 | 110 |
| Sex | 54% male | 51% male | 49% male | NR |
| Age | 11.2 | 11.9 | 12.3 | NR |
| Race | 100% w hite | 100% w hite | 100% w hite | 100%  w hite |
| BMI SDS | 2.23 | 2.1 | 2.11 | NR |
| Interventions | |  |  |  |
|  | Control | HOX (Home-Based) | GRX (Hospital Clinic Group-Based) |  |
| Intervention as described by authors | Control group participants w ere instructed about diet and other lifestyle changes during their regular visits to the hospital, but neither received the exercise nor the nutrition educational sessions as for the intervention groups. Control group participants maintained their usual levels of daily activity, w ith no additional exercise components. | HOX group participants w ere instructed to complete all exercises in their home environment.  Their program also consisted of 5 sessions per w eek (6 months, 120 sessions). The duration of each session w as approximately 60 minutes and involved both resistance and aerobic training exercises (circuit training; Fig. 2). | GRX subjects w ere provided w ith 5 supervised exercise sessions per w eek for 6 months (120 sessions). The participants and their parents w ere strongly advised to attend a minimum of 3 sessions per w eek (minimum attendance rate). Subjects  w ere made to understand that “three” w as the  minimum required number of sessions per w eek to improve body composition. Exercise training w as conducted at the hospital by a physical education instructor. Parents w ere allow ed to remain present |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | during the sessions. Each session lasted 60 minutes, during w hich time 5 minutes w ere allocated for w arming up and cooling dow n (stretching), 35 minutes w ere allocated to moderate aerobic activity, and 20 minutes to resistance training (low -load, high-repetition  exercises). |
| Intervention  type | Lifestyle | Lifestyle | Lifestyle |
| Intervention  length | 6 months | 6 months | 6 months |
| Intensity as described by authors | "Regular visits" | Study volunteers belonging to GRX and HOX groupsand their parents jointly attended tw o 1-hour educationalsessions conducted by 2 pediatricians at the Hospital. HOX group participants w ere instructed to complete allexercises in their home environment. Their program alsoconsisted of 5 sessions per w eek (6 months, 120 sessions).The duration of each session w as approximately 60minutes and involved both resistance and aerobic trainingexercises | Study volunteers belonging to GRX and HOX groupsand their parents jointly attended tw o 1-hour educationalsessions conducted by 2 pediatricians at the Hospital. GRX subjects w ere provided w ith 5 supervised exercisesessions per w eek for 6 months (120 sessions). The partic-ipants and their parents w ere strongly advised to attenda minimum of 3 sessions per w eek (minimum attendancerate). Subjects w ere made to understand that “three”  w asthe minimum required number of sessions per w eek toimprove body composition. |
| Assigned intensity | <5 hours | <5 hours | 52+ hours |
| Provider types | Primary care | Primary care, exercise provider | Primary care, exercise provider |
| Clinic setting | Multidisciplinary w eight management | Multidisciplinary w eight management | Multidisciplinary w eight management |
| Components | Usual care | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, activity  training |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | p (w ithin group) | p (across groups) |
| Control | 20 | 2.22 | 0.882 | 0.002 |
| HOX (Home-Based) | 32 | 1.88 | <0.0001 |  |
| GRX (Hospital Clinic Group-Based) | 32 | 1.94 | <0.0001 |  |
| BMI | | | | |
|  | 6 months |  |  |  |
|  | N | Mean | p (w ithin group) | p (across groups) |
| Control | 20 | 30.8 | <0.0001 | <0.0001 |
| HOX (Home-Based) | 32 | 27.3 | <0.0001 |  |
| GRX (Hospital Clinic Group-Based) | 32 | 29.3 | 0.104 |  |

**Looney, Sm; Raynor, Ha**

**Examining the effect of three low-intensity pediatric obesity interventions: a pilot randomized controlled trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This research w as partially funded by the Amy Joye Memorial Research Aw ard from the Academy of Nutrition and Dietetics Foundation. | | |  |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the institutional r review boards at the University of Tennessee, Cherokee Health Systems, | | |  |
| Outcomes  other than BMI | Behaviors |  |  |  |
| Population | | | | |
| Inclusion  criteria | Participants w ere overw eight or obese, BMI-for-age ≥85th percentile,7 children aged 4- to 10-years. | |  |  |
| Exclusion criteria | Families w ere excluded if the child had a medical condi-tion that affected grow th, dietary intake, or physical activity; the child w as participating in a w eight loss pro-gram and/or taking w eight loss medication; the primary caretaker did not w ant to participate; the caretaker did not speak or read English; the child did not speak English; the family did not have a w orking telephone number; the child spent <50% of their time at the primary caretaker’s home; or the family planned to  move out of the East Tennessee area w ithin the time frame of the study. | | | |
| Group  differences | Randomized |  |  |  |
| Special  Populations | None |  |  |  |
|  | N | N+GM | N+GM+BC | Overall |
| N Enrolled | 8 | 7 | 7 | 8 |
| Sex (%  female) | % female 85.7 | 85.7 | 85.7 | % female  37.5 |
| Age in years  (M ± SD) | 7.3 +- 1.8 | 8.6 +- 1.8 | 8.2 +- 1.8 | 7.3 ± 1.8 |
| Race (%) | Asian 0%/AA 12.5%/White 62.5%/2 or more races 25% | Asian 0%/AA 0%/w hite 85.7%/2 or more races 14.3% | Asian 14.3%/AA 0%/White 71.4%/2 or more races 14.3% | Asian 0.0; Black or AA, 12.5; White, 62.5; Tw o or more races  25.0 |
| BMIz | 2.21 + - 0.66 | 2.39 +- 0.34 | 2.45 +- 0.36 | 2.21 ± 0.66 |
| Interventions | |  |  |  |
|  | N | N+GM | N+GM+BC |  |
| Intervention as defined by author | In addition to the child’s usual care (eg, w ell- child visits, sick visits) from the pediatrician,  families in the N condition w ere mailed 6 monthly educational new sletters on nutrition and leisure-time activity topics. Each topic provided nutrition and leisure-time activity recommendations to assist w ith child  overw eight and obesity. | Families in the N + GM condition, continued to receive usual care (eg, w ell-child visits, sick visits) and w ere mailed the same monthly new sletter as in the N condition, but also monitored and received feedback monthly about their child’s grow th over 6 months. Each family in the N + GM condition w as provided w ith  grow th monitoring materials, w hich included a scale,  w all grow th chart, a BMI w heel, a BMI-for-age grow th chart, a graph ease plotting tool, and a self -monitoring | ach family continued to receive usual care (eg, w ell child visits, sick visits) from the child’s pediatrician, w as mailed a monthly new sletter as in the N and N + GM conditions and given all materials to monitor their child’s grow th as in the N+GM |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | diary to record the child’s height, w eight, BMI, and BMI  percentile. |  |
| Intervention  type (choose one) | Lifestyle | Lifestyle | Lifestyle |
| Intervention  length | 6 months | 6 months | 6 months |
| Intensity as described by authors | Because of the only additional contact being through mail, families w ere considered to have minimal contact time over the 6 months. | Over the 6 months of intervention, families had monthly contact (3, 15-minute in-person appointments, and 3, 10-minute phone calls) for a total of 1 hour and 15 minutes of contact time. | Over the 6 months of interven-tion, families had monthly contact (3, 30- minute in-per-son appointments, and 3, 20-minute phone calls) for a total of 2 hours and 30 minutes of  contact time. |
| Assigned  Intensity | < 5 hours | < 5 hours | < 5 hours |
| Provider type (select all) | primary care | primary care, background/training of the interventionist w as not specified | primary care, nutrition, mental health for behavioral counseling,  interventionist |
| Clinic setting (choose one—  probably) | primary care | Primary care | Primary care |
| Components  (choose all) | Usual care | Nutritional counseling | Nutritional and behavioral  counseling |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMIZ |  |  |  |  |  |  |  |  |  |  |
|  | Baseline |  |  |  |  | 6 months |  |  |  |  |
|  | Mean | SD | Condition | P-value (Time) | Condition x Time | Mean | SD | Condition | P-value (Time) | Condition x Time |
| N | 2.21 | 0.66 |  |  |  | 2.14 | 0.54 |  |  |  |
| N+GM | 2.39 | 0.34 |  |  |  | 2.31 | 0.26 |  |  |  |
| N+GM+BC | 2.45 | 0.36 |  |  |  | 2.29 | 0.55 | ns | 0.036 | ns |

**Love-Osborne, K; Fortune, R; Sheeder, J; Federico, S; Haemer, Ma**

**School-based health center-based treatment for obese adolescents: feasibility and body mass index effects**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by the Colorado Health Foundation. In-kind support w as provided by Denver Health and Hospitals | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Participants had parental consent to be treated in the SBHC. The Colorado Multiple Institutional Review Board approved the study, w hich included w aiver of  parental consent. Students completed inf ormed consent, and letters w ere sent to parents w ith instructions to contact study staff if they did not w ant their adolescent to participate in the study. | | |
| Outcomes other  than BMI | CV fitness |  |  |
| Population | | | |
| Inclusion criteria | During the fall of 2010, adolescents w ith BMI >= 85% w ere recruited from the SBHC population at tw o schools. Both SBHCs are located w ithin public schools  w ith high percentages of underserved students, largely ethnic minorities. | | |
| Exclusion criteria | None noted. |  |  |
| Group differences | Randomized |  |  |
| Special populations | School, underserved and largely ethnic minorities |  |  |
|  | Intervention | Control | Overall |
| N | 82 | 83 | 165 |
| Sex | 58% female | 46% female | NR |
| Age | 15.7 | 16 | NR |
| Race | 88% Hispanic | 89% Hispanic | NR |
| BMI SDS | 1.92 | 1.89 | NR |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as defined by authors  Intervention type | IG participants w ere seen by the educator for visits afterrecruitment w as complete.Both groups received preventive services, including physical examinations and laboratory screening in the SBHC. The educator met w ith the IG during the academic year, utilizing motivational interview ing techniques to set lifestyle goals. Text messaging w as used to reinf orce goals betw een visits  Lifestyle | Both groups received preventive services, including physical examinations and laboratory screening in the SBHC.  Lifestyle |  |
| Intervention length Intensity as described by | 6 months  Frequency designed to be participant directed; at end of each visit, student asked if w ished to return in 2 | 6 months  Usual care |  |
| authors  Assigned intensity | w eeks, 1 month, or 2 months.  <5 hrs | <5 hours |  |
| Provider types | Primary care, other (health educator) | Primary care |  |
| Clinic setting | School based health center | School based health center |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |  |

|  |
| --- |
| Outcomes |
| BMI z-score (85-95% subgroup) |
| 6 months |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | N | Median | Range (low er bound) | Range (upper bound) | p (across groups) |
| Intervention | 20 | 0.11 | -0.39 | 0.72 | 0.65 |
| Control | 23 | -0.03 | -0.67 | 0.46 |  |
| BMI z-score (95-99% subgroup) | | | | | |
|  | 6 months |  |  |  |  |
|  | N | Median | Range (low er bound) | Range (upper bound) | p (across groups) |
| Intervention | 40 | 0.02 | -0.67 | 0.47 | 0.81 |
| Control | 35 | -0.07 | -0.48 | 0.45 |  |
| BMI z-score (99%+ subgroup) |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Median | Range (low er bound) | Range (upper bound) | p (across groups) |
| Intervention | 17 | 0.01 | -0.09 | 0.15 | 0.36 |
| Control | 14 | 0.01 | -0.22 | 0.12 |  |

**MacDonell**

**A pilot study of motivational interviewing targeting weight-related behaviors in overweight or obese African American adolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This project w as funded by the Children’s Research Center of Michigan. The authors thank all the families w ho participated and made this possible. | | |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Human Investigation Committee approved the trial. |  |  |
| Outcomes other than BMI | Behavior |  |  |
| Population |  |  |  |
| Inclusion criteria | Eligibility criteria included the follow ing: (1) BMI85th percentile based on CDC age- and sex-specific norms; (2) self-identified as African American;  (3) age betw een 13 and 17 years;band (4) residing w ith a caregiver w illing to participate in thetreatment. | | |
| Exclusion criteria | Exclusion criteria w ere pregnancy, moderate mentalretardation, psychosis, or medical comorbidities. | |  |
| Group differences | Yes, the intervention group had a significantly higher BMI percentile (df=42, p=0.04). |  |  |
| Special Populations | African American population |  |  |
|  | MI | Nutrition Counseling | Overall |
| N Enrolled | NR? | NR? | 44 |
| Sex | (%female) 81.8 | 77.3 | 79.5 |
| Age in years | 15.05 | 15.18 | 15.11 |
| Race | All AA | All AA | All AA |
| BMI | 3668 | 34.04 | 35.36 |
| BMI percentile | 98.03 | 95.44 | 96.74 |
| Interventions | |  |  |
|  | MI | Nutrition Counseling |  |
| Intervention as defined by author | Healthy Choices, a four-session MI intervention to reduce HIV-related risk behaviors in African American youth. Healthy Choices w as adapted by asking adolescents to choose changes in nutrition or activity in w eek 1, w ith the second behavior discussed in w eek 2 by using standard MI techniques to elicit and reinf orce change talk. The dietitian met first w ith the adolescent and then w ith the caregiver, and later devised a change plan w ith the dyad using a menu of change  options specific to w eight loss. Subsequent sessions focused on barriers and facilitators to eating/activity behaviors and revision of the change plan. | For the control condition, a manual w as developed for four sessions of nutritional counseling w ith caregivers and adolescents together, based on recommendations of the Expert Committee |  |
| Intervention type (choose  one) | Lifestyle | Lifestyle |  |
| Intervention length | 3 months | 3 months |  |
| Intensity as described by authors | Intervention and control conditions w ere matched for dose, timing, and interventionist—both w ere four 60-minute sessions w ith adolescent–caregiver dyads delivered by registered dietitians at w eeks 1, 2, 6, and 10. | Intervention and control conditions w ere matched for dose, timing, and interventionist—both w ere four 60- minute sessions w ith adolescent– caregiver dyads delivered by registered  dietitians at w eeks 1, 2, 6, and 10. |  |
| Assigned Intensity | <5 hours | <5 hours |  |
| Provider type (select all) | Nutrition provider | Nutrition provider |  |
| Clinic setting (choose one—probably) | Primary Care | Primary care |  |
| Components (choose all) | Nutrition counseling, activity counseling, motivational Interview ing | Nutrition counseling |  |

Outcomes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BMI |  |  |  |  |  |  |  |  |
|  | Baselin  e |  | 3-months |  |  |  |  |  |
|  | Mean | SD | Mean | SD | Independent sample t-test (betw een  subjects) p-value | Cohen's  d | Paired samples t-test (w ithin subjects) p-  value | Cohen's  d- |
| MI | 37.6 | 6.82 | 38.1 | 6.9 | 0.74 | 0.12 | 0.24 | 0.07 |
| Nutrition Counseling | 34.92 | 8.44 | 35.78 | 9.88 |  |  | 0.36 | 0.09 |

**Makkes, S; Renders, Cm; Bosmans, Je; Baan-Slootweg, Oh; Hoekstra, T; Seidell, Jc**

**One-year effects of two intensive inpatient treatments for severely obese children and adolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship  source | The study is funded by The Netherlands Organization for Health Research and Development (ZonMw ) | |  |
| Country | The Netherlands |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Medical Ethics Committee of the VU University Medical Center(Amsterdam, the Netherlands) approved the study protocol. Prior torandomization,  w ritten inf ormed consent w as obtained from both theparticipants and their parents/caregivers. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids |  |  |
| Population |  |  |  |
| Inclusion criteria | (8–19 years) w ith severe obesity (BMIz>3.0 or BMIz>2.3 w ith comorbidity) |  |  |
| Exclusion criteria | Participants w ere excluded from the study if they had syndromal or chromosomal determined obesity; obesity caused by endocrine abnormalities or  medicine use; psychiatric problems; an IQ below 75 or if their parents/caregivers w ere not w illing or able to participate in the treatment and/or study | | |
| Group differences | Randomized |  |  |
| Special  Populations | Severe obesity |  |  |
|  | Short-stay group | Long-stay group | Overall |
| N | 40 | 40 | 80 |
| Sex | 70% female | 62.5% female | 66.3% female |
| Age | 14.5 | 15 | 14.8 |
| Race | 69.2% Western, 30.8% non-Western | 53.8% Western, 46.2% non-Western | 61.5% Western,  38.5% non- Western |
| BMI SDS | 3.4 | 3.4 | 3.4 |
| Interventions | |  |  |
|  | Short-stay group | Long-stay group |  |
| Intervention as defined by author | The treatment focused on nutri-tion, physical activity and behavior change and requiredactive participation of the parents/caregivers. | The treatment focused on nutri-tion, physical activity and behavior change and requiredactive participation  of the parents/caregivers. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 1 year | 1 year |  |
| Intensity as described by  authors | During w eekdays, the short-stay group participated in a tw omonth inpatient treatment, follow ed by biw eekly return visits of tw o days during the next four  months, then follow ed by six monthly return visits of tw o days. | The long-stay group participated in a six-month inpatient treatment during w eekdays, follow ed by six  monthly return visits of tw o days. |  |
| Assigned intensity | 52+ hours | 52+ hours |  |
| Provider types | Specialist | Specialist |  |
| Clinic setting | Inpatient; Multidisciplinary w eight management program | Inpatient; Multidisciplinary w eight management  program |  |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training,  mental health | Nutrition counseling, activity counseling, nutrition  training, activity training, mental health |  |

Outcomes

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Short-stay group | 40 | 3.1 | 0.5 | <0.05 | 37 | 3.1 | 0.6 | NS |
| Long-stay group | 37 | 2.9 | 0.6 |  | 30 | 2.9 | 0.7 |  |

**Martinez-Andrade, Go; Cespedes, Em; Rifas-Shiman, Sl; Romero-Quechol, G; Gonzalez-Unzaga, Ma; Benitez-Trejo, Ma; Flores-Huerta, S; Horan, C; Haines, J; Taveras, Em; Perez-Cuevas, R; Gillman, Mw**

**Feasibility and impact of Creciendo Sanos, a clinic-based pilot intervention to prevent obesity among preschool children in Mexico City**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed |  |  |
| Country | Mexico |  |  |
| Methods | | | |
| Design | Cluster randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Institutional Review Boards in theUnited States (Harvard Pilgrim Health Care HumanStudies Committee) and Mexico (Comisión de Ética,Comisión Nacional  de Investigación Científica, IMSS) ap-proved the study. | | |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Participants comprised children aged 2 - <5 years of age w hose BMI (calculated as w eight in kilograms divided by height in meters squared) w as above the median for age and sex (BMI z-score 0 - 3); w ho attended one of the participating IMSS clinics during the recruitment period for pediatric care, vaccination, or  accompanying a family member; and w hose parent or caregiver gave w ritten con- sent to participate. | | |
| Exclusion criteria | Families w ere excluded if they planned to move residences or change primary care clinics duringthe study period; the child had motor limitations  (e.g.,physical disability or delay); or required a special diet bymedical indication. | |  |
| Group  differences | Intervention had more normal w eight (cluster randomized). |  |  |
| Special populations | Very young children (2-5 years) |  |  |
|  | Intervention | Usual Care | Overall |
| N | 168 | 138 | 306 |
| Sex | 51.8% male | 53.6% male | 52.6%  male |
| Age | 3.34 | 3.43 | 3.38 |
| Race | NR | NR | NR |
| BMI SDS (WHO) | 1.28 | 1.26 | 1.27 |
| Interventions | Intervention | Usual Care |  |
| Intervention as described by authors | Participants randomized to intervention received a 6w eek curriculum focused on obesity aw areness and pre-vention. A trained nutritionist led diet, healthy grow thand physical activity w orkshops, w hile a health educatorled w orkshops on instilling healthy habits and routinesin childhood. The nurse provided child care and devel-oped relevant games and activities for children w hileparents attended the w orkshops. | Usual care only, there are no standardizedintervention programs specific to providing treatment to overw eight or obese children at IMSS health care sys-tem. |  |
| Intervention type | Lifestyle | Usual care only |  |
| Intervention  length | 6 w eeks | NA |  |
| Intensity as described by  authors | The 6 educational sessions w ere 2 hours each | NA |  |
| Assigned  intensity | 5-25 hours | NA |  |
| Provider types | Primary care, nutrition provider, other (health educator) | Primary care |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training, motivational  interview ing | Usual Care only |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  | 6 months |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Intervention | 99 | -0.26 | 0.01 | NS | 109 | -0.32 | 0.01 | NS |
| Usual Care | 102 | -0.44 | 0.01 |  | 102 | -0.43 | 0.01 |  |
| BMI SDS | | | | | | | | |
|  | 3 months |  |  |  | 6 months |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Intervention | 99 | -0.18 | 0.01 | NS | 109 | -0.18 | 0.01 | NS |
| Usual Care | 102 | -0.25 | 0.01 |  | 102 | -0.25 | 0.01 |  |

**McCallum, Z; Wake, M; Gerner, B; Baur, La; Gibbons, K; Gold, L; Gunn, J; Harris, C; Naughton, G; Riess, C; Sanci, L; Sheehan, J; Ukoumunne, Oc; Waters, E Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This study w as funded by anAustralian Health Ministers’ Advisory Council PriorityDriven Research Project Grant (AHMAC PDR 2001/15). | |  |
| Country | Australia |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The project w as approved by the RoyalChildren’s Hospital Ethics in Human Research Committee( EHRC 2109) | |  |
| Outcomes other  than BMI | Psychosocial, behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | All children classified as overw eight or mildly obese in the BMI survey, w ho w ere not receiving ongoing w eight management in a secondary or  tertiary care programme and w hose parents had provided contact details, w ere eligible to take part in the LEAP RCT | | |
| Exclusion criteria | Any chromosomal, endocrine ormedical condition/disability/ medication w hich, in the judge-ment of the investigators, could have an impact on  theirw eight or grow th. | |  |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Intervention | Control | Overall |
| N | 82 | 81 | 163 |
| Sex | 49% female | 54% female | 52%  female |
| Age | 7.5 | 7.4 | 7.4 |
| Race | NR | NR | NR |
| BMI SDS (UK) | 2 | 1.9 | 1.9 |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as  defined by authors | GPs used a brief solution-focused approach10to setand record appropriate, healthy lifestyle  goals w ith thef amily, assisted by a personalized 20-page ‘Family Folder’designed at a 12-year-old reading level and previously piloted. | Control families w ere notified of their  status vialetter and w ere not identified to the GPs at any time. |  |
| Intervention type | Lifestyle | Usual care |  |
| Intervention length | 12 w eeks | NA |  |
| Intensity as  described by authors | Parents w ere asked to attend four consultations over a 12-w eek period. | NA |  |
| Assigned intensity | <5 hours | NA |  |
| Provider types | Primary care | Primary care |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI |  |
| 9 months | 15 months |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention | 73 | 21 | 2.6 | 0.61 | 70 | 21.7 | 3.1 | 0.31 |
| Control | 80 | 20.8 | 2.2 |  | 76 | 21.2 | 2.4 |  |
| BMI SDS (UK) |  |  |  |  |  |  |  |  |
|  | 9 months |  |  | 15 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention | 73 | 1.96 | 0.64 | 0.71 | 70 | 2 | 0.68 | 0.42 |
| Control | 80 | 1.93 | 0.57 |  | 76 | 1.92 | 0.59 |  |

**Mirza, Nm; Palmer, Mg; Sinclair, Kb; McCarter, R; He, J; Ebbeling, Cb; Ludwig, Ds; Yanovski, Ja**

**Effects of a low glycemic load or a low-fat dietary intervention on body weight in obese Hispanic American children and adolescents: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | 3Supported by NIH grants K23-RR022227 (NMM), MO1-RR-020 359, and UL1RR03198 8, w hich w ere aw arded by the National Center for Re-search Resources to support the General Clinical Research Center and theChildren’s Research Institute at Children’s National Medical Center, andZIA-HD-00641 (JAY) and the  follow ing foundations and organizations:Consumer Health Foundation, The Jessie Ball DuPont Foundation, andUnited Way of the National Capital Area. JAY is supported by the IntramuralResearch Program of theEunice Kennedy ShriverNational Institute of ChildHealth and Human Development and the National Institute on MinorityHealth and Health Disparities of the NIH. DL is supported in part by careeraw ard K24DK082730 from the National Institute of Diabetes and  Digestiveand Kidney Diseases. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the CNMC Institutional Review Board. Signed consents w ere obtained from parents of partici- pating children, and assents w ere  obtained from the children and adolescents. | | |
| Outcomes other  than BMI | Behaviors, glucose metabolism |  |  |
| Population | | | |
| Inclusion  criteria | Hispanic children aged 7–15 y w ith a BMI $ 95th percentile for age and sex w ho w ere otherw ise healthy w ere eligible. | |  |
| Exclusion criteria | xclusion criteria included any know n medical condition that w ould interfere w ith study ob- jectives or procedures, such as preexisting T2D, Cushing syn- drome,  untreated hypothyroidism, pervasive developmental disorder, severe asthma, untreated depression, use of medica- tions know n to promote w eight gain or loss, and obesity-associated genetic syndromes | | |
| Group  differences | Randomized |  |  |
| Special  populations | Hispanic youth |  |  |
|  | Low -Glycemic Load Diet | Low -fat diet | Overall |
| N | 57 | 56 | 113 |
| Sex | 44% male | 59% male | NR |
| Age | 11.8 | 11.5 | NR |
| Race | 100% Hispanic | 100% Hispanic | 100%  Hispanic |
| BMI SDS | 2.25 | 2.24 | NR |
| Interventions | |  |  |
|  | Low -Glycemic Load Diet | Low -fat diet |  |
| Intervention as described by authors | The nutrition educationsessions w ere divided into 12 modules taught over a 12-w kcourse. For the LGD group, participants and their parents w eregiven instructions and specific examples to low er the GL of theirdiets by replacing high-GI sources of carbohydrates w ith LGIfood sources, replacing energy from carbohydrates w ith energyfrom protein and fat, and balancing meals and snacks w ith LGIcarbohydrates, protein, and low -fat food sources. ypicallyconsumed foods or favorite foods that had a high GI. The ob-jective w as to achieve macronutrient composition for the LGD of 45–50% LGI carbohydrates, 20–25% protein, and 30–35% fateach day, w ith an emphasis on achieving the  target macronu-trient distribution at each meal. All subjects also | The nutrition educationsessions w ere divided into 12 modules taught over a 12-w kcourse. For the LFD group, participantsand their parents w ere given instructions and specific examplesto limit dietary fat intake and increase the intake of grains on thebasis of current low -fat dietary recommendations (23). Thecomposition of the LFD w as targeted to  achieve 55–60% car-bohydrates (w ith no discrimination by GI), 15–20% protein, and25–30% fat. All subjects also participated in sessions to increase theirphysical activity and reduce their sedentary behaviors. |  |

|  |  |  |
| --- | --- | --- |
|  | participated in sessions to increase theirphysical activity and reduce  their sedentary behaviors. |  |
| Intervention  type | Specific diet | Specific diet |
| Intervention  length | 12 w eeks | 12 w eeks |
| Intensity as described by authors | Program delivery w as through 12 w eekly group sessions, w hich w ere separate for parents and children, and w eekly family sessions at w hich the interventionist met w ith each child and parent individually. Follow -up after the intensive w eekly phase of the intervention consisted of monthly follow -ups for 9 mo and then 3-monthly follow -ups for 12 mo for a total  follow -up interval of 2 y. | Program delivery w as through 12 w eekly group sessions, w hich w ere separate for parents and children, and w eekly family sessions at w hich the interventionist met w ith each child and parent individually. Follow -up after the intensive w eekly phase of the intervention consisted of monthly follow -ups for 9 mo and then 3-monthly follow -ups for 12 mo for a total  follow -up interval of 2 y. |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider | Primary care, nutrition provider |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition training, activity  training | Nutrition counseling, activity counseling, nutrition training, activity  training |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS (ITT) |  |  |  |  |  |  |  |  |  |  |
|  | 12  months |  |  |  |  | 24  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Low -Glycemic Load  Diet | 36 | 2.1 | 2.05 | 2.16 | 0.185 | 33 | 2.1 | 2.02 | 2.16 | 0.199 |
| Low -fat diet | 33 | 2.16 | 2.1 | 2.11 |  | 31 | 2.16 | 2.09 | 2.22 |  |

**Naar-King, S; Ellis, D; Kolmodin, K; Cunningham, P; Jen, Kl; Saelens, B; Brogan, K**

**A randomized pilot study of multisystemic therapy targeting obesity in African-American adolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This project w asfunded by the American Diabetes Association. |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Human Investigation Committee of the university affiliated w ith the hospital approved the research | |  |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | Eligibility included primary obesity based on BMI 95th percentile using age/gender norms from the Centers for Disease Control and Prevention (CDC); self -  identified African-American race/ethnicity; age 12–17 years; and resi- dence in a home w ith a caregiver w illing to participate in treat- ment. | | |
| Exclusion criteria | Exclusion criteria w ere pregnancy and moderate/severe mental retardation, psychosis, or medical co-morbidities requiring treatment. | |  |
| Group  differences | Randomized |  |  |
| Special  populations | African American adolescents |  |  |
|  | Multisystemic therapy (MST) | Control (Shapedow n/SH) | Overall |
| N | 24 | 25 | 49 |
| Sex | 73.9% female | 80% female | 77.1%  female |
| Age | 14.4 | 14.5 | 14.5 |
| Race | 100% African American | 100% African American | 100%  African American |
| BMI | 38.1 | 38.4 | NR |
| Interventions | |  |  |
|  | Multisystemic therapy (MST) | Control (Shapedow n/SH) |  |
| Intervention as described by authors | all participants met for 1 hour w ith a regis- tered dietitian to receive a 1500–1800 kcal diet plan and recommendations for 60 minutes of exercise daily. Families w ere subsequently randomized by the project manager to 6 months of MST | all participants met for 1 hour w ith a regis-tered dietitian to receive a 1500– 1800 kcal diet plan andrecommendations for 60 minutes of exercise daily. Shapedow n[6], a traditional 10-w eek family group w eight managementprogram w ith three follow -up monthly sessions added tomatch  MST treatment length. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 6 months | 6 months |  |
| Intensity as  described by authors | 6 months, 2-3 sessions per w eek | 10 w eekly sessions, monthly for 3 more months |  |
| Assigned intensity | 26-51 hours | 5-25 hours |  |
| Provider types | Primary care, nutrition provider, mental health | Primary care, nutrition provider |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational  interview ing | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 7 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Multisystemic therapy (MST) | 20 | 37.2 | 7.9 | 0.15 |
| Control (Shapedow n/SH) | 22 | 38.4 | 5.7 |  |

**Nemet 2005**

**Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This w ork w as supported by a grant from the Israeli HeartFund | |  |
| Country | Israel |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by theinstitutional  review board of the Meir General Hospital. |  |  |
| Outcomes other than BMI | Other obesity, lipids, behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | obese self-ref erred children and adolescents (6–16years of age) | |  |
| Exclusion criteria | None of the subjectshad an organic cause for his or her obesity, and none of thesubjects received any medication that might interfere w ith grow thor  w eight control (eg, corticosteroids or thyroid hormone). | | |
| Group differences | Randomized |  |  |
|  | Control | Intervention | Overall |
| N | 22 | 24 | 46 |
| Sex | 12/22 male | 14/24 male | 26/46  male |
| Age | 11.3 | 10.9 | NR |
| Race | NR | NR | NR |
| BMI | 27.8 | 28.5 | NR |
| Interventions | |  |  |
|  | Control | Intervention |  |
| Intervention as described by authors | Control subjects w ere ref erred to an ambulatorynutritional consultation at least once and w ere instructed to per-form physical activity  3 times per w eek on their ow n. | Subjects and parents in the intervention group w ere invited together for a series of 4 evening lectures; The participants met w ith the dietitian 6 times during the 3-month program; All intervention subjects participated in a tw ice-w eekly training program (1 hour  per training session) |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 3 months | 3 months |  |
| Intensity as described by authors | Control subjects w ere ref erred to an ambulatorynutritional consultation at least once and w ere instructed to per-form physical activity  3 times per w eek on their ow n. | Subjects and parents in the intervention group w ere invitedtogether for a series of 4 evening lectures. The participants met w ith the dietitian 6 times during the3-month program. All intervention subjects participated in a tw ice-w eekly trainingprogram (1 hour  per training session). |  |
| Assigned intensity | <5 hours | 26-51 hours |  |
| Provider types | Primary care, nutrition provider | Primary care, nutrition provider, exercise |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, activity training |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI |  |
| 3 months | 1 year |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Control | 22 | 26.8 | 2.9 | NS | NR | 20 | 28.6 | 5.8 | NS | <0.05 |
| Intervention | 24 | 26.8 | 3.9 | <0.05 |  | 20 | 26.1 | 4.7 |  |  |

**Nemet 2013**

**Effects of a multidisciplinary childhood obesity treatment intervention on adipocytokines, inflammatory and growth mediators**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This w ork w as supported in part by a grant from the Israeli So-ciety for Clinical Pediatrics. | |  |
| Country | Israel |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the institutional review  board of the Meir Medical Center. |  |  |
| Outcomes other than BMI | Other obesity, behaviors, glucose metabolism |  |  |
| Population |  |  |  |
| Inclusion criteria | obese self-ref erred children (aged 6–13 years). only pre- and early pubertal children w ere selected (Tanner stage 1–2 for pubic hair). | |  |
| Exclusion criteria | None of the subjects had an organic cause for obesity, and none of the subjects received any medication that may have interfered w ith grow th or  w eight control (e.g. corticosteroids, thyroid hormone) | | |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Control | Intervention | Overall |
| N | 20 | 21 | 41 |
| Sex | 55% female | 48% female | NR |
| Age | 10.49 | 10.41 | NR |
| Race | NR | NR | NR |
| BMI Percentile | 97.5 | 97.3 | NR |
| Interventions | |  |  |
|  | Control | Intervention |  |
| Intervention as described by authors | Control subjects w ere ref erred to an ambulatory nu- tritional consultation at least once, and w ere instructed to perform physical activity at least 3 times per w eek on their ow n. | The participants met w ith the dietitian 6 times during the in-tervention. These meetings differed according to the age of the patients. Intervention subjects participated in a tw ice-w eekly training program (1 h per training session). Children exercised in groups according to age (5–6, 7–9, 10–13 years). Exercise w as done in an age-appropriate manner. The intervention w as designed to mim-ic the type and intensity of exercise that elementary and middle school children normally  perform. All intervention subjects participated in a w eekly 45-min movement  therapy session. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 3 months | 3 months |  |
| Intensity as described by  authors | At least 1 consultation | Tw ice w eekly for 1 hour, 6 nutrition sessions |  |
| Assigned intensity | <5 hours | 26-51 hours |  |
| Provider types | Primary care, nutrition provider | Primary care, nutrition provider, exercise provider |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, activity training |  |

Outcomes

BMI percentile

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 3 months |  |  |  |  |
|  | n | Mean | SD | p (w ithin group) | p (betw een groups) |
| Control | 20 | 97.7 | 1.9 | NS | <0.01 |
| Intervention | 21 | 96.3 | 2.2 | <0.05 |  |

**Norman, G; Huang, J; Davila, Ep; Kolodziejczyk, Jk; Carlson, J; Covin, Jr; Gootschalk, M; Patrick, K**

**Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval for thestudy w as obtained from participating healthcare organi-zations and from the University of California, San Diego(UCSD) Human  Subjects Review Board. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |  |
| Population | | | |
| Inclusion criteria | Adolescents w ith obesity (BMI >95 percentile for age and gender) aged 11–13 years w ere recruited through their primary care providers w ithin three sites of the Children’s Primary Care Medical Group in Chula Vista, California. Participants w ere literate in English, planned to be a San Diego County resident for the next year, had a parent or guardian w illing to participate, w ere w illing to return to the physician office for counselling sessions and could attend measurement  visits. Parents w ere eligible if they w ere literate in English or Spanish | | |
| Exclusion criteria | Adolescents w ere excluded if theyw ere w ithout reliable transportation, taking w eight-alteringmedications w ithin 6 months prior to study initiation, unableto do moderate-to-vigorous PA, more than 300 lb, in fostercare, receiving special needs education, a previous partici-pant in our w eight loss studies, currently enrolled in a w eightloss programme, or diagnosed w ith obesity-related disordersrequiring immediate w eight loss management or diseasesaffecting absorption  or processing of nutrients | | |
| Group  differences | Randomized |  |  |
| Special  populations | sample w as 82% Hispanic |  |  |
|  | Stepped Care | Enhanced Usual Care | Overall |
| N | 53 | 53 | 106 |
| Sex | 29 girls/28 boys | 25 girls/24 boys | 51% female |
| Age | 12.0 girls/12.0 boys | 11.8 girls/11.7 boys | 11.9 |
| Race | girls: 24 (83% Hispanic) Boys 17 (71%) Hispanic | girls 23 (92%)Hispanic; boys 23 (81%) Hispanic | 4% African  American, 2%  Asian/PI, 82%  Hispanic, 7% White,  5% other |
| BMI SDS | girls 2.1 (CI: 1.9, 2.1); boys 2.1 (2.0, 2.3) | girls 2.0 (1.9, 2.2); boys 2.1 (2.0, 2.2) | NR |
| Interventions | |  |  |
|  | Stepped Care | Enhanced Usual Care |  |
| Intervention as described by authors | The intervention follow ed modified recommendations fromthe American Academy of Pediatrics for treatment of child-hood obesity (20) and consisted of three 4- month steps(Fig. 1). The goal w as for adolescents to lose at least 4 lbevery 4 months. If the participant did not meet the goal, thenthe step w as repeated. If a 4- lb w eight loss w as achieved,the participant w as ‘stepped-dow n’ to the next level ofreduced intensity. At the start of the programme, thephysician provided brief counselling on healthy dietary andPA behaviours. If progress is not made, then  follow -up phy-sician visit occurred at month 8 and focused on w eightmanagement  strategies. Face-to-face health educator visitsoccurred monthly in step 1 and bi- | The EUC participants received an initial counselling visit bythe physician, one visit w ith a health educator, materials onhow to improve  w eight-related behaviours, and monthlyfollow -up  mailings on w eight-related issues. |  |

|  |  |  |
| --- | --- | --- |
|  | monthly in step 2. hone calls, w hich w ere bi-w eekly in steps 1 and 2, and monthly  in step 3,w ere used toreview progress. |  |
| Intervention type | Lifestyle | Lifestyle |
| Intervention  length | 12 months | 12 months |
| Intensity as described by authors | 2 physician visits, montlhy/bimonthly health educator visits, biw eekly/monthly telephone calls. | The EUC participants received an initial counselling visit by the physician, one visit w ith a health educator, materials on how to improve  w eight-related behaviours, and monthly follow -up mailings on w eight-related issues. |
| Assigned  intensity | 5-25 horus | <5 hours |
| Provider types | Primary care, other (health educator) | Primary care, other (health educator) |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI (Girls) |  |  |  |  |  |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Stepped Care | 29 | 30.7 | 29.1 | 32.4 | 0.15 |
| Enhanced Usual Care | 25 | 29.1 | 27.4 | 30.9 |  |
| BMI Boys | | | | | |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Stepped Care | 24 | 28.8 | 27.1 | 30.4 | 0.003 |
| Enhanced Usual Care | 28 | 29.5 | 27.9 | 31 |  |
| BMI SDS (Girls) | | | | | |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Stepped Care | 29 | 2 | 1.8 | 2.1 | 0.42 |
| Enhanced Usual Care | 25 | 1.9 | 1.7 | 2.1 |  |
| BMI SDS (Boys) | | | | | |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Stepped Care | 24 | 2 | 1.8 | 2.1 | 0.008 |
| Enhanced Usual Care | 28 | 2.1 | 1.9 | 2.2 |  |

**Nova, A; Russo, A; Sala, E**

**Long-term management of obesity in paediatric office practice: experimental evaluation of two different types of intervention**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | There is no organization w ith adirect financial interest in the subject matter discussedin the manuscript | |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Cluster randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Type of inf ormed consent obtained: w e consideredthat a verbal consent for a treatment that does notrequire new experimental drugs or procedures  w assufficient. | |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | The subjects of this study w ere obese children aged from 3 to 12 years, w ho attended the FP office during the period from 15 November 1997 to  31 March 1998 | | |
| Exclusion criteria | No additional |  |  |
| Group  differences | Cluster randomized, group B more overw eight at baseline. |  |  |
| Special populations | None |  |  |
|  | Group A | Group B | Overall |
| N | 114 | 72 | 186 |
| Sex | 58.4% male | 52.8% male | NR |
| Age | 8.6 | 8.6 | 8.6 |
| Race | NR | NR | NR |
| BMI-based  percentage overw eight | 38.7 | 46 | NR |
| Interventions | |  |  |
|  | Group A | Group B |  |
| Intervention as described by authors | During the first visit, the children and theirparents w ere given the inf ormation leaflets. In groupA, these leaflets contained only general inf ormationregarding obesity and associated risks, generaladvice on healthy eating, and an invitation to practicesome physical activity. | In group B, a specific diet (onlyone scheme suitable in composition and caloric input – approximately 1400 calories – for all theenrolled children), detailed guidelines regarding phys-ical activity and active parental commitment, and analimentary diary w ith instructions for use w ere sup-plied to the children and their families. In group B, the paediatrician also asked the child andhis/her parents if the child w as on a diet. The alimen-tary diary w as review ed by the  paediatrician togetherw ith the child and the parents. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 24 months | 24 months |  |
| Intensity as  described by authors | Follow -up visits w ere performed at 6, 12 and24 months in group A | intensively follow ed up at 1, 2.5, 4, 6, 9, 12, 15, 18 and 24 months |  |
| Assigned  intensity | <5 hours | 5-25 hours |  |
| Provider types | Primary care | Primary care |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| Percentage overw eight | | | | | | | | |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Group A | 92 | -2.95 | 8.47 | 0.0001 | 80 | -2.92 | 10.8 | 0.002 |
| Group B | 51 | -8.8 | 6.62 |  | 50 | -8.5 | 9.72 |  |

**Novotny, R.; Nigg, C. R.; Li, F.; Wilkens, L. R.**

**Pacific kids DASH for health (PacDASH) randomized, controlled trial with DASH eating plan plus physical activity improves fruit and vegetable intake and diastolic blood pressure in children**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | NR but author disclosure is negative: "No competing financial interests exist." |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the institutional review boards at KP and the University of Haw aii (Honolulu, HI). | |  |
| Outcomes other  than BMI | Other obesity, blood pressure, behaviors |  |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria for PacDASH included: ages 5–8 years; BMI betw een the 50th and 99th percentile (initially ‡ 85th percentile, expanded to increase enrollment), based on CDC ref erence data 2000 12 ; primary care provider at one of four KP clinics; lives on Oahu; and due for, or scheduled for, a w ell-child/  physical exam visit during months of the study. | | |
| Exclusion criteria | Exclusion criteria w ere: diabetes mellitus, polycystic ovarian syn- drome, gastroesophageal reflux, gallbladder disease, non- alcoholic fatty liver disease,  pseudo tumor cerebri, slipped capital femoral epiphysis, Blount’s disease, obstructive sleep apnea/sleep disturbance, and other chronic disease conditions that w ould affect participation. | | |
| Group  differences | Randomized |  |  |
| Special populations | High minority population (79%) See table below . |  |  |
|  | Treatment | Control | Overall |
| N | 41 | 44 | 85 |
| Sex | 56% female | 86% female | 62% female |
| Age | 7 | 7.1 | 7 |
| Race | 46% Asian, 22% NHPI, 22% w hite, 10% other | 41% Asian, 34% NHPI, 20% w hite, 5% other | 44% Asian,  28% NHPI,  21% w hite,  7% other |
| BMI SDS | 1.3 | 1.4 | 1.3 |
| Interventions | |  |  |
|  | Treatment | Control |  |
| Intervention as defined by authors | The PacDASH intervention w as designed to delivertailored inf ormation to each member of the child, parent,and physician team. The inf ormation w as specifically tai- lored to improve FV intake and PA level of each childbased on his or her stage of readiness to change and self -efficacy.9Children w ere addressed directly, and  parentsassisted children as needed. | Child and parent in the control group received a w el- come letter and attention control mailings on unrelatedhealth topics, such as importance of hand w ashing, sunprotection, and dental hygiene, at 2, 5,  and 8 months. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 9 months | 9 months |  |
| Intensity as  described by authors | The trial consisted of a baseline visit w ith study inf or-mational packet and child and  parent ES recommendation/rep orts and tw o subsequent visits, a physician ES recom- mendation/report, three stage-based mailings, and threesupport behavior mailings | Mailings only |  |
| Assigned  intensity | <5 hours | <5 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider types | Primary care, research staff | Primary care, research staff |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, other ("Electronic Support System") | Usual care |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  | | | | | | |
| BMI SDS |  |  |  |  |  |  |  |
|  | 6 months (Visit 3)  N | Mean | SE | p (across groups) | 15 months (Visit 5)  N | Mean | SE p (across groups) |
| Treatment | 41 | 1.3 | 0.1 | 0.97 | 41 | 1.4 | 0.1 0.97 |
| Control | 44 | 1.4 | 0.1 |  | 44 | 1.5 | 0.2 |

**O'Connor, Tm; Hilmers, A; Watson, K; Baranowski, T; Giardino, Ap**

**Feasibility of an obesity intervention for paediatric primary care targeting parenting and children: helping HAND**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork is a publication of the US Department of Agriculture(USDA/ARS) Children’s Nutrition Research Center, Depart-ment of Pediatrics, BCM funded  in part by the USDA/ARS(Cooperative Agreement 6250-51000) and the Gillson Longen-baugh Foundation BCM Seed Funds. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Inf ormed w ritten consent w as obtained from families w homet the prescreening criteria follow ed by full screening. All study protocols w ere approved by  the BaylorCollege of Medicine Institutional Review Board. | | |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Study inclusion criteria w ere healthy 5- to8-year-old children w ho w ere overw eight (BMI85%), but notmorbidly obese (BMI<99%) (Barlow 2007); attended  participat-ing Texas Children's Pediatric Associate clinics; and w ere Texas Children's Health Plan members. | | |
| Exclusion criteria | Exclusion criteria included children (1) w ith medical consequences of obesity (such as hypertension or type 2 diabetes) that required more intensive treatment;  (2) on medications that could affect w eight status; (3) w ho had medical problems that could make it difficult to partici- pate in a behaviour change programme;  (4) w ho participated in other w eight treatment programmes; (5) w hose parent w as unable to read or w rite in English or Spanish; or (6) w hose parents participated in formative studies to develop Helping HAND. One child per family w as eligible. | | |
| Group  differences | Randomized |  |  |
| Special  populations | 65% w ith household income $30, 000 or less; 83% Hispanic |  |  |
|  | Intervention (Helping HAND) | Waitlist Control | Overall |
| N | 20 | 20 | 40 |
| Sex | 90% female | 70% female | 80%  female |
| Age | 7 | 6.6 | NR |
| Race | 80% Hispanic, 15% African American, 5% w hite/other | 85% Hispanic, 10% African American, 5% w hite/other | 82.5%  Hispanic |
| BMI Percentile | 95.8 | 95.9 | NR |
| Interventions | |  |  |
|  | Intervention (Helping HAND) | Waitlist Control |  |
| Intervention as described by authors | The HAs met w ith each family individually once a month andw orked w ith the family to self-select one behaviour to targetfrom a menu of behaviours that included: ‘Be more active’,‘Watch less TV’, ‘Eat more fruit’, ‘Eat more vegetables’, ‘Eathealthy snacks’, ‘Drink less sw eet drinks’, ‘Drink more w ater’.Modular Helping HAND w orksheets w ere used to assist thechild in setting behaviour-specific goals and developing animplementation plan to reach the goal by the end of the month. The HA follow ed up w ith the family by telephone 2w eeks after each session to assess progress of goal attainmentand help problem  solve as necessary. Families w ere given theoption to continue to w ork on the same behaviour for 1 addi-tional month or select a new behaviour | Families in the w ait-list CG w ere instructed to see their doctor as regularly scheduled and follow their doctor’s advice and treatment plans (usual paediatric care). They w ere re- contacted after 7 months for post-intervention data collec- tion and to start Helping HAND. They w ere asked to avoid participating in other obesity prevention or treatment pro- grammes during this time. |  |

|  |  |  |
| --- | --- | --- |
|  | to target. Families couldreschedule a missed sessions w ithin 2–3 w eeks,  but had to com-plete the programme w ithin 7 months. The HA |  |
| Intervention  type | Lifestyle | Usual care |
| Intervention  length | 6 month | 6 month |
| Intensity as described by authors | the HAs at regularly scheduled meetings. The HAs met w ith each family individually once a month and w orked w ith the family to self-select one behaviour to target. The HA follow ed up w ith the family by telephone 2  w eeks after each session to assess progress of goal attainment and help problem solve as necessary.Families could reschedule a missed sessions w ithin 2–3 w eeks, but had to com- plete the programme w ithin 7 months. | Usual care |
| Assigned intensity | 5-25 hours | <5 hours |
| Provider types | Primary care, other (health advisor) | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, motivational interview ing, other  (parenting) | Usual care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 7-8 months (Time 2) | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Intervention (Helping HAND) | 18 | 1.77 | 0.05 | 0.86 |
| Waitlist Control | 16 | 1.75 | 0.06 |  |

**Parillo, M; Licenziati, Mr; Vacca, M; Marco, D; Iannuzzi, A**

**Metabolic changes after a hypocaloric, low-glycemic-index diet in obese children**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None reported |  |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as in accordance w ith the Ethics Guidelines of our Institutional Committee. Bef ore initiating the study, both parents of all children provided w ritten  inf ormed consent | | |
| Outcomes other  than BMI | Blood pressure, glucose metabolism, lipids |  |  |
| Population | | | |
| Inclusion criteria | Patients in Outpatient Weight Clinic of the Department of Pediatrics, A.Cardarelli Hospital (Naples, Italy), | |  |
| Exclusion  criteria | BMI Z-score <2 and w ere excluded from statistical analyses. None of the children had acute or chronic disease and none w ere on pharmacologic therapy.(not  sure if this w as an exclusion criteria or just a description of w ho entered the study. | | |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | High glycemic index (HGI) diet | Low glycemic index (LGI) diet | Overall |
| N | 11 | 11 | 22 |
| Sex | NR | NR | 46%  male |
| Age | 9.8 | 9.5 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.4 | 2.4 | NR |
| Interventions | |  |  |
|  | High glycemic index (HGI) diet | Low glycemic index (LGI) diet |  |
| Intervention as described by authors | All subjects received a hypocaloric diet that provided an ener-gy intake 30% less than the intake sufficient to maintain the ide-al w eight. The low and high glycemic diets w ere matched formacronutrient composition: fat (25-30%), protein (15-20%), car-bohydrate (50-60%), and fiber intake (0.5 g/kg). The diets pre-scribed w ere based exclusively on natural food  stuffs. The HGI diet had a calculated GI of 90. | All subjects received a hypocaloric diet that provided an ener-gy intake 30% less than the intake sufficient to maintain the ide-al w eight. The low and high glycemic diets w ere matched formacronutrient composition: fat (25-30%), protein (15-20%), car-bohydrate (50-60%), and fiber intake (0.5 g/kg). The diets pre-scribed w ere based exclusively on natural food  stuffs. The LGI diet had a calculated GI of 60, |  |
| Intervention  type | Specific diet | Specific diet |  |
| Intervention  length | 6 months | 6 months |  |
| Intensity as described by authors | Dietary counseling w ith in-struction to recognize carbohydrate-rich foods and lifestyle coun-seling w ere explained by an experienced dietitian to all childrenand at least 1 their parents, in individual sessions, at the begin- ning of the study and after 15 and 30 days..Adherence to the dietary treatment w as assessed monthly on the basis of clinical assessments,  structured interview s and 7-day food records. | Dietary counseling w ith in-struction to recognize carbohydrate-rich foods and lifestyle coun-seling w ere explained by an experienced dietitian to all childrenand at least 1 their parents, in individual sessions, at the begin-ning of the study and after 15 and 30 days.Adherence to the dietary treatment w as assessed monthly on the basis of clinical  assessments, structured interview s and 7-day food records. |  |
| Assigned  intensity | 5-25 hours | 5-25 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider types | Nutrition provider | Nutrition provider |
| Clinic setting | Multidisciplinary w eight management | Multidisciplinary w eight management |
| Components | Nutrition counseling, activity counseling, specific diet | Nutrition counseling, activity counseling, specific diet |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| High glycemic index (HGI) diet | 11 | -0.2 | -0.29 | -0.1 | 0.038 |
| Low glycemic index (LGI) diet | 11 | -0.34 | -0.43 | -0.24 |  |
| BMI | | | | | |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| High glycemic index (HGI) diet | 11 | -1.6 | -2.5 | -0.6 | 0.02 |
| Low glycemic index (LGI) diet | 11 | -3.2 | -4.1 | -2.3 |  |

**Parra-Medina, D; Mojica, C; Liang, Y; Ouyang, Y; Ramos, Ai; Gomez, I**

**Promoting Weight Maintenance among Overweight and Obese Hispanic Children in a Rural Practice**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This project described w as funded by the Centers for Medicare and Medicaid Services (CMS030457) and also supported by the National Ins titutes of Health’s  National Center for Research Resources and the National Center for Advancing Translational Sciences, through Grant 8UL1TR000149. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocol w as approved by The University of Texas Health Science Center at San Antonio (UTHSCSA; San Antonio, TX) Institutional Review Board  bef ore participant recruitment. | | |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | met all criteria: (1) w ere Hispanic based on parent self-report; (2) 5–14 years of age; (3) overw eight (BMI betw een the 85th and 95th percentile for age and gender) or obese (BMI ‡ 95th percentile for age and gender); (4) one parent or adult caregiver w ho resided w ith the participant had to agree to participate in  intervention and evaluation activities; and (5) parent had access to a telephone. | | |
| Exclusion  criteria | Had one of the follow ing: (1) a mental, emotional, or physical handicap identified by a parent or provider that may interfere w ith study participation; (2) a  diagnosis of cardiovascular, pulmonary, or digestive disease; or (3) planning to move from the local area w ithin the time span of the study | | |
| Group  differences | Randomized |  |  |
| Special  Population | Hispanic |  |  |
|  | Standard Care | Intervention | Overall |
| N | 61 | 57 | 118 |
| Sex | 45.9% male | 33.3% male | 39.8%  male |
| Age | 9.92 | 9.4 | 9.67 |
| Race | 100% Hispanic | 100% Hispanic | 100%  Hispanic |
| BMI | 26.64 | 27.15 | 26.89 |
| Interventions | |  |  |
|  | Standard Care | Intervention |  |
| Intervention as described by authors | Healthy Lifestyle Prescription (HLP) from their clinical provider. The HLP lists 11 healthy lifestyle strategies (i.e. eat breakfast every day, play outside 1 hour a day) that are recommended in the prevention plus stage for the pre- vention and treatment of childhood obesity. A computerized algorithm w as applied to self -reported behavioral data collected at baseline to identify the most appropriate healthy lifestyle behavioral strategies for each family. | Parents and children assigned toINT received all elements of SC, plus face-to-face coun-seling, telephone counseling, and new sletters. NT participants received one30-minute, face-to-face counseling session at the clinicw ith a masters-level health educator immediately aftervisit 1. The face-to-face counseling session targeted thef amily and included at least the child and parent. INT parents also received monthlytelephone counseling calls (approximately 15 minuteseach) from the health educator. INT parents and children also received fourmonthly bilingual  (English and Spanish) new sletters. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 18 w eeks | 18 w eeks |  |

|  |  |  |
| --- | --- | --- |
| Intensity as  described by authors | 4 clinic visits | 4 clinic visits, 1 counseling session, 4 calls |
| Assigned  intensity | <5 hours | <5 hours |
| Provider types | Primary care | Primary care, other (research nurse, health educator) |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| Percent w ith zBMI decrease or zero | | | |
| 18 w eeks | | | |
|  | N | Mean | P (betw een groups) |
| Standard Care | 61 | 55.7 | 0.46 |
| Intervention | 57 | 63.2 |  |

**Partsalaki, I; Karvela, A; Spiliotis, Be**

**Metabolic impact of a ketogenic diet compared to a hypocaloric diet in obese children and adolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None reported |  |  |
| Country | Greece |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The protocol w as approved by the Ethics Committee of the University Hospital of Patras. Inf ormed parental consent and children ’ s assent w ere obtained in all  cases | | |
| Outcomes other  than BMI | Other obesity, glucose metabolism, lipids, blood pressure, other labs |  |  |
| Population | | | |
| Inclusion criteria | Fifty-eight obese [ > 95th percentile body mass index (BMI) for gen-der and age] (24, 25) children and adolescents (aged 8 – 18). The inclusion criteria speci-fi ed that all subjects w ere not follow ing any specialized diet and had normal liver, respiratory, kidney, and gastrointestinal functions. All children w ith thyroid dysfunction w ere on treatment w ith thyroxine and w ere euthyroid during the entire study. Individuals w ith diabetes or genetically associated obesity  syndromes w ere excluded from the study | | |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Ketogenic diet | Hypocaloric diet | Overall |
| N | 29 | 29 | 58 |
| Sex | 48% male | 45% male | NR |
| Age | 13.6 | 12.3 | NR |
| Race | NR | NR | NR |
| BMI | 20.8 | 28 | NR |
| Interventions | |  |  |
|  | Ketogenic diet | Hypocaloric diet |  |
| Intervention as described by authors | The ketogenic diet group aimed for < 20 g/day carbohydrates, w ith a gradual increase tow ards 30 – 40 g/day, if the measurements of urinary ketones continued to indicate ketosis. There w ere no restrictions on caloric intake or the type of fat or cholesterol concentration of the foods. Both groups w ere encouraged to have at  least 1 h daily of vigor-ous exercise. | The children and adolescents on the hypocaloric diet w ere instructed to reduce their caloric intake by 500 calories daily w hile deriving 28 % – 33  % and 50 % – 55 % of these calories from fat and carbohy- drates, respectively, w hich is in accordance w ith the dietary guide-lines for children and adolescents of the American Heart Association. Both groups  w ere encouraged to have at least 1 h daily of vigor-ous exercise. |  |
| Intervention type | Specific diet | Specific diet |  |
| Intervention  length | 6 months | 6 months |  |
| Intensity as  described by authors | The dietitian met w ith them individually at baseline and w eekly for the fi  rst month and biw eekly thereafter in order for the appropriate education and counseling on the diets to take place. | The dietitian met w ith them individually at baseline and w eekly for the fi rst  month and biw eekly thereafter in order for the appropriate education and counseling on the diets to take place. |  |
| Assigned intensity  Provider types | 5-25 hours  Specialist, nutrition provider | 5-25 hours  Specialist, nutrition provider |  |
| Clinic setting | Specialty clinic | Specialty clinic |  |

Components Nutrition counseling, activity counseling, specific diet Nutrition counseling, activity counseling, specific diet

BMI

Outcomes

6 months

N Mean SD p (w ithin group) p (betw een groups)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ketogenic diet | 21 | -3.7 | 0.001 | NS |
| Hypocaloric diet | 17 | -3.3 | 0.001 |  |

**Pedrosa, C; Oliveira, Bm; Albuquerque, I; SimÃµes-Pereira, C; Vaz-de-Almeida, Md; Correia, F**

**Markers of metabolic syndrome in obese children before and after 1-year lifestyle intervention program**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This w ork w as supported by a SPEDM (Sociedade Portuguesa de  Endocrinologia, Diabetes e Metabolismo)/ ABBOTT grant. |  |  |
| Country | Portugal |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Each parent gave w ritten inf ormed consent, and children gave assent for participation. Assessments w ere done at the Department of Endocrinol-  ogy, Diabetes and Nutrition. The study w as approved by the Hospital Ethics Committee. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids, behaviors |  |  |
| Population | | | |
| Inclusion criteria | > 85th BMI percentile, children, seems to be focused on below 10 year olds but not listed as inclusion specif ically. | |  |
| Exclusion  criteria | None of the children had primary dyslipidemia, hypertension, diabetes or glucose intoler- ance, secondary obesity, and w ere not receiving  pharma- cological treatment. | | |
| Group  differences | randomized |  |  |
| Special Population | None |  |  |
|  | Individual conventional treatment (IT) | Group-based treatment (GT) | Overall |
| Age | NR | NR | 8.6 (0.7SD) |
| Sex | NR | NR | 55.7%  Male/44.3%  Female; n=61 |
| Race | NR | NR | NR |
| BMI SDS |  | 1.86 (0.25SD) | 1.93 (0.28SD) |
| Interventions | |  |  |
|  | Individual conventional treatment (IT) | Group-based treatment (GT) |  |
| Intervention as defined by the author | In IT, a healthy eating plan meeting nutrient needs according to the recommended daily allow ance (&1,800 kcal) w as prescribed and explained to children and their parents. The diet recommended the reduced intake of refined carbohydrates and saturated fats, w ith an increased consumption of vegetables and fruits. Additionally, physical activity w as encouraged and sedentary behaviors, such as TV  w atching and computer/video game playing, w ere discouraged | In GT, children and their parents participated in a group-based nutrition education program (4 children per group), w hich consisted of 4 consecutive sessions each of 60 min duration, conducted by a nutritionist. These sessions covered several topics regarding childhood obesity and comorbidities, healthy eating habits, healthy cooking methods, portion size control, food labeling and physical  activity promotion. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 1 year | 1 year |  |
| Intensity as described by authors | One baseline visit w here diet w as prescribed. Follow -up visits w ere held at 3- and 6 months and 1 year after the first visit. | In GT, children and their parents participated in a group-based nutrition education program (4 children per group), w hich consisted of 4 consecutive sessions each of 60 min duration, conducted by a nutritionist. The acquired know ledge w as reinf orced at each session and w henever necessary at follow -up visits that w ere held at 3- and  6 months and 1 year after the first visit. |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity | < 5 hours | 5-25 hours |
| Provider type | Nutrition provider | Nutrition provider |
| Clinic setting | research unit | research unit |
| Components | Nutrition counseling, Activity counselling | nutrition counseling; activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI z-score |  |  |  |  |  |  |  |  |
|  | 6 month |  |  |  | 1 year |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| Individual conventional treatment (IT) | 42 | 1.83 | 0.34 | NR | 42 | 1.78 | 0.33 | 0.582 |
| Group-based treatment (GT) | 19 | 1.73 | 0.35 |  | 19 | 1.61 | 0.34 |  |
| BMI | | | | | | | | |
|  | 6 month |  |  |  | 1 year |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| Individual conventional treatment (IT) | 42 | 23.08 | 2.69 | NR | 42 | 23.39 | 2.77 | 0.579 |
| Group-based treatment (GT) | 19 | 22.28 | 1.75 |  | 19 | 22.14 | 1.81 |  |

**Quattrin, T.; Roemmich, J. N.; Paluch, R.; Yu, J.; Epstein, L. H.; Ecker, M. A.**

**Efficacy of family-based weight control program for preschool children in primary care**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | Supported by National Institutes of Health grant1R01HD053 773-01. Funded by the National Institutes of Health(NIH). | |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the In-stitutional Review Boards of the Womenand Children’sHospitalof Buffaloandthe University at Buffalo and w as con-ducted  in accordance w ith the Declara-tion of Helsinki. | | |
| Outcomes other  than BMI | None |  |  |
| Population |  |  |  |
| Inclusion criteria | Girls and boys aged 2 to 5 years w ith BMI > (or equal to) 85th percentile for age and gender, w ith normal developmental milestones and having 1  participating parent w ith a BMI > (or equal to) 27. Participating parents had to be w illing to attend all treatment sessions, speak English or Spanish at a fifth- grade level, and continue care for their child at the same pediatric practice throughout the study. | | |
| Exclusion criteria | Exclusion criteria included child’s height below 2 SD from the mean for age and gender or pathologic grow th velocity, history of small for gestational age, medications know n to affect w eight, and child or parent w ith psychiatric/eating disorder or a pathology preventing performance of physical activity. Families w ere also excluded if the participating mother w as pregnant or planning a pregnancy, if parents w ere acquainted w ith the family of a child enrolled in the  program, or the child’s family resided w ithin .5 miles from another participating child. | | |
| Group differences | Randomized |  |  |
| Special populations | Preschool children |  |  |
|  | Intervention | Inf ormation Control (IC) | Overall |
| N | 46 | 50 | 96 |
| Sex | 67% female | 66% female | NR |
| Age | 4.6 | 4.4 | NR |
| Race | 72% w hite, 15% black, 11% Hispanic, 2% Asian | 74% w hite, 8% black, 8% Hispanic, 10% other | NR |
| BMI SDS | 2.2 | 2.1 | NR |
| Interventions | |  |  |
|  | Intervention | Inf ormation Control (IC) |  |
| Intervention as  described by authors | Trained staff delivered dietary and physical/sedentary activities education to parents  over 6 months (10 group meetings and 8 calls). Parents in the intervention also received individualized behavioral modification. | Trained staff delivered dietary and physical/sedentary  activities education to parents over 6 months (10 group meetings and 8 calls). |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as  described by authors | Ten 60-minute sessions over 6 months, 8 phone calls betw een meetings. Bef ore or after the group sessions parents attended a 1:1 meeting w ith an assigned coach | Ten 60-minute sessions over 6 months, 8 phone calls betw een meetings |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |
| Provider types | Primary care, other ("coach") | Primary care, other ("coach") |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing, other (parenting) | Nutrition counseling, activity counseling |  |

|  |  |
| --- | --- |
| Outcomes |  |
| BMI SDS |  |
| 3 months | 6 months |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention | 46 | 1.87 |  | <0.02 | 46 | 1.72 |  | <0.001 |
| Inf ormation Control (IC) | 50 | 2.01 |  |  | 50 | 1.98 |  |  |

**Quattrin, T; Cao, Y; Paluch, Ra; Roemmich, Jn; Ecker, Ma; Epstein, Lh Cost-effectiveness of family-based obesity treatment**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This research w as funded by the National Institutes of Health grant 1R01HAD053773-01, Principal Investigator, Teresa Quattrin. Funded by the National  Institutes of Health (NIH). | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the institutional review board of the Women and Children’s Hospital of Buffalo and w as conducted in concordance w ith the  Declaration of Helsinki. | |  |
| Outcomes  other than BMI | BMI, Other (parent BMI) |  |  |
| Population | | | |
| Inclusion  criteria | Children w ho had a BMI over the 85th percentile for their age and sex w ith a parent w ho had a BMI ≥25 w ere included. | |  |
| Exclusion  criteria | The main exclusion criteria w ere as follow s: small for gestational age, short stature, and child and/or parent inability to perform physical activity. | |  |
| Group  differences | Randomized |  |  |
| Special  Populations | 2 to 5 year olds |  |  |
|  | IC | FBT | Overall |
| Age | 4.4 (0.2) | 4.6 (0.2) | NR |
| Sex | 33F/15M | 31F/15M | NR |
| Race | 13Minoriity/37Caucasian | 13Minority/33Caucasian | NR |
| BMI | 20.1 (0.4) | 20.4 (0.5) | NR |
| %OBIM | 29.8 (17.1) | 32.4 (22.4) | NR |
| Interventions | |  |  |
|  | IC | FBT |  |
| Intervention as defined by author | Child only focus, w ith child ta all sessions and dietary counselling for the child | Behavior modification and education on parenting techniques w ere delivered by the group leader during group sessions and by the PEA, assigned as a health coach to each family, during brief individual  sessions. |  |
| Intervention  type | Life style | Life style |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as described by authors | Parents attended 16 treatment meetings. During the 12-month treatment period there w ere 13 group sessions (4 w eekly, 2 biw eekly, 4 monthly, and 3 at 8- to 10-w eek intervals), and during the follow -up period there  w ere 3 group sessions (w eeks 65, 78, and 91). These w ere follow ed by a final visit for assessment only at w eek 104, so that there w ere a total of 17 visits to the pediatrician’s office. PEA, assigned to each family and  ref erred to as a health coach, telephoned the parent betw een scheduled meetings (10 times during treatment and 3 times during follow -up) to remind him or her of the upcoming meeting in the IC group and to counsel and problem solve in the FBT group | Parents attended 16 treatment meetings. During the 12-month treatment period there w ere 13 group sessions (4 w eekly, 2 biw eekly, 4 monthly, and 3 at 8- to 10-w eek intervals), and during the follow -up period there  w ere 3 group sessions (w eeks 65, 78, and 91). These w ere follow ed by a final visit for assessment only at w eek 104, so that there w ere a total of 17 visits to the pediatrician’s office. PEA, assigned to each family and  ref erred to as a health coach, telephoned the parent betw een scheduled meetings (10 times during treatment and 3 times during follow -up) to remind him or her of the upcoming meeting in the IC group and to counsel and problem solve in the FBT group |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider | primary care, health coach | primary care, health coach |
| Clinic Setting | primary care | primary care |
| Components | nutrition counseling, activity counseling | nutrition counseling, activity counseling, parent as an added focus in  nutrition and activity counseling, parent training, parent monitoring |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |
| %0BMI |  |  |  |  |  |  |  |
| Changes over 24 months | | | | | | | |
|  | n | Mean | 95% CI upper | 95% CI low er | Effect | Effect 95% CI upper | Effect 95% CI low er |
| IC | 50 | -4.4 | -8.9 | -2.2 | 6.4 | 0.7 | 9.2 |
| FBT | 46 | 2 | -3.6 | 3.4 |  |  |  |

**Quattrin, T; Roemmich, Jn; Paluch, R; Yu, J; Epstein, Lh; Ecker, Ma**

**Treatment outcomes of overweight children and parents in the medical home**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by National Institutes of Health grant 1R01HD053773-01, Principal Investigator, Teresa Quattrin. Funded by the National Institutes of Health(NIH). | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w asapproved by the Institutional Review Board of the Women and Children’sHospital of Buffalo and w as conductedin concordance w ith the  Declaration of Helsinki. | |  |
| Outcomes other  than BMI | None |  |  |
| Population | | | |
| Inclusion criteria | Children w ho had a BMI over the 85thpercentile for age and gen-der and having a parent w ho had a BMI.25 kg/m2w ere included. | |  |
| Exclusion  criteria | The main ex-clusion criteria w ere: small for gesta-tional age, short stature, and child/parent inability to perform physical ac-tivity. | |  |
| Group  differences | Randomized |  |  |
| Special populations | Preschool children |  |  |
|  | Intervention | Inf ormation Control (IC) | Overall |
| N | 46 | 50 | 96 |
| Sex | 67% female | 66% female | NR |
| Age | 4.6 | 4.4 | NR |
| Race | 72% w hite, 15% black, 11% Hispanic, 2% Asian | 74% w hite, 8% black, 8% Hispanic, 10% other | NR |
| BMI SDS | 2.2 | 2.1 | NR |
| Interventions | |  |  |
|  | Intervention | Inf ormation Control (IC) |  |
| Intervention as described by authors | Parents attended thirteen 60-minute groupsessions over the 12-month treat-ment period (4 w eekly, 2 biw eekly, 4monthly, and 3 at 8- to 10- w eek intervals),follow ed by a 12-month follow -up(3 meetings at month 16, 20, and 24). A PEA assigned to eachf amily telephoned the parent betw eenscheduled meetings 10 times duringtreatment and 3 times during follow -up. Bothgroups received dietary, physical, andsedentary activity guidelines in keepingw ith the Expert Committee Recom-  mendations. In the Intervention behavior modificationand education on parenting techniques(ie, positive reinf orcement, modelinghealthy diet and activity, and stimuluscontrol) w ere delivered by the groupleader during the group meetings and bya PEA, assigned to each family, duringbrief individual sessions held the sameevenings as the group  meetings. | Parents attended thirteen 60-minute groupsessions over the 12-month treat-ment period (4 w eekly, 2 biw eekly, 4monthly, and 3 at 8- to 10- w eek intervals),follow ed by a 12-month follow -up(3 meetings at month 16, 20, and 24). A PEA assigned to eachf amily telephoned the parent betw eenscheduled meetings 10 times duringtreatment and 3 times during follow -up. Bothgroups received dietary, physical, andsedentary activity guidelines in keepingw ith the Expert Committee Recom- mendations |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 12 months | 12 months |  |

|  |  |  |
| --- | --- | --- |
| Intensity as  described by authors | 13 60-min groups sessions, 3 meetings at months 16, 20, 24. 13 phone calls, | 13 60-min groups sessions, 3 meetings at months 16, 20, 24. 13 phone calls, |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, other (parenting) | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 18 months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention | 46 | 1.66 | 0.06 | 0.005 | 46 | 1.61 | 0.06 | 0 .001 |
| Inf ormation Control (IC) | 50 | 1.86 | 0.05 |  | 50 | 1.86 | 0.05 |  |

**Resnicow, K; McMaster, F; Bocian, A; Harris, D; Zhou, Y; Snetselaar, L; Schwartz, R; Myers, E; Gotlieb, J; Foster, J; Hollinger, D; Smith, K; Woolford, S; Mueller, D; Wasserman, Rc**

**Motivational interviewing and dietary counseling for obesity in primary care: an RCT**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | Supported by a grant (HL085400) from the US National Institutes of Health National Heart, Lung, and Blood Institute. T | | |  |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Cluster randomized  controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | Ethics approval w as obtained from the University of Michigan and the American Academy of Pediatrics (AAP). Most PROS (Pediatric Research in Office Settings) practices (n = 38) operated under the AAP Institutional Review Board, w hereas the remaining practices (n = 4), obtained local institutional review  board approval. | | | |
| Outcomes other  than BMI | None |  |  |  |
| Population | | | | |
| Inclusion  criteria | The target population w as children aged 2 to 8 w ith a BMI 85th and 97th percentile. | |  |  |
| Exclusion criteria | Exclusion criteria w ere type 1 or type 2 diabetes, non-English-speaking parent, no w orking telephone, chronic medical disorders, chromosomal disorders, syndromes and nonambulatory conditions (such as myelodysplasia, cerebral palsy), medications know n to affect grow th, enrollment in a w eight loss program,  or seen by w eight loss specialist in past 12 months. | | | |
| Group  differences | Cluster randomized, but some baseline differences in race, income, education | |  |  |
| Special  populations | 2 to 8 year olds |  |  |  |
|  | Group 1 (Usual care) | Group 2 (PCP) | Group 3 (PCP + RD) | Overall |
| N | 198 | 212 | 235 | 645 |
| Sex | 47.0% male | 42.9% male | 39.6% male | 43.0% male |
| Age | 4.9 | 5.1 | 5.3 | 5.1 |
| Race | 67.9% w hite, 2.6%  black, 13.3%  Hispanic, 6.6% Asian,  9.7% other | 53.6% w hite, 11.0% black, 30.1% Hispanic, 1.4% Asian,  3.8% other | 59.1% w hite, 6.1% black, 20.9% Hispanic, 8.7%  Asian, 5.2% other | 60.0%w hite, 6.6%  black, 21.6%  Hispanic, 5.7%  Asian, 6.1% other |
| BMI Percentile | 91.5 | 92.2 | 92.1 | 91.9 |
| Interventions | |  |  |  |
|  | Group 1 (Usual care) | Group 2 (PCP) | Group 3 (PCP + RD) |  |
| Intervention as described by authors | Usual care and half day orientation on current treatment guidelines, handouts  for patients | 2 day training of MI and behavior therapy, and an interactive DVD. PCPs in group 2 w ere asked to schedule 3 counseling sessions w ith a parent of the index child in year 1 and 1 additional “booster” visit in year 2, although  they w ere given latitude in their appointment scheduling. | Group 3 (PCP+RD) included the same interventioncomponents as group 2 but addedMI- based counseling from a trained RD w ho w as linked to the practice. The RD sessions  w eredelivered either in-person or bytelephone. |  |
| Intervention  type | Usual care | Lifestyle | Lifestyle |  |
| Intervention  length | 2 years | 2 years | 2 years |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Intensity as described by authors | Usual care | PCPs in group 2 w ere asked toschedule 3 counseling sessions w itha parent of the index child in year 1and 1 additional“booster”visit inyear 2, although they w ere  givenlatitude in their appointmentscheduling. | 6 MI-based counseling sessions over 2 years. |
| Assigned  intensity | <5 hours | <5 hours | <5 hours |
| Provider types | Primary care | Primary care | Primary care, nutrition provider |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Usual care | Nutrition counseling, activity counseling, motivational  interview ing | Nutrition counseling, activity counseling,  motivational interview ing |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI Percentile |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SE | p (across groups) |
| Group 1 (Usual care) | 158 | -1.8 | 0.98 | p<0.05 vs group 3 |
| Group 2 (PCP) | 145 | -3.8 | 0.96 | NS |
| Group 3 (PCP + RD) | 154 | -4.9 | 0.99 |  |

**Rifas-Shiman, Sl; Taveras, Em; Gortmaker, Sl; Hohman, Kh; Horan, Cm; Kleinman, Kp; Mitchell, K; Price, S; Prosser, La; Gillman, Mw Two-year follow-up of a primary care-based intervention to prevent and manage childhood obesity: the High Five for Kids study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This study w as supported by a grant from the EuniceKennedy Shriver National Institute of Child Health andHuman Development (R01 HD 050966) | | |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Cluster randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The institutional review board of Harvard Pilgrim Health Care approved all study procedures. |  |  |
| Outcomes other than  BMI | Behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | children age 2 – 6years w ith BMI ≥ 95th percentile or 85th to < 95th percentile if at least one parent w as overw eight | |  |
| Exclusion criteria | No additional |  |  |
| Group differences | Cluster randomized, more w hite in the usual care group |  |  |
| Special populations | Preschoolers |  |  |
|  | Intervention | Usual Care | Overall |
| N | 253 | 192 | 445 |
| Sex | 47.8% female | 49.0% female | 48.3% female |
| Age | 4.8 | 5.2 | 4.9 |
| Race | 46.6% w hite, 27.7% black, 19.0% latino, 6.7% other | 69.8% w hite, 7.3%  black, 13.5% latino,  9.4% other | 56.6% w hite, 18.9%  black, 16.6% latino,  7.9% other |
| BMI SDS | 1.88 | 1.82 | 1.85 |
| Interventions | |  |  |
|  | Intervention | Usual Care |  |
| Intervention as described by authors | Inter-vention practices received primary care restructuring,and families received motivational  interview ing byclinicians and educational modules targeting televi-sion view ing and intakes of fast food and sugar-sw eetened beverages. | Usual Care |  |
| Intervention type | Lifestyle | Usual care |  |
| Intervention length | 12 months (+12 months maintenance) | 12 months |  |
| Intensity as described by authors | During the 1-year interventionperiod, w e aimed for participants to complete four in-person visits and tw o phone calls w ith clinicians. Du-ring the subsequent 1-year maintenance period, w eaimed for  participants to complete tw o in-person in-tervention visits. | Usual care |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider types | Primary care | Primary care |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
| 2 years |  |  |  |
| N | Mean | SD | p (betw een groups) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intervention | 249 | -0.2 | 0.51 | NS |
| Usual Care | 192 | -0.18 | 0.47 |  |
| BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Intervention | 249 | 1.11 | 1.99 | NS |
| Usual Care | 192 | 1.22 | 1.82 |  |

**Rolland-Cachera, Mf; Thibault, H; Souberbielle, Jc; SouliÃ©, D; Carbonel, P; Deheeger, M; Roinsol, D; Longueville, E; Bellisle, F; Serog, P Massive obesity in adolescents: dietary interventions and behaviours associated with weight regain at 2 y follow-up**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as supported by LESIEUR and NESTLE FranceCompanies |  |  |
| Country | France |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Ethical Committee for the protection of persons participating in biological experimentation of Hospital Paris Saint-Louis approved the protocol and  parents gave consent allow ing the child to participate in the study | | |
| Outcomes other  than BMI | Other obesity, behaviors |  |  |
| Population | | | |
| Inclusion criteria | The inclusion criteria w ere the follow ing: a body mass index(BMI) exceeding the 97th centile of the French ref erencevalues,11age betw een 11 and 16 y,  no pathologies contribut-ing to obesity and no use of regular medication | | |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | Severe obesity |  |  |
|  | PROT- | PROT+ | Overall |
| N | 61 | 60 | 121 |
| Sex | 74% female | 72% female | 74%  female |
| Age | 14.1 | 14.4 | NR |
| Race | NR | NR | NR |
| BMI SDS | 4.29 | 4.27 | NR |
| Interventions | |  |  |
| Intervention as | PROT-  The participants lived for one school year in a medical centre(also boarding school) specialised in the treatment of obesechildren. The treatment included diet, physical exercise andpsychological support. The nutrient content of the PROTdiet w as 15% proteinand 54% CHO. | PROT+  The participants lived for one school year in a med boarding school) specialised in the treatment of treatment included diet, physical exercise andps The nutrient content of the PROT+ diet w as 19% | ical centre(also obesechildren. The ychological support. proteinand 50% CHO. |
| described by  authors  Intervention type Intervention | Physical activityPhysical activity consisted in 7 h/w eek of vigorous sports(sw imming, tennis, handball, aerobic) and 7 h/w eek  of outdoor activities (such as w alking or playing). Childrenhad no possibility to w atch TV in the centre.  Lifestyle, specific diet  9 months | Physical activityPhysical activity consisted in 7 sports(sw imming, tennis, handball, aerobic)  of outdoor activities (such as w alking or playing possibility to w atch TV in the centre.  Lifestyle, specific diet  9 months | h/w eek of vigorous and 7 h/w eek  ). Childrenhad no |
| length Intensity as described by  authors | Inpatient for 9 months | Inpatient for 9 months |  |
| Assigned  intensity | 52+ hours | 52+ hours |  |

|  |  |  |
| --- | --- | --- |
| Provider types | Primary care, nutrition provider, mental health, exercise | Primary care, nutrition provider, mental health, exercise |
| Clinic setting | Inpatient | Inpatient |
| Components | Nutrition counseling, activity counseling, nutrition training, activity  training, mental health | Nutrition counseling, activity counseling, nutrition training, activity  training, mental health |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
| 11 months (T4) | |  |  | 35 months (T6) | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| PROT- | 53 | 24.2 | 2.6 |  |  |  |  |  |
| PROT+ | 46 | 24 | 2.5 |  |  |  |  |  |
| BMI SDS | | | | | | | | |
| 11 months (T4) | |  |  | 35 months (T6) | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| PROT- | 53 | 1.74 | 0.6 | 0.7 | 31 |  |  | NS |
| PROT+ | 46 | 1.72 | 0.6 |  | 36 |  |  |  |

**Saelens, Be; Sallis, Jf; Wilfley, De; Patrick, K; Cella, Ja; Buchta, R**

**Behavioral weight control for overweight adolescents initiated in primary care**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This research w as supported in part by a Young Investigator’s Grant aw arded by the North American Association for the Study of Obesity to the first author | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Parental consentand adolescent assent w ere obtained. Study proceduresw ere approved by the San Diego State University Committeeon the Protection of  Human Subjects and the InstitutionalReview Boards of each of the clinics. | | |
| Outcomes  other than BMI | Behaviors, psychosocial |  |  |
| Population | | | |
| Inclusion  criteria | betw een 12 and 16 years old, 20% to 100% above the median (50th percentile) for body mass index (BMI) for sex and age (21), interested in w eight control,  but not currently engaged in another w eight control program, and otherw ise healthy as determined by a pediatrician. | | |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Healthy Habits (HH) | Typical Care (TC) | Overall |
| N | 23 | 21 | 44 |
| Sex | NR | NR | 59.1% male |
| Age | NR | NR | 14.2 |
| Race | NR | NR | 70.5% w hite, 15.9% Hispanic, 4.5% African  American, 2.3% Asian, 6.8% multi-ethnic |
| BMI | NR | NR | 30.7 |
| Interventions | |  |  |
|  | Healthy Habits (HH) | Typical Care (TC) |  |
| Intervention as described by authors | Immediat ely after baseline assessment in the clinic, HHadolescents engaged in a computer program adapted fromPACE(Patient- Centered Assessment and Counseling forExercise plus Nutrition) softw are designed for adolescents(24) and modified for  overw eight adolescents. The com-puter program assessed eating, physical activity, and sed-entary behavior and guided adolescents through individual-ized plans generated to increase physical activity ordecrease sedentary behavior and decrease dietary fat orincrease fruits/vegetables or decrease overeating/snacking. Approximately 1 w eek after the clinic visit, each HHadolescent and his/her parent met in-person w ith the firstauthor (B.E.S.) to discuss upcoming mail and phone con-  tacts and to learn food self -monitoring. Calls from a phonecounselor began 1 w eek after this meeting. elephonecounselors used detailed telephone scripts to address ado-lescents’w eight change since the last call (adolescents w ereencouraged to w eigh  once w eekly), the link betw een w eightchange and eating and | Immediat ely after baseline assessment,TC adolescents met w ith a pediatrician. Based on expertcommittee recommendations regarding pediatric obesitythat w ere given to pediatricians (28), pediatricians w ereinstructed to assess/encourage adolescent’s motivation forw eight-related behavior change, provide inf ormation aboutshort- and long-term health consequences of high w eightstatus and benefits of better w eight control, make recom- mendations for healthf ul eating consistent w ith the FoodGuide  Pyramid (29), review physical activity  recommenda-tions for adolescents (60 |  |

|  |  |  |
| --- | --- | --- |
|  | physical activity behaviors, instruc-tion and feedback on previous self-monitoring, eating andphysical activity goals, and the use of behavioral skillsrelevant to goal achievement. | min/d of at least moderate intensityphysical activity) (27), and encourage consistency and per-sistence  w ith health behavior changes. |
| Intervention  type | Lifestyle | Lifestyle |
| Intervention length | 16 w eeks | 16 w eeks |
| Intensity as described by authors | Telephonecontact w as structured to last 10 to 20 minutes and sched-uled w eekly for the first eight calls and biw eekly for the lastthree calls, thus, lasting a total of 14 to 16 w eeks | After thisnon-tailored physician- counseling session, TC adolescents w ere not contacted again until scheduling for the post-treatment  assessment4 months later |
| Assigned  intensity | 5-25 hours | <5 hours |
| Provider types | Primary care, other (phone counselors) | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 4 months |  |  |  | 7 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Healthy Habits (HH) |  |  |  |  |  |  |  |  |
| Typical Care (TC) |  |  |  |  |  |  |  |  |
| BMI | | | | | | | | |
|  | 4 months |  |  |  | 7 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Healthy Habits (HH) | 20 | 30.9 | 3.8 | NR | 18 | 31.1 | 4.5 | NR |
| Typical Care (TC) | 19 | 31.8 | 3.4 |  | 19 | 32.1 | 3.8 |  |

**Savoye, M; Nowicka, P; Shaw, M; Yu, S; Dziura, J; Chavent, G; O'Malley, G; Serrecchia, Jb; Tamborlane, Wv; Caprio, S Long-term results of an obesity program in an ethnically diverse pediatric population**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | Clinical Translation Science Aw ard (UL1-RR024139) from the National Center for Research Resources; NIDDK (P30-DK-45735); NIH grants (R01-HD28016 and R01-HD40787); Yale University School of Medicine grant; an unrestricted gift from the McPheeFoundation (Bristol, CT); the Tegger Foundation; and  the Fulbright Commission | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Yale Human Investigation Committee, and w ritten inf ormed assent and consent w ere obtained from participants and parents. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |  |
| Population | | | |
| Inclusion criteria | Major inclusion criteria: English-speaking, 8- to 16-year-old children w ith a BMI > or equal to the 95th percentile attending the Yale Pediatric Obesity Clinic. | | |
| Exclusion criteria | Exclusion criteria included serious medical conditions that w ould preclude participation in the program, use of medications that may cause significant w eight  gain/loss, or involvement in a coexisting w eight management program | | |
| Group differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Weight management | Control | Overall |
| N | 105 | 69 | 174 |
| Sex | 55.2% female | 58.1% female | NR |
| Age | 12 | 12.5 | NR |
| Race | 38.1% w hite, 38.1% black, 23.8% Hispanic | 34.8% w hite, 39.1% black, 26.1% Hispanic | NR |
| BMI SDS | 2.47 | 2.48 | NR |
| Interventions | |  |  |
|  | Weight management | Control |  |
| Intervention as described by authors | Bright Bodies. The program consistedof exercise tw ice (50 minutes each) and nutrition/behavior modificationonce (40 minutes each) per w eek, The nutrition education component ofthe program used a nondiet approachthat emphasized low -fat, nutrient-dense foods of moderate portions.The  exercise component of the pro-gram w as facilitated by exercise phys-iologists. | Received general nutrition and exercise counseling and brief psychosocial counseling every 6 months through the Yale  Pediatric Obesity Clinic |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 1 year | 1 year |  |
| Intensity as described by  authors | Lifestyle intervention sessions occurred tw ice w eekly for the first 6 months, then every other w eek for the second 6 months. The program consisted of exercise tw ice (50 minutes each) and  nutrition/behavior modification once (40 minutes each) per w eek. | Pediatric clinic every 6 months, 30 min diet counseling and psychosocial counseling. |  |
| Assigned intensity | 52+ hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, exercise, psychosocial | Specialist, nutrition provider, psychosocial |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management  program |  |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training, CBT | Nutrition counseling, activity counseling |  |

Outcomes

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 12  months |  |  |  |  | 24  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Weight  management | 105 | -0.21 | -0.25 | -0.17 | <0.0001 | 105 | -0.2 | -0.25 | -0.16 | <0.0001 |
| Control | 69 | 0.01 | -0.04 | 0.07 |  | 69 | -0.05 | -0.1 | 0.01 |  |
| BMI |  |  |  |  |  |  |  |  |  |  |
|  | 12  months |  |  |  |  | 24  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Weight  management | 105 | -1.8 | -2.4 | -1.1 | <0.0001 | 105 | -0.9 | -1.7 | -0.1 | <0.0001 |
| Control | 69 | 1.9 | 1.1 | 2.9 |  | 69 | 1.9 | 0.9 | 2.9 |  |

**Savoye, M; Shaw, M; Dziura, J; Tamborlane, Wv; Rose, P; Guandalini, C; Goldberg-Gell, R; Burgert, Ts; Cali, Am; Weiss, R; Caprio, S**

**Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | NIH grants to the General Clinical Research Center (M01-RR00125) and Dr. Caprio (R01-HD28016 and R01-HD40787), Yale University School of Medicine,  and an unrestricted gift from the McPhee Foundation. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Yale Human Investigation Committee and w ritten inf ormed assent and consent w ere obtained from participants and parents. | | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |  |
| Population | | | |
| Inclusion criteria | BMI > 95th percentile based on the CDC grow th chart, age 8 to 16 years old, and English-speaking ability. Participants had to show an interest in the w eight  management program and have a caregiver w ho w as w illing to participate in the educational component of the program. | | |
| Exclusion criteria | Participants w ere excluded if they had diabetes, a psychiatric disorder (eg, schizophrenia, severe autism or mental retardation, or psychosis), or other serious medical condition that w ould preclude participation in the program. Participants taking medications that potentially cause significant w eight gain(eg, risperidone, olanzapine, clozopine) w ere also excluded, as w ell as participants using medications for w eight loss or involved in a co-existing w eight  management program. | | |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Weight management group | Control Group | Overall |
| N | 105 | 69 | 174 |
| Sex | 56.2% female | 68.1% female | NR |
| Age | 11.9 | 12.4 | NR |
| Race | 38.1% w hite, 38.1% black, 23.8% Hispanic | 34.8% w hite, 39.1% black, 26.1% Hispanic | NR |
| BMI | 35.8 | 36.2 | NR |
| Interventions | |  |  |
|  | Weight management group | Control Group |  |
| Intervention as described by authors | Intensive family-based program including exercise, nutrition, and behavior modification. | Control Group.The control groupparticipants w ere seen in the pediatric obesity clinic every 6 months and re-ceived diet and exercise counseling byregistered dietitians and physicians  alongw ith brief psychosocial counseling by asocial w orker. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as described by authors | Participants randomized to the w eight management group attended the program tw ice a w eek for 6 months and then every other w eek for an additional 6 months. During the first 6 months, the program consisted of exercise tw ice (50 minutes each) and nutrition/behavior modification once (40 minutes each) per  w eek. | Clinic every 6 months |  |
| Assigned  intensity | 52+ hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, exercise provider, social w orker | Primary care, nutrition provider, social w orker |  |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training,  psychosocial | Nutrition counseling, activity counseling, psychosocial |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Weight management group | 105 | -2.1 | -2.6 | -1.5 | <0.001 | 105 | -1.7 | -2.3 | -1.1 | <0.001 |
| Control Group | 69 | 1.1 | 0.4 | 1.8 |  | 69 | 1.6 | 0.8 | 2.3 |  |

**Serra-Paya, N; Ensenyat, A; Castro-Vinuales, I; Real, J; Sinfreu-Bergues, X; Zapata, A; Mur, Jm; Galindo-Ortego, G; Sole-Mir, E; Teixido, C Effectiveness of a multi-component intervention for overweight and obese children (nereu program): a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This research is partially funded by theInstituto de Salud Carlos III in Spain, from the Ministryof Economy and Competitiveness (Grant PI12/02220)cof unded  by FEDER and the Institute of PhysicalEducation of Catalonia (INEFC), University of Lleida,Spain | | |
| Country | Spain |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | All children and their parents or guardians gave w ritten inf ormed consent. The studyprotocol w as approved by the Clinical Research Ethics Committee  (CEIC) of the Primary CareResearch Institute IDIAP-Jordi Gol (Registration number: P12/040) and w as carried outaccording to the principles of the Declaration of Helsinki and subsequent revisions | |  |
| Outcomes other  than BMI | Other obesity, behaviors |  |  |
| Population | | | |
| Inclusion criteria | children from Lleida aged 6 to 12 years w ho w ere overw eight or obeseaccording to the International Obesity Task Force (IOTF) criteria [17], engaged in low  levels of activity (less than 2 hours per w eek of outside of school hours), and for w hom complete dataw ere available. | | |
| Exclusion criteria | All children w ere free of medical comorbidi-ties, not using any medications that might affect w eight loss or physiological responses to exer-tion, and had not  been enrolled in any other obesity treatment interventions in the previous 6months. | | |
| Group differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Nereu Program | Counseling | Overall |
| N | 54 | 59 | 113 |
| Sex | 50% male | 56% male | NR |
| Age | 10.1 | 9.7 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.47 | 2.42 | NR |
| Interventions | |  |  |
|  | Nereu Program | Counseling |  |
| Intervention as described by authors | The NP is an intensive, 8-month, family-based multi-component, behavioural intervention inprimary care settings, consisting of 4 components: (a) Supervised physical activity sessions forchildren, (b) Family theoretical and practical sessions for parents, (c) Behaviour  strategy ses-sions for both children and parents, and (d) Weekend activities. | Eight monthly, 10-minute, structured, family meetings w ere scheduled w ith the child’s paediat- rics unit. The content of these family sessions w as  the same as the Nereu Program intervention. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 8 months | 8 months |  |
| Intensity as described by authors | Supervised physical activity sessions for children. The program offered 90 one-hour sessions(3 per w eek).The 21 theoretical and practical group counselling sessions took place just once a w eek (60 minutes each) at the same time as the children’s sessions three behaviour strategy sessions Extra family activities (e.g. a ski or w ater-park party) w ere  organized on3 w eekends, | Eight monthly, 10-minute, structured, family meetings |  |
| Assigned intensity | 52+ hours | <5 hours |  |
| Provider types | Mental health, Exercise, nutrition provider | Primary care |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, activity training | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 8 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Nereu Program | 54 | -0.12 | 0.22 | 0.415 |
| Counseling | 59 | -0.09 | 0.23 |  |

**Shelton, D; Gros, K; Norton, L; Stanton-Cook, S; Morgan, J; Masterman, P**

**Randomised controlled trial: a parent-based group education programme for overweight children**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | Golden Casket’s Working Wonders Grant. |  |  |
| Country | Australia |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Inf ormed consent to participate in this study w as obtained fromparents or care givers in accordance w ith approval from theHuman Research Ethics  Committee of The Gold Coast DistrictHealth Service | |  |
| Outcomes other  than BMI | Behaviors, other (parenting) |  |  |
| Population |  |  |  |
| Inclusion criteria | Families w ere included inthe study if the child w as 3–10 years old and had a BMI ≥ 85thpercentile after adjusting for age and gender (i.e. National Healthand Medical Research Council definition of overw eight). Oneparent or primary care giver w as required to attend all assess-ment and treatment sessions. Parents or care givers w ererequired to read a treatment manual and complete child foodintake, physical activity and sedentary electronic media  moni-toring inventories. | | |
| Exclusion criteria | Exclusion criteria included the presence of amedical diagnosis for the child’s w eight, or if either parent orchild had a disability causing dietary or exercise  restrictions. | | |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Treatment | Control | Overall |
| N | 28 | 15 | 43 |
| Sex | 50% male | 40% male | NR |
| Age | 7.89 | 7.33 | NR |
| Race | NR | NR | NR |
| BMI | 26.37 | 26.91 | NR |
| Interventions | |  |  |
|  | Treatment | Control |  |
| Intervention as described by authors | Each family received a comprehensive parent treatment manualdeveloped by the project team. All treatment sessions  w ereintegrated w ith the parent manual and a slide presentation. Allparticipants then attended a follow -up session w here post- treatment measures w ere taken. Content of manual included know ledge tools, nutritional tools, activity tools, and motivation tools. | Usual care (not w ell described) |  |
| Intervention type | Lifestyle | Usual care |  |
| Intervention length | 3 months | 3 months |  |
| Intensity as  described by authors | Components included an initial assessment session attended bythe parent and child, follow ed by four group sessions at w eeklyintervals of 2-hour duration each attended by the parent only | Not described |  |
| Assigned intensity | 5-25 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, exercise provider, mental health | Primary care |  |
| Clinic setting | Primary care, research | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |  |

Outcomes

BMI

3 months (Time 2)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (betw een groups) |
| Treatment | 28 | 24.8 | 3.2 | <0.05 |
| Control | 15 | 26.5 | 4 |  |

**Sherwood, Ne; JaKa, Mm; Crain, Al; Martinson, Bc; Hayes, Mg; Anderson, Jd**

**Pediatric Primary Care-Based Obesity Prevention for Parents of Preschool Children: a Pilot Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The project described w as supported by grant numbersA1R21DK078239 (principal investigator [PI]: Sherw ood),P30DK050456 (PI: Levine), and  P30DK092924 (PI:Schmittdiel) from the National Institute of Diabetes andDigestive and Kidney Diseases (NIDDK). | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Consent forms w ere review ed w ith and signed by theparent. This study w as approved by the HealthPartners Institutional Review Board | |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Eligibility criteria included: (1) child at risk for obesity (BMI percentile betw een 50th and 85th w ith one overw eight parent) or overw eight (85th percentile £ BMI <  95th percentile); (2) English-speaking parent; and (3) child not using a steroid medication for more than 1 month. | | |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special populations | Preschoolers |  |  |
|  | Busy Bodies/Better Bites | Healthy Tots/Safe Spots | Overall |
| N | 30 | 30 | 60 |
| Sex | 50% female | 40% female | 45%  female |
| Age | 2.6 | 2.9 | NR |
| Race | 77% w hite, 7% Hispanic | 83% w hite, 7% Hispanic | NR |
| BMI SDS | 1.01 | 0.86 | NR |
| Interventions | |  |  |
|  | Busy Bodies/Better Bites | Healthy Tots/Safe Spots |  |
| Intervention as described by authors | The pilot intervention programs included a brief pedi- atric primary care component and eight phone coaching sessions. Participants received pediatric PCP counseling during their w ell-child visit to raise parental aw areness of their child’s obesity risk and provide messaging regarding obesity and injury prevention behaviors. The eight-session phone coaching program focused on healthy eating and PA. | The pilot intervention programs included a brief pedi-atric primary care component and eight phone coachingsessions. Participants received pediatric PCP counselingduring their w ell-child visit to raise parental aw areness oftheir child’s obesity risk and provide messaging regardingobesity and injury prevention behaviors. Healthy Tots/Safe Spots goals included:(1) distracted driving reduction; (2) fall prevention;  (3) firesaf ety; (4) poison control; and (5) sun protection. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 4 months (8 phone sessions held bi-w eekly) | 4 months (8 phone sessions held bi-w eekly) |  |
| Intensity as  described by authors | The first phone coaching session w as scheduled and 15- to 30-minute  calls inf ormed by social ecological models, 30 social cognitive theory, 31 and motivational interview ing 32 w ere held biw eekly. | The first phone coaching session w as scheduled and 15- to 30-minute  calls inf ormed by social ecological models, 30 social cognitive theory, 31 and motivational interview ing 32 w ere held biw eekly. |  |
| Assigned  intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, other ("experienced interventionists") | Primary care, other ("experienced interventionists") |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Injury prevention |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Busy Bodies/Better Bites | 26 | 0.99 | 0.37 | 0.89 |
| Healthy Tots/Safe Spots | 29 | 0.85 | 0.61 |  |

**Small, L; Bonds-McClain, D; Melnyk, B; Vaughan, L; Gannon, Am**

**The preliminary effects of a primary care-based randomized treatment trial with overweight and obese young children and their parents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Funding w as provided by the National Institute of Diabetes,Digestive, and Kidney Diseases and the Aetna Foundation forHealthy Communities | |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | "After obtaining IRB approval" |  |  |
| Outcomes other  than BMI | Other obesity |  |  |
| Population | | | |
| Inclusion criteria | 4-8 year olds w ith overw eight |  |  |
| Exclusion  criteria | uncontrolled medical problems (e.g., asthma)that might preclude them from fully participating in theintervention. | |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Treatment Group | Control Group | Overall |
| N | 33 | 27 | 60 |
| Sex | 48.5% male | 29.6% male | 40%  male |
| Age | 5.73 | 5.41 | 5.58 |
| Race | 63% w hite, 9% black, 24% other, 0% other | 66% w hite, 0% black, 25% Hispanic, 7% other | NR  (typos) |
| BMI Percentile | 96.7 | 95.4 | 96.1 |
| Interventions | |  |  |
|  | Treatment Group | Control Group |  |
| Intervention as described by authors | In both condi-tions, parents w ere asked to attend a total of foursessions at their child’s primary care office. ar-ents in the treatment group (n= 34) w ere  offerededucational inf ormation about the establishment of healthy habits in young children, nutritional inf orma-tion, inf ormation regarding increasing physical activityand decreasing sedentary time, and age-specific inf or-mation  regarding the child’s behavior in responseto change | In both condi-tions, parents w ere asked to attend a total of  foursessions at their child’s primary care office. parents assigned to the controlcondition (n= 33) w ere provided w ith educationalage- appropriate, evidence-based health and saf ety in-formation (e.g., care for thermal injuries, first-aid care,andcaref or insect bites andstings) |  |
| Intervention type | Lifestyle | Control |  |
| Intervention  length | 16 w eeks | 16 w eeks |  |
| Intensity as  described by authors | 4 visits of 30 to 60 minutes | 4 visits of 30 to 60 minutes |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, other (researcher) | Primary care, other (researcher) |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Control |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI Percentile |  |  |  |  |  |  |  |  |
| 3 months (Time 3) | |  |  | 6 months (Time 4) | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Treatment Group | 33 | 92.42 | 6.81 | NS | 33 | 95.13 | 4.91 | NS |
| Control Group | 27 | 90.19 | 11.9 | - | 27 | 94.74 | 5.98 | - |

**Stark, Lj; Clifford, Lm; Towner, Ek; Filigno, Ss; Zion, C; Bolling, C; Rausch, J**

**A pilot randomized controlled trial of a behavioral family-based intervention with and without home visits to decrease obesity in preschoolers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship source | The project described w as supported by the NationalInstitutes of Digestive Diseases and Kidney through grantD24 DK 059492 (L.J.S.) and National Center for ResearchResources and the National Center for AdvancingTranslational Sciences through Grant 8 UL1 TR000077-04, National Institutes of  Health. | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The protocol w as ap-proved by the institutional review board, and parents pro-vided inf ormed consent for participation bef ore datacollection. | | |  |
| Outcomes  other than BMI | Behavior, other (parenting, parent w eight) |  |  |  |
| Population | | | | |
| Inclusion  criteria | Inclusion criteria w ere (1) child age of 2–5 years; (2) child 95th percentile BMI (Kuczmarski et al., 2000), but <100% above the mean BMI; (3) one  parent w ith a BMI 25; and (4) medical clearance from the child’s pediatrician. | | | |
| Exclusion  criteria | (1) non-Englishspeaking; (2) living50 miles from the medical center; (3)disability or illness that w ould interfere w ith moderatephysical activity; (4) medical  condition/medication associ-ated w ith w eight gain; or (5) enrolled in a w eight controlprogram | | | |
| Group  differences | Randomized |  |  |  |
| Special  populations | Children 2-5 |  |  |  |
|  | Pediatrician Counseling (PC) | LAUNCH-HV (Clinic & Home) | LAUNCH-Clin ic | Overall |
| N | 12 | 10 | 11 | 33 |
| Sex | 67% female | 80% female | 64% female | NR |
| Age | 4.8 | 4.7 | 4.2 | NR |
| Race | 75% w hite | 90% w hite | 91% w hite | NR |
| BMI SDS | 2.4 | 2.1 | 2.5 | NR |
| Interventions | |  |  |  |
|  | Pediatrician Counseling (PC) | LAUNCH-HV (Clinic & Home) | LAUNCH-Clin ic |  |
| Intervention as described by authors | A board-certified pediatrician meteach family individually for one 45 min visit to explainBMI, BMI percentiles and to review the child’s grow thchart. Modeled on the Stage 1 Intervention ‘‘PreventionPlus’’ (Barlow , 2007),  the pediatrician recommended(1) screen time2 h daily; (2) active play60 min daily;(3) eliminating soda and4 ounces daily; (4) fruits andvegetables5 servings daily; (5) limiting  eating out; and(6) appropriate portion sizes for  preschoolers. Each familyw as given a one-page healthy food and activity brochure | LAUNCH-HV w as an 18-session manualized interventiondesigned to produce small decreases or stabilize the rate ofchild w eight gain, consistent w ith current recommenda-tions for treatment of preschool obesity. The parent-group clinicsessions (90 min each) w ere conducted by a licensed clin-ical psychologist or second-year psychology postdoctoralfellow and included education on diet (Weeks 2–7), phys-ical activity (Weeks 8–12), and parenting skills (all sessionsto f acilitate diet and activity goals). A ‘‘home clean-out’’ w as  conductedf ollow ing each clinic session on diet. | LAUNCH-clinic intervention content w as identical toLAUNCH- HV  clinic sessions. n lieu of home visits,parents w ere provided a ‘‘home clean-out’’ box to use ontheir ow n to eliminate high-calorie low -nutrient  foods fromthe home. |  |
| Intervention type | Lifestyle | Lifestyle | Lifestyle |  |
| Intervention  length | 6 months | 6 months | 6 months |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Intensity as described by authors | A board-certif ied pediatrician met each family individually for one 45 min visit to explain BMI,  BMI percentiles and to review the child’s grow th chart. | haseI (Intensive Intervention), 12 w eekly sessions, alternatingbetw een group-based clinic sessions (parent and child con-current groups), and individual home visits and Phase II(Maintenance), 12 w eeks of every-other-w eek sessions, al-ternating betw een  group clinic, and individual homesessions. | LAUNCH-clinic sessions w ere conductedevery other w eek during Months 1–3 and monthlyduring Months 4–6 of the intervention, for 10  treatmentsessions |
| Assigned intensity | <5 hours | 5-25 hours | 5-25 hours |
| Provider types | Primary care | Primary care, other (psychology fellow ) | Primary care, other (psychology  fellow ) |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, nutrition training, motivational interview ing, other (parenting skills) | Nutrition counseling, activity counseling, nutrition training, motivational interview ing, other  (parenting skills) |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12  months |  |  |  |  |
|  | N | Mean | SD | p (PC vs LAUNCH-  HV) | p (PC vs LAUNCH-  clinic) | N | Mean | SD | p (PC vs LAUNCH-  HV) | p (PC vs LAUNCH-  clinic) |
| Pediatrician Counseling  (PC) | 12 | -0.07 | 0.18 | 0.007 | 0.08 | 12 | -0.03 | -  0.36 | 0.0003 | 0.04 |
| LAUNCH-HV (Clinic &  Home) | 10 | -0.37 | 0.42 |  |  | 10 | -0.5 | 0.43 |  |  |
| LAUNCH-Clin ic | 11 | -0.25 | 0.25 |  |  | 11 | -0.59 | 0.75 |  |  |

**Stark, Lj; Spear, Filigno S; Bolling, C; Ratcliff, Mb; Kichler, Jc; Robson, Sm; Simon, Sl; McCullough, Mb; Clifford, Lm; Odar, Stough C; Zion, C; Ittenbach, Rf Clinic and Home-Based Behavioral Intervention for Obesity in Preschoolers: a Randomized Trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (R01DK091251), the National Center for Advancing Translational Sciences of the  National Institutes of Health (NIH) (UL1 TR001425), and the NIH (T32 DK063929). | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the institutional review board at the primary medical center w here the study w as conducted, and w ritten inf ormed consent w as  obtained from caregivers. | | | |
| Outcomes  other than BMI | None |  |  |  |
| Population | | | | |
| Inclusion  criteria | Inclusion criteria w ere (1) ages 2-5 years; (2) BMI percentile for age and sex ≥95th17 but no more than 100% above the median BMI; (3) medical clearance  from their pediatrician; (4) active patient w ith anthropometric measurements w ithin the previous year; and (5) living w ithin 50 miles from the medical center | | | |
| Exclusion criteria | Exclusion criteria included (1) developmental disability or medical conditions know n to promote obesity (eg, Prader-Willi syndrome); (2) child enrolled in another  w eight control program; (3) taking w eight-affecting medications (eg, steroids); (4) condition that w ould preclude full participation in the program; and (5) non- English-speaking. | | | |
| Group  differences | Randomized |  |  |  |
| Special populations | Preschoolers |  |  |  |
|  | LAUNCH | Motivational Interview ing | Standard Care | Overall |
| N | 47 | 50 | 54 | 151 |
| Sex | 53.2% female | 58.0% female | 59.3% female | 57.0%  female |
| Age | 4.6 | 4.6 | 4.6 | 4.6 |
| Race | 6.4% black, 78.2% w hite, 14.9% other; 2.1% Hispanic | 12% black, 76% w hite, 12% other; 6% Hispanic | 9.3% black, 74.1% w hite,  16.7% other, 9.3% Hispanic | 9.3% black,  76.2%  w hite, 14.6% other,  6% Hispanic |
| BMI SDS | 2.41 | 2.41 | 2.48 | 2.44 |
| Interventions | |  |  |  |
|  | LAUNCH | Motivational Interview ing | Standard Care |  |
| Intervention as described by authors | Parent clinic-based group sessions w ere 90 minutes each andled by a licensed clinical psychologist.  Sessions consisted of edu-cation and problem-solving around parent and child diet,dietary and physical activity changes, and child behavior man-agement strategies such as differential attention (eg, ignoringcomplaints about food, praising trying vegetables), contin-gency management (eg, rew arding  healthy behaviors), limitsetting, effective use of time- out to manage tantrums, shaping(eg, gradually | Motivational interview ing w as a parent only intervention consisting of 18 sessions over 6months, delivered w eekly during the initial 3 months and every other w eek months  4-6. At the initial 60-minute session parents met w ith a pediatrician trained in motivational interview ing during w hich they completed questionnaires to assess their  values and motivation for change, w ere given inf ormation about their child’s w eight and BMI percentile, and a  packet of publicly available materials/brochures from the “Let’s Go 5-2-1-0” program. Subsequent motivational | Standard care inf ormed caregivers of their child’s w eightstatus during the recruitment process, but neither the chil-dren nor caregivers received any treatment. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | introducing change), and exposure to intro-duce new  foods, and implementing stimulus control mea-sures to improve food choices and physical activity. | interview ing intervention sessions w ere delivered by a licensed clinical psychologist trained in motivational interview ing in either the families’ home (sessions 2,12,16) or over the telephone (14 sessions). The median phone session length w as 15 minutes w ith 22% (135 of 625 of phone sessions) being ≤10 minutes. All home  visits w ere scheduled for 60 minutes. |  |
| Intervention  type | Lifestyle | Lifestyle | Usual care |
| Intervention  length | 6 months | 6 months | 6 months |
| Intensity as described by authors | LAUNCH is an 18-session clinic and home family- based be-havioral w eight management intervention, consisting of a3-month intensive treatment phase  (w eekly sessions) fol-low ed by a 3-month maintenance phase (every other w eek ses-sions). Intervention sessions alternated betw een clinic (10sessions) and  home (8 sessions) visits. | Motivational interview ing w as a parent only interventionconsisting of 18 sessions over 6 months, delivered w eekly duringthe initial 3 months and every other w eek months 4-6. | Recruitment appointment only |
| Assigned  intensity | 5-25 hours | 5-25 hours | <5 hours |
| Provider types | Primary care, nutrition provider, mental health | Primary care, nutrition provider, mental health | Primary care |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition training, other (parenting) | Nutrition counseling, activity counseling, motivational interview ing | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SD | p (LAUNCH vs MI) | p (LAUNCH vs Standard) |
| LAUNCH | 47 | -0.32 | 0.33 | <0.001 | 0.004 |
| Motivational Interview ing | 50 | -0.05 | 0.27 |  |  |
| Standard Care | 54 | -0.13 | 0.31 |  |  |

**Stark, Lj; Spear, S; Boles, R; Kuhl, E; Ratcliff, M; Scharf, C; Bolling, C; Rausch, J**

**A pilot randomized controlled trial of a clinic and home-based behavioral intervention to decrease obesity in preschoolers**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as supported by grant D24 DK 059492 from the National Institutes of Health (L.j.S.) and USPHS grant UL1RR026314 from the  National Center for Research Resources of the NIH | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The protocol w as approved by the institutional review board and parents provided inf ormed consent for participation. | |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion  criteria | Inclusion criteria w ere (i) child age betw een 2 and 5 years; (ii) child ≥95th percentile BMI (12), but not more than 100% above the mean BMI; (iii) at  least one parent w ith a BMI ≥25; and (iv) medical clearance from the child’s pediatrician. | | |
| Exclusion  criteria | Exclusion criteria w ere (i) non-English speaking; (ii) living >50 miles from the medical center; (iii) a disability or illness that w ould interfere w ith at least  moderate physical activity; (iv) medical condition/medication associated w ith w eight gain; or (v)currently enrolled in another w eight-control program. | | |
| Group  differences | Randomized |  |  |
| Special populations | Preschoolers |  |  |
|  | LAUNCH | Pediatrician Counseling (PC) | Overall |
| N | 8 | 10 | 18 |
| Sex | 25% female | 40% female | female 6  (33.3%) |
| Age | 4.4 | 3.9 | NR |
| Race | 75% w hite, 25% Hispanic | 90% w hite, 10% Hispanic | 15 ( 83%)  White, 3  (17%)  Hispanic |
| BMI Percentil | 99 | 97.7 | NR |
| Interventions | |  |  |
|  | LAUNCH | Pediatrician Counseling (PC) |  |
| Intervention as described by authors | Parent-group clinic sessions (90min each) addressed three compo- nents: dietary education, physical activity and parenting skills.  Throughout treatment, parents w ere taught to use child behavior management skills (16) to implement dietary and activity changes including: (i) praise and attention to increase healthy eating and physical activity; (ii) ignoring and time-out to manage tantrums; (iii) contingency management; and (iv) modeling. Children w ere seen concurrently in a group format. They received nutrition education through games and art activities, tried new foods during a structured meal, and completed 15min of moderate to vigorous activity. In- home sessions (60–90min each) w ere designed to support gener-  alization of the clinic-taught skills to the home environment and w ere conducted by psychology postdoctoral fellow s. | Pediatricial Counseling. PC w as designed to deliver dietary and physical activity recommendations outlined by the American Academy of Pediatrics (13). Follow ing a scripted manual a board-certified pediatrician met each family individually for one 45-min visit to review the child’s grow th chart and to explain BMI, BMI per-centiles, and the child’s current BMI percentile. The follow ing recom-mendations w ere made in accordance w ith the Stage 1 Intervention: “Prevention Plus” for obese preschool children (14); (i) ≤2h/day of screen time;  (ii) 60min/day of active play; (iii) eliminating soda and limiting juice to 4oz./day); (iv)providing ≥5servings/day of fruits and vegetables; (v) limiting eating out; and (vi) appropriate portion sizes for preschoolers. |  |
| Intervention  type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 6 months | 6 months |
| Intensity as described by authors | The 6-month intervention consisted of tw o phases. Phase 1 (Intensive Intervention) w as 12 w eekly sessions that alternated betw een group-based clinic sessions (parent and child concurrent groups) and individual home visits. Phase 2  (Maintenance) w as 12 w eeks of every other w eek sessions, alternating betw een group sessions in clinic and home sessions. | One 45 minute visit |
| Assigned  intensity | 26-51 hours | <5 hours |
| Provider types | Psychologist, psychology fellow s nutritionist | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition training, activity  training, other (parenting) | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| LAUNCH | 7 | -0.49 | 0.36 | 0.003 | 7 | -0.37 | 0.41 | 0.005 |
| Pediatrician Counseling (PC) | 10 | 0.1 | 0.32 |  | 9 | 0.4 | 0.49 |  |

**Stettler, N.; Wrotniak, B. H.; Hill, D. L.; Kumanyika, S. K.; Xanthopoulos, M. S.; Nihtianova, S.; Shults, J.; Leff, S. S.; Pinto, A.; Berkowitz, R. I.; Faith, M. S.**

**Prevention of excess weight gain in paediatric primary care: beverages only or multiple lifestyle factors. The Smart Step Study, a cluster-randomized clinical trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | The study w as funded by a National Institutes of Health(NIH) grant, 5R01HL084056. | |  |  |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Cluster randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the InstitutionalReview Boards of CHOP and the other institutions involvedw ith subjects | | |  |
| Outcomes other than  BMI | Other obesity |  |  |  |
| Population | | | | |
| Inclusion criteria | subjects w ere selected w ith a BMI betw een the 75th and the 95th percentile based on the last clinic visit w hen their w eight and height w ere measured (18). At the baseline visit, some subjects w ere measured to be outside of this range, but w ere included, as they w ere still considered at risk for excess w eight gain, based on their BMI at the previous clinic visit. Other inclusion criteria w ere: age 8.0–12.9 years, consulting at the selected practice in the past 3 years and  consuming an average of at least 4 oz of sugar-sw eetened beverages (see definition in Table S1) per day, to insure relevance of the beverage-only intervention. | | | |
| Exclusion criteria | Exclusion criteria w ere serious physical or psychiatric conditions or medications potentially interfering w ith nutrition or physical activity, as determined by the primary care paediatrician. Home-schooled patients w ere excluded, so that the control intervention (bullying prevention) w ould be relevant to those randomized  to it. | | | |
| Group  differences | Cluster randomized, but some large differences in race and baseline BMIz | |  |  |
| Special  populations | None |  |  |  |
|  | Control | Beverage-only | Multiple Behaviors | Overall |
| N | 33 | 76 | 63 | 172 |
| Sex | 45% female | 51% female | 57% female | F 75  (54%) |
| Age | 10.8 | 10.8 | 10.7 | 10.7 |
| Race | 70% w hite, 24% black, 6% other; 9% Hispanic | 63% w hite, 33% black, 4% other; 4% Hispanic | 32% w hite, 63% black, 5% other; 8% Hispanic | w hite 68  (49%);  black 65  (47%) |
| BMI SDS | 1.34 | 1.21 | 1.22 | 1.17 |
| Interventions | |  |  |  |
|  | Control | Beverage-only | Multiple Behaviors |  |
| Intervention as described by authors | The theory-based (behavioural economics),  family-based, culturally and developmentally appropriateintervention consisted of tw elve 15– 25 min clinician, childand at least one parent or guardian encounters over 12months. Children earned points, based on session attend-ance and goal achievements, w hich they could exchangef or small prizes selected from a study catalogue. Control w as bullying prevention. | The theory-based (behavioural economics),  family-based, culturally and developmentally appropriateintervention consisted of tw elve 15– 25 min clinician, childand at least one parent or guardian encounters over 12months. Children earned points, based on session attend-ance and goal achievements, w hich they could exchangef or small prizes selected from a study catalogue. Addressed only beverage  consumption. | The theory-based (behavioural economics),  family-based, culturally and developmentally appropriateintervention consisted of tw elve 15– 25 min clinician, childand at least one parent or guardian encounters over 12months. Children earned points, based on session attend-ance and goal achievements, w hich they could exchangef or small prizes selected from a study catalogue. Addressed multiple behaviors |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Intervention  type | Control | Lifestyle | Lifestyle |
| Intervention  length | 12 months | 12 months | 12 months |
| Intensity as  described by authors | 12 15-25 mi sessions | 12 15-25 mi sessions | 12 15-25 mi sessions |
| Assigned  intensity | 5-25 hours | 5-25 hours | 5-25 hours |
| Provider types | Primary care | Primary care | Primary care |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Control | Nutrition counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 12 months | | | | |
|  | N | Mean | SD | p (vs control) |
| Control | 24 | 1.44 | 0.44 |  |
| Beverage-only | 51 | 1.18 | 0.62 | 0.03 |
| Multiple Behaviors | 46 | 1.16 | 0.53 | 0.03 |

**Stovitz, Sd; Berge, Jm; Wetzsteon, Rj; Sherwood, Ne; Hannan, Pj; Himes, Jh**

**Stage 1 treatment of pediatric overweight and obesity: a pilot and feasibility randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This research w assupported by a pilot grant offered by the University of Minnesota Obesity Prevention Center and Grant NumberP30 DK050456 from  the National Institute of Diabetes andDigestive and Kidney Diseases. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the University of Minne-sota’s Institutional Review Board ( Minneapolis, MN) | |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Patients 4.0 to<9.0 years of age w ith a BMI‡85th percentile w ere eligible. |  |  |
| Exclusion criteria | Patients w ere excluded if they had any chronic or current health condition that might affect w eight stability ( e . g ., autism, acute gastrointestinal illness, and w eight-altering medications). In addition, the parent needed to be conversationally fluent in English to participate in follow -up phone calls w ithout the use of  an interpreter | | |
| Group  differences | Randomized |  |  |
| Special Populations | None |  |  |
|  | Intervention | Control | Overall |
| N | 35 | 36 | 71 |
| Sex | 54% female | 47% female | 51% female |
| Age | 6.23 | 5.7 | 5.96 |
| Race | 49% w hite, 29% black, 11% Hispanic, 9% Asian, 3% other | 42% w hite, 25% black, 11%  Hispanic, 17% Asian, 6% other | 45% w hite, 27%  black, 11%  Hispanic, 13%  Asian, 4% other |
| BMI SDS | 1.9 | 1.89 | 1.9 |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as described by authors | The intervention group received management patterned after the ‘‘Prevention plus, Stage 1’’ treatment recommended by the expert panel and approved by the committee. 16,17 Given the age of the children, the counseling w as primarily directed tow ard the parents. 21–23 On the day of enrollment, after randomization, the RA review ed the BMI 2 survey 20 and discussed evidence-based recommendations for childhood obesity treatment w ith the parent. For this study, monthly follow -up w as chosen, allow ing the parent to choose the format, either through a  telephone conversation or in person. | the RA provided age- and ability- appropriate inf ormational handouts on school readinessand/or performance. |  |
| Intervention type | Lifestyle | None |  |
| Intervention  length | 3 months | 3 months |  |
| Intensity as described by  author | Given that these phone callslasted approximately 15–30 minutes, this treatment w ouldf all under the category of ‘‘very low intensity’’ as defined byWhitlock and colleagues (as less than 10 hours  per year) | Handouts only |  |
| Assigned  intensity | <5 hours | <5 hours |  |
| Provider types | Primary care, researcher | Primary care, researcher |  |

|  |  |  |
| --- | --- | --- |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, motivational interview ing | Usual care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 3 months |  |  |  |
|  | N | Mean | SE | p (across groups) |
| Intervention | 35 | -0.02 | 0.05 | 0.06 |
| Control | 36 | -0.08 | 0.05 |  |

**Taveras, Em; Gortmaker, Sl; Hohman, Kh; Horan, Cm; Kleinman, Kp; Mitchell, K; Price, S; Prosser, La; Rifas-Shiman, Sl; Gillman, Mw Randomized controlled trial to improve primary care to prevent and manage childhood obesity: the High Five for Kids study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as supported by grant R01HD 050966 from the Eunice Kennedy Shriver NationalInstitute of Child Health and Human Development. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Cluster randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | All study procedures w ere approved by the human subjects committee of Harvard Pilgrim Health Care. | |  |
| Outcomes other than  BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Participants comprised children aged 2.0 to 6.9 years w hose BMI (calculated as w eight in kilograms divided by height in meters squared) w as in the 95th percentile or higher or w hose BMI w as in the 85th to less than 95th percentile if at least 1 parent w as overw eight (BMI >= 25) and w ho received their pediatric care  at Harvard Vanguard Medical Associates betw een August 2006 and October 2008. | | |
| Exclusion criteria | We excluded (1) children w hose parent or guardian could not respond to interview s in English or Spanish, (2) children w hose families w ere planning to leave  Harvard Vanguard Medical Associates, (3) families for w hom the primary care clinician thought the intervention w as not ap- propriate, and (4) children w ith chronic medical conditions | | |
| Group  differences | Randomized |  |  |
| Special  populations | Preschoolers are included |  |  |
|  | Intervention | Usual Care | Overall |
| N | 253 | 192 | 445 |
| Sex | 48% female | 49% female | 48% female |
| Age | 4.8 | 5.2 | 4.9 |
| Race | 47% w hite, 28% black, 19% Latino, 7% other | 70% w hite, 7% black, 14% Latino, 9% other | 57% w hite, 19% black, 17%  Latino, 8% other |
| BMI SDS | 1.88 | 1.82 | 1.85 |
| Interventions | |  |  |
|  | Intervention | Usual Care |  |
| Intervention as described by authors | Major components ofthe intervention involved changes to the health care system.We trained all members of the practice team to play an activerole in the intervention. We enhanced the electronic medicalrecord system to assist clinicians w ith decision support, pa-tient tracking,  follow -up, scheduling, and billing (Figure 1).After reorganization of the delivery of primary and acute care,the pediatric nurse practitioners conducted chronic disease man-agement visits w ith intervention participants. Prior to the startof the intervention, w e negotiated w ith the regional insurancecompanies to pay for up to 4 visits for both  overw eight and obesepatients in the first year of the study. We trained the pediatric nurse practitioners to be the keyintervening clinicians and  to use motivational interview ing | Participants randomized to usual care received the current stan- dard of care offered by their pediatric practice. This included w ell-child care visits and follow -up appointments for w eight checks w ith their pediatrician or a subspecialist (eg, nutrition- ist). Visits for families in the usual care group included the base- line and annual w ell-child care visits |  |
| Intervention  type | Lifestyle | Usual care |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 12 months | 12 months |
| Intensity as  described by authors | four 25-minute, in-person chronic disease management vis-its and three 15-minute telephone calls in the first year of theintervention. | Usual care |
| Assigned  intensity | <5 hours | <5 hours |
| Provider  types | Primary care | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, motivational interview ing,  activity training (TV monitoring device to reduce TV View ing) | Usual care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 1 year |  |  |  |
|  | N | Mean | SE | p (across groups) |
| Intervention | 253 | 19.5 | 0.09 | 0.15 |
| Usual Care | 192 | 0.49 | 0.1 |  |

**Taveras, Em; Marshall, R; Kleinman, Kp; Gillman, Mw; Hacker, K; Horan, Cm; Smith, Rl; Price, S; Sharifi, M; Rifas-Shiman, Sl; Simon, Sr Comparative effectiveness of childhood obesity interventions in pediatric primary care: a cluster-randomized clinical trial**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |  |
| Sponsorship  source | This study w as supported by aw ard R18 AE000026 from the American Recovery and Reinvestment Act (Dr Taveras). | | |  |  |
| Country | USA |  |  |  |  |
| Methods | | | | | |
| Design | Cluster randomized controlled trial |  |  |  |  |
| Group | Parallel group |  |  |  |  |
| IRB | All study activities w ere approved by the institutional review board at Harvard Pilgrim Health Care, Boston, Massachusetts. | | |  |  |
| Outcomes other than  BMI | None |  |  |  |  |
| Population | | | | | |
| Inclusion  criteria | Eligibility for STAR includes 1) child is 6.0–12.9 years old at baseline, 2) child's BMI≥90th percentile for age and sex at the baseline w ell-child visit, 3) child has  received w ell childcare at HVMA w ithin the past 15 months, and 4) at least one parent can communicate in English. | | | | |
| Exclusion  criteria | Children w ere excluded if: 1) their sibling had already been enrolled in the study, 2) their family w as planning to leave HVMA w ithin the study time frame, 3) their  clinician did not feel the study w as appropriate for them or their families, or 4) they had a chronic medical condition that impacted their diet or physical activity. | | | | |
| Group  differences | Randomized |  |  |  |  |
| Special  Populations | Latino |  |  |  |  |
|  | CDS | CDS + coaching | Usual care | CDS vs CDS +  coaching | Overall |
| N Enrolled | 194 | 171 | 184 |  | 549 |
| Sex | 93 (47.9% female), 101 (52.1% male) | 80 (46.8% female), 91  (53.2% male) | 84 (45.7%)  female, 100  (54.3%) male |  | 257 (46.8%)  female, 292  (53.2%) male |
| Age in years | 9.8 (2.0) | 9.8 (1.8) | 9.8 (1.9) |  | 9.8 (1.9) |
| Race | 64.4% w hite, 16% black, 6.2% Latino, 4.6% Asian, 8.8% other | 43.5% w hite, 25.9%  black, 14.7% Latino,  5.3% Asian, 10.6%  other | 44.8% w hite,  22.4% black,  21.9% Latino,  4.9% Asian, 6.0%  other |  | 51.4% w hite,  21.2% black,  14.1% Latino,  4.9% Asian,  8.4% other |
| BMI | 25.6 (4.5) | 26.0 (4.2) | 25.7 (4.2) |  | 25.8 (4.3) |
| BMI z-score | 2.04 (0.30) | 2.08 (0.30) | 2.05 (0.30) |  | 2.06 (0.30) |
| Interventions | | | | | |
|  | CDS | CDS + coaching | Usual care | CDS vs CDS +  coaching |  |
| Intervention as defined by author | In the 10 practices randomized to the 2 intervention arms (CDS and CDS + coaching), w e modified the existing electronic health record to deploy a computerized, point-of-care CDS alert to pe- diatric clinicians at the time of a w ell- child visit for a child w ith a BMI at the 95th percentile or greater. 21 The alert contained links to grow th charts, 22 evidence-based childhood obesity screening  and management guidelines, 3 and a prepopulated standardized note template specific for obesity that included options for | CDS + In the CDS + coaching intervention arm, families w ere as- signed a health coach w ho used motivational  interview ing 23 to support families by | Participants at practices randomized to the control arm re- ceived the current  standard of care offered by their |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | (1)documentingandcodingf ortheBMIpercentile,(2)document- ing and coding for nutrition and physical activity counseling, (3) placing ref errals for w eight management programs, (4) plac- ing orders for laboratory studies if appropriate, and (5) printing educational materials. In these 10 practices, w e also trained the clinicians to use brief motivational interview ing to negotiate a follow -up w eight management plan w ith the patient and their family. These training sessions w ere conducted in person at each of the 10 sites during regularly scheduled clinical meetings and w ere led by expert faculty (E.M.T. and R.M.) and inf ormation technology specialists. tients at w ell-child and follow -up visits that focused on indi- vidual- and family-level behaviors (eFigure in Supplement 2). These behaviors included (1) decreases in screen time, (2) decreases in consumption of sugar-  sw eetened beverages, (3) increases in moderate and vigorous physical activity, and (4) improvement of sleep duration and quality. Families in the CDS arm also received 4 new sletters throughout the interven- tion period encouraging self -guided behavior change. | telephone at 1, 3, 6, and 9 months. Par- ents w ere also invited to participate in an interactive text mes- sage program. Any parent w ho chose not to receive texts had the option to receive the same messages by email. Texts re- ceived tw ice w eekly during the 1-year  follow -up provided sup- port for behavior change for the patient  and their family. A pre- vious STAR investigation 20 described the procedures and content of the text  message program | pediatric office. No new decision support tools for obesity w ere made available in the electronic health records of the 4 usual care practices |
| Intervention type (choose  one) | Lifestyle | Lifestyle | Usual care |
| Intervention  length | 12 months | 12 months | 12 months |
| Intensity as described by authors | Not specified - appear to occur at the usual care visits | support families by telephone at 1, 3, 6, and 9 months; Texts re- ceived tw ice  w eekly during the 1- year follow -up provided sup- port for behavior change for the patient and their  family. | Usual care visits |
| Assigned Intensity | <5 hrs | <5 hours | <5 hrs |
| Provider type (select  all) | primary care | primary care, mental health ("health coach") | primary care |
| Clinic setting (choose one—  probably) | primary care | primary care | primary care |
| Components (choose all) | nutrition counseling, activity counseling, sleep counseling | nutrition counseling,  activity counseling, sleep counseling | Usual care |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outc  omes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI  z-  score |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Init ial St ud y  Vis it |  |  |  |  |  |  |  |  |  |  | 1-  yea r Foll ow - up |  |  |  |  |  |  |  |  |  |  |
|  | Me an | S D | Mea n Cha nge | Unadj usted β Value | Unadj usted 95%  CI\_lo w er bound | Unadj usted 95%  CI\_up per bound | Unadj usted P-  Value | Adju sted β Valu e | Adju sted 95%  CI\_l ow er boun  d | Adju sted 95%  CI\_u pper boun  d | Adju sted P-  Valu e | Me an | S D | Mea n Cha nge | Unadj usted β Value | Unadj usted 95%  CI\_lo w er bound | Unadj usted 95%  CI\_up per bound | Unadj usted P-  Value | Adju sted β Valu e | Adju sted 95%  CI\_l ow er boun  d | Adju sted 95%  CI\_u pper boun  d | Adju sted P-  Valu e |
| CDS | 2.0  4 | 0  . 3 |  |  |  |  |  |  |  |  |  | 1.9  3 | 0.  3  9 | -0.1 | -0.06 | -0.1 | -0.01 |  | - 0.06 | - 0.11 | -0.02 |  |
| CDS  +  coac hing | 2.0  8 | 0  . 3 |  |  |  |  |  |  |  |  |  | 1.9  9 | 0.  3  5 | - 0.08 | -0.04 | -0.09 | 0.01 | 0.04 | - 0.05 | - 0.09 | 0 | 0.03 |
| Usual care | 2.0  5 | 0  . 3 |  |  |  |  |  |  |  |  |  | 2.0  1 | 0.  3  3 | - 0.04 |  |  |  |  |  |  |  |  |
| CDS  vs CDS  +  coac hing |  |  |  | -0.02 | -0.06 | 0.03 | 0.49 | - 0.02 | - 0.06 | 0.03 | 0.49 |  |  |  |  |  |  |  |  |  |  |  |
| BMI | | | | | | | | | | | | | | | | | | | | | | |
|  | Init ial St ud y  Vis it |  |  |  |  |  |  |  |  |  |  | 1-  yea r Foll ow - up |  |  |  |  |  |  |  |  |  |  |
|  | Me an | S D | Mea n Cha nge | Unadj usted β Value | Unadj usted 95%  CI\_lo | Unadj usted 95%  CI\_up | Unadj usted P-  Value | Adju sted β Valu  e | Adju sted 95%  CI\_l  ow er | Adju sted 95%  CI\_u  pper | Adju sted P-  Valu  e | Me an | S D | Mea n Cha nge | Unadj usted β Value | Unadj usted 95%  CI\_lo | Unadj usted 95%  CI\_up | Unadj usted P-  Value | Adju sted β Valu  e | Adju sted 95%  CI\_l  ow er | Adju sted 95%  CI\_u  pper | Adju sted P-  Valu  e |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | w er bound | per bound |  |  | boun d | boun d |  |  |  |  | w er bound | per bound |  |  | boun d | boun d |  |
| CDS | 25.  6 | 4  . 5 |  |  |  |  |  |  | 26.  3 | 4.  6 | 0.7 | -0.48 | -0.88 | -0.08 |  | - 0.51 | - 0.91 | -0.11 |  |
| CDS  +  coac hing | 26 | 4  . 2 |  |  |  |  |  |  | 26.  8 | 4.  6 | 0.9 | -0.32 | -0.73 | 0.09 | 0.06 | - 0.34 | - 0.75 | 0.07 | 0.04 |
| Usual care | 25.  7 | 4  . 2 |  |  |  |  |  |  | 26.  9 | 4.  6 | 1.2 |  |  |  |  |  |  |  |  |
| CDS  vs CDS  +  coac hing |  | -0.17 | -0.57 | 0.24 | 0.42 | - 0.17 | - 0.58 | 0.23 | 0.4 |  |  |  |  |  |  |  |  |  |  |

**Taveras, Em; Marshall, R; Sharifi, M; Avalon, E; Fiechtner, L; Horan, C; Gerber, Mw; John, Orav Eo; Price, Sn; Sequist, T; Slater, D Comparative effectiveness of clinical-community childhood obesity interventions a randomized clinical trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | his w ork w as supported through aw ard IH-1304-6739 from the Patient- Centered Outcomes Research Institute. Dr Taveras w as also supported by K24 grant DK10589 from the National Institutes of Health. Dr Sharifi w as supported by grant K12 HS 022986 from the Agency for Healthcare Research and Quality. Dr Fiechtner w as supported by training grant T32 DK 007747 from the National Institute of Diabetes and Digestive and Kidney Diseases to the Division of  Gastroenterology and Nutrition and grant K12 HS022986 from the Agency for Healthcare Research and Quality. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Study activities w ere approved by the Part-ners Health Care institutional review board. | |  |
| Outcomes  other than BMI | Psychosocial (quality of life) |  |  |
| Population | | | |
| Inclusion  criteria | Eligibility included the follow ing: (1) child age 2 to 12.9 years, (2)BMIin the85th or greater percentile,and(3) family not planning to leave HVMA w ithin the study  time frame. | | |
| Exclusion  criteria | None listed |  |  |
| Group  differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Enhanced Primary Care | Enhanced Primary Care plus Coaching | Overall |
| N | 361 | 360 | 721 |
| Sex | 52.1% female | 50.0% female | 51% female |
| Age | 8 | 8.1 | 8 |
| Race | 37.1% w hite, 30.5% black, 23.5% Hispanic, 8.9% other | 32.9% w hite, 36.2% black, 20.1% Hispanic, 10.9% other | 35.0% w hite,  33.3% black,  21.8%  Hispanic, 9.9% other |
| BMI SDS | 1.91 | 1.87 | 1.88 |
| Interventions | |  |  |
|  | Enhanced Primary Care | Enhanced Primary Care plus Coaching |  |
| Intervention as described by authors | All pediatric clinicians received a computerized clinical deci-sion support alert during primary care visits identifying chil-dren w ith a BMI in the 85th or greater percentile, and 2 addi-tional clinical decision support tools to assist in treatingchildren w ith  overw eight or obesity.15-17Clinicians also gaveparents a set of evidence-supported educational materials fo-cusing on  specified behavioral targets to support self -guidedbehavior change.17 Participants randomized to the enhanced primary care groupw ere exposed to the clinical best practices described  here. Inaddition, participants received monthly text messages | All pediatric clinicians received a computerized clinical deci-sion support alert during primary care visits identifying chil-dren w ith a BMI in the 85th or greater percentile, and 2 addi-tional clinical decision support tools to assist in treatingchildren w ith overw eight or obesity.15-17Clinicians also gaveparents a set of evidence-supported educational materials fo-cusing on specified behavioral targets to support self -guidedbehavior change.17 In the enhanced primary care plus coaching arm, families re-ceived individualized health coaching tailored to their socio-environmental context. Health coaches used a motivational interview ing style  ofcounseling and shared decision-making techniques19,20to pro-vide |  |

|  |  |  |
| --- | --- | --- |
|  | that con-tained links to publicly available resources to support  behav-ior change | family-centered care in addressing childhood obesity riskfactors and  management. |
| Intervention  type | Lifestyle | Lifestyle |
| Intervention  length | 12 months | 12 months |
| Intensity as described by authors | Pediatrician visit, Monthly text | Pediatrician visit, plus Four trained health coaches con-tacted families every other month for 1 year using telephone,videoconf erence (Vidyo), or in-person visits, according to par-ent pref erence. These contacts w ere  approximately 15 to 20minutes. |
| Assigned  intensity | <5 hours | <5 hours |
| Provider types | Primary care | Primary care, other(health coaches) |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, motivational interview ing,  nutrition training (grocery tour) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 12 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Enhanced Primary Care | 361 | -0.06 | -0.1 | -0.02 | 0.39 |
| Enhanced Primary Care plus Coaching | 360 | -0.09 | -0.13 | -0.05 |  |

**Taylor, Rw; Cox, A; Knight, L; Brown, Da; Meredith-Jones, K; Haszard, Jj; Dawson, Am; Taylor, Bj; Williams, Sm A Tailored Family-Based Obesity Intervention: a Randomized Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by the Health Research Council of New Zealand. Dr Daw son w as in receipt of a Freemasons New Zealand Fellow ship at the time the data  w erecollected. Dr R.W. Taylor is funded by the KPS Research Fellow shi | |  |
| Country | New Zealand |  |  |
| Setting | - |  |  |
| Comments | - |  |  |
| Authors name | - |  |  |
| Institution | - |  |  |
| Email | - |  |  |
| Address | - |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval w as obtained from the Low er Regional South Ethics Committee (LRS/09/09/039), and parents gave inf ormed consent. A separate inf ormation sheet and consent form w as used for children. | | |
| Outcomes  other than BMI | Other obesity, psychosocial, behaviors |  |  |
| Population | | | |
| Inclusion  criteria | All families w ith children 4 to 8 years of age enrolled at 9 general practices or attending secondary care clinics at 1 hospital w ere invited to participate. Parents  of all children identified as overw eight or obese (BMI $85th percentile | | |
| Exclusion  criteria | excluded (mostly medical conditions affecting grow th), |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | overw eight and obese (BMI $85th percentile) children aged 4 to 8 years |  |  |
|  | Usual Care (UC) | Tailored Package (TP) | Overall |
| N | 102 | 104 | 206 |
| Sex | 45% male | 44% male | 45% Male |
| Age | 6.4 | 6.5 | 6.5 |
| Race | 77% NZ European, 22% Maori, 8% Pacific | 81% NZ European, 16% Maori, 3% Pacific | NR75%  European |
| BMI SDS | 1.56 | 1.69 | NR |
| Interventions | |  |  |
|  | Usual Care (UC) | Tailored Package (TP) |  |
| Intervention as described by authors | UC families (predominantly mothersonly) met w ith a trained researcherat baseline and 6 months. Thefirst appointment lasted 30 to 45minutes, and parents receivedindividualized feedback about theirchild’s diet and activity habits, basedon the comprehensive data collectedat the screening and baselineappointments. A second appointment at 6 monthsreview ed progress, provided  supportandansw eredqueries.Nonew information/resources w ere provided,and these sessions lasted 15 to30 minutes. | The TP condition consisted of a single multidisciplinary consultant session (usually both parents, mentor, dietitian, exercise specialist, and clinical psychologist all together) follow ed by regular, brief contact (predominantly mothers only) w ith a MInT mentor (1 nutritionist, 1 exercise trainer) over the 2-year intervention. All specialists used an individualized report to identify potential targets for change, specific to each family, to guide prioritization.  These could be specific (dietary goals) or general (approaches to parenting). The consultant sessions |  |

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| --- | --- | --- |
|  |  | w ere 1 to 2 hours long in total, w ith the family taking the lead in identifying targets for change. The consultant sessions w ere 1 to 2 hours long in total,  w ith the family taking the lead in identifying targets for change. Each family then met w ith their MInT mentor, monthly in year 1 and every 3 months in year 2, typically alternating betw een faceto- face sessions (30–40 minutes) at the university or in their home and  phone calls (5–10 minutes). |
| Intervention  type | Lifestyle | Lifestyle |
| Intervention  length | 2 years | 2 years |
| Intensity as described by  authors | Estimated total interventioncontact time per family over the 2- yearinterventionw as45to75minutes. | Estimated total interventioncontact time over the 2- yearintervention w as 6 to 7 hours perfamily. |
| Assigned  intensity | <5 hours | <5 hours (year 1) |
| Provider types | Primary care | Primary care, nutrition provider, exercise, mental  health |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, sleep counseling | Nutrition counseling, activity counseling, motivational  interview ing, sleep counseling, other (parenting) |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 12 Months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Usual Care (UC) | 90 | 1.46 | 0.43 | NR | 92 | 1.42 | 0.45 | <0.05 |
| Tailored Package (TP) | 91 | 1.5 | 0.53 |  | 89 | 1.42 | 0.56 |  |
| BMI | | | | | | | | |
| 12 months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Usual Care (UC) | 90 | 19.4 | 2.2 | NR | 92 | 20.2 | 2.5 | <0.05 |
| Tailored Package (TP) | 91 | 19.9 | 2.8 |  | 89 | 20.6 | 3.3 |  |

**TjÃ¸nna, Ae; StÃ¸len, To; Bye, A; Volden, M; SlÃ¸rdahl, Sa; OdegÃ¥rd, R; Skogvoll, E; WislÃ¸ff, U**

**Aerobic interval training reduces cardiovascular risk factors more than a multitreatment approach in overweightadolescents**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | The present study w as supported by the Foundation forOutstanding Young Investigators from the Norw egianResearch Council (U.W.); The Norw egian Council of Cardiovascular Disease; Funds for Cardiovascular andMedical Research at St. Olav’s University Hospital,Trondheim, Norw ay; Ship Ow ner Tom  WilhelmsensFoun dation; Ingerborg and Anders Nordheims Found-ation, EWS Foundation and Agnes Sars legacy. | | |
| Country | Norw ay |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | All adolescents and parents provided w ritten in-formed consent, and the Regional Committee forMedical Research Ethics approved the protocol. | |  |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids, other (CV fitness) | |  |
| Population | | | |
| Inclusion criteria | A total of 62 overw eight and obese adolescents fromTrøndelag County in Norw ay, ref erred for medicaltreatment at St Olav’s Hospital, Trondheim,  Norw ay,w ere invited to participate in the study. Of these, 54 ad-olescents (28 girls and 26 boys; mean age, 14 years) agreedto participate. | |  |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | MTG (Multidisciplinary approach) | AIT (Aerobic interval training) | Overall |
| N | 26 | 28 | 54 |
| Sex | 54% female | 50% female | 26  boys |
| Age | 14.2 | 13.9 | 14 |
| Race | NR | NR | NR |
| BMI | 33.3 | 33.2 | NR |
| Interventions | |  |  |
|  | MTG (Multidisciplinary approach) | AIT (Aerobic interval training) |  |
| Intervention as defined by authors | 12 month regimen(at St. Olav’s Hospital, Trondheim, Norw ay) consistingof group meetings every 2 w eeks involving a physician,psychologist, physiotherapist and clinical nutritionalphysiologist. | AIT w as performed as w alking/running ‘uphill’ ona treadmill tw ice a w eek for 3 months. Only a 30 min meeting w ithgeneral nutritional advice w as given at inclusion; noother advice about diet and exercise training w as givento the AIT group. Follow ing the 3 months of training,the adolescents w ere encouraged to perform at leasttw o interval sessions each w eek at home or at a gym.Adolescents met for one session every second w eekfor 6 months, and one  session each month for the last3 months bef ore the 12 month follow -up testing. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 3 months | 3 months |  |
| Intensity as described by authors | The MTG grouphad a total of 21 h of treatment during the first 3 months ofintervention. During the 3 month intervention, the MTGgroup had three activity sessions and three group conver- sations, each lasting 3 and 4 h respectively; this  frequencycontinued through the w hole intervention. | Tw ice a w eek, 3 months, 40 minutes |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider, exercise provider | Exercise provider, nutrition provider |
| Clinic setting | Multidisciplinary w eight management program | Multidisciplinary w eight management program |
| Components | Nutrition counseling, activity counseling, activity training | Nutrition counseling, activity counseling, activity training |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  | 12 months | |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| MTG (Multidisciplinary approach) | 22 | 33.1 | 0.4 | NS | NS | 14 | 32.9 | 0.5 | NS | NS |
| AIT (Aerobic interval training) | 20 | 32.5 | 0.4 | <0.01 |  | 13 | 31.4 | 0.5 | NS |  |

**Truby, H; Baxter, K; Ware, Rs; Jensen, De; Cardinal, Jw; Warren, Jm; Daniels, L; Davies, Ps; Barrett, P; Blumfield, Ml; Batch, Ja**

**A Randomized Controlled Trial of Two Different Macronutrient Profiles on Weight, Body Composition and Metabolic Parameters in Obese Adolescents Seeking Weight Loss**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | The study w as funded by the NationalHeart Foundation Grant-in-Aid, the Royal Children’sHospital Foundation, ANZ Trustees, and theUniversity of Queensland.  KAB w as supported by anAustralian Post Graduate Aw ard Scholarship. | | | |
| Country | Australia |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as conducted according to the guidelines laid dow n in the Declaration of Helsinki and all proceduresi nvolving human subjects w ere approved by the Royal Children’s Hospital & Health Service District Ethics Committee (05/02/2008; #2008/005) that included the inclusion of a w ait listed control. Written  inf ormed consent w as obtained from all parents/guardians and assent by their child. | | | |
| Outcomes other than  BMI | Other obesity, lipids, glucose metabolism, other labs, behaviors |  |  |  |
| Population | | | | |
| Inclusion  criteria | aged 10–17 years w ith a BMI>90thpercentile |  |  |  |
| Exclusion criteria | Exclusion criteria w ere use of stimulants or psychotropicdrugs know n to alter body composition or metabolism including insulin sensitisers (eg. Bigua-nides such as metformin), glucocorticoids and thyroxin. Those w ith obesity related to a medi-cal condition (eg. Prader Willi Syndrome) and those w ith Type 1 diabetes or complex foodallergies w ere excluded. In the event that the psychological interview suggested the pres-ence of significant or clinically relevant levels of anxiety,  depression, dysthymia, or other men-tal health co-morbidity, participants w ere excluded from further participation and ref erred forclinical psychological service | | | |
| Group  differences | Randomized |  |  |  |
| Special  populations | Aboriginal |  |  |  |
|  | Control | SLF (Structured Low -Fat) | SMC (Structured Modified Carbohydrate) | Overall |
| N | 14 | 36 | 37 | 87 |
| Sex | 71% female | 72% female | 73% female | 63 (72%) |
| Age | 13.6 | 13.2 | 3.2 | NR |
| Race | 71% caucasian, 0% SE Asian, 29% Aboriginal/Pacific Islander | 94% Caucasian, 3% SE Asian, 3% Aboriginal/Pacific Islander | 89% Caucasian, 3% SE Asian, 8% Aboriginal/Pacfic Islander | Caucasian 77 (87%) SE Asian 2 (2%) Aboriginal and Torres Strait  Islander (9%) |
| BMI SDS | 2.27 | 2.19 | 2.2 | NR |
| Interventions | |  |  |  |
|  | Control | SLF (Structured Low -Fat) | SMC (Structured Modified  Carbohydrate) |  |
| Intervention as described by authors | Controls w ere not provided w ith any dietary advice; how ever, they w ere offered the dietary program of their choice at the end of the study.All groups received the Australian National Health and Medical Research Councils‘Get outand get active’booklet [30].  They w ere encouraged to set a goal to decrease sedentary behav-iour. No formal  exercise or activity w as prescribed. Retention | The intervention comprised of an intensive treatment phase w ith the study dieticians providingfive face- to-face counselling sessions for the subject and their carer (w eek 0,2,4,8 and 12) andtw o via telephone (w eeks 6 and 10). Plate template for SLF, 55%  carbohydrate, 20% protein, 25% fat. | The intervention comprised of an intensive treatment phase w ith the study dieticians providingfive face- to-face counselling sessions for the subject and their carer (w eek 0,2,4,8 and 12) andtw o via telephone (w eeks 6 and 10). Plate template for SMC SMC, 35%  carbohydrate; 30% protein; 35% |  |

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| --- | --- | --- | --- |
|  | strategies included flexibleappointment times, day-bef ore text message appointment reminders and covering the cost of parking at  the hospital. | All groups received the Australian National Health and Medical Research Councils‘Get outand get  active’booklet | fat. All groups received the Australian National Health and Medical Research Councils‘Get  outand get active’booklet |
| Intervention  type | Lifestyle | Specific diet | Specific diet |
| Intervention length | 12 w eeks | 12 w eeks | 12 w eeks |
| Intensity as described by  authors | Assessment, but no specific dietary advice | Intake assessment, 5 FTF counseling sessions, 2 telephone | Intake assessment, 5 FTF counseling sessions, 2 telephone |
| Assigned  intensity | <5 hours | 5-25 hours | 5-25 hours |
| Provider types | Specialist | Specialist , nutrition provider | Specialist , nutrition provider |
| Clinic setting | Specialty clinic | Specialty Clinic | Specialty Clinic |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity  counseling | Nutrition counseling, activity  counseling |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 12 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Control | 14 | 2.29 | 0.42 | <0.001 |
| SLF (Structured Low -Fat) | 32 | 2.1 | 0.46 | vs SMC 0.83 |
| SMC (Structured Modified Carbohydrate) | 33 | 2.05 | 0.41 |  |

**Verbeken, S; Braet, C; Goossens, L; Oord, S**

**Executive function training with game elements for obese children: a novel treatment to enhance self-regulatory abilities for weight-control**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship  source | Grants for development of“Braingame Brian”w ere provided bythe“VSB Bank”and the“Stichting Kinderpostzegels”. |  |  |
| Country | Belgium |  |  |
| Setting | - |  |  |
| Comments | - |  |  |
| Authors name | - |  |  |
| Institution | - |  |  |
| Email | - |  |  |
| Address | - |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Ethics Committee of the Ghent Universityapproved the study |  |  |
| Outcomes other than BMI | Other- Executive functions, including memory and inhibition training |  |  |
| Population |  |  |  |
| Inclusion criteria | All overw eight children in thefinal phase of a 10-month inpa-tient treatment program in a medical paediatric centre (Belgium)w ere invited to participate. Inclusion criteria for participation in thestudy w ere: primary obesity determined by a medical doctor of theclinic, age betw een 9 and 14 years, an IQ w ithin the normal range asestablished w ith the Raven Progressive Matrices, and absence of pervasive development disorders as deter-mined by a child  psychiatrist of the clinic. | | |
| Exclusion criteria | No additional |  |  |
| Group differences | Randomized |  |  |
| Special  Populations | Severe obesity |  |  |
|  | EF-Training | Care as usual | Overall |
| N | 22 | 22 | 44 |
| Sex | 50% female | 40.9%  female | NR |
| Age | 11.5 | 11.41 | NR |
| Race | NR | NR | NR |
| BMI | 131.58 | 132.91 | NR |
| Interventions | |  |  |
|  | EF-Training | Care as  usual |  |
| Intervention as  defined by authors | The intervention is a training of cognitive EF, embedded in agame-w orld. The game consists of 25 training sessions of about40 min. Each session contains tw o blocks (of about 20 min) of tw otraining tasks in afixed order. Thefirst training task is a w orkingmemory training task, and the second an inhibition training task.Over a period of 6 w eeks, the child trains about 4 times a w eek onfixed days  (Monday, Tuesday, Wednesday, Thursday). | Usual care |  |
| Intervention type | Lifestyle | Usual  care |  |
| Intervention length | 6 w eeks | 6 w eeks |  |
| Intensity as described by  authors | 25 game sessions of 40 min each | Usual care |  |
| Assigned Intensity | 5-25 hours | <5 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider types | Other- Research assistant | Mental  health |
| Clinic setting | Inpatient | Inpatient |
| Components | Other (executive function training) | Usual  care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Adjusted BMI |  |  |  |  |
| 12 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| EF-Training | 18 | 131.08 | 20.19 | <0.001 |
| Care as usual | 18 | 134.11 | 17.39 |  |

**Vos, R. C.; Wit, J. M.; Pijl, H.; Houdijk, E. C.**

**Long-term effect of lifestyle intervention on adiposity, metabolic parameters, inflammation and physical fitness in obese children: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The study w as partly funded by an unrestricted educationalgrant by Pfizer and an unrestricted educational grant by anon-profit foundation (de Stichting  Vrienden van het JKZ). | |  |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as conducted according tothe ‘Declaration of Helsinki’ and approval w as obtainedfrom the Regional Medical Ethics Committee (Zuid-  WestHolland). All parents and children gave their w ritteninf ormed consen | |  |
| Outcomes other  than BMI | Other obesity, lipids, glucose metabolism, blood pressure, other (CV fitness) |  |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere simple obesity, subjects of 8–17 years of age and ref erral to a pediatrician. | |  |
| Exclusion criteria | Potential participants w ere excluded if their know ledge of the Dutch language, intelligence or social skills w ere insufficient to participate in the trial. Other exclusion criteria w ere the use of medication that might have an effect on w eight loss, medical comorbidity that could affect participation or previous  enrollment in another cognitive behavioral treatment program w ith focus on reducing obesity. | | |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | Intervention Group | Obese Control Group | Overall |
| N | 40 | 39 | 79 |
| Sex | 45% male | 49% male | NR |
| Age | 13.3 | 13.1 | NR |
| Race | 35% Northern European, 65% other | 28% Northern European, 72% other | NR |
| BMI SDS | 4.2 | 4.3 | NR |
| Interventions | |  |  |
|  | Intervention Group | Obese Control Group |  |
| Intervention as described by authors | The family-based multidisciplinary lifestyle intervention ofthe intervention group consisted of a screening phase ofindividual counseling of the children w ith their parents,follow ed by an intensive phase of group sessions during3 months. The group treatment consisted of seven groupmeetings for the children, five separate parent meetings andone parent meeting together w ith the children. Meetings of duration of  2.5 h w ere held once every 2 w eeks. | The control group received standard care and advice, atstart of the trial, on how to increase their physical activity,decrease their sedentary activities and improve their eatingbehavior according to the Dutch standards for healthynutrition. (WLC for one year.) |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 3 months- follow up sessions 2 to 3 times a year for 2 years. | 1 year |  |
| Intensity as described by  authors | Screening phase plus seven group meetings for children, five for parents, one combined. 2.5 hours each. | Usual care |  |
| Assigned  intensity | 26-51 hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, mental health, exercise, psychosocial | Primary care |  |
| Clinic setting | Multidisciplinary w eight management, research | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, motivational interview ing, mental health,  other (parenting) | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 12 months | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Intervention Group | 32 | -0.4 | -0.8 | 0 | 0.02 |
| Obese Control Group | 35 | -0.1 | -0.4 | 0.3 | - |

**Vos, Rc; Huisman, Sd; Houdijk, Ec; Pijl, H; Wit, Jm**

**The effect of family-based multidisciplinary cognitive behavioral treatment on health-related quality of life in childhood obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by the Canadian Institutes of Health Research (CIHR). B.W. w as supported by a CIHR Charles Best and Frederick Banting Doctoral  Research Aw ard. | | |
| Country | The Netherlands |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Approval w as obtained from aregional medical ethical committee South West Holland(approval number; ID 06-091). All parents and children gavetheir  w ritten inf ormed consent | | |
| Outcomes other  than BMI | Psychosocial (health related quality of life) |  |  |
| Population | | | |
| Inclusion criteria | Children w ith obesity (according to Cole et al. [2]) aged 8-17 years, living in the Hague and in the area around the Hague and ref erred to a pediatrician, are invited to participate. Reasons for ref erral are overw eight or obesity, and increased risk of co-morbidity (e.g. hypertension, family history of diabetes mellitus  and/or hypercholesterolemia and/or cardiovascular disease bef ore the age of 55, Hindustani ethnicity). | | |
| Exclusion criteria | Potential participants are excluded if their know ledge of the Dutch language, intelligence or social skills are insufficient to participate in the group. Other  exclusion criteria are use of medication that might have an effect on w eight loss, medical co-morbidities that could affect participation, or previous enrollment in another cognitive behavioral treatment program w ith the focus on reducing obesity. | | |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Cognitive behavioral treatment program intervention | Control | Overall |
| N enrolled | 41 | 39 | 81 |
| Sex | 54% female | 51% female | 52%  female |
| Race | NR | NR | NR |
| BMI-SDS | 4.2 ± 0.7 | 4.3 ± 0.6 | NR |
| Interventions | |  |  |
|  | Cognitive behavioral treatment program intervention | Control |  |
| Intervention as defined by author | The intervention is carried out in groups of 8-11 children, and consists of respectively 7 and 5 separate group meetings for the children and their parents and 1 joint group meeting of 2 ½ hours. Main topics are education on nutrition, self -control techniques, social skills, physical  activity and improvement of self -esteem. | "During the 12 month study period children are seen after three months and at study end." After 12 months they w ere offered to participate in the multidisciplinary cognitive behavioral treatment. There w as also a "normal w eight control group w as measured only  once at the beginning of the study." |  |
| Intervention type  (choose one) | Lifestyle | Lifestyle |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as described by authors | The intervention is carried out in groups of 8-11 children, and consists of respectively 7 and 5 separate group meetings for the children and their parents and 1 joint group meeting of 2 ½ hours. | "During the 12 month study period children are seen after three months and at study end." After 12 months they w ere offered to participate in the multidisciplinary cognitive behavioral treatment.  There w as also a "normal w eight control group w as measured only once at the beginning of the study." |  |
| Assigned  Intensity | 26-51 hours | <5 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider type  (select all) | Primary care, nutrition provider, mental health, exercise provider,  psychosocial | Primary care |
| Clinic setting  (choose one— probably) | primary care | Primary care |
| Components  (choose all) | Nutrition counseling, activity counseling, mental health | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI-SDS |  |  |  |  |  |  |
|  | Baseline |  | 3 Months | 1 year-follow up | |  |
|  | Mean | SD | Mean | SD | Mean | SD |
| Cognitive behavioral treatment program intervention | 4.2 | 0.7 | 4 | 0.9 | 3.8 | 1.1 |
| Control | 4.3 | 0.7 | 4.2 | 0.7 | 4.2 | 0.7 |

**Wake, M; Baur, La; Gerner, B; Gibbons, K; Gold, L; Gunn, J; Levickis, P; McCallum, Z; Naughton, G; Sanci, L; Ukoumunne, Oc**

**Outcomes and costs of primary care surveillance and intervention for overweight or obese children: the LEAP 2 randomised controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This study w as funded by the Australian National Health and Medical Research Council (NH&MRC) Project Grant 334309. MW is supported by NH&MRC Career Development Aw ard 284556; LG by NH&MRC Capacity Building Grant 425855; and OCU by NH&MRC Capacity Building Grant 436914. The  researchers w ere independent of the funders. | | |
| Country | Australia |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The project w as approved by the Royal Children’s Hospital Ethics in Human Research Committee (EHRC 25006). |  |  |
| Outcomes other  than BMI | Behaviors, pscyhosocial, other (parent w eight) |  |  |
| Population |  |  |  |
| Inclusion criteria | All children aged 5 years 0 months up to their 10th birthday attending participating practices for any reason during May 2005 to July 2006 w ere eligible. Children in the survey w ere eligible for the trial if they w ere not receiving an ongoing w eight management programme and w ere overw eight or obese  according to the cut-off points of the International Obesity Taskforce | | |
| Exclusion criteria | Children w ereexcluded if their BMI z score w as≥3.0 |  |  |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Intervention group | Control group | Overall |
| N Enrolled | 139 | 119 | 258 |
| Sex | 60% female | 61%  female | NR |
| Age in years | 7.4 | 7.6 | NR |
| Race | NR | NR | NR |
| BMI z-score | 1.9 | 1.9 | 1.9 |
| Interventions | |  |  |
|  | Intervention group | Control  group |  |
| Intervention as defined by author | GPs used a brief, solution focused approach21to set and record appropriate, healthy lifestyle goals,assisted by a 16 page“family folder”w ritten at a12 year old reading level to be sure that virtually allparents could understand it. This folder included fivetopic  sheets, each targeting one area of behaviouralchange (sedentary time, physical activity, w ater con-sumption, family eating habits, and low er fat optionsfor food). Bef ore the first appointment, the GP received thechild’s named intervention materials, BMI, and atw o page summary of parent responses from thebaseline questionnaire regarding current nutrition,physical activity patterns, and concern  regardingtheir child’s w eight status. Parents w ere offered fourconsultations over a 12 w eek period. | NA |  |
| Intervention type  (choose one | Lifestyle | Usual  care |  |
| Intervention length | 12 w eeks | 12 w eeks |  |
| Intensity as  described by authors | fourconsultations over a 12 w eek period | Usual care |  |
| Assigned Intensity | <5 hours | <5 hours |  |
| Provider type  (select all) | Primary care | Primary  care |  |
| Clinic setting  (choose one— probably) | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components  (choose all) | Nutrition counseling, activity counseling | Usual  care |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
|  | 6 months |  |  |  | 12 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Intervention group | 132 | 20.5 | 2.6 | 0.7 | 127 | 20.8 | 2.8 | 0.7 |
| Control group | 118 | 20.6 | 2.2 |  | 115 | 21 | 2.4 |  |

**Wake, M; Lycett, K; Clifford, Sa; Sabin, Ma; Gunn, J; Gibbons, K; Hutton, C; McCallum, Z; Arnup, Sj; Wittert, G Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | HopSCOTCH w as funded by the Australian National Health and Medical Research Council (NHMRC Priority Driven Research Grant 491212). | |  |
| Country | Australia |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The project w as approved by the Royal Children’s Hospital Ethics in Human Research Committee (HREC 280178) and the University of Melbourne Human  Research Ethics Committee (0827435). | | |
| Outcomes other  than BMI | Other obesity, psychosocial, behaviors, other (parent w eight) |  |  |
| Population |  |  |  |
| Inclusion criteria | 3-10 years old, obese but not receiving an ongoing w eight management programme |  |  |
| Exclusion criteria | Know n endocrine or chromosomal cause for obesity, major health and developmental conditions,and insufficient English to comprehend sessions or  complete questionnaires | |  |
| Group differences | Randomized |  |  |
| Special populations | None |  |  |
|  | Intervention | Control | Overall |
| N | 62 | 56 | 118 |
| Sex | 50% male | 59% male | NR |
| Age | 7.2 | 7.4 | NR |
| Race | NR | NR | NR |
| BMI SDS | 2.2 | 2.1 | NR |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as described by authors | One hour appointment w ith a specialist tertiary care w eight management service. One long (20-40 min) appointments w ith GP  follow ed by four to eight w eekly standard (6-20 min) appointments. Shared care, w eb-based softw are for physicians, designed to  provide collaboration and communication betw een the specialists and the general practitioners, structured approach to w eight management care, joint recording and tracking of progress. | Usual care only |  |
| Intervention type | Lifestyle | Usual  care only |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as described by  authors | 1 20-40 min appt, 4-8 additional short appts. | NA |  |
| Assigned intensity | 5-25 hours | NA |  |
| Provider types | Primary care, specialist, nutrition provider | NA |  |
| Clinic setting | Primary care | Primary  care |  |
| Components | Nutrition counseling, activity counseling | Usual  care only |  |

Outcomes

BMI SDS

12 months

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (betw een groups) |
| Intervention | 56 | 2 | 0.5 | 0.9 |
| Control | 49 | 2 | 0.4 |  |

**Walpole, B; Dettmer, E; Morrongiello, Ba; McCrindle, Bw; Hamilton, J**

**Motivational interviewing to enhance self-efficacy and promote weight loss in overweight and obese adolescents: a randomized controlled trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by the Canadian Institutes of Health Research (CIHR). B.W. w as supported by a CIHR Charles Best and Frederick Banting Doctoral  Research Aw ard. | | |
| Country | Canada |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Verbal and w ritten consent/assent w as obtained from youth (and parents, if aged <16 years) at the treatment site. Study procedures and measures w ere  approved by all associated Research Ethics Boards. | | |
| Outcomes other  than BMI | Other obesity, psychosocial |  |  |
| Population | | | |
| Inclusion criteria | Overw eight and obese youth, w ith BMI 85th percentile for age and gender (World Health Organization, 2002) aged 10–18 years, attending a local pediatric  outpatient clinic in Toronto, Ontario, w ere eligible, and both new and current clients had the option to participate. | | |
| Exclusion  criteria | Exclusion criteria included the follow ing: under 10 or over 18 years of age, current use of medication w ith possible side effects of w eight gain/loss, non-English  speaking, developmental delay, pregnant and/or diagnosed w ith an active eating disorder | | |
| Group  differences | Randomized |  |  |
| Special  Populations | None |  |  |
|  | Control | MI | Overall |
| N Enrolled | 20 | 20 | 40 |
| Sex | 9 female (45%) | 14 female (70%) | NR |
| Age in years | 13.7 (1.7) | 14.1 (1.8) | NR |
| Race | w hite- 25; African Canadian-3; Native Canadian-0; Asian- 1; south Asian-  1; other- 4 | caucasian-19, african canadian- 2, native canadian- 2, asian- 1, other- 1 | NR |
| BMI | 30.4 (5.0) | 30.2 (2.8) | NR |
| BMI z-score | 2.64 (0.73) | 2.51 (0.47) | NR |
| Interventions | |  |  |
|  | Control | MI |  |
| Intervention as defined by author | Both groups received individual therapy (30 min/month) in addition to usual care of diet/exercise counseling. standard care program (i.e., treatment focused on improved nutrition and physical activity behaviors). Social-skills training w as selected as the ‘‘control’’ intervention for its contrast to MI. Although MI is strongly rooted in collaborative client- centered care, social skills training traditionally takes a prescriptive stance (Lane, 1999). The social skills interventionist, unlike the MI therapist, w as expected to offer advice rather than attempt to elicit ideas from the client, and clients w ere prescribed goals to w ork on w ithout  specific regard for the client’s readiness to change. | Participants in the MI treatment group met w ith a clinical psychology doctoral student trained in MI. The interventionist attempted to guide clients tow ard increasing their aw areness of unhealthy behaviors, to consider w hether their current behavior w as consistent w ith his or her personal values, and to envision how change may be helpf ul to them. To address the client’s ambivalence or resistance to change, the MI therapist used, w hen appropriate, agenda setting, decisional balances, and scale questions w hile focusing on continued demonstration of empathy and supporting autonomy. |  |
| Intervention type (choose one) | Lifestyle | Lifestyle |  |
| Intervention  length | 6 months | 6 months |  |

|  |  |  |
| --- | --- | --- |
| Intensity as  described by authors | The target number of sessions for both groups w as six,Counseling  sessions w ere 30 min in length at the time of their regularly scheduled Healthy Lifestyles appointments. | The target number of sessions for both groups w as six, Counseling  sessions w ere 30 min in length at the time of their regularly scheduled Healthy Lifestyles appointments. |
| Assigned  Intensity | < 5 hrs | < 5 hrs |
| Provider type  (select all) | mental health | mental health |
| Clinic setting (choose one—  probably) | primary care | primary care |
| Components  (choose all) | Nutrition counseling, activity counseling, other (social skills training) | Motivational Interview ing , nutrition counseling , activity counseling |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI z-score |  |  |  |  |  |  |
|  | Baseline |  |  | 6 months |  |  |
|  | Mean | SD | P-value | Mean | SD | P-value |
| Control | 2.64 | 0.73 | 0.49 | 2.41 | 0.78 | 0.84 |
| MI | 2.51 | 0.47 |  | 2.46 | 0.47 |  |
| BMI | | | | | | |
|  | Baseline |  |  | 6 months |  |  |
|  | Mean | SD | P-value | Mean | SD | P-value |
| Control | 29.7 | 5 | 0.84 | 29.5 | 5.2 | 0.69 |
| MI | 30.3 | 2.9 |  | 30.1 | 2.6 |  |

**Warschburger, P; Kroeller, K; Haerting, J; Unverzagt, S; Egmond-FrÃ¶hlich, A**

**Empowering Parents of Obese Children (EPOC): a randomized controlled trial on additional long-term weight effects of parent training**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This study w as funded by a DFG (German Research Foundation) grant (WA 1143/4-1; 4-2). | |  |
| Country | Germany |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the ethics committee of the Uni-versity of Potsdam on 19th May 2006 and w as conducted in linew ith the Declaration of Helsinki. All  participants provided theirw ritten inf ormed consent to participate in this study. | | |
| Outcomes other  than BMI | Psychosocial, behavior |  |  |
| Population | | | |
| Inclusion criteria | All parents of obese children (BMI > 97th percentile) aged 7 to 12 w ere asked to participate at the beginning of their child's stay. Due to recruitment problems,  the age range w as later extended up to 13 years. | | |
| Exclusion  criteria | Parents w ho had already completed parent training and those w ith inadequate language skills or severe mental disorder (e.g. depression, psychosis) as w ell  as children w ith secondary causes of obesity or those suffering from severe mental health problems (e.g. ADHD, eating disorder) w ere excluded. | | |
| Group  differences | Randomized |  |  |
| Special  populations | None |  |  |
|  | CBT | Inf ormation-only | Overall |
| N | 249 | 274 | 523 |
| Sex | 53.4% female | 51.5% female | NR |
| Age | 11.3 | 11.3 | 11 |
| Race | NR | NR | NR |
| BMI SDS | 2.6 | 2.5 | NR |
| Interventions | |  |  |
|  | CBT | Inf ormation-only |  |
| Intervention as described by authors | The children stayed in a specialized out-of-home inpatient fa-cility for around 3-6 w eeks, and w ere not accompanied by theirparents. During this time, all children participated in a multi-disciplinary lifestyle intervention encompassing nutrition educa-tion, diet modification, controlled meal options, scheduled activitysessions several times a  w eek, and cognitive-behavioral grouptraining (CBT) and w hen necessary individual counseling sessions. Parents received a compact (10 unitsover 2 days) cognitive-behaviorally oriented training course in agroup setting (8e12 parents). All par-ents of the CBT group received a short parent guide (incl. videomaterial) and 2 telephone booster sessions  after one (T3) and 3months (T4) follow ing the discharge of their child. | The children stayed in a specialized out-of-home inpatient fa-cility for around 3-6 w eeks, and w ere not accompanied by theirparents. During this time, all children participated in a multi-disciplinary lifestyle intervention encompassing nutrition educa-tion, diet modification, controlled meal options, scheduled activitysessions several times a  w eek, and cognitive-behavioral grouptraining (CBT) and w hen necessary individual counseling sessions. Parents received a brief w rittenparent guide summarizing w hat their child had learned duringtheir stay and giving advice on how to further support their child. |  |
| Intervention  type | Lifestyle | Lifestyle |  |
| Intervention  length | 3 months | 3 months |  |
| Intensity as  described by authors | "10 units over 2 days", plus 3-6 w eeks inpatietn | 3-6 w eeks inpatient |  |

|  |  |  |
| --- | --- | --- |
| Assigned  intensity | 52+ hours | 52+ hours |
| Provider types | Primary care, nutrition providers, mental health | Primary care, nutrition providers, mental health |
| Clinic setting | Inpatient | Inpatient |
| Components | Nutrition counseling, activity counseling, nutrition training, activity  training, mental health | Nutrition counseling, activity counseling, nutrition training, activity  training, mental health |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS (ITT) |  |  |  |  |  |  |  |  |
|  | 6 months |  |  |  | 12 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| CBT | 249 | 2.24 | 0.52 | NS | 249 | 2.38 | 0.5 | NS |
| Inf ormation-only | 274 | 2.12 | 0.5 |  | 274 | 2.3 | 0.48 |  |

**Weigel, C.; Kokocinski, K.; Lederer, P.; Dotsch, J.; Rascher, W.; Knerr, I.**

**Childhood obesity: concept, feasibility, and interim results of a local group-based, long-term treatment program**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | This project w as funded by the Bavarian State Ministry of Environment, Public Health, and Consumer Protectionand the health insurance company Siemens  Betriebskran-kenkasse, Germany. | | |
| Country | Germany |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the local ethics committee (Friedrich-Alexander-University of Erlangen-Nuremberg), and inf ormed consent w as obtained from  the parents of each subject | | |
| Outcomes other  than BMI | Other obesity, blood pressure |  |  |
| Population | | | |
| Inclusion criteria | Obese children aged 7 to 15 years |  |  |
| Exclusion  criteria | No additional |  |  |
| Group  differences | Randomized |  |  |
| Special Populations | None |  |  |
|  | Intervention | Control | Overall |
| N | 37 | 36 | 73 |
| Sex | 59% female | 50% female | NR |
| Age | 10.9 | 11.6 | 11.2 |
| Race | NR | NR | NR |
| BMI SDS | 2.24 | 2.48 | NR |
| Interventions | |  |  |
|  | Intervention | Control |  |
| Intervention as defined by author | It consisted of lessons on physical activity (alter-nating sw imming and indoor sports), dietary education(adapted from the “Food Guide Pyramid” fruit and vegeta-ble template),10-12and coping strategies (eg, aw areness of eating behavior, habit books) suitable for each age. The first meeting in the w eek w as reserved for sports,the second session for nutrition and coping strategies. Di-etitians and psychologists took turns w ith a 4-w eek teach-ing block. Parental support w as provided separately atmonthly meetings and feedback discussions of up to 2 hours(including parent-child activities and social reinf orce-ment). There w ere also monthlyparental meetings and medical supervision  including lab-oratory tests at 0, 6, and 12 months. | The controls re-ceived w ritten therapeutic advice  from a physician dur-ing an outpatient visit at 0 and 6 months in theoutpatient clinic and w ere given medical supervision andlaboratory tests at 0, 6, and 12 months. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention  length | 12 months | 12 months |  |
| Intensity as  described by authors | 12 months tw ice w eekly, including during the summervacation. Eachsession lasted for 45 to 60 minutes and w as performed in thelate afternoon. | 2 outpatient visits |  |
| Assigned  intensity | 52+ hours | <5 hours |  |
| Provider types | Primary care, nutrition provider, exercise, mental health | Primary care |  |
| Clinic setting | Primary care | Primary care |  |

|  |  |  |
| --- | --- | --- |
| Components | Nutrition counseling, activity counseling, nutrition training, activity training, motivational  interview ing | Nutrition counseling, activity counseling, motivational  interview ing |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 6 months |  |  |  | 12 months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Intervention | 36 | 2.1 | 0.52 | NS | <0.05 | 36 | 1.9 | 0.52 | <0.05 | <0.05 |
| Control | 34 | 2.66 | 0.56 |  |  | 30 | 2.74 | 0.55 |  |  |
| BMI | | | | | | | | | | |
|  | 6 months |  |  |  | 12 months | |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Intervention | 36 | 27.2 | 4.1 | <0.05 | NS | 36 | 25.8 | 2.7 | <0.05 | <0.001 |
| Control | 34 | 31.7 | 4.1 | <0.05 |  | 30 | 32.8 | 4 | <0.05 |  |

**Wilfley, De; Saelens, Be; Stein, Ri; Best, Jr; Kolko, Rp; Schechtman, Kb; Wallendorf, M; Welch, Rr; Perri, Mg; Epstein, Lh Dose, Content, and Mediators of Family-Based Treatment for Childhood Obesity: a Multisite Randomized Clinical Trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship source | This study w as funded by the National Institute of Child Health and Human Development (NICHD) (grant R01HD036904 to Dr Wilfley); National Institute of Mental Health (grant K24MH070446 to Dr Wilfley); National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (grant K23DK060476 to Dr Saelens); National Center for Research Resources (NCRR) (grants KL2RR024994 [Dr Stein], UL1RR024992, and UL1RR02501 4); National Heart, Lung, and Blood Institute (grant T32HL007456 to Dr Kolko); the NIDDK Nutrition Obesity Research Center (grant P30DK056341); National Center for Advancing Translational Sciences (University of Washington Clinical and Translational Science Aw ard) of the National Institutes of Health (grants UL1TR000448 and UL1TR000423); St. Louis Children’s Hospital Foundation (Washington University Pediatric and Adolescent Research Consortium); and institutional support  from Washington University School of Medicine and Seattle Children’s Research Institute | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | Parents and children provided w ritten inf ormed consent and assent, respectively. Each site’s institutional review board approved the study. | | |  |
| Outcomes other than BMI | None |  |  |  |
| Population | | | | |
| Inclusion criteria | Children (aged 7-11 years) w ith overw eight or obesity (body mass index [BMI; calculated as w eight in kilograms divided by height in meters squared] ≥85th  percentile for age and sex) and at least 1 parent w ith overw eight or obesity (BMI ≥25) | | | |
| Exclusion  criteria | Exclusion criteria included child or par- ent participation in other w eight loss treatment, use of w eight- affecting medications, or psychiatric and medical  conditions that w ould hinder participation. | | | |
| Group  differences | Randomized |  |  |  |
| Special  Populations | None |  |  |  |
|  | HIGH | LOW | CONTROL | Overall |
| N | 59 | 56 | 57 | 172 |
| Sex | 62.7% female | 64.3% female | 57.9% female | 61.6% female |
| Age | 9.5 | 9.4 | 9.5 | 9.4 |
| Race | 61.0% w hite, 5.1% Hispanic, 23.7% African  American, 10.2% other | 64.3% w hite, 7.1% Hispanic, 23.2% African  American, 5.4% other | 64.9% w hite, 10.5% Hispanic, 19.3% African American, 5.3% other | 63.4% w hite,  7.6%  Hispanic, 22.1% African American, 7.0% other |
| BMI Percent  overw eight (at randomization) | 54.1 | 50.8 | 47.3 | 50.8 |
| Interventions | |  |  |  |
|  | HIGH | LOW | CONTROL |  |
| Intervention as defined by author | Enhanced social facilitation maintenance (HIGH and LOW) w as a multicomponent intervention designed to optimize the durability and generalizability of eating and physical activity changes from FBT via  practice across multiple social and environmental contexts (eg, w ithin the | Enhanced social facilitation maintenance (HIGH and LOW)w as a multicomponent intervention designed to optimize thedurability and generalizability of eating and physical activitychanges from FBT via practice across  multiple social andenvironmental contexts (eg, w ithin the home, school, w ork, res-taurants, | CONTROL w as a w eight management education interven-tion. Families received novel inf ormation on nutrition and ex-ercise beyond w hat FBT provided, (eg, details about benefitsof fiber). CONTROL families  participated in hands-on activi-ties, including cooking, stretching, and grocery store tours. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | home, school, w ork, res- taurants, w ith  friends). In addition, SFM+ bolstered skills in- troduced in FBT to manage negative peer interactions (eg, teas- ing) that hinder healthy behaviors 21-25 and focused on building supportive family and peer  environments conducive to healthy w eight- control behaviors | w ith friends). In addition, SFM+ bolstered skills in-troduced in FBT to manage negative peer interactions (eg, teas-ing) that hinder healthy behaviors21-25and focused on buildingsupportive family and peer environments conducive to healthyw eight- control behaviors | Useof self-regulatory skills w as not discussed or encouraged; iffamilies requested skills instruction, they w ere ref erred to theirFBT materials. |
| Intervention type | Lifestyle | Lifestyle | Lifestyle |
| Intervention  length | 32 w eeks | 32 w eeks | 32 w eeks |
| Intensity as described by  authors | 32 w eekly ses-sions; 30-minute family sessions plus 45-minute separatechild and  parent group sessions. | 16 every-other-w eek sessions; 30-minute  family sessions plus 45-minute separatechild and parent group sessions. | 16 every-other-w eek sessions; 30-minute family sessions plus 45-minute  separatechild and parent group sessions. |
| Assigned  intensity | 26-51 hours | 5-25 hours | 5-25 hours |
| Provider types | "Interventionist" | "Interventionist" | "Interventionist" |
| Clinic setting | Multidisciplinary w eight management  program | Multidisciplinary w eight management program | Multidisciplinary w eight management  program |
| Components | Nutrition counseling, activity counseling,  other (social facilitation) | Nutrition counseling, activity counseling, other  (social facilitation) | Nutrition counseling, activity counseling,  nutrition training, activity training |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percentage overw eight |  |  |  |  |
| 8 months (Month 4 to 12) | | | | |
|  | N | Mean | SD | p (vs control) |
| HIGH | 59 | 49.15 | 29.27 | <0.001 |
| LOW | 56 | 48.23 | 27.36 | 0.02 |
| CONTROL | 57 | 48.58 | 29.11 |  |

**Wilfley, De; Stein, Ri; Saelens, Be; Mockus, Ds; Matt, Ge; Hayden-Wade, Ha; Welch, Rr; Schechtman, Kb; Thompson, Pa; Epstein, Lh Efficacy of maintenance treatment approaches for childhood overweight: a randomized controlled trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | 5R01HD36904-5 from the National Institute of Child Health and Human Development (NICHD)and supported by grant 1K24MH070446-01 fromthe National  Institute of Mental Health (Dr Wilfley)and grant 1K23DK060476-01 from the NationalInstitute of Diabetes and Digestive and Kidney Dis-eases (Dr Saelens). | | | |
| Country | USA |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The institutional review boards of San Diego State University and Southern California Kaiser Permanente (a ref erral source) approved the study. Participants  w ere unpaid volunteers and provided w ritten inf ormed consent (participating par- ent) and assent (child) | | | |
| Outcomes  other than BMI | Psychosocial |  |  |  |
| Population | | | | |
| Inclusion  criteria | Children aged 7 to 12 years w ho w ere 20% to 100% overw eight and had at least 1 parent w ith a body mass index > 25 w ere recruited through media  announcements or advertisements and physician ref errals. | | |  |
| Exclusion  criteria | Families w ere excluded if either the child or parent w as currently involved in psychological or w eight loss treat- ment, w as using appetite or w eight-affecting  medications, or had a psychiatric condition (eg, eating disorder, psychosis) that w ould interfere w ith participation. | | | |
| Group  differences | Randomized |  |  |  |
| Special  Populations | None |  |  |  |
|  | Behavioral Skills Maintenance | Social Facilitation Maintenance | Control | Overall |
| N | 51 | 50 | 49 | 150 |
| Sex | 72.5% female | 70.0% female | 65.3% female | NR |
| Age | 9.9 | 9.9 | 9.8 | NR |
| Race | 5.9% black, 70.6% w hite, 21.6% Hispanic, 2.0% other | 14.0% black, 64.0% w hite, 16.0% Hispanic, 6.0% other | 2.0% black,  77.6% w hite,  18.4% black,  2.0% other | NR |
| BMI | 27.1 | 28.2 | 27.3 | NR |
| Interventions | |  |  |  |
|  | Behavioral Skills Maintenance | Social Facilitation Maintenance | Control |  |
| Intervention as described by author | Post-5 month w eight loss treatment. SPECIFIC TO BSM during w eight maintenance phase: The BSM approach is based on the premise that specific strategies are needed for w eight loss maintenance. Phase 1 (w eeks 1-5) focused on en- hancing motivation and promoting small changes in eating and physical ac- tivity to support w eight maintenance. Phase 2 (w eeks 6-11) taught children and parents to (1) identify high-risk situations  for overeating or missing physical activity, (2) preplan to avoid these situations or problem solve to cope more effectively w ith them, and (3) use cognitive restructuring and posi- tive self-talk to decrease the likeli- hood that behavioral slips w ould re- sult in full relapse. In phase 3 (w eeks 12-16), families reassessed their eat- ing and physical activity behaviors and developed plans for permanent life- style change. | Post-5 month w eight loss treatment. SPECIFIC TO SFM during w eight maintenance phase: The SFM approach is based on the premise that relapse results from the ab- sence of a social environment support-ive of continued w eight control. Phase 1 (w eeks 1-5) guided parents to en- courage children to form  friendships w ith physically active peers and/or en- sure that children’s playdates w ith ex- isting friends involved physical activ- ity and healthf ul eating. Phase 2 (w eeks 6-11) addressed body image concerns (eg, fear of body exposure) that might limit overw eight children from engag- ing in peer-related physical activity. Families also learned effective strate- gies to curtail w eight-related teasing or criticism. Phase 3 (w eeks 12- 16) fo- cused on solidifying children’s social support netw ork to maximize its effi- cacy in promoting long-term behav- ioral  changes. | Usual care |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Intervention  type | Lifestyle | Lifestyle | Lifestyle |
| Intervention  length | 16 w eeks | 16 w eeks | 16 w eeks |
| Intensity as  described by authors | 16 w eekly sessions, 20 minutes family and 40 minutes separate | 16 w eekly sessions, 20 minutes family and 40 minutes separate | Discontinued contact |
| Assigned  intensity | 5-25 hours | 5-25 hours | <5 hours |
| Provider type | Mental health | Mental health | Primary care |
| Clinic setting | Multidisciplinary w eight management, research | Multidisciplinary w eight management, research | Primary care |
| Components | Nutrition counseling, activity counseling, motivational  interview ing, other (parenting) | Nutrition counseling, activity counseling, motivational  interview ing, other (parenting) | Usual care |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
|  | 1 year |  |  |  |  | 2 years |  |  |  |  |
|  | N | Mean | SD | p (vs control) | p (pooled) | N | Mean | SD | p (vs control) | p (pooled) |
| Behavioral Skills Maintenance | 50 | 1.99 | 0.39 | 0.19 | 0.07 | 50 | 1.98 | 0.48 | 0.51 | 0.25 |
| Social Facilitation Maintenance | 50 | 2.03 | 0.51 | 0.06 |  | 50 | 2.02 | 0.5 | 0.17 |  |
| Control | 48 | 2.07 | 0.38 |  |  | 48 | 2.11 | 0.36 |  |  |

**Williams, Cl; Strobino, Ba; Brotanek, J**

**Weight control among obese adolescents: a pilot study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Supported by a grant from the American Beverage Association. (Comment from ACS: Specifically stated that regular sodas could be included in the snacks,  and that the lack of difference meant that "beverages such as soda could be consumed several times a w eek as part of a w eight control program".) | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by both thepediatric human subjects review committee and the full Institutional Review Board of Columbia University. | |  |
| Outcomes other  than BMI | Other obesity, lipids, behavior |  |  |
| Population | | | |
| Inclusion  criteria | 1115 years old at their last birthday,and w ere overw eight (BMI/95th percentile) but otherw ise healthy. | |  |
| Exclusion criteria | Potential participants w ere excluded if they had a significant medical, physical, mental or social problem that could negatively affect participation in the study or could preclude normal food consumption or daily physical activity, or if they w ere extremely 218 C. L. Williams et al. overw eight (BMI/45 kg per M2), currently  enrolled in another w eight loss program, or currently taking appetite suppressants or other medications that affect appetite or w eight. | | |
| Group  differences | Randomized |  |  |
| Special  populations | Females only |  |  |
|  | Free snack | Restricted Snack | Overall |
| N | 19 | 19 | 38 |
| Sex | 100% female | 100% female | 100% female |
| Age | 13.4 | 12.9 | 13.2 |
| Race | NR | NR | 44.7% African American, 34.2% Latino,  21.1%  Caucasian |
| BMI | 32.2 | 33.7 | NR |
| Interventions | |  |  |
|  | Free snack | Restricted Snack |  |
| Intervention as described by authors | Subjectsassigned to Diet A w ere instructed to follow a 1,500 kcal/day free snack diet, w hich allow edf or three meals and tw o 150 kcal snacks. One snack had to be chosen from a list of healthy snacks, but the other snack w as a free choice\*as long as it w as 150 calories orless. Treatment included parent/family support counseling,  frequent assessment andmonitoring (every 2 w eeks), behavioral counseling, guidelines for dietary intake,and specific physical activity goals. | Subjects assigned to Diet B w ere instructed to follow a 1,500 kcal/day balanced(RS) diet, also w ith three meals and tw o snacks. How ever, both of the snacks in Diet Bw ere restricted to the healthy snack list.Subjects assigned to Diet B w ere instructed to follow a 1,500 kcal/day balanced(RS) diet, also w ith three meals and tw o snacks. How ever, both of the snacks in Diet Bw ere restricted to the healthy snack list. Treatment included parent/family support counseling, frequent assessment andmonitoring (every 2  w eeks), behavioral counseling, guidelines for dietary intake,and specific physical activity goals. |  |
| Intervention  type | Specific diet | Specific diet |  |
| Intervention  length | 12 w eeks | 12 w eeks |  |

|  |  |  |
| --- | --- | --- |
| Intensity as  described by authors | Subjects w ere monitored every 2 w eeks throughout the 12-w eek study. | Subjects w ere monitored every 2 w eeks throughout the 12-w eek study. |
| Assigned  intensity | 5-25 hours | 5-25 hours |
| Provider types | Primary care, nutrition provider | Primary care, nutrition provider |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 3 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Free snack | 17 | -1 | 1.17 | <0.01 | NS |
| Restricted Snack | 15 | -1.05 | 0.67 | <0.001 |  |

**Wright, Ja; Phillips, Bd; Watson, Bl; Newby, Pk; Norman, Gj; Adams, Wg**

**Randomized trial of a family-based, automated, conversational obesity treatment program for underserved populations**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | National Institute of Child and Human Development (NICHD R21 HD050939-02) |  |  |
| Country | USA |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the Boston University Medical Campus Institutional Review Board. Inf ormed w ritten consent from parents and assent from  children w as obtained. | | |
| Outcomes other  than BMI | Behaviors (parent and child) |  |  |
| Population | | | |
| Inclusion criteria | Patients w ere eligible to participate if they w ere (1) betw een 9 and 12 years old, (2) had a BMI 0-5 BMI points above the 95th percentile for age and gender,  (3) attended a pediatric visit w ithin the last year, and (4) w ere due for an annual w ell-child exam in the next 4 months. | | |
| Exclusion criteria | Exclusion criteria included cognitive impairment, terminal illness, eating disorder, special diet restrictions, participation in another w eight treatment program, or  spoke limited English. | | |
| Group  differences | Randomized |  |  |
| Special  populations | Low income, African American |  |  |
|  | HEAT (Healthy Eating and Activity Today) | WLC (Waitlist control) | Overall |
| N | 24 | 26 | 50 |
| Sex | 37.5% female | 46.2% female | 42% female |
| Age | 10.9 | 10.5 | 10.3 |
| Race | 70.8% African American, 0% w hite, 29.2% other | 73.1% African American, 15.4% w hite, 11.5% other | 72% African  AMerican, 6%  w hite, 22% other |
| BMI SDS | 1.9 | 2 | 1.9 |
| Interventions | |  |  |
|  | HEAT (Healthy Eating and Activity Today) | WLC (Waitlist control) |  |
| Intervention as described by authors | Both parents and children received a 12-w eek telephone counselingintervention delivered by an automated IVR system. The interven-tion also included an EHR behavioral counseling tool used by thePC clinician during w ell-child follow -up visits. Similar but separate interventions w ere developed for parents and children. The IVR w as designed to monitor, educate, and counsel parents andchildren on healthy w eight management and television time throughw eekly IVR telephone conversations. Both HEAT parents and children used the HEAT-IVR via w eekly‘‘inbound’’ telephone calls for 12 w eeks. The IVR w as designed to monitor, educate, and counsel parents andchildren on healthy w eight management and television time throughw eekly IVR telephone conversations. The PC component of HEAT  w as an EHR templatedesigned to provide data to the child’s pediatrician to support thepatient’s behavior change efforts and document the clinical encoun-ter. Data captured in the child IVR system w ere sent to the child’sEHR to assist the clinician w ith providing  counseling and clinicaldecision support at the point of care. | Dyads in the WLC condition received the same assessments as theHEAT group, w ere reminded to attend their w ell-child visit, andw ere offered the HEAT intervention post study. |  |
| Intervention type | Lifestyle | Lifestyle |  |

|  |  |  |
| --- | --- | --- |
| Intervention  length | 12 w eeks | 12 w eeks |
| Intensity as  described by authors | Both HEAT parents and children used the HEAT-IVR via w eekly‘‘inbound’’ telephone calls  for 12 w eeks. Participants w ho w ere notmaking calls received a reminder call from a research assistant. TheIVR system consisted of tw o calls per w eek. | Usual care |
| Assigned  intensity | 5-25 hours | <5 hours |
| Provider types | Primary care | Primary care |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, other (automated system) | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 3 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| HEAT (Healthy Eating and Activity Today) | 21 | -0.06 | 0.1 | <0.05 | 0.48 |
| WLC (Waitlist control) | 22 | -0.03 | 0.1 | NS |  |

**Yackobovitch-Gavan, M.; Wolf Linhard, D.; Nagelberg, N.; Poraz, I.; Shalitin, S.; Phillip, M.; Meyerovitch, J. Intervention for childhood obesity based on parents only or parents and child compared with follow-up alone**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This research w assupported by a Health Policy Research Grant fromthe Clalit Research Institute, Chief Physician Office | |  |  |
| Country | Israel |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the Institutional Review Board. Written inf ormed consent w as obtained from the parents prior to enrol- ment in the study | | |  |
| Outcomes  other than BMI | Blood pressure, lipids, glucose metabolism, behaviors |  |  |  |
| Population | | | | |
| Inclusion  criteria | clusion criteria w ere age 5 – 11 years and body mass index (BMI) betw een the 85th and 98th percentiles for age and sex. | |  |  |
| Exclusion  criteria | Exclu-sion criteria w ere chronic conditions (e.g. diabetesmellitus, cardiac or renal problems, uncontrolled hy-pertension, liver enzyme levels more than  threef oldabove the upper normal limit, genetic-syndromesand organic diseases associated w ith obesity), useof medication that might influence w eight. | | |  |
| Group  differences | Randomized |  |  |  |
| Special populations | None |  |  |  |
|  | Parents-only | Parents-Child | Control | Overall |
| N | 89 | 84 | 74 | 247 |
| Sex | 65.1% female | 70.2% female | 66.2%  female | 67%  female |
| Age | 8.7 | 8.5 | 8.1 | 8.4 |
| Race | NR | NR | NR | NR |
| BMI SDS | 1.8 | 1.78 | 1.78 | 1.79 |
| Interventions | |  |  |  |
|  | Parents-only | Parents-Child | Control |  |
| Intervention as defined by authors | The family-based intervention included 12 once-w eekly group meetings of 60 min each (12–15participants per meeting) w ith a dietician and psychol-ogist and focused on cognitive behavioural changesin the family lifestyle. In the parents-only group, at leastone parent attended the meeting. Each meetingf ocused on a  different nutritional or lifestyle goal | The family-based intervention included 12 once-w eekly group meetings of 60 min each (12–15participants per meeting) w ith a dietician and psychol-ogist and focused on cognitive behavioural changesin the family lifestyle. In theparents–child group, at least one parent and childattended separate group meetings. Each  meetingf ocused on a different nutritional or lifestyle goal | Usual care only |  |
| Intervention  type | Lifestyle | Lifestyle | Usual  care |  |
| Intervention  length | 12 w eeks | 12 w eeks | NA |  |
| Intensity as described by  authors | 12 60-min meetings, endocrinologist at 0, 3, 12, 24 months | 12 60-min meetings, endocrinologist at 0, 3, 12, 24 months | NA |  |
| Assigned  intensity | 5-25 hours | 5-25 hours | NA |  |
| Provider types | Specialist, nutrition provider, mental health | Specialist, nutrition provider, mental health | NA |  |
| Clinic setting | Specialty clinic | Specialty clinic | NA |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling | Usual  care only |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 3 months |  |  | 24 months | |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Parents-only | 58 | -0.08 | 0.03 | 0.44 | 45 | -0.05 | 0.05 | 0.208 |
| Parents-Child | 61 | -0.05 | 0.03 |  | 45 | -0.17 | 0.05 |  |
| Control | 49 | -0.03 | 0.03 |  | 37 | -0.1 | 0.05 |  |

**Yackobovitch-Gavan**

**Influence of weight-loss diets with different macronutrient compositions on health-related quality of life in obese youth**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Identification |  |  |  |  |
| Sponsorship  source | None listed |  |  |  |
| Country | Israel |  |  |  |
| Methods |  |  |  |  |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study w as approved by the local Ethics Committee for Research in Humans of the Israel Ministry of Health. Written inf ormed consent w as obtained  from all participants and their parents/legal guardian. | | | |
| Outcomes other  than BMI | Other obesity, psychosocial |  |  |  |
| Population |  |  |  |  |
| Inclusion criteria | adolescents aged 12–18 years,attending the Institute of Endocrinology and Diabetes at SchneiderChildren’s Medical Center of Israel betw een January and  March2005. Only subjects w ith a body mass index (BMI) above the 95thpercentile for age and sex w ere considered eligible. | | | |
| Exclusion criteria | Other exclusion criteria w ere presence of a chronic disease (such as diabetes, renal, heart or liver diseases, thyroid function disorder, or diagnosed psychological disorder), current treatment w ith a w eight-loss-inducing medication, and participation in another w eight-loss study or slimming diet w ithin the  previous 2 months | | | |
| Group differences | Randomized |  |  |  |
| Special populations | None |  |  |  |
|  | LCLF | LCHF | HCLF | Overal l |
| N | 18 | 17 | 36 | 71 |
| Sex | 7 male | 4 male | 18 males | 29  males |
| Age | 14.9 | 14.3 | 14.1 | 14.3 |
| Race | NR | NR | NR | NR |
| BMI SDS | 4.6 | 3.9 | 4.3 | 4 |
| Interventions | |  |  |  |
|  | LCLF | LCHF | HCLF |  |
| Intervention as described by authors | Low -carbohydrate (60 g, 20%), high-protein (150 g, 50%),low -fat (40 g, 30%); LCLF. All participant received menus and detailed instructionaccording to their diet group. | Low -carbohydrate (60 g, 20%), low -protein (60 g, 20%),high-fat (80 g, 60%); LCHF. All participant received menus and detailed instructionaccording to their diet group. | High-carbohydrate (150–180 g, 50– 60%), low -protein(60 g, 20%), low -fat (40 g, 30%); HCLF. All participant received menus and detailed instructionaccording to their diet  group. |  |
| Intervention type | Specific diet | Specific diet | Specific diet |  |
| Intervention length | 3 months | 3 months | 3 months |  |
| Intensity as  described by authors | Aspart of the intervention, they attended w eekly sessions w ith adietitian and a psychologist. | Aspart of the intervention, they attended  w eekly sessions w ith adietitian and a psychologist. | Aspart of the intervention, they  attended w eekly sessions w ith adietitian and a psychologist. |  |
| Assigned intensity | 5-25 hours | 5-25 hours | 5-25 hours |  |
| Provider types | Dietitian, mental health | Dietitian, mental health | Dietitian, mental health |  |
| Clinic setting | Research | Research | Research |  |
| Components | Nutrition counseling | Nutrition counseling | Nutrition counseling |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 3 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| LCLF | 15 | -0.93 | 0.9 | <0.001 | NS |
| LCHF | 12 | -0.62 | 0.5 | <0.001 |  |
| HCLF | 25 | -0.44 | 0.65 | 0.002 |  |
| BMI | | | | | |
|  | 3 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| LCLF | 15 | -2.8 | 2.3 | <0.001 | NS |
| LCHF | 12 | -2 | 1.7 | 0.002 |  |
| HCLF | 25 | -1.5 | 1.8 | <0.001 |  |

**Banos 2019**

**Efficacy of a cognitive and behavioral treatment for childhood obesity supported by the ETIOBE web platform**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This work was supported by grants PSI2008-04392/PSIC from de MICINN (Spain), PROMETEO/2008/157, CIBER Fisiopatologia de la Obesidad y Nutricion - ISCIII CB06/03/0052 from the SpanishGovernment, and grants from Ministry of Economy and Competitiveness (FPI-MINECO) (BES-2015-073982) and Ministry of Education  (FPU-MINECO) (FPU 14/04053). | | |
| Country | Spain |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Their parents signed the informed consent prior to their inclusion, following the guidelines ofthe Helsinki Declaration. The study was approved  by the Ethics Committee of the University of Valencia. | |  |
| Outcomes other  than BMI | Other obesity, behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | Inclusion criteria were age between 8 and 12 years, ability to use a computer andhaving an Internet connection at home, ability to understand and read  Spanish,availability to attend face-to-face sessions in the hospital, and the presence of over-weight valued with a BMI percentile >85 and a Z-score > 1. | | |
| Exclusion criteria | Exclusioncriteriawerethepresenceofany medical problem or pathology thatcould explain the overweight or obesity, suffering from an eating disorder or anysevere mental  disorder, and any physical problem that could hinder the PA practice. | | |
| Group differences | Randomized |  |  |
| Special Populations |  |  |  |
|  | CBT | CBT-E | Overall |
| N | 25 | 22 | 47 |
| Sex |  |  | 15 males, 32 females |
| Age |  |  | 10.43 |
| Race |  |  | NR |
| BMI-SDS | 2.27 | 2.14 |  |
| Interventions |  |  |  |
|  | CBT | CBT-E |  |
| Intervention as defined by author | Both treatments (CBT and CBT-E) are based on the  multidisciplinary protocol by Braetetal. (2007), which aims to achieve weight control in children through the promotionand  establishment of healthy eating habits and optimal PA levels. It is part of a CBTapproach that consists of three fundamental components in 10 sessions (90 minuteseach) with groups of 5–6 children: 1)Behavioral therapy techniques(i.e. self-observation,  self-instruction, role playing, stimulus control, self-reinforcement, pro-blem-solving); 2)Diet management strategies(i.e. know the nutritional pyramid, learnto eat consciously, learn healthy  recipes); and 3)Physical education guidelines(i.e. learnand perform  the different types of PA, know the frequency, duration, and intensity ofPA recommended by health guidelines). | The ETIOBE system is composed of 3 interconnected platforms through the Internet: 1)theClinician Support System(the clinician can set up both the evaluation and theintervention tofit the needs and progress of the patient); 2) theHome Support System(through their computers, children can contact their clinicians and access tasks and a series of serious  games (Baños, Cebolla, Oliver, Alcañiz, & Botella,2013) to consolidatetheir learning process); and 3) theMobile Support  System(children can register theirintake and the number of physical activities performed in real time, thus allowing thetreatment components to be adapted to the evolution of each patient (Oliver et  al.,2013).For more information about the ETIOBE web platform, see the article (Baños et al.,2011). |  |
| Intervention length | 10 weeks | 10 weeks |  |
| Intensity as  described by authors | 10 sessions (90 minuteseach) | 10 sessions (90 minuteseach) |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |
| Provider type | Psychologist | Psychologist |  |

|  |  |  |
| --- | --- | --- |
| Clinic setting | Specialty clinic (unit specialized in cardiovascular disease risk  associated with obesity) | Specialty clinic (unit specialized in cardiovascular disease risk associated  with obesity) |
| Components | Nutrition counseling, activity counseling, mental health (CBT) | Nutrition counseling, activity counseling, mental health (CBT) |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | Baseline |  |  | 3 months | |  |  |  |
|  | N | Mean | SD | p (between groups) | N | Mean | SD | p (between groups) |
| CBT | 25 | 2.27 | 0.32 |  | 25 | 2.21 | 0.36 | 0.18 |
| CBT-E | 22 | 2.14 | 0.21 |  | 22 | 1.99 | 0.33 |  |

**Bean 2018**

**Impact of motivational interviewing on outcomes of an adolescent obesity treatment: results from the MI Values randomized controlled pilot trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This study was supported by the American Cancer Society to MKB (PFT-08-144-01-CPPB) and the National Institutes of Health (K23HD053742 to EPW and UL1TR000058 to VCU). TEENS was funded by Virginia Premier Health Plan. These funding sources had no involvement with the conduct of the research or  preparation of the manuscript | |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Parents and adolescents provided informed consent and assent, respectively, prior to participation. Study procedures were approved by Virginia  Commonwealth University’s Institutional Review Board | |  |
| Outcomes other  than BMI | Behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | Eligibility criteria included: 1) ages 11–18 years, 2) body mass index (BMI) ≥85th percentile for age and gender,8 3) no underlying secondary etiology of  obesity (e.g., hypercortisolemia), and 4) a participating parent/caregiver. | |  |
| Exclusion criteria | No additional |  |  |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | MI (+TEENS) | Control (TEENS only) | Overall |
| N | 58 | 41 |  |
| Sex | 75.9% female | 70.7% female |  |
| Age | 13.6 (1.8) | 14.1 (1.7) |  |
| Race | 75.4% Black, 19.3% white, 5.3% other | 68.3% Black, 19.5% white, 12.2% other |  |
| BMI-SDS | 2.4 (0.3) | 2.4 (0.3) |  |
| Interventions | |  |  |
|  | MI (+TEENS) | Control (TEENS only) |  |
| Intervention as defined by author | Followed TEENS 6-mo behavioral treatment; Adolescents in the MI treatment participated in 30-minute, individual MI sessions at weeks 1 and 10 of TEENS. Interventionists followed a session roadmap, remaining adherent to MI throughout, with goals to elicit participant-determined reasons for change, highlight how engaging in TEENS is consistent with participant goals and values,  and build self-efficacy. (Not including TEENS overall, which is both groups.) | In the Control group, participants viewed 30-minute videos, focused on healthy eating and exercise. Control sessions were proctored by study interventionists, matched on contact, and delivered at the same intervals (weeks 1 and 10) as MI sessions. TEENS was a 6-month empirically-supported behavioral weight loss treatment implemented  at an academic medical center. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 10 weeks (MI addition only) | 10 weeks |  |
| Intensity as described by  authors | 30-minute, individual MI sessions at weeks 1 and 10 of TEENS | 30 minute education videos |  |
| Assigned intensity | <5 hours | <5 hours |  |
| Provider type | Other ("interventionist") | Other |  |
| Clinic setting | Multidisciplinary weight management clinic | Multidisciplinary weight management clinic |  |
| Components | Motivational interviewing, nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

Outcomes

BMI SDS

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Baseline |  |  | 3 months | |  |  | 6 months | |  |  |  |
|  | N | Mean | SD | p (between groups) | N | Mean | SD | p (between groups) | N | Mean | SD | p (between groups) |
| MI (+TEENS) | 58 | 2.41 | 0.32 |  | 58 | 2.37 | 0.34 | 0.472 | 58 | 2.38 | 0.34 | 0.977 |
| Control (TEENS only) | 41 | 2.39 | 0.29 |  | 41 | 2.36 | 0.29 |  | 41 | 2.36 | 0.27 |  |

**Crespo 2018**

**A randomized controlled trial to prevent obesity among Latino paediatric patients**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | All phases of this study were supported by an NIH NIDDK Grant # R01DK084331 |  |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The trial was conducted from 2012 to 2016 following Institutional Review Board (IRB) approval. | |  |
| Outcomes other than BMI | Other obesity |  |  |
| Population |  |  |  |
| Inclusion criteria | A two-stage recruitment process was undertaken, first identifying children from medical charts who had a BMI between the 75th and 98.9th percentile. These children were then invited for further screening to measure BMI and determine final eligibility. Other eligibility criteria for families were: 1) planning on living  in the target area for the study duration, 2) ability to understand and read Spanish or English, 3) willing to be randomized into one of the two experimental conditions and 4) willing/able to attend the intervention classes if randomized to that condition. | | |
| Exclusion criteria | Exclusion criteria included: 1) children on a medically-prescribed restricted diet, 2) children with a condition that limits their ability to be physically active or that would affect growth or participation in the intervention, and 3) children who participated in other clinic-based overweight/obesity programs within the  past year. | | |
| Group differences |  |  |  |
| Special populations | Latino, FQHC |  |  |
|  | Luces Intervention | Usual care | Overall |
| N | 149 | 148 | 297 |
| Sex | 46.3% female | 53.4% female | 49.8% female |
| Age (in months) | 98.0 (17.6) | 96.3 (19.6) | 91.2 (18.0) |
| Race | NR | NR | NR (All Hispanic) |
| BMI-SDS | 1.57 (0.44) | 1.54 (0.46) | 1.6 (0.5) |
| Interventions | |  |  |
|  | Luces Intervention | Usual care |  |
| Intervention as described by authors | The Luces intervention was structured within the Obesity Care Model and from expert panel recommendations. 9,10Luces emphasized changes in  parenting behaviors and improving parent-provider communication to reduce  child BMI and promote weight maintenance. The intervention targeted three child health behaviors (dietary behaviors, physical activity, and sedentary behaviors) and corresponding parenting behaviors (role modeling, parenting strategies, and restructuring the home environment). | The usual care condition consisted of standard clinical practices offered by pediatricians to pediatric patients with overweight/obesity (e.g., basic nutrition education, health education handouts, didactic education), including two one-on-one visits with a Health Educator, supplemented by follow-up visits with the patient’s primary care physician when  deemed clinically-appropriate. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 12 months | Varied |  |
| Intensity as described by authors | The components of the 12-month Luces program included: a) seven 1.5 – 2-  hour group classes with parents and children led by trained bilingual Luces Lay Health Educators, held over 6-months (four classes the first two months and three classes between three to six months; b) two visits at the clinic with a clinic mid-level provider (MLP; physician assistant) once before and once  after the seven group classes to reinforce key messages from the program; c)  six scripted phone calls (averaging 10 minutes in length) with the Lay Health Educator (LHE) after each of the first six group classes to reinforce concepts | The total contact time for participants in the usual care condition ranged from 1.25 to 2.25 hours. |  |

|  |  |  |
| --- | --- | --- |
|  | taught in class; and d) six monthly group booster classes. The total contact  time totaled 19.75 hours over the 12-month period. | |
| Assigned intensity | 5-25 hours | <5 hours |
| Provider type | Primary care, other (lay health educator) | Primary care, other (lay health educator) |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition training | Usual care only |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 12 months (T3) | | | | |
|  | N | Mean | SE | p (across groups) |
| Luces Intervention | 149 | 1.5 | 0.03 | 0.33 |
| Usual care | 148 | 1.46 | 0.03 |  |

**Ek 2019**

**A Parent Treatment Program for Preschoolers With Obesity: A Randomized Controlled Trial**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Identification |  |  |  |  |
| Sponsorship source | Supported by the Swedish Research Council (2014-02404), Karolinska Institutet Doctoral Funds, the Swedish Society of Medicine, Vinnova (2011-3443), theJerring Foundation, the Samariten Foundation for Paediatric Research, the Magnus Bergvall Foundation, the Ingrid and Fredrik Thuring Foundation, the Helge Ax:sonJohnsons Foundation, the Her Royal Highness Crown Princess Lovisa’s Foundation, the Frimurare Barnhuset Foundation, the Pediatric Care Foundation, the MartinRind Foundation, the Jane and Dan Olssons Foundation, the ClasGroschinsky Foundation, the Sigurd and Elsa Golje’s Memory Foundation, the ìShizu Matsumuraîs Donation, the National  Institute on Drug Abuse United States Public Health Service grant P50DA035763 from the Division of Epidemiology, Services, and Prevention Research | | | |
| Country | Sweden |  |  |  |
| Methods |  |  |  |  |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study was approved by the ethics committee in Stockholm, Sweden on November 16th, 2011 (dnr: 2011/1329-31/4),and the trial protocol is available in Supplemental Information. | |  |  |
| Outcomes other  than BMI | Other obesity |  |  |  |
| Population |  |  |  |  |
| Inclusion criteria | Families were eligible for participation if the child was 4 to 6 years old, was diagnosed with obesity according to international recommendations, and had no other chronic diseases or developmental problems likely to influence child weight and height. In addition, parents had to be able to communicate in Swedish well enough to  complete questionnaires and participate in treatment conducted in Swedish. | | | |
| Exclusion criteria | No additional |  |  |  |
| Group differences | Randomized |  |  |  |
| Special populations | Young children (4-6 yo) |  |  |  |
|  | Booster | No booster | ST | Overall |
| N | 44 | 43 | 87 | 174 |
| Sex | 43.2% female | 53.2% female | 64.4% female | 56.3%  female |
| Age | 5.2 (0.8) | 5.2 (0.8) | 5.3 (0.7) | 5.3 (0.8) |
| Race | NR | NR | NR | NR |
| BMI-SDS | 3.0 (0.5) | 3.1 (0.7) | 2.9 (0.6) | 3.0 (0.6) |
| Interventions | |  |  |  |
|  | Booster | No booster | ST |  |
| Intervention as  described by author | The ML program was developed incollaboration with the KEEP programdevelopers,8–12with conceptual  andcultural adaptations designed tofitthe Swedish  population of parents ofpreschoolers with obesity. The keyconcept of KEEP is to support parentsin positive  parenting practices (eg,encouragement and limit- settingstrategies) to improve parent-  childcommunication.8,10,12Contentregarding healthy food habits andphysical activity was also included.  Inaddition, inspired by the PMTO,techniques to regulate emotionalcontrol were added. The booster  sessionsconsisted of 30-minute phone calls(maximum 7) every 4 to 6 weeks for9 months. During the  boostersessions, a group leader encouragedthe parents to maintain healthy habitsand provided support for | The ML program was developed incollaboration with the KEEP programdevelopers,8–12with conceptual andcultural adaptations designed tofitthe Swedish population of parents  ofpreschoolers with obesity. The keyconcept of KEEP is to support parentsin positive parenting practices (eg,encouragement and limit-  settingstrategies) to improve parent- childcommunication.8,10,12Contentregarding healthy food habits andphysical activity was also included. Inaddition, inspired by the PMTO,techniques to regulate emotionalcontrol were added. No booster calls | ST focused on healthy food choices and active lifestyle habits during clinic visits. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | challengesby reminding them about thestrategies  covered during theprogram. |  |  |
| Intervention type | Lifestyle | Lifestyle | Lifestyle |
| Intervention length | 10 weeks + 9 months [30-minute phone calls (maximum  7) every 4 to 6 weeks] | 10 weeks | 12 months |
| Intensity as described by authors | Ten 90-minute weekly sessions with parents. The booster  sessions consisted of 30-minute phone calls (maximum 7) every 4 to 6 weeks for 9 months to support lifestyle  changes. . | Ten weekly 90 minute sessions with parents | Families were offered individual visits of ∼30 minutes over 12 months |
| Assigned intensity | 5-25 hours | 5-25 hours | <5 hours |
| Provider type | Primary care, nutrition provider | Primary care, nutrition provider | Primary care |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Nutrition counseling, other (parenting) | Nutrition counseling, other (parenting) | Nutrition counseling, activity  counseling |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS ` |  |  |  |
| 12 months | | | |
|  | N | Mean | P (between groups) |
| Booster | 44 | -0.54 | <0.01 |
| No booster | 43 | -0.11 |  |
| ST | 87 | -0.04 |  |

**Farpour-Lambert 2019**

**Effectiveness of individual and group programmes to treat obesity and reduce cardiovascular disease risk factors in pre-pubertal children**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | This project was supported financially by the Swiss National Science Foundation (#3200B0-120437) and the Geneva University Hospitals  Research and Development Fund | | |  |
| Country | Switzerland |  |  |  |
| Methods | | | | |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The Ethics Committee of the University Hospitals of Geneva approved this study and informed  written consent was obtained from all participating parents and children. | |  |  |
| Outcomes other than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other labs(hsCRP), other (CV fitness) | |  |  |
| Population | | | | |
| Inclusion criteria | 74 pre-pubertal newpatients with obesity aged 7.5 to 11.9 years who were recruited overa 4-year period at the Obesity Clinic of the Children's Hospital ofGeneva (tertiary centre), if their BMI was >97th age- and gender-specific percentile according to the World Health  Organization(WHO) references | | | |
| Exclusion criteria | Subjects were excluded from the study if they: (a) had a Tanner stageassessed by clinical examination (sizeof the breasts or testicular  volume,and development of pubic hair) >1; (b) were involved in any weight con-trol, physical activity, behavioural intervention or bariatric surgery; (c) hada family history of dyslipidaemia or essential hypertension; (d) took anymedications or hormones that could affect  cardiovascular function, bodycomposition, lipid or glucose metabolism; (e) had an orthopaedic conditionthat limited physical activity; (f) had a  genetic disorder or another chronicdisease; and (g) received therapy for psychiatric problems | | | |
| Group differences | Self selection in group/individual. Differences in gender, but reported NS. | |  |  |
| Special populations |  |  |  |  |
|  | Individual | Group | Control | Over  all |
| N | 21 | 31 | 22 | 74 |
| Sex | 62% male | 39% male | 59% male | 38 |
| Age | 9.5 (1.2) | 9.7 (1.1) | 9.7 (1.0) | NR |
| Race | NR | NR | NR | Whit  e = 87% |
| BMI-SDS CDC | 2.1 (0.5) | 2.1 (0.3) | 2.0 (0.5) | NR |
| Interventions | |  |  |  |
|  | Individual | Group | Control |  |
| Intervention as described by  authors | The moderate-intensity individually delivered intervention (treatment A) comprised 7 monthly 60-minute  sessions with the child and his/her parent/s(at least the mother), which were conducted by a trained  paediatrician (at 0, 3 and 6 months) and a dietician (at 1, 2, 4 and 5 months). | The high-intensity group delivered intervention  (treatment B) comprised 14 sessions (11 weekly then 3 monthly meetings, total35 hours) over a 6-month period. Ideally both parents, but at least themother, were asked to participate. Parental and child sessions wereheld separately. The parental group sessions consisted of 90 minutes with a dietician (at all  sessions), a psychologist trained in cognitive  behavioural therapy (at least four sessions) or a paediatrician experienced in therapeutic patient | Controls received standard care for 12 months, which included four 45- minute paediatric consultations (every 3 months) and instruction to maintain their current level of  physical activity. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | education. The child sessions consisted of 60 minutes  with the same therapists. Each group included 10 to  12 children and their parents. |  |
| Intervention type | Lifestyle | Lifestyle | Lifestyle |
| Intervention length | 6 months | 6 months | 12 months |
| Intensity as described by authors | 7 monthly 60-minute sessions (at 0, 3 and 6 months) and a dietician (at 1, 2,  4 and 5 months) - 7 hours + 44 hours physical activity | 14 sessions (11 weekly then 3 monthly meetings, total 35 hours) over a 6-month period. +44 hours physical activity | four 45-minute paediatric consultations |
| Assigned intensity | 26-51 hours (including PA sessions) | > 52 hours (including PA sessions) | <5 |
| Provider type | Primary care, nutrition provider,  exercise | Primary care, nutrition provider, exercise, mental  health | Primary care |
| Clinic setting | Multidisciplinary weight management  + school (PA) | Multidisciplinary weight management + school (PA) | Multidisciplinary weight  management clinic |
| Components | Nutrition counseling, activity  counseling, activity training | Nutrition counseling, activity counseling, activity  training | Usual care |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  | 12 months | |  |  |  |  |  |
|  | N | Mean | CI (lower) | CI (upper) | p (vs control) | p (compare tx groups) | N | Mean | CI (lower) | CI (upper) | p (vs control) | p (compare tx groups) |
| Individual | 21 | -0.06 | -0.13 | 0.03 | NS | NS |  | -0.02 | -0.15 | 0.11 | NS | <0.05 |
| Group | 31 | -0.08 | -0.15 | 0 | <0.05 |  |  | -0.1 | -0.22 | 0.01 | <0.05 |  |
| Control | 22 |  |  |  |  |  | 22 | |  |  |  |  |

**Fedele 2018**

**A Behavioral Family Intervention for Children with Overweight and Asthma**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This work was supported by grant ALASB88692 from the American Lung Association and UL1TR001427 from the National Institutes of Health. | | |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The Institutional review board approved the current study. |  |  |
| Outcomes other than BMI | Mental health (quality of life), other (asthma-related measures) |  |  |
| Population |  |  |  |
| Inclusion criteria | children were 6–12 years-old, had a physician-verified persistent asthma diagnosis, and had a BMI ≥ 85th percentile for Centers for  Disease Control and Prevention age and gender norms | |  |
| Exclusion criteria | Youth were excluded if they had history positive for dietary restrictions, medical conditions in which physical activity is contraindicated, prescribed antipsychotic agents, or significant developmental delay. Families could not be enrolled in another weight loss program. | |  |
| Group differences | Note large dropout, including greater intervention dropout. |  |  |
| Special populations | Children with asthma |  |  |
|  | CHAMP | Health education control | Overall |
| N | 14 | 10 | 24 |
| Sex | 57% female | 50% female |  |
| Age | 8.64 (1.78) | 8.70 (2.16) |  |
| Race | 21% white, 71% Black, 7% other | 10% white, 60% Black, 30% other |  |
| BMI-SDS | 2.16 (0.50) | 2.26 (0.58) |  |
| Interventions | |  |  |
|  | CHAMP | Health education control |  |
| Intervention as described by authors | roups emphasized modeling and providing support to work together to establish healthier eating and exercise patterns. Both parent and child sessions were designed to last approximately 90 minutes and include  three segments: 1) a review of parent and child progress in implementing the strategies recommended for changing their eating or exercise in the previous session; 2) skills training and implementation; and 3) goal  setting, feedback, and encouragement from group leaders and members.  Parent group topics included benefits of weight loss, basics of energy balance and nutrition, appropriate methods for increasing physical  activity, establishing healthy eating patterns, proper portion size for  foods, healthy cooking strategies, meal planning on a limited budget,  eating healthy when eating out, improving self-esteem and body image, behavior management, and positive parenting skills (e.g., goal setting,  self-monitoring, stimulus control, etc.). Guidelines driven asthma  management education components including asthma physiology,  medication administration guidance, trigger control, and effective collaboration with the health care system were reviewed. | Dyads randomized to the HEC condition received national guidelines on asthma management, proper nutrition, physical activity, stress management, dental hygiene, and school-related difficulties, among other health-related topics. Families in the HEC condition did not receive  training in behavioral self-regulation strategies, such as goal-setting, self-monitoring, or problem-solving. Children participated in fun, physically active games during each  session (e.g. freeze tag, relay races) but there was no  discussion of implementing these activities in other  settings. Similar to the CHAMP condition, sessions were approximately 90 minutes. In between sessions, families were asked to complete tasks related to session content  (e.g. finding a newspaper article related to healthy eating) |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intensity as described by authors | 12 group-based sessions (3 sessions per month) and 4 individual family sessions (1 session per month) that occurred on weekday evenings. (90  minutes) | 12 group-based sessions (3 sessions per month) and 4 individual family sessions (1 session per month) that  occurred on weekday evenings. (90 minutes) |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider type | Primary care (referral), Health educator and subspecialist (asthma) | Primary care (referral), Health educator and subspecialist  (asthma) |
| Clinic setting | Primary care, specialty clinics | Primary care, specialty clinics |
| Components | nutrition counseling, activity counseling, mental health, motivational  interviewing | Nutrition counseling, activity counseling, activity training |
| Intervention length | 16 weeks | 16 weeks |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| Post-treatment (16 weeks) | |  |  | 6 month follow-up | |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| CHAMP | 6 | -0.08 | 0.16 | 0.47 | 6 | -0.12 | 0.24 | 0.32 |
| Health education control | 6 | -0.02 | 0.07 |  | 6 | 0.01 | 0.2 |  |

**Forsell 2019**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | Research grants from The Healthcare sub-committee, Region V€astra G€otaland, Sweden and The Local Researchand Development Council, So¨ dra A¨ lvsborg, Sweden. | | |
| Country | Sweden |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study was approved by the Ethics Committee of G€oteborg University (registered as € O348-03 addendum T276-09). Informed consent was  obtained from the parents of all participants. | |  |
| Outcomes other than BMI | Other obesity, blood pressure |  |  |
| Population |  |  |  |
| Inclusion criteria | Pre-pubertal childrenwith obesity (n=64) at four paediatric primary care clinicsin western Sweden | |  |
| Exclusion criteria | A second original control group with obesity (n=138) did not participate. |  |  |
| Group differences | No difference for intervention groups at baseline (randomized). After 4 years, the mean age was 15.1 (SD 1.4) and 15.5 (SD 1.0) years and the  mean follow-up time 4.5 (SD0.72) and 4.5 (SD 0.47) years in the Nurse-Dietician-Physiotherapist Treatment and Nurse-Dietitian-Treatment groups, respectively. For the Normal Weight controls, their mean age was 15.1 (SD 1.3) and mean follow-up time 4.1 (SD 0.70) years. | |  |
| Special populations |  |  |  |
|  | Nurse, dietician, physiotherapist (NDPT) | Nurse & dietician (NDT) | Overall |
| N | 27 | 29 | 56 |
| Sex | NR | NR | NR |
| Age | 15.1 (1.4) | 15.5 (1.0) | NR |
| Race | NR | NR | NR |
| BMI-SDS | 3.19 (0.56) | 3.15 (0.39) | 3.17 (SD 0.48) |
| Interventions | |  |  |
|  | Nurse, dietician, physiotherapist (NDPT) | Nurse & dietician (NDT) |  |
| Intervention as described by authors | Both treatment arms targeted behaviours related to diet and physical activity in the child and its family aiming to promote  stepwise changes to a healthier lifestyle (15). The roles of the nurse  and dietician were described in a common protocol. Non-  stigmatising communication motivational interviewing and elements of cognitive from behavioural treatment were used. On top of these common parts, the physiotherapist used incentives, pedometers and special fill-in forms to  encourage changes behaviours related to physical activity | 12-monthsintervention managed by r by a nurse anda dietician (six  appointments each). Both treatment armstargeted behaviours related to diet and physical activity inthe child and its family aiming to promote  stepwise changesto a healthier lifestyle |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 12 months | 12 months |  |
| Intensity as described by  authors | 12 appointments | 12 appointments |  |
| Assigned intensity | 5-25 hours | 5-25 hours |  |
| Clinic setting | Primary care | Primary care |  |
| Components | Nutrition counseling, motivational interviewing, mental health (CBT  elements), activity counseling | Nutrition counseling, motivational interviewing, mental health (CBT  elements), activity counseling |  |

**Four-year outcome of randomly assigned lifestyle treatments in primary care of children with obesity**

Provider type Primary care, nutrition, exercise Primary care, nutrition

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
| 4 years (change from baseline) | | | |
|  | N | Mean | SD |
| Nurse, dietician, physiotherapist (NDPT) | 27 | -0.5 | 0.73 |
| Nurse & dietician (NDT) | 29 | -0.26 | 0.73 |

**Kokkvoll 2020**

**No additional long-term effect of group vs individual family intervention in the treatment of childhood obesity-A randomised trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | The research study was supported by Northern Norway Regional Health Authority. GDCB was supported by an Alberta Health Services Chair in Obesity Research. | |  |
| Country | Norway |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | TheRegionalCommitteeforMedicalandHealthResearchEthics,RegionNorthapprovedthestudy,anditwasconductedinaccord‐  ancewiththeHelsinkiDeclaration.Theparentsprovidedwritteninformedconsent,andallchildren≥12yearsgavetheir | |  |
| Outcomes other than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other labs, other (fitness) |  |  |
| Population |  |  |  |
| Inclusion criteria | childrenaged6‐12yearswithoverweightorobesity10fromsixmunicipalitiesinFinnmarkcounty  Also see previous reports | |  |
| Exclusion criteria | None noted |  |  |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | Individual family intervention | Group intervention | Overall |
| N | 46 | 45 |  |
| Sex | 48% female | 60% female |  |
| Age | 10.5 (1.7) | 10.1 (1.7) |  |
| Race | NR | NR |  |
| BMI-SDS | 2.81 (0.60) | 2.76 (0.58) |  |
| Interventions | |  |  |
|  | Individual family intervention | Group intervention |  |
| Intervention as  described by authors | 8). Individual family intervention included counselling by a  paediatric hospital team and a pub ‐lic health nurse in the local community. | Group intervention included meetings with other families and a multidisciplinary hospital team, weekly physical activity sessions and a family camp. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 24 months | 24 months |  |
| Intensity as described by authors | children in individual family intervention were offered 11 hoursof health‐care provider contact | peers in the group in ‐tervention were offered 119 hours of contact, which included 76 hours of PA sessi |  |
| Assigned intensity | 5-25 hours | >=52 hours |  |
| Provider type | Primary care, nutrition provider | Primary care, nutrition provider, exercise |  |
| Clinic setting | Primary care | Inpatient, primary care |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling, activity training |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
| 36 months | | | |
|  | N | Mean | P (between groups) |
| Individual family intervention | 46 | -0.13 | 0.15 |
| Group intervention | 45 | -0.24 |  |

**Koziol-Kozakowska 2019**

**A Comparison of the Impact of Two Methods of Nutrition-Behavioral Intervention on Selected Auxological and Biochemical Parameters in Obese Prepubertal Children-Crossover Preliminary Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This research was funded by Jagiellonian University Medical College grant number K/ZDS/007918. |  |  |
| Country | Poland |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Crossover |  |  |
| IRB | All parents of participants gave their informed consent for inclusion before they participated in thestudy. The study was conducted in accordance with  the Declaration of Helsinki, and the protocol was approved by the Jagiellonian University Medical College Committee of Bioethics—Decision number1072.6120.231.2017 | |  |
| Outcomes other than BMI | Other obesity, blood pressure, glucose metabolism, lipids, other labs, other (physical function) |  |  |
| Population |  |  |  |
| Inclusion criteria | Age was 6.1–11.4 before puberty (Tanner stage 1) with obesity |  |  |
| Exclusion criteria | Exclusion criteria were: Overt metabolic complications ofobesity (hypertension or diabetes mellitus) except abnormal lipid values and fatty liver  features inan ultrasound examination, diagnosed abnormalities of the endocrine system, or a lack of consentto participate in the study. | |  |
| Group differences | Randomized, but large difference in BMI at baseline |  |  |
| Special populations |  |  |  |
|  | Intensive intervention | Standard intervention | Overall |
| N | 11 | 9 | 20 |
| Sex | NR | NR | 30% male |
| Age | NR | NR | 8.9 (1.4) |
| Race | NR | NR | NR |
| BMI-SDS | 3.19 (1.3) | 4.47 (1.8) | 3.76 (1.6) |
| Interventions | |  |  |
|  | Intensive intervention | Standard intervention |  |
| Intervention as  described by authors | At the first visit (60 min), the dietician (A.K-K) assessed the current diet based on the 24- hnutritional interview. At subsequent control visits, which took place every 2–3 weeks, diets were discussed on the basis ofdietary records, modifications of the diet were introduced, and the progress of each child and family wasmonitored. Though the program was not based on any  specific psychological strategies, the dieticianand doctors continuously tried to give the children a positive motivation for lifestyle change. At every visit, all participants underwent two motor and fitness tests. These included the standingbroad jump (explosive muscular strength) and crunches for 30 s (abdominal muscular endurance).Data were obtained using the procedures described in the Eurofit Test Handbook, adjusted for obesechildren [20]. All children received encouragement from the investigators in order to achieve maximum  performance. Everyone received the recommendation to do exercises every day at home. | Patients received a diet appropriate to their age and recommendations for modifying  dietarybehaviors the same as the patients in the  intensive group, but there were no follow-up visits nor dietarymodifications made on a current basis. All children and parents received encouragement from the investigators in order to increase  dailyphysical activity, and 60 min of exercise per day were recommended. No diary or other forms of controlwere used. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 3 months | 3 months |  |
| Intensity as  described by authors | First visit, control visits every 2-3 weeks | No follow-up visits |  |
| Assigned intensity | 5-25 hours | <5 hours |  |
| Provider type | Primary care, nutrition provider | Primary care, nutrition provider |  |
| Clinic setting | Multidisciplinary weight management program | Multidisciplinary weight management program |  |
| Components | Nutrition counseling, activity counseling | Nutrition counseling, activity counseling |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| End of intensive intervention (3 months) | | | | |
|  | N | Mean | SD | P Value |
| Intensive intervention | 20 | -0.5 | 0.5 | 0.09 |
| Standard intervention | 20 | -0.2 | 0.6 |  |

**Kumar 2018**

**Family-Based Mindful Eating Intervention in Adolescents with Obesity: A Pilot Randomized Clinical Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | The funding for the study was provided by the Sanford T. Denny Sanford Pediatric Collaborative Research Fund. | |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The trial was registered on ClinicalTrials.gov (NCT01764113), and was approved by the Mayo Clinic Institutional Review Board (12-006349) | |  |
| Outcomes other than BMI | Other obesity, glucose metabolism, lipids, other labs, other  (self-efficacy) |  |  |
| Population |  |  |  |
| Inclusion criteria | Adolescents between the ages of 14–17 years were considered eligible if their body mass index (BMI) was at or above the 95th percentile for  age and gender. | |  |
| Exclusion criteria | Exclusion criteria included: (i) currently attending a supervised weight loss program; (ii) underlying genetic or endocrine cause for weight  gain; (iii) type 1 or type 2 diabetes mellitus; (iv) ongoing treatment with receiving insulin, metformin, or oral hypoglycemic medications; (v) use of oral glucocorticoids in the previous two months; (vi) current cancer; (vii) established diagnosis of psychiatric illness in the previous six months;  (viii) inability of the participant or parent to provide informed assent/consent or inability of the same parent to attend all of the intervention sessions and(ix) study visits along with their adolescent. | |  |
| Group differences | Randomized |  |  |
| Special populations | Adolescents |  |  |
|  | Standard Dietary Counseling | Mindful Eating Intervention | Overall |
| N | 11 | 11 | 22 |
| Sex | 63.6% male | 45.5% male | Male =54.5% |
| Age | 15.6 | 17.1 | NR |
| Race | 10/11 white | 9/11 white | White=19 |
| BMI-SDS | 2.4 | 2.5 | NR |
| Interventions | |  |  |
|  | Standard Dietary Counseling | Mindful Eating Intervention |  |
| Intervention as described by authors | The dietary counseling in the SDC group focused on portion control, decreasing intakesof calorie dense fast food/convenience store foods, and substituting with healthier foods consistentwith routine care for youth with obesity.  Throughout each session, the focus was on further  educatingteens and their caregiver through discussion and utilization of educational tools, such as using theprovided meal to discuss portion control, satiety, energy density, and the nutrients provided in thefood. In addition, using  meaningful food labels, food models, and various plate, cup, and bowl sizesto engage thought provoking discussion were used along with the didactic means of educating teensand their care provider. | The program had two components: an approach toward mindfulness, and an  application of themindfulness principles to eating. The first session emphasized mindfulness and stress managementstrategies, including brief practices to improve attention and bring greater gratitude and compassionin life. In the next three sessions, participants learned mindful eating principles, including learning tobe more cognizant of what one is eating, attuning with one’s body to assess hunger and appropriatesize of serving, cultivating gratitude for food  and its preparers, relaxing for a moment prior to eating,paying purposeful  attention to the color and aroma of food, eating slowly in small bites, enjoying eachbite fully, and paying attention to the sensation of fullness from the  stomach. Participants were alsotaught skills to avoid automatic eating, develop better self-control when offered appetitive caloriedense foods, and shopping with better awareness of the calorie density and nutritive value of foods.Each session offered a combination of a scientific perspective combined with stories  and specific skillsin mindfulness and mindful eating. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 24 weeks | 10 weeks |  |

|  |  |  |
| --- | --- | --- |
| Intensity as described by authors | Adolescent/parent pairs in the SDC arm received three 90-min  sessions of dietary counseling(parents and adolescents  together) by a registered pediatric dietician at baseline, 12 weeks, and24 weeks. | The mindful eating program was administered over four 90-min sessions (baseline, 1 week,6 weeks, and 10 weeks |
| Assigned intensity | <5 hours | 5-25 hours |
| Provider type | Primary care, nutrition | Primary care, other ("mind-body therapist") |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling | Nutrition counseling, other (mindfulness) |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
| 12 weeks | |  |  |  | 24 weeks | |  |  |  |  |
|  | N | Mean | CI (lower bound) | CI (upper bound) | p (across groups) | N | Mean | CI (lower bound) | CI (upper bound) | p (across groups) |
| Standard Dietary Counseling | 10 | -0.1 | -0.2 | 0 | NS | 10 | 0.2 | 0.1 | 0.2 | NS |
| Mindful Eating Intervention | 11 | 0.1 | 0 | 0.2 |  | 11 | 0.2 | 0 | 0.4 |  |

**Miguet 2019**

**Effect of HIIT versus MICT on body composition and energy intake in dietary restrained and unrestrained adolescents with obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | The authors want to thank the French National Academy of Medicine, the French National University institute, the Nestlé Foundation and the Auvergne Rhône-Alpes County for their support. | |  |
| Country | France |  |  |
| Setting |  |  |  |
| Comments |  |  |  |
| Authors name |  |  |  |
| Institution |  |  |  |
| Email |  |  |  |
| Address |  |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | This study was conducted in accordance with the Helsinki declaration and received an ethical agreement from official authorities (CPP Sud Est VI:  AU1178; Clinical Trial NCT02482220).All of the adolescents and their legal representatives received information sheets and signed consent forms as requested by the local ethical authorities. | |  |
| Outcomes other than  BMI | Other obesity, behaviors, other (dietary restraint, V02) |  |  |
| Population |  |  |  |
| Inclusion criteria | Convenience sampling was employed based on our clinical recruitment  through local pediatrician consultations. To be included, participants had to: i) be aged between 11 and 15 years; ii) be between Tanner stage 3 to 5 iii) present a BMI greater than or equal to  the 95th percentile for their gender and age; iv) be free of any medication that could interact with the protocol (e.g., thyroid medication, stimulant medication, medication for diabetes); v) present no contraindication to physical activity; vi) self-report less than 2 hours of physical  activity per week (International Physical Activity Questionnaire – IPAQ). | |  |
| Exclusion criteria | No additional |  |  |
| Group differences | No differences |  |  |
| Special populations |  |  |  |
|  | MICT | HIIT | Overall |
| N | 21 (25 initially) | 22 (25 initially) | 43 (50  initially  enrolled) |
| Sex |  |  | 72% female |
| Age |  |  | 13.6 (1.5) |
| Race |  |  | NR |
| BMI-SDS | 36.6 (4.3) BMI | 34.8 (4.5) BMI | 2.3 (0.3) |
| Interventions | |  |  |
|  | MICT | HIIT |  |
| Intervention as  described by authors | The 16-week residential multidisciplinary weight loss program combined physical activity (4/week), nutritional education (2/month) and psychological support (1/month). During the intervention, the adolescents were prescribed a isocaloric diet  based on their age and sex recommendations (Murphy and Poos 2002). Physical activity included aquatic activities | The 16-week residential multidisciplinary weight loss program combined physical activity (4/week), nutritional education (2/month) and psychological support (1/month). During the intervention, the adolescents were prescribed a isocaloric diet based on their age and sex recommendations (Murphy and  Poos 2002). Physical activity included aquatic activities (1/week, activities such as water aerobics and various games realized while immersed), leisure-time |  |

|  |  |  |
| --- | --- | --- |
|  | (1/week, activities such as water aerobics and various games  realized while immersed), leisure-time activities (e.g., soccer and basketball games and exercises, 1/week) and either MICT +  strength training or HIIT + strength training (2/week). The MICT group (n=21) trained 45 minutes two times per week on ergometer bicycle at 60% of their initial VO2peak, followed by  strength training. | activities (e.g., soccer and basketball games and exercises, 1/week) and  either MICT + strength training or HIIT + strength training (2/week). The HIIT group (n=22) performed 15 minutes intermittent exercise two times per week on ergometer bicycle, alternating 30 seconds intense exercise and 30 seconds active recovery (free but compulsory pedaling), also followed by strength training. The intensity for HIIT followed a progressively increased from 75% of baseline  VO2peak, ending at 90%. |
| Intervention type | Lifestyle | Lifestyle |
| Intervention length | 16 weeks | 16 weeks |
| Intensity as described by authors | The 16-week residential multidisciplinary weight loss program  combined physical activity (4/week), nutritional education (2/month) and psychological support (1/month). | The 16-week residential multidisciplinary weight loss program combined  physical activity (4/week), nutritional education (2/month) and psychological support (1/month). |
| Assigned intensity | >=52 hours | >=52hours |
| Provider type | Primary care, nutrition provider, exercise, mental health | Primary care, nutrition provider, exercise, mental health |
| Clinic setting | Inpatient multidiscplinary weight management | Inpatient multidisciplinary weight management |
| Components | Nutrition counseling, activity counseling, activity training, mental  health | Nutrition counseling, activity counseling, activity training, mental health |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 16 weeks | | | | |
|  | N | Mean | SD | P Value |
| MICT | 21 | -2.26 | 1.3 | 0.069 |
| HIIT | 22 | -3.03 | 1.4 |  |

**Moschonis 2019**

**Assessment of the Effectiveness of a Computerised Decision-Support Tool for Health Professionals for the Prevention and Treatment of Childhood Obesity. Results from a Randomised Controlled Trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This research is implemented through IKY scholarships programme and co-financed by the EuropeanUnion (European Social Fund—ESF) and  Greek national funds through the action entitled “Reinforcement ofPostdoctoral Researchers”, in the framework of the Operational Programme “Human Resources DevelopmentProgram, Education and Lifelong Learning” of the National Strategic Reference Framework (NSRF) 2014–2020. | |  |
| Country | Greece |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB |  |  |  |
| Outcomes other than BMI | Other obesity, behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | The main eligibility criteriafor inclusion in the RCT were children aged 6–12 years old, as well as overweight or obese status(i.e., BMI-for-age85th  percentile). | |  |
| Exclusion criteria | No additional |  |  |
| Group differences | Maternal mean BMI of children in control group was higher than the intervention group . |  |  |
| Special populations |  |  |  |
|  | DST | Control | Overall |
| N | 35 | 30 | 65 |
| Sex | NR | NR | NR |
| Age | 9.8 (0.3) | 9.6 (0.2) | 9.7 (0.2) |
| Race | NR | NR | NR |
| BMI (SDS not reported) | 2.56 (0.7) | 25.2 (0.7) | 25.1 (0.5) |
| Interventions | |  |  |
|  | DST | Control |  |
| Intervention as described by authors | The development of the computerised DST is based on decision-tree algorithms  (SupplementaryFigure S1 provides an example of these algorithms), which include five different levels, namely the“assessment of children’s current weight status” (level 1), the “assessment of the likelihood for thefuture manifestation of obesity in normal-weight children” (level 2), the “evaluation of the mostappropriate body weight management goal” (level 3), the “estimation of children’s  dietary energy andmacronutrients intake needs” (level 4) and the delivery of “personalised diet and lifestyle optimisationadvice” (level 5). Those children that were randomly allocated to theintervention group (IG), were examined by paediatricians (i.e., general paediatricians and  paediatricendocrinologists) and a dietitian, who were all trained in the use of the DST. A manual of operation withdetailed instructions on the use of the DST was prepared and distributed to medical practitioners priorto the commencement of the study. The dietitian also assisted the paediatricians to assess children’sweight status, to set appropriate weight management goals and to provide  personalised meal plansand/or recommendations to children and their families. I | Those families whose children  wererandomly allocated to the control group (CG), were provided with general recommendations of dietand physical  activity and follow-up appointments were  made for weight checks. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | Unclear (I think one encounter) | Unclear (I think one encounter) |  |
| Intensity as described by authors | Varies: "The DST follows five steps dictated by the decision tree algorithms (Supplementary Figure S1provides the relevant steps) to propose personalised lifestyle optimisation recommendations  andweekly meal plans." | Varies: "The DST follows five steps  dictated by the decision tree algorithms (Supplementary Figure S1provides the relevant steps) to propose personalised |  |

|  |  |  |
| --- | --- | --- |
|  |  | lifestyle optimisation recommendations  andweekly meal plans." |
| Assigned intensity | <5 hours | <5 hours |
| Provider type | Primary care, subspecialist, nutrition provider | Primary care |
| Clinic setting | Specialty clinic | Primary care |
| Components | Nutrition counseling, other (decision support tree for providers) | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 3 months | | | | | |
|  | N | Mean | CI (lower bound) | CI (upper bound) | p (across groups) |
| DST | 35 | -0.2 | -0.3 | 0.05 | 0.318 |
| Control | 30 | 0.1 | -0.02 | 0.2 |  |

**Njardvik 2018**

**Incorporating Appetite Awareness Training Within Family-Based Behavioral Treatment of Pediatric Obesity: A Randomized Controlled Pilot Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This work was supported by the Landspitali UniversityHospital Research Fund (to RB); The Doctoral Grants ofThe University of Iceland Research Fund (to TG); theUniversity of Iceland Research Fund (to ASO); and a grantfrom the Thorvaldsen Society (to RB) | |  |
| Country | Iceland |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Written informed consent was obtained from both parents and children before data were collected, and the study was approved by the  National Bioethics Committee (licensenumber: VSNb2006110005/03-15). | |  |
| Outcomes other than BMI | Mental health, other (parent BMI and mental health) |  |  |
| Population |  |  |  |
| Inclusion criteria | Inclusion criteria for study participation were a child with obesity, defined as Body Mass Index Standard Deviation Score (BMI-SDS)>2, one  parent agreed to participate in treatment, child obesity was not because of an identifiable medical cause, no significant dietary or exercise restrictions, no family member taking part in another weight control program, and the child being able to comprehend written material and complete self-monitoring tasks. | |  |
| Exclusion criteria | No additional |  |  |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | FBT--AAT | FBT Only | Overall |
| N | 41 | 43 | 84 |
| Sex | 41% female | 49% female | F = 38 |
| Age | 11.1 (1.4) | 10.9 (1.4) | 11.0 (1.4) |
| Race | NR | NR | NR |
| BMI-SDS | 3.10 (0.49) | 3.11 (0.53) | 3.11 (SD 0.5  ,2.14--4.59) |
| Interventions | |  |  |
|  | FBT--AAT | FBT Only |  |
| Intervention as described by authors | Based on the CAAT (Zucker & Craighead, 2003). The first four sessions from the CAAT manual were integrated into the first 8 weeks of FBT. Sessions 5 and 6 from the CAAT addressed issues already covered by FBT (self-acceptance  and dealing with teasing) and were therefore not included. In Week 1,  participants were introduced to the hunger-meter (Figure 2) and instructed to rate their hunger and fullness levels be-fore and after each time they ate. Participants were en-couraged to avoid becoming too hungry before eating,to stop eating at moderate fullness (not get stuffed),and to eat in response to hunger rather than environmental or emotional cues. The difference between“true” and “tricky” hunger was discussed along with the different triggers (called “traps”) that lead people to eat when they are not hungry. 1 Cognitive and behavioral strategies to reduce eating when not hungry were  discussed. In Week 3, monitoring of food, beverage, and physical activity (as  done in FBT) was added to their forms to encourage more nutritious choices.From then on, participants in the FBT-AAT condition monitored food  and drink as well as rating appetite cues. At the end of treatment, “mental-monitoring”was introduced that involved continuing to attend to | Written materials were provided based on the TrafficLight Diet (Epstein, 2003,2005;Epstein et al., 2001;Epstein & Squires, 1988) and a lifestyle physical activ-ity program, including education about weight con-trol, self- monitoring, behavior change techniques, andmaintenance of behavior change. Additional educa-tion materials were provided based on the Icelandicnational recommendations for balanced nutrition andphysical  activity behavior (Directorate of Health,2006).  Starting in Week 1, parent and child partici-pants each monitored their daily food and beverage in-take and physical activity during treatment, andweekly goals were set for specific behaviors with pre-determined reinforcers (for the child) provided by theparent, based on the child meeting behavioral goalsfor the week. At the end of treatment, families wereencouraged to  continue some form of self-monitoring,even if just keeping |  |

|  |  |  |
| --- | --- | --- |
|  | appetite cues, which was to be maintained even when they were no longer  using the written forms. Mental monitoring was presented as an unobtrusive and easy way to maintain some level of self-monitoring of appetite during follow-up. The AAT component was reviewed again at the 1-year booster  session. | track mentally of foods and drinksand physical activity  levels. Self-monitoring food andactivity was reviewed again at the 1-year boostersession. |
| Intervention type | Lifestyle | Lifestyle |
| Intervention length | 18 weeks | 18 weeks |
| Intensity as described by authors | Participants attended treatment sessions weekly for 8 weeks, biweekly for 3 weeks and during a final week 1 month later. During each week in treatment, participants attended two separate treatment sessions: a family session (20 min for the parent and child dyad) and a group session (60–90 min in a  separate [but con-current] session for parents and children, with  approximately 10 families in each group). The total number of treatment  sessions was thus 24, 12 family sessions,and 12 group sessions, which were then followed by a single family booster session 1-year post treatment | Participants attended treatment sessions weekly for 8 weeks, biweekly for 3 weeks and during a final week 1 month later. During each week in treatment, participants attended two separate treatment sessions: a family session (20 min for the parent and child dyad) and a group  session (60–90 min in a separate [but con-current]  session for parents and children, with approximately 10 families in each group). The total number of treatment sessions was thus 24, 12 family sessions,and 12 group  sessions, which were then followed by a single family  booster session 1-year post treatment |
| Assigned intensity | 5-25 hours (22 hours) | 5-25 hours (22 hours) |
| Provider type | Primary care, nutrition provider, mental health (psychologist), exercise | Primary care, nutrition provider, mental health (psychologist), exercise |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling (Traffic Light Diet), activity counseling, Mental health  (CBT - appetite regulation) | Nutrition counseling, activity counseling |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes | | | | | |  | | | | | | |
| BMI SDS | | | | | |  | | | | | | |
| P | osttreatme  N | nt  Mean | SD | P Value | 1 year  N | Mean | SD | P Value | 2 years  N | Mean | SD | P Value |
| FBT--AAT | 41 | 2.62 | 0.65 | NS | 41 | 2.64 | 0.58 | <0.05 | 41 | 2.44 | 0.95 | <0.01 |
| FBT Only | 43 | 2.82 | 0.62 |  | 43 | 2.86 | 0.47 |  | 43 | 2.94 | 0.82 |  |

**Sepulveda 2020**

**Feasibility, acceptability, and effectiveness of a multidisciplinary intervention in childhood obesity from primary care: Nutrition, physical activity, emotional regulation, and family**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | Dr. Sepulveda had a postdoctoral Ramon and Cajal scholarship from the Spanish Ministry of Science and Innovation (RYC‐2009‐05092). The above project also receivedthe First edition Award by the BBVA Foundation (2014)and obtained an Award Lafourcade by Oficial School of Psychology, Applied Modality (2014). Ms. M.  Blanco was awarded with a Research Fellowship (FPU) for stu-dents of PhD Programs. | | |
| Country | Spain |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB |  |  |  |
| Outcomes other than BMI | Other obesity, behavior, mental health, other (family functioning, maternal  mental health) |  |  |
| Population |  |  |  |
| Inclusion criteria | The inclusion criteria for this study were (a) agebetween 8 and 12 years, (b) body mass index (BMI) > Per-centile 85, and (c) good understanding of  Spanish. | |  |
| Exclusion criteria | No additional |  |  |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | ENTREN | ENTREN-F | Overall |
| N | 40 | 30 |  |
| Sex | 51.7% male | 59.3% male |  |
| Age | 9.93 (1.28) | 9.81 (1.36) |  |
| Race | NR | NR |  |
| BMI SDS | 2.12 (1.21) | 2.17 (0.73) |  |
| Interventions | |  |  |
|  | ENTREN | ENTREN-F |  |
| Intervention as described by author | using a cognitive behavioural perspective,some contents from“LEARN Program  for Weight Management”were adapted to childhood stages for theENTREN programme (Brownell, 2004). This author pro-poses an approach to obesity from five main dimensions:lifestyle, physical activity, health attitudes, social relation- ships, and nutrition. Finally, Spanish health guidelinesfrom the Health Ministry related to childhood obesity(NAOS, 2005), aimed to promote healthy eating  habitsand physical activity, were taken into account. Motiva-tional interviewing techniques (Miller & Rollnick, 2004)have also been used to promote children's  commitmentto their health, and they have been integrated into thesesessions. | intervention was exactly the same as ENTREN for chil-dren. ENTREN ‐ F was designed to work on family environment and communi- cation and was administered separately in six 2 ‐ hr ses- sions to parents and nine 2 ‐ hr sessions to their children, with a further three 2 ‐ hr  sessions attended by both fami- lies and children |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 6 months | 6 months |  |
| Intensity as described by authors | the duration of theENTREN programme was 6 months (12 sessions of 2 hrof duration every 15 days. One 2‐hr sessionat 6‐month follow‐up was provided to refresh skills, theirphysical activity, and nutritional behaviours. | the  intervention was exactly the same as ENTREN for chil-  dren (see Appendix A). In this manner, ENTREN‐F was designed to work on family environment and communi-  cation and was administered separately in six 2‐hr ses-  sions to parents and nine 2‐hr sessions to their children,  with a further three 2‐hr sessions attended by both fami- lies and children |  |
| Assigned intensity | 26-51 hours | 26-51 hours |  |

|  |  |  |
| --- | --- | --- |
| Provider type | Primary care, mental health, exercise | Primary care, mental health, exercise |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, activity training, mental health | Nutrition counseling, activity counseling, activity training, mental  health |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| Post-intervention | |  |  |  | 6 months |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| ENTREN | 25 | 1.49 | 0.95 | 0.6 | 24 | 1.72 | 1.06 | 0.001 |
| ENTREN-F | 26 | 1.39 | 0.72 |  | 25 | 1.34 | 0.69 |  |

**Sherwood 2019**

**The Healthy Homes/Healthy Kids 5-10 Obesity Prevention Trial: 12 and 24-month outcomes**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | National Institute of Diabetes and Digestiveand Kidney Diseases, Grant/Award Numbers:1R01DK084475, P30DK050456 andP30DK092924 | |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Written parental/primary caregiverinformed consent and child assent were then obtained and baselinemeasures administered by study staff. The studywas approved by the HealthPartners Institutional Review Board | |  |
| Outcomes other than BMI | Behaviors |  |  |
| Population |  |  |  |
| Inclusion criteria | Eligibility criteria were (1) 5 to 10‐year‐old child attending a well‐child visit conducted by a pediatric or family practice care provider;(2) child at risk for obesity defined as BMI between the 70th and95th percentile for age and gender on the CDC growth charts; (3) nomedical problems that  would preclude study participation (eg, a chro-mosomal abnormality, kidney disease, Type I diabetes, lupus, or can-cer); (4) no steroid medication  use more than 1 month; and (5) childnot participating in another health‐related research study | |  |
| Exclusion criteria | No additional |  |  |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | Obesity Prevention | Control (injury prevention) | Overall |
| N | 212 | 209 | 421 |
| Sex | 47.6% female | 51.2% female | 49.4%  female |
| Age | 6.6 (1.6) | 6.6 (1.7) | 6.6 (1.7) |
| Race | 73.0% white, 3.8% Hispanic | 65.2% white, 10.1% Hispanic | 69.1% white,  6.9%  Hispanic |
| BMI-SDS | 1.07 (0.31) | 1.09 (0.32) | 1.08 (0.31) |
| Interventions | |  |  |
|  | Obesity Prevention | Control (injury prevention) |  |
| Intervention as described by authors | The HHHK 5‐10 study included an OP intervention and a contactcontrol (CC) intervention focused on general health, safety, and injury prevention. Social cognitive theory (SCT) provided the theoretical basis for both interventions, and the interventions were also families received tailored guidance from their primary care provider regarding the child's BMI percentile and obesity and prevention topics. Study staff provided an HHHK flipchart to facilitate intervention delivery and HHHK pamphlets which included relevant anticipatory guidance. Following the well‐child visit, families were randomized to the OP or CC condition. Families in both conditions received a treatment group‐specific workbook, six biweekly phone coaching calls from a trained phone coach over the first 3  months,and eight monthly phone coaching calls during the remainder of their first year of the study. OP arm behavioral target areas based on pediatric obesity guidelines,included limiting sugar‐sweetened beverage consumption, encouraging fruit and vegetable consumption, limiting  television and other screen time, eating breakfast daily, limiting restaurant eating, encouraging family meals, and limiting portion size. | All families received tailored guidance from their primary care pro- vider regarding the child's BMI percentile and obesity and preventiontopics. Study staff provided an HHHK flipchart to  facilitate interven-tion delivery and HHHK pamphlets which included relevant anticipa-tory guidance. Following the well‐child visit,  families wererandomized to the OP or CC condition. Families in both conditionsreceived a treatment group‐specific workbook, six biweekly phonecoaching calls from a trained phone coach over the first 3 months,and eight monthly phone coaching calls during the remainder of theirfirst year of the study. heCC intervention focused on home safety and injury prevention, firesafety, bicycle safety, and sun protection. |  |

|  |  |  |
| --- | --- | --- |
| Intervention type | Lifestyle | Lifestyle |
| Intervention length | 12 months |  |
| Intensity as described by authors | Families in both conditions received a treatment group‐specific workbook, six biweekly phone coaching calls from a trained phone coach over the first  3 months,and eight monthly phone coaching calls during the remainder of their first year of the study. | six biweekly phonecoaching calls from a trained phone coach over the first 3 months,and eight monthly phone coaching calls during  the remainder of theirfirst year of the study. Control arm injury prevention. |
| Assigned intensity | 5-25 hours | 5-25 hours |
| Provider type | Primary care, other ("coach") | Primary care, other ("coach") |
| Clinic setting | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling | NA (injury prevention) |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes | | | | |  | | | |
| BMI SDS | | | | |  | | | |
| 12 months | |  |  |  | 24 months |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| Obesity Prevention | 181 | 0.97 | 0.42 |  | 180 | 0.96 | 0.49 | 0.71 |
| Control (injury prevention) | 183 | 1.01 | 0.42 |  | 187 | 0.98 | 0.48 |  |

**Stark 2019**

**Maintenance Following a Randomized Trial of a Clinic and Home-based Behavioral Intervention of Obesity in Preschoolers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Identification |  |  |  |  |
| Sponsorship source | Supported by the National Institute of Diabetes andDigestive and Kidney Diseases (NIDDK) (R01DK091251),the National Center for Advancing Translational Sciencesof the National Institutes of Health (UL1 TR001425), andNational Institute of Diabetes and Digestive and KidneyDisease of the National Institutes of  Health (T32DK063929). | | | |
| Country | USA |  |  |  |
| Methods |  |  |  |  |
| Design | Randomized controlled trial |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | The study was approved by institutional review board at the primary medical center where the study was conducted, and written informed consent was obtained  from caregivers. | | | |
| Outcomes other than BMI | Other obesity, behaviors, other |  |  |  |
| Population |  |  |  |  |
| Inclusion criteria | active patient, aged 2-5 years, and BMIpercentile³95th | |  |  |
| Exclusion criteria | Developmentaldisability, medical condition promoting obesity or condi-tion that precluded full participation, weight affectingmedication, enrolled in a weight-management program,or non-English speaking | | |  |
| Group differences |  |  |  |  |
| Special populations |  |  |  |  |
|  | LAUNCH | Motivational Interviewing | Standard Care | Overall |
| N | 47 | 50 | 54 | 151 |
| Sex | 53.19% female | 58.00% female | 59.26% female | 56.95% female |
| Age (months) | 55.10 (12.07) | 55.00 (10.67) | 55.30 (11.06) | 55.14 (11.19) |
| Race | 6.38% Black, 78.72% white, 14.89% other; 2.13% Hispanic | 12.00% Black, 76.00% white, 12.00% other; 6.00% Hispanic | 9.26% Black, 74.07%  white, 16.67% other; 9.26% Hispanic | 9.27% Black,  76.16% white,  14.57% other; 5.96% Hispanic |
| BMI-SDS | 2.41(0.53) | 2.41 (0.56) | 2.48 (0.70) | 2.44 (0.60) |
| Interventions | |  |  |  |
|  | LAUNCH | Motivational Interviewing | Standard Care |  |
| Intervention as described by authors | LAUNCH was a family-based, behavioral interventiondelivered in sessions that alternated weekly between groupclinic sessions (90 minutes) at a medical facility and individ-ual home visits (60 minutes). The clinic sessions includedsimultaneous parent and child groups. Parent-groupsessions provided nutrition education, problem-  solvingaround/monitoring of dietary intake for children and parentsand physical activity  changes, and child behavior-management  strategies (across all sessions) such as differen-tial attention (eg, ignoring complaints about food,  praisingtrying vegetables), contingency  management (eg, rewardinghealthy behaviors),  limit setting, effective use of time-outto manage | Motivational interviewing was conducted with care-givers and targeted improvement in the child’s dietaryand activity behaviors. At the first visit, caregivers metwith a  pediatrician trained in motivational interviewing,at which time they completed questionnairestoassesstheirvalues  and motivation for change and were given informa-tion  about their child’s weight and BMI percentile and apacket of publicly available materials/brochures from theAmerican Academy of Pediatrics “Let’s Go” program.Following the  tenets of motivational interviewing, care-givers were asked  about their concern with their pre-schoolers’ weight, diet, and physical activity and askedabout their desired child outcome, motivation, and confi-dence to make changes in any area of concern. If receptive,they were asked to select  a nutrition or physical activitybehavior as a primary target | Participants in the  standard care group received routinecare from their pediatrician and were only seen by the studyteam at the assessment visits. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | tantrums, shaping (eg, gradually  introducingchange) and exposure to introduce new foods, and imple-menting stimulus control  measures to improve food choicesand physical  activity. Child groups provided nutrition educa-tion about healthy eating, opportunities to try new foodsduring a structured meal, and engagement in MVPA.Home visits were designed to support the generalization ofthe clinic-taught skills to the home including parenting skills and changing the home environment. Parent clinic groupsessions were conducted by a PhD-licensed psychologist.The child group and home visits were conducted by a post- doctoral fellow in pediatric psychology or nutrition. | of discussion from a menuof the American Academy of  Pediatrics recommendationsand the “Let’s Go” materials.  Subsequent motivational in-terviewing intervention sessions were delivered by alicensed clinical  psychologisttrained in motivational inter-viewing in either the family’s home (3 sessions) or over thetelephone (14  sessions). These sessions consisted of a dis-cussion of previous goals selected by the caregiver, explora-tion of the caregiver’s perception of their success inreaching these goals, determination of caregiver’s confi-dence and willingness to continue working on existinggoal(s) vs  establishing new behavioral goals, enhancementof  motivation to address ambivalence and readiness tochange behaviors in the caregivers, and identification ofself-  selected strategies for goal attainment |  |
| Intervention type | Lifestyle | Lifestyle | Usual care |
| Intervention length | 6 months | 6 months | 6 months |
| Intensity as described by authors | LAUNCH and motivational interviewing were deliveredover 18 sessions (weekly in months 1-3; every other weekin months 4-6). alternated weekly between groupclinic sessions (90 minutes) at a medical facility and individ-ual home visits (60 minutes). | LAUNCH and motivational interviewing were deliveredover 18 sessions (weekly in months 1-3; every other weekin months 4-6). Subsequent motivational in-terviewing intervention sessions were delivered by alicensed clinical psychologisttrained in motivational inter-viewing in either the family’s home (3 sessions) or over thetelephone (14  sessions). | Usual care |
| Assigned intensity | 5-25 | 5-25 hours | <5 hours |
| Provider type | Primary care, mental health (psychologist),  nutrition provider | Primary care, mental health (psychologist) | primary care |
| Clinic setting | Primary care | Primary care | Primary care |
| Components | Nutrition counseling, activity counseling, nutrition  training, mental health, other (home visits, parenting) | Nutrition counseling, activity counseling, motivational interviewing | Usual care |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 6 months | |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| LAUNCH | 43 | -0.2 | 0.54 | 0.397 | 41 | -0.2 | 0.6 | 0.428 |
| Motivational Interviewing | 39 | -0.12 | 0.31 |  | 39 | -0.16 | 0.32 |  |
| Standard Care | 47 | -0.13 | 0.4 | 0.217 | 47 | -0.17 | 0.45 | 0.359 |

**Warschburger 2018**

**Evaluation of an approach-avoidance training intervention for children and adolescents with obesity: A randomized placebo-controlled prospective trial**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | This work was supported by the German Statutory Pen-sion Insurance Association (Deutsche RentenversicherungBund) under Grant 8011‐106‐ 31/31.113. | |  |
| Country | Germany |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval was obtained from the local ethicscommittee. The eligible families wereasked to provide informed assent (children) and  writteninformed consent (parents). | |  |
| Outcomes other than BMI | Behaviors, psychosocial |  |  |
| Population |  |  |  |
| Inclusion criteria | Age 8-16, BMI >97th |  |  |
| Exclusion criteria | BMI 97th percentile, secondary causes of obesity, mental retardation, medication for attention-deficit / hyperactivity disorder; acute illness | |  |
| Group differences |  |  |  |
|  | Approach-Avoidance Training | Placebo training | Overall |
| N | 110 | 122 | 232 |
| Sex |  |  | 53.9% female |
| Age |  |  | 13.09 (1.84) |
| Race |  |  | NR |
| BMI SDS |  |  | 2.7 (0.47) |
| Interventions |  |  |  |
|  | Approach-Avoidance Training | Placebo training |  |
| Intervention as  described by authors | AT was implemented supple-mentary to the multidisciplinary treatment as usual inthree specialized clinics. The inpatient stay usuallylasted 4–6 weeks (depending on the coverage by thehealth insurance  companies). During that time, allchildren and adolescents participated in a cognitivebehavioural group training that aimed to support thechildren and adolescents to modify their lifestyle (nutri-tional  behaviour; activity behaviour) in order to loseweight. In addition, the children and adolescents partic-ipated in regular exercise classes and received abalanced diet.Participants were allocated either to an interventiongroup (IG) receiving the AAT or to a control group(CG) receiving placebo training. Training was imple-mented on 6 days over two consecutive weeks at thebeginning of the inpatient stay. Children and adolescents were instructed to pullcircular plates towards them and to push square platesaway using a joystick. Approach and avoidance reac-tions were visualized by increasing and decreasing thesize of the pictures. In the IG, an implicit learning par-adigm was implemented: Vegetables were placed oncircular plates and snacks on square plates to  trainapproaching vegetables and avoiding snacks.. | AT was implemented supple-mentary to the multidisciplinary treatment as usual inthree specialized clinics. The inpatient stay usuallylasted 4– 6 weeks (depending on the coverage by thehealth insurance  companies). During that time, allchildren and adolescents participated in a cognitivebehavioural group training that aimed to support thechildren and adolescents to modify their lifestyle (nutri-tional  behaviour; activity behaviour) in order to loseweight. In addition, the children and adolescents partic-ipated in regular exercise classes and received abalanced diet.Participants were allocated either to an interventiongroup (IG) receiving the AAT or to a control group(CG) receiving placebo training. Training was imple-mented on 6 days over two consecutive weeks at thebeginning of the inpatient stay. Children  and adolescents were instructed to pullcircular plates towards them and to push square platesaway using a joystick. Approach and avoidance  reac-tions were visualized by increasing and decreasing thesize of the pictures. In theCG, vegetables and snacks were presented equally oncircular and square plates. |  |
| Intervention type | Lifestyle | Lifestyle |  |
| Intervention length | 6 days over two weeks (training component only); 4-6 weeks inpatient  stay | 6 days over two weeks (training component only); 4-6 week inpatient  stay |  |

|  |  |  |
| --- | --- | --- |
| Intensity as described  by authors | The inpatient stay usuallylasted 4–6 weeks | The inpatient stay usuallylasted 4–6 weeks |
| Assigned intensity | >52 hours | >52 hours |
| Provider type | Not specified (inpatient staff). Training was computer-based. | Not specified (inpatient staff). Training was computer-based. |
| Clinic setting | Inpatient | Inpatient |
| Components | Nutrition counseling, activity counseling, nutrition training, activity  training, other (AAT behavioral training) | Nutrition counseling, activity counseling, nutrition training, activity  training |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 6 months | |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | P Value | N | Mean | SD | P Value |
| Approach-Avoidance Training | 62 | 2.47 | 0.6 | 0.115 | 49 | 2.52 | 0.62 | 0.276 |
| Placebo training | 69 | 2.49 | 0.58 |  | 63 | 2.53 | 0.56 |  |

# Randomized Pharmaceutical Studies (Priority 2)

**Aa, Mp; Elst, Ma; Garde, Em; Mil, Eg; Knibbe, Ca; Vorst, Mm**

**Long-term treatment with metformin in obese, insulin-resistant adolescents: results of a randomized double-blinded placebo-controlled trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | ZonMw Program of Priority Medicines for Children |  |
| Country | The Netherlands |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study protocol w as approved by the Medical Ethical Committee of the St Antonius Hospital, Nieuw egein/Utrecht, the Netherlands, and w ritten inf ormed  consent w as obtained from the parents and if applicable, from the children (aged ⩾ 12 years) | |
| Outcomes other  than BMI | Glucose metabolism, other obesity, psychosocial, other (physical fitness) |  |
| Population | | |
| Inclusion criteria | Age 10-16 years; BMI-SDS > 2.3; HOMA-IR >= 3.4; Caucasian descent; w ritten inf ormed consent |  |
| Exclusion criteria | Type 2 diabetes mellitus; endocrine disorders treated w ith corticosteroids; height < 1.3 SD from target height; syndromal disorders; pregnancy; (history of) alcohol abuse; impaired renal function (GFR <80 mL/min); impaired hepatic function (ALT > 150% of normal value for age); insufficient know ledge of Dutch  language | |
| Group  differences | None noted in results or Table 1; not explicitly stated if tests w ere done to examine group differences at  baseline. |  |
|  | Metformin w ith physical training | Placebo w ith physical training |
| Interventions | | |
|  | Metformin w ith physical training | Placebo w ith physical training |
| Brief description | Immediate release 500 mg tablets in an increasing dose regimen w ith a maximum dose of 2 tablets tw ice/day  in the fourth study w eek. In cases of GI complaints, doseae w as reduced to last w ell-tolerated dose and then increased as tolerated to max dose. Physical training offered tw ice w eekly by a physical therapist. | 500 mg placebo in an increasing dosing  regimen. Physical training offered tw ice w eekly by a physical therapist. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 18 months | | | | | |
|  | N | Median | IQR (low er bound) | IQR (upper bound) | p (betw een groups) |
| Metformin w ith physical training | 23 | -0.12 | -0.5 | 0.08 | 0.08 |
| Placebo w ith physical training | 19 | 0.04 | -0.24 | 0.1 |  |
| BMI |  |  |  |  |  |
| 18 months | | | | | |
|  | N | Median | IQR (low er bound) | IQR (upper bound) | p (betw een groups) |
| Metformin w ith physical training | 23 | 0.2 | -2.9 | 1.3 | 0.02 |
| Placebo w ith physical training | 19 | 1.2 | -0.3 | 2.4 |  |

**Akcam, M; Boyaci, A; Pirgon, O; Kaya, S; Uysal, S; Dundar, Bn**

**Therapeutic effect of metformin and vitamin E versus prescriptive diet in obese adolescents with fatty liver**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed. |  |  |
| Country | Turkey |  |  |
| Methods | | | |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The study protocols w ere approved by the institutional review board of SD University Hospital Ethical Committee.Signed inf ormed consent forms w ere obtained  from the parents of the children. | | |
| Outcomes  other than BMI | Other obesity, glucose metabolism, lipids, other labs |  |  |
| Population | | | |
| Inclusion  criteria | The subjects w ere required to meet the follow ing inclusion criteria: 1) age, 9- 17 years; 2) BMI greater than or equal to the 95th percentile for age and gender  based on the standards of the U.S. Centers for Disease Control and Prevention; and 3) liver steatosis. | | |
| Exclusion  criteria | Patients w ere excluded if they had a diagnosed dis-ease, including type 1 or type 2 diabetes mellitus, took medications. or had a condition know n to influence  body composition, insulin action, or insulin secretion(e. g. glucocorticoid therapy, hypothyroidism, Cushing's disease). | | |
| Group  differences | Randomized |  |  |
|  | Diet and exercise | Metformin | Vitamin E |
| Interventions | | | |
|  | Diet and exercise | Metformin | Vitamin E |
| Brief description | Advised to adopt a diet sup-plying 30 kcal/kg based on current body w eight; 50  %of the diet's energy w as derived from carbohydrates, 30 % from lipids, and 20Yo fromproteins. All patientsreceived a list of recommended food portions and possible combinations. All patients w ere advised to perform at least 30 minutes of aerobic physical activity per day. | Oral treatment w ith 850 mg metformin daily (Glucophage; Bristol-Myers Squibb Company, Princeton, NJ) as w ell as diet and exercise therapy | Oral vitamin E capsules 400 U/daily, w hich w ere self- administered for 6 months [also diet and exercise therapy] |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI-SDS |  |  |  |  |
|  |  | 6 months |  |  |
|  | N | mean | SD | p (diet v met) |
| Diet and exercise | 22 | -0.1 | 0.5 | <0.05 |
| Metformin | 22 | -0.3 | 0.2 | p (diet v vit e) |
| Vitamin E | 23 | -0.2 | 0.2 | p<0.05 |
|  |  |  |  | p (met v vit e) |
|  |  |  |  | NS |

**Allen, H. F.; Mazzoni, C.; Heptulla, R. A.; Murray, M. A.; Miller, N.; Koenigs, L.; Reiter, E. O.**

**Randomized controlled trial evaluating response to metformin versus standard therapy in the treatment of adolescents with polycystic ovary syndrome**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | None listed |  |  |
| Country | US |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB |  |  |  |
| Outcomes other than BMI | Lipids, glucose metabolism, other labs |  |  |
| Population |  |  |  |
| Inclusion criteria | post-menarchal female adolescents aged 12-21 years, w ith laboratory verified hyperandrogenemia and hyperinsulinemia. Also oligomenorrhea and  obesity, | | |
| Exclusion criteria | no evidence of androgen secreting tumor or adrenal source of androgenesis (by ACTH stimulation test if suspected); not diabetic ; no current or past  sexual activity, OCP use w ithin 6 moths, positive urine pregnancy at baseline. abnormal BUN, CR, AST, or positive personal or family history of thrombosis. | | |
| Group differences | Randomized |  |  |
|  | Metformin | Oral Contraceptive pills | Overall |
| Interventions | |  |  |
|  | Metformin | Oral Contraceptive pills |  |
| Brief description | metformin 500 mg bid for 2 w eeks; if w ell tolerateed increased to 1g bid | Ethinyl Estradiaol/norgestimate (35ug/.25 mg) |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI Percentage Change |  |  |  |  |  |  |
|  | 6 months |  |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Metformin | 16 | -1.7 | -0.5 | -1 | <0.05 | NS |
| Oral Contraceptive pills | 15 | -3.6 | -0.5 | -2 | <0.05 |  |

**Atabek, Me; Pirgon, O**

**Use of metformin in obese adolescents with hyperinsulinemia: a 6-month, randomized, double-blind, placebo-controlled clinical trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Turkey |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study protocol w as approved by the institutional review board of Selcuk University Ethics Committee. Signed inf ormed consent forms w ere obtained from  the parents of the adolescents. | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other labs |  |
| Population | | |
| Inclusion criteria | 1) age 9-17 years; 2) BMI greater than or equal to the 95th percentile for age and gender based on the standards of the Centers for Disease Control and  Prevention; | |
| Exclusion criteria | Children w ere excluded if they had prior major illness, including type 1 or type 2 diabetes mellitus, took medications, or had a condition know n to influence body composition, insulin action, or insulin secre-tion (e.g. glucocorticoid therapy, hypothyroidism, Cushing's syndrome), and none of the patients had a family  history for diabetes mellitus. | |
| Group  differences | Randomized |  |
|  | Metformin | Control |
| Interventions | | |
|  | Metformin | Control |
| Brief Description | The metformin group received oral treatment w ith 1,000 mg metformin (500 mg tw ice daily) (Glucophage®; Bristol-Myers Squibb Company, Princeton, NJ)  as w ell as diet and exercise therapy for 6 months. | Patients in both groups w ere advised to adopt a diet supplying 30 kcal/kg of the current body w eight; 50% of the diet's energy w as derived from  carbohydrates, 30% from lipids, and 20% from proteins. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 90 | -2.08 | 2.32 | 0.001 |
| Control | 30 | 0.65 | 2.5 |  |

**Burgert, Ts; Duran, Ej; Goldberg-Gell, R; Dziura, J; Yeckel, Cw; Katz, S; Tamborlane, Wv; Caprio, S**

**Short-term metabolic and cardiovascular effects of metformin in markedly obese adolescents with normal glucose tolerance**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | This study w as supported by grants from the NationalInstitutes of Health (K23 DK 074439 to Dr Burgert, R01-HD40787, R01- HD280 16 and K24-HD01464 to Dr Caprio; K12-DK063709 to Dr Tamborlane, M01-RR0012 5) to the YaleCenter for Clinical Investigation, Center, R01-EB006494 (Bio-image Suite), and the  Stephen I. Morse Pediatric DiabetesResearch Fund. | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The Yale Human Investigation Committee approvedthe study, and w ritten inf ormed consent and assentw ere obtained from the parents and subjects | |
| Outcomes other  than BMI | Other obesity, lipids, blood pressure, other labs, glucose metabolism |  |
| Population | | |
| Inclusion criteria | healthy, have Tanner stage 3–5 pubertal develop-ment, be 13–18 yr and have a fasting insulin level.30 mU/L and a fasting plasma glucose,100 mg/dLat a  recent screening clinic visit | |
| Exclusion  criteria | abnor-malities in glucose tolerance or diabetes (14) w ere dis-covered. Further exclusion criteria included cigarettesmoking, hepatic disease w ith elevated liver  functiontests.23normal and use of medications that mightinterfere w ith metabolism or cardiovascular health. | |
| Group  differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions | | |
|  | Metformin | Placebo |
| Brief description | Both placebo and MET (500 mg/tablet) w ere increasedover a 3-w k period to  one pill in the morning and tw opills in the evening. Lifestyle counseling for both groups involvednutritional and exercise recommendations. | Both placebo and MET (500 mg/tablet) w ere increasedover a 3-w k period to  one pill in the morning and tw opills in the evening. Lifestyle counseling for both groups involvednutritional and exercise recommendations. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 4 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 15 | -0.9 | 2.5 | 0.02 |
| Placebo | 13 | 1.2 | 1.9 |  |

**Canas, J. A.; Lochrie, A.; McGowan, A. G.; Hossain, J.; Schettino, C.; Balagopal, P. B.**

**Effects of Mixed Carotenoids on Adipokines and Abdominal Adiposity in Children: A Pilot Study**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | This study w as funded by The Players Center for Child Health at Wolfson Childrens Hospital. |  |
| Country | USA |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | study approved by theInstitutional Review Committee at Wolfson Children’s Hos-pital, Jacksonville, Florida |  |
| Outcomes other than BMI | Other obesity, glucose metabolism, lipids |  |
| Population |  |  |
| Inclusion criteria | Otherw ise healthy children aged 8 to 11 years w ith a BMI at or above the 90th percentile w ere asked to participate |  |
| Exclusion criteria | Participants w ith a history of chronic illness or receiving long-term medications, those w ith cognitive or neuromuscular impairment, those w ith any organic cause of obesity, or those w ho had metal implants that w ould preclude them from saf ely undergoing MRI w ere excluded from the study. To avoid illness-related acute changes in the markers of interest, partic- ipants w ere studied only if they had no history of recent illness or bone fracture  w ithin 2 w eeks of their blood draw . | |
| Group differences | Randomized |  |
|  | Mixed Carotenoids | Placebo |
| Interventions |  |  |
|  | Mixed Carotenoids | Placebo |
| Brief description | The supplement contained 2000 IU of beta-carotene and 500 mg of-carotene; 10 mg of lutein; 2 mg of zeaxanthin and 10 mg of lycopene; 500 mg of astax- anthin; and 10 mg of -tocopherol per capsule; light-protected containers. The participants w ere instructed to take one capsule w ith meals tw ice daily. They w ere then asked to participate, along w ith a parent or caregiver, in a 3-hour-per-day, 10-day, intense family-based afterschool lifestyle interventionprogram at a local YMCA (Young Mens Christian Association)site. Famlies contacted monthly by phone to encourage them to continue healthy lifestyle prac- tices, address and record any side effects, and ensure consumption of the  supplement as prescribed. At the 6-month visit they w ere also encouraged to enroll in our w eight management clinic. | Placebo |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | P Value |
| Mixed Carotenoids | 17 | -0.19 | 0.13 | 0.024 |
| Placebo |  |  |  |  |

**Casteels, K.; Fieuws, S.; van Helvoirt, M.; Verpoorten, C.; Goemans, N.; Coudyzer, W.; Loeckx, D.; de Zegher, F.**

**Metformin therapy to reduce weight gain and visceral adiposity in children and adolescents with neurogenic or myogenic motor deficit**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | The present w ork w as supported by the Fund for Scientific Research (G.0326.06); KC and FdZ are Clinical Investigators, and DL is a Postdoctoral  Fellow , each of the Fund for Scientific Research (Flanders, Belgium). | |
| Country | Belgium |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the Ethical Review Board of the University Hospitals Leuven. The study w as registered as NCT00720161 | |
| Outcomes other than BMI | Other obesity, glucose metabolism, lipids |  |
| Population |  |  |
| Inclusion criteria | Patients w ith neurogenic or myogenic motor deficit, They w ere included if they met the follow ing inclusion criteria: older than 8 yr of age, fat mass  >30% (absorptiometry) or insulin resistance [screened by fasting glucose (mg/dl) over insulin (mU/l)<7] (28–30). | |
| Exclusion criteria | Exclusion criteria w ere know n type 1 or type 2 diabetes mellitus and hepatic or renal failure (31). |  |
| Group differences | Randomized |  |
| Special populations | Motor deficits |  |
|  | Placebo | Metformin |
| Interventions |  |  |
|  | Placebo | Metformin |
| Brief description | Placebo capsules given in the evening at a dose of 425 mg/d (age<10 yr) or 850 mg/d (age≥10 yr).  Standard advice on a healthy diet and—if possible—exercise w as given to all patients. | metformin capsules given in the evening at a dose of 425 mg/d (age<10 yr) or 850 mg/d (age≥10 yr). Standard advice on a healthy diet and—if possible—exercise w as given to all  patients. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Placebo | 22 | 0.68 | 0.13 | 1.24 | 0.016 |
| Metformin | 14 | -0.28 | -0.72 | 0.17 |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Placebo | 22 | 0.05 | -0.04 | 0.15 | 0.0015 |
| Metformin | 14 | -0.15 | -0.23 | -0.06 |  |

**Chanoine, Jp; Hampl, S; Jensen, C; Boldrin, M; Hauptman, J**

**Effect of orlistat on weight and body composition in obese adolescents: a randomized controlled trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Funded by F. Hoffmann-La Roche Ltd (industry) |  |
| Country | United States and Canada |  |
| IRB | The study w as conducted in accordance w ith good clinical practice, the Declaration of Helsinki, and the law s and regulations of the countries in w hich the  research w as conducted, w hichever afforded greater protection to the individual. The study w as approved by the institutional review board at each participating center. Written in- formed consent w as received from the parents or guardians and w ritten assent w as received from each patient. | |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as conducted in accordance w ith good clinical practice, the Declaration of Helsinki, and the law s and regulations of the countries in w hich the research w as conducted, w hichever afforded greater protection to the individual. The study w as approved by the institutional review board at each  participating center. Written in- formed consent w as received from the parents or guardians and w ritten assent w as received from each patient. | |
| Outcomes other than BMI | Lipids, blood pressure, other obesity, glucose metabolism |  |
| Population | | |
| Inclusion criteria | Adolescents (aged 12-16 years) w ere eligible for enrollment if they (1) had a BMI 2 units or higher than the US w eighted mean for the 95th percentile based on age and sex; (2) had a parent or guardian prepared to attend study visits w ith them, and (3) w ere w illing to be actively involved in behavioral modification. Because this w as the first long-term study investigating the saf ety and efficacy of orlistat in the pediatric age group, 2 units w ere added to the 95th percentile of BMI at the request of the US Food and Drug Administration to ensure that only patients w ith the greatest potential for ben- efiting from study participation  w ere included. Using these criteria, minimum BMI for inclusion ranged from 28.5 in boys and 29.5 in girls at 12 years to 31.8 and 31.9, respectively, at 16 yrs . | |
| Exclusion criteria | Exclusion criteria w ere BMI of 44 or higher (to increase homogeneity of the group); body w eight of 130 kg or higher or less than 55 kg; w eight loss of 3 kg or higher w ithin 3 months prior to screening; diabetes requiring anti-diabetic medication; obesity associated w ith genetic disorders; history or presence of psychiatric disease; use of dexamphetamine or methylphenidate; active gastrointestinal tract disorders; ongoing bulimia or laxative abuse; and use of  anorexiants or w eight-reduction treatments during the 3 months bef ore randomization. | |
| Group  differences | Randomized |  |
|  | Placebo | Orlistat |
| Interventions | | |
|  | Placebo | Orlistat |
| Brief description | Identical placebo. Generalguidelines for diet, exercise, and be-havioral modification w ere supplied toall centers involved in the study (as de-tailed below ), but each center re-mained  free to use its ow n strategy. | A 120-mg dose of orlistat or placebo 3 times daily for 1 year, plus a mildly hypocaloric diet (30% fat calories), exercise, and  behavioral therapy. |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI |  |  |  |
|  | 12 months |  |  |
|  | N | Mean | P (betw een groups) |
| Placebo | 181 | 0.31 | 0.001 |
| Orlistat | 352 | -0.55 |  |

**Clarson, Cl; Mahmud, Fh; Baker, Je; Clark, He; McKay, Wm; Schauteet, Vd; Hill, Dj**

**Metformin in combination with structured lifestyle intervention improved body mass index in obese adolescents, but did not improve insulin resistance**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | Law son Foundation, the Canadian Institutes of Health Research and the Law son Health Research Institute |  |
| Country | Canada |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | This study w asapproved by the University of Western Ontario ResearchEthics Board and Health Canada and inf ormed consent w asobtained from  all the study subjects. | |
| Outcomes other than  BMI | Glucose metabolism, lipids |  |
| Population |  |  |
| Inclusion criteria | Obese subjects aged 10–16 years, defined as BMI greater than the 95th percentile for age and gender, and w ho w ere also insulin resistant (defined by HOMA greater than 3.0, calculated as fasting plasma insulin (mU/l) fasting serum blood glucose (mmol/l)/22.5) w ere enrolled over a 15 month period betw een 2005 and 2007. All the subjects w ere assessed to be in puberty throughout the study | |
| Exclusion criteria | Exclusion criteria included fasting blood glucose greater than or equal to 6.0 mmol/l and contraindications to metformin therapy | |
| Group differences | Randomized |  |
|  | Lifestyle intervention only | Lifestyle intervention & metformin |
| Interventions |  |  |
|  | Lifestyle intervention only | Lifestyle intervention &  metformin |
| Brief description | A structured lifestyle intervention comprising nutritional and exercise education and motiva- tional support in both  individual and group sessions w as delivered over 6 months | maintenance dose of 1500 mg  daily and lifestyle intervention |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Lifestyle intervention only | 14 | 0.5 | 0.3 | NS | <0.05 |
| Lifestyle intervention & metformin | 11 | -1.8 | 0.8 | <0.05 |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Lifestyle intervention only | 14 | -0.02 | 0.03 | NS | <0.05 |
| Lifestyle intervention & metformin | 11 | -0.16 | 0.07 | <0.05 |  |

**Evia-Viscarra, Ml; Rodea-Montero, Er; Apolinar-JimÃ©nez, E; MuÃ±oz-Noriega, N; GarcÃ-a-Morales, Lm; LeaÃ±os-PÃ©rez, C; Figueroa-BarrÃ³n, M; SÃ¡nchez- Fierros, D; Reyes-GarcÃ-a, Jg**

**The effects of metformin on inflammatory mediators in obese adolescents with insulin resistance: controlled randomized clinical trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Mexico |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The protocol for this study w as review ed and accepted by the Research and Ethics Committees of the “ Federico G ó mez ” Mexico Children ’ s Hospital (Hospital Inf antil “ Federico G ó mez ” de Mexico, HIMFG) and by the Research Committee of the High Specialty Regional Bajio Hospital (Hospital  Regional de Alta Especialidad del Baj í o, HRAEB). Patients ’ parents signed w ritten consents w hen they and their adolescent children agreed to enroll. | |
| Outcomes other  than BMI | Other obesity, glucose metabolism |  |
| Population | | |
| Inclusion criteria | This study enrolled adolescents (Tanner stage ≥ 2) aged 9 – 18 years w ho w ere found to be obese. | |
| Exclusion criteria | The exclusion criteria w ere glucose intolerance, type 1 diabetes mellitus or 2DM, anemia (hemoglobin < 100 g/L), plasma creati-nine ≥ 106 μ mol/L,  abnormal hepatic function tests, any associated disease (pulmonary, inf ection, autoimmune disease), or a history of lactic acidosis. | |
| Group  differences | Randomized |  |
|  | Placebo | Metformin |
| Interventions | | |
|  | Placebo | Metformin |
| Brief Description | Placebo +eating and exercise recommendations | 500mg/day for 8 days; 1g/day for 3 months +eating and exercise recommendations |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 3 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Placebo | 14 | 32.1 | 6.52 | 0.011 | 0.064 |
| Metformin | 12 | 32.71 | 5.77 | 0.015 |  |

**Fox, Ck; Kaizer, Am; Rudser, Kd; Nathan, Bm; Gross, Ac; Sunni, M; Jennifer, Abuzzahab M; Schwartz, Bl; Kumar, S; Petryk, A; Billington, Cj; Ryder, Jr; Kelly, As Meal replacements followed by topiramate for the treatment of adolescent severe obesity: a pilot randomized controlled trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | Funding for this study w as provided by grants from the University of Minnesota Clinical and Translational Science Institute and the Vikings Children’sFund, the Minnesota Obesity Center (NIH Grant P30DK050456 NORC), the National Center for Advancing Translational Sciences (Aw ard Number UL1TR000114), and  anindividual training grant from the NIH/NHLBI (F32-HL127851 to JRR). | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The protocol w as approved by the University of Minnesota institu- tional review board. Consent and assent w ere obtained from parents and participants, respectively. An investigational new drug exemp- tion w as obtained from the FDA bef ore study initiation and the study w as registered on the  clinicaltrials.gov w ebsite (NCT01859013) | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | Adolescents 12 to 18 years old w ith severe obesity(BMI1.2 times the 95th percentile or BMI35 kg/m2) | |
| Exclusion criteria | Exclusion criteria w ere Tanner stage I, II, or III; type 1 or 2 diabetes mellitus; previous (w ithin 6 months) orcurrent use of medication(s) prescribed primarily  for w eight loss; ifcurrently using w eight altering drug(s), any change in drug(s) ordose w ithin the previous 6 months; previous bariatric surgery; recentinitiation (w ithin 3 months) of antihypertensive or lipid medication;major psychiatric disorder; females w ho w ere pregnant, planning tobecome pregnant, or unw illing to use tw o or more acceptable meth-ods of contraception w hen engaging in sexual activity throughoutthe study; tobacco use; liver/renal dysfunction; glaucoma;  obesityassociated w ith genetic disorder (monogenetic obesity); hyper-thyroidism or uncontrolled hypothyroidism; medically documentedhistory of suicidal thoughts/attempts; history of nephrocalcinosis orcholelithiasis; and current use of other carbonic anhydrase inhibitor. | |
| Group  differences | Randomized |  |
|  | Placebo | Topiramate |
| Interventions | | |
|  | Placebo | Topiramate |
| Brief Description | 4 w eeks of meal replacement, follow ed by 24 w eeks placebo | 4 w eeks of meal replacement, follow ed by 24 w eeks 75mg topiramate |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 28 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 14 | -0.04 | 0.11 | 0.206 |
| Topiramate | 16 | -0.07 | 0.07 |  |
| BMI |  |  |  |  |
| 28 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 14 | -0.3 | 2.05 | 0.244 |
| Topiramate | 16 | -1.16 | 1.58 |  |

**Freemark, M; Bursey, D**

**The effects of metformin on body mass index and glucose tolerance in obese adolescents with fasting hyperinsulinemia and a family history of type 2 diabetes**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This study w as supported by an investigator-initiated grantfrom Bristol-Myers Squibb Corporation and by General ClinicalResearch Center (Grant  MO1RR-30). | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as ap-proved by the institutional review board of Duke University Med-ical Center | |
| Outcomes other  than BMI | Glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | All w ere betw een 12 and 19 yearsold and had a BMI exceeding 30 kg/m2. Criteria for enrollmentincluded: 1) a fasting insulin concentration exceeding 15mU/mLand 2) at least 1 first- or second-degree relative (parent, sibling, orgrandparent) w ith type 2 diabetes. All patients had normal f astingglucose  concentrations (,110 mg%) and HbA1c concentrations(#6.0%), and none had glycosuria or ketonuria. | |
| Exclusion criteria | Unclear if exclusions or descriptive: No patients had renal, adrenal, hepatic or thyroid dysfunction,or galactorrhea, and none w ere taking medications  chronically forsystemic illness. All patients had normal linear grow th and sexualdevelopment for age, w ith no marked hirsutism, severe acne, ormenstrual irregularities characteristic of polycystic ovary syn-drome. | |
| Group  differences | Randomized |  |
|  | Placebo | Metformin |
| Interventions | | |
|  | Placebo | Metformin |
| Brief description | Placebo for 6 months | 1g metformin for 6 months |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
|  | 6 months |  |  |
|  | N | Mean | P (betw een groups) |
| Placebo | 15 | 0.23 | 0.02 |
| Metformin | 14 | -0.12 |  |

**Kelly, As; Metzig, Am; Rudser, Kd; Fitch, Ak; Fox, Ck; Nathan, Bm; Deering, Mm; Schwartz, Bl; Abuzzahab, Mj; Gandrud, Lm; Moran, A; Billington, Cj; Schwarzenberg, Sj**

**Exenatide as a weight-loss therapy in extreme pediatric obesity: a randomized, controlled pilot study**

|  |  |  |
| --- | --- | --- |
| Study Identificatio  n |  |  |
| Sponsorshi  p source | The funding for this study w as provided by Minnesota Obesity Center (NIH grant P30DK050456 NORC) and GCRC (M01-RR00400, General Clinical Research  Center Program, NCRR/ NIH). Glucose meters w ere generously donated by Bayer HealthCare. | |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Crossover |  |
| IRB | The protocol w as approved by the University of Minnesota institutional review board and consent/assent w as obtained from parents/participants. An investigational new drug exemp- tion w as obtained from the United States Food and Drug Administration bef ore study initiation and the study w as registered on the clinicaltrials.  gov w ebsite (NCT00886626). | |
| Outcomes other than  BMI | Other obesity, glucose metabolism, blood pressure, lipids, other labs |  |
| Population | | |
| Inclusion  criteria | Inclusion criteria consisted of age 8–19 years old and extreme obesity (BMI ≥1.2 times the 95th percentile or BMI ≥35kg/m2) | |
| Exclusion  criteria | Exclusion criteria included: diabetes mellitus (type 1 or 2), use of w eight-loss medication w ithin 3 months of screening, initiation of new drug therapy w ithin 30 days  of screening, BMI ≥55 kg/m 2 , history of bariatric surgery, and obesity from an established genetic cause or know n syndrome (e.g., Prader–Willi). | |
| Group  differences | Randomized |  |
|  | Exenatide | Control |
| Interventio  ns |  |  |
|  | Exenatide | Control |
| Brief description | For the drug treatment phase, participants initiated exenatide at a dose of 5 mcg, tw ice per day, delivered by subcutaneous injection. After 1 month, exenatide w as uptitrated to 10 mcg, tw ice per day for the remain- ing 2 months of the drug treatment phase. If the 10 mcg dose w as not tolerated, the exenatide dose w as reduced to 5 mcg. | Control- clinical-offered lifestyle modification generally consisted of counseling by a physician (and  registered dietician at some centers)  w ith particular focus on making healthier food choices and increasing levels of physical activity |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (vs control) |
| Exenatide | 5 | -0.9 | 1.22 | 0.01 |
| Control | 6 | 0.84 | 1.28 |  |

**Kelly, As; Rudser, Kd; Nathan, Bm; Fox, Ck; Metzig, Am; Coombes, Bj; Fitch, Ak; Bomberg, Em; Abuzzahab, Mj**

**The effect of Glucagon-like peptide-1 receptor agonisttherapy on body mass index in adolescents with severe obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | unding for this study w as providedby a Community Health Collaborative grant from the Uni-versity of Minnesota Clinical and Translational ScienceInstitute, by aw ard 1UL1RR033183 from the NationalCenter for Research Resources, and by grant8UL1TR000114-02 from the National Center for Ad-vancing  Translational Sciences of the National Insti-tutes of Health | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | he protocol w as approved by theUniversity of Minnesota and the Children’s Hospitals and Clin-ics of Minnesota institutional review boards. Consent and as-  sent w ere obtained from parents and patients, respectively. | |
| Outcomes other  than BMI | Other obesity, lipids, glucose metabolism |  |
| Population | | |
| Inclusion criteria | Ado-lescents 12 to 19 years of age w ith severe obesity (BMI1.2times the 95th percentile or BMI35) | |
| Exclusion criteria | Exclu-sion criteria included the follow ing: diabetes mellitus (type 1or 2), use of medications associated w ith w eight loss/gain w ithin3 months of screening, history of bariatric surgery, initiationof a new drug therapy w ithin 30 days of screening, psychiatricdisorders, current pregnancy/plans to become pregnant, cur-rent tobacco use, renal or liver dysfunction, history of pancre-atitis, obesity-associated genetic disorders (eg, Prader-Willi syn-drome), hypothyroidism,  uncontrolled hypertriglyceridemia(300 mg/dL), and history of an eating disorder. | |
| Group  differences | Randomized |  |
|  | Exenatide | Placebo |
| Interventions | | |
|  | Exenatide | Placebo |
| Brief description | 5-10 mcg, 2x/day + lifestyle modification (5 face-to-face sessions and 2  telephone sessions) | Placebo + lifestyle modification (5 face-to-face sessions and 2 telephone  sessions) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 3 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Exenatide | 12 | -1.18 | 0.67 | 0.02 |
| Placebo | 10 | -0.04 | 1.23 |  |

**Kendall, D; Vail, A; Amin, R; Barrett, T; Dimitri, P; Ivison, F; Kibirige, M; Mathew, V; Matyka, K; McGovern, A; Stirling, H; Tetlow, L; Wales, J; Wright, N; Clayton, P; Hall, C**

**Metformin in obese children and adolescents: the MOCA trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This w ork w as supported by grants from the Central Man-chester University Hospitals NHS Foundation Trust and theChild Grow th Foundation UK. | |
| Country | United Kingdom |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | Inf ormed consent w as obtained from all partic-ipants’ parents and assent w as obtained from all children andyoung people w ho took part in the trial. | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | Ages 8-18. BMI greater than the 98th centile on U.K. BMIcentile charts; and impaired glucose tolerance,i.e.OGTT 2-hplasma glucose value 7.8 or greater to  11.1 mmol/liter or less(w ith or w ithout impaired fasting glucose6.1 to7.0 mmol/liter) or hyperinsulinemia,i.e.fasting insulin greater than 26mIU/liter or 120-min insulin greater than 89 mIU/liter (pubertal/postpubertal children); fasting insulin greater than 15 mIU/literor 120-min insulin greater than 89 mIU/liter (prepubertal chil-dren). | |
| Exclusion criteria | The exclusion criteria included glycosuria, ketonuria, otherchronic illness or chromosomal abnormality or syndrome,e.g.Prader-Willi, renal insufficiency,  hepatic dysfunction [raised al-anine aminotransferase (ALT)70 IU/liter], chronic diarrhea,and a previous episode of lactic acidosis | |
| Group  differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions | | |
|  | Metformin | Placebo |
| Brief description | 1.5g metformin + lifestyle advice | 1.5g placebo + lifestyle advice |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Metformin | 59 | 3.35 | 0.57 | 0.003 | 55 | 3.35 | 0.65 | 0.02 |
| Placebo | 65 | 3.3 | 0.51 |  | 55 | 3.31 | 0.54 |  |
| BMI |  |  |  |  |  |  |  |  |
|  | 3 months |  |  |  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Metformin | 59 | 36.56 | 6.56 | 0.004 | 55 | 36.85 | 6.29 | 0.005 |
| Placebo | 65 | 35.78 | 6.4 |  | 55 | 36.16 | 6.49 |  |

**Mauras, N; DelGiorno, C; Hossain, J; Bird, K; Killen, K; Merinbaum, D; Weltman, A; Damaso, L; Balagopal, P**

**Metformin use in children with obesity and normal glucose tolerance-effects on cardiovascular markers and intrahepatic fat**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship  source | Thrasher Research Fund and a generous grant from Mr. W.J. Wadsw orth and the support of theNemours Research Programs. | |
| Country | USA |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The institutional review committee at Wolfson Children’s Hospital approved the studies,and inf ormed parental consent and child’s assent w ere obtained. | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids |  |
| Population |  |  |
| Inclusion criteria | Uncomplicated (exogenous) obesity w as defined as a body massindex (BMI) >95th percentile for US standards for <5 years, and normal blood  pressure(BP), glucose tolerance, and total cholesterol. Age 7-18 years. | |
| Exclusion criteria | Chronic illness,medications, alcohol use, and smoking w ere exclusions from participation. |  |
| Group differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions |  |  |
|  | Metformin | Placebo |
| Brief description | Dietary and exercise guidance given; Metformin w as started at 250 mg orally, tw ice daily (bid), bef ore meals  titrating up to 500 mg bid in those <12 years old and 1000 mg bid as tolerated in older children. | 1-2g/day placebo, based on age; dietary  counseling, YMCA membership |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Metformin | 23 | -2.4 | 0.5 | <0.001 | 0.086 |
| Placebo | 19 | -1.1 | 0.5 | 0.045 |  |

**Molnar, D.; Torok, K.; Erhardt, E.; Jeges, S.**

**Safety and efficacy of treatment with an ephedrine/caffeine mixture. The first double-blind placebo-controlled pilot study in adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | The project w as supported by NYCOMED DAKPharmaceutical Company, Roskilde, Denmark, andin part by the Hungarian National Research  Fund(OTKA T-026663 to DM) and by the HungarianMinistry of Welfare (081=1996 to DM). | |
| Country | Hungary |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The trial w as run in accordance w ith the Declaration of Helsinki II and w as approved by the local and the Hungarian National Ethical Committees and by  the Hungarian National Pharmaceutical Institute. | |
| Outcomes other  than BMI | Blood pressure, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | The inclusion criteria w ere age betw een 14 and 18 y (Tanner stage: III ± V); relative body w eight > 140%; and inf ormed consent signed by the patient and the  parents. T | |
| Exclusion criteria | Theexclusion criteria w ere hypertension (systolic bloodpressure (BP)>140 mmHg and=or diastolic BP100 mmHg); any metabolic or endocrine disease;psychiatric or somatic disease; any drug treatment;evidence of alcohol or drug abuse; treatment w ithmethylxanthines less than 1 month prior  to the start ofthe study; w eight loss of more than 5 kg 3 monthsprior to the start of the study; and any contraindicationto the trial medication | |
| Group  differences | Randomized |  |
|  | Active group | Placebo |
| Interventions | | |
|  | Active group | Placebo |
| Brief description | The active tablets contained10 mg ephedrine and 100 mg caffeine. Lifestyle advice | Identical placebo. Lifestyle advice. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Weight (kg) |  |  |  |  |
| 20 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Active group | 13 | -7.9 | 6 | <0.01 |
| Placebo | 13 | -0.5 | 4.3 |  |

**Ozkan, B; Bereket, A; Turan, S; Keskin, S**

**Addition of orlistat to conventional treatment in adolescents with severe obesity**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | This w ork w as supported by the TurkishAcademy of Sciences w ithin the framew ork of the Young ScientistAw ard program (EA/TUBA-GEBIP/ 2001–1-  1). | |
| Country | Turkey |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | After obtaining approval of theinstitutional ethics committee, |  |
| Outcomes other than BMI | Other obesity, other (side effects) |  |
| Population |  |  |
| Inclusion criteria | the patients w ere selectedaccording to follow ing criteria: (1) severe exogenousobesity, described as w eight for height index >140% inotherw ise healthy subjects, not associated w ith endo-crinopathy, genetic syndromes or medications, (2) ado-lescents (Tanner stage 2 or higher) aged betw een  10–16years, and (3) inf ormed consent for the study. | |
| Exclusion criteria | No additional |  |
| Group differences | They say "randomized", but it's alternating patients, then in other places say "matched". |  |
|  | Orlistat | Control |
| Interventions |  |  |
|  | Orlistat | Control |
| Brief description | . A total of 22patients in the treatment group received orlistat (120 mgtid) and a daily oral multivitamin preparation. Both groups got lifestyle treatment. | Thecontrol group consisted of 20 obese patients matched forage, sex, pubertal stage and the degree of  obesity. Both groups got lifestyle treatment. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| Last visit (5-15 months) | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Orlistat | 15 | -4.09 | 2.9 | <0.001 |
| Control | 15 | 0.11 | 2.49 |  |

**Pastor-Villaescusa, B; Canete, Md; Caballero-Villarraso, J; Hoyos, R; Latorre, M; Vazquez-Cobela, R; Plaza-Diaz, J; Maldonado, J; Bueno, G; Leis, R; Gil, A; Canete, R; Aguilera, Cm**

**Metformin for obesity in prepubertal and pubertal children: a randomized controlled trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | Funded by the Spanish Ministry of Health, Social and Equality, General Department for Pharmacy and Health Products (codes: EC10-243, Dr Cañete, Reina Sofía Hospital, Córdoba; EC10-056, Dr Gil, university of Granada and Virgen de las Nieves university Hospital, Granada; EC10-281, Dr Leis, Clinic university  Hospital of Santiago, Santiago de Compostela; and EC10-227, Dr Bueno, Lozano Blesa university Clinical Hospital, Zaragoza) | |
| Country | Spain |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | Details of the trial protocol and ethics committees have been previously published in Trials. | |
| Outcomes other  than BMI | Other obesity, glucose metabolism, lipids, other labs | |
| Population | | |
| Inclusion criteria | BMI <95th, age 7-14 years, no underlying disease or history of pathology, no w eight treatment, no participation in a previous trial | |
| Exclusion criteria | Use of medication w ith metabolic site effects, monogenic obesity, children subjected to long periods of rest | |
| Group  differences | Randomized |  |
|  | Placebo | Metformin |
| Interventions | | |
|  | Placebo | Metformin |
| Brief description | Lifestyle advice. Placebo. | Lifestyle advice. Increasing metformin dose, from 50-500 mg bid. The participants attended an initial trial baseline visit, follow ed  by 2 additional control visits at 2-month intervals. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI (Prepubertal) |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 34 | 28.2 | 0.6 | 0.19 |
| Metformin | 33 | 26.5 | 0.7 |  |
| BMI SDS (Prepubertal) |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 34 | 3.4 | 0.2 | 0.04 |
| Metformin | 33 | 2.6 | 0.2 |  |
| BMI (Pubertal) |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 38 | 30.2 | 0.5 | 0.22 |
| Metformin | 35 | 28.5 | 0.6 |  |
| BMI SDS (Pubertal) |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Placebo | 38 | 3 | 0.2 | 0.19 |
| Metformin | 35 | 2.8 | 0.2 |  |

**Rynders, C; Weltman, A; Delgiorno, C; Balagopal, P; Damaso, L; Killen, K; Mauras, N Lifestyle intervention improves fitness independent of metformin in obese adolescents**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | This project w as supported in part by the Thrasher ResearchFund, YMCA, Nemours Research Programs, and a development re-search donation from W.  J. Wadsw orth to Nelly Mauras, principalinvestigator. | |
| Country | USA |  |
| Methods |  |  |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | Studies w ere approved by the Wolfson Children’s Hospital institutional review board. Inf ormed w ritten consent of the parent/guardian and the child’s  assent w ere obtained. | |
| Outcomes other than  BMI | Other obesity, Glucose metabolism, other (CV fitness) |  |
| Population |  |  |
| Inclusion criteria | Thirty-seven adolescents in late puberty (Tannerstages IV and V, age = 14.3T2.4 yr) w ith uncomplicatedobesity w ere recruited for the present study. Ages  10-17. | |
| Exclusion criteria | All other causes of endocrine or genetic obesity w ere excluded, and obese subjects had to have been overw eight for less than 5 yr. Subjects could not  have any history of chronic illness, chronic medications, or smoking. | |
| Group differences | Randomized |  |
|  | Diet and Exercise | Diet and Exercise + Metformin |
| Interventions |  |  |
|  | Diet and Exercise | Diet and Exercise + Metformin |
| Brief description | 6 month intensive lifestyle intervention | Up to 2g/gay metformin + lifestyle |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 6 months | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Diet and Exercise | 9 | 33.6 | 3.4 | 0.02 |
| Diet and Exercise + Metformin | 7 | 30.9 | 6.5 |  |

**Slattery, M; Bredella, Ma; Stanley, T; Torriani, M; Misra, M**

**Effects of recombinant human growth hormone (rhGH) administration on body composition and cardiovascular risk factors in obese adolescent girls**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | his study w asfunded by an investigator initiated grant (L4716N) from Genentech, SanFrancisco, CA (w ith no influence on data collection/analysis). Dr.  Misrareceived support from NIH grants UL1 RR025758 and K24 HD071843-01A1. | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the Institutional Review Board of Partners HealthCare system. Written inf ormedconsent (for patients≥18 years) or parental  consent w ithparticipant assent (for patients <18 years) w as obtainedfrom all. | |
| Outcomes other  than BMI | Other obesity, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | Inclusion criteria comprised (i) a boneage≥14 years, (ii) body mass index (BMI) > 95th percent-ile for age (based on the 2000 Centers for Disease Controland Prevention Grow th Charts) [15], or >30 kg/m2if age>18 years, (iii) insulin like grow th factor-1 (IGF-1) levelbelow the median for pubertal stage or age, (iv)  abdominalobesity w ith a w aist to hip ratio (W/H) >0.85, and (v)stable w eight (<5 kg change in w eight in the prior3 months). Ages 13-21 | |
| Exclusion criteria | Exclusion criteria included diabetes mellitus, untreated thyroid dysfunction, chronic renal insufficiency, current or past malignancy, syndromic obesity, pregnancy, breast-feeding, and use of medications know n to alter glucose metabolism or body composition (contraceptive pills, daily glucocorticoid use,  metformin, sibutramine and Orlistat). Additionally, w e excluded girls w ith new (<6 months) or unstable dosing (dosage change w ithin 3- months) of antipsychotic medications know n to cause w eight gain. | |
| Group  differences | Randomized |  |
|  | rhGH+ | rhGH- |
| Interventions | | |
|  | rhGH+ | rhGH- |
| Brief Description | The starting rhGH dose w as 0.4mg and increased at w eek-1 and w eek-2 to 0.6 mg and 0.8 mg  respectively. Lifestyle counseling w as offered | Placebo for some; no treatment for others Lifestyle  counseling w as offered. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| rhGH+ | 5 | 0.2 | 2 | 0.81 |
| rhGH- | 7 | 1.4 | 2.5 |  |

**Srinivasan, S; Ambler, Gr; Baur, La; Garnett, Sp; Tepsa, M; Yap, F; Ward, Gm; Cowell, Ct**

**Randomized, controlled trial of metformin for obesity and insulin resistance in children and adolescents: improvement in bodycomposition and fasting insulin**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This w ork w as supported in part by a National Health MedicalResearch Scholarship (to S.S.) and a Diabetes Australia Research Trustgrant (to G.R.A. and  L.A.B.). | |
| Country | Australia |  |
| Address | - |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Crossover |  |
| IRB | his studyw as approved by The Children’s Hospital at Westmead Ethics Com-mittee | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism |  |
| Population | | |
| Inclusion criteria | Participants w ere 9 to 18 yr olds w ith obesity and clinical suspicion of insulin resistance, as defined by either a fasting insulin (milliunits per liter) to glucose  (millimoles per liter) ratio greater than 4.5 (15) or the presence of acanthosis nigricans. | |
| Exclusion criteria | Exclusion criteria w ere know n type 1 or type 2 diabetes mellitus, contraindications to metformin therapy, and/or magnetic resonance imaging (MRI) scan- ning  and w eight greater than 120 kg due to technical difficulties w ith dual-energy x-ray absorptiometry (DXA) scans. | |
| Group  differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions | | |
|  | Metformin | Placebo |
| Brief description | Both metformin and placebo doses w ere gradually built up over a 3-w k period to a final dose o f 1 g tw ice daily. Standardized inf ormation on healthy eating  and exercise w as given to all patients | Both metformin and placebo doses w ere gradually built up over a 3-w k period to a final dose o f 1 g tw ice daily. Standardized inf ormation on healthy eating  and exercise w as given to all patients |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI (difference betw een groups) |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 10 | -1.26 |  | 0.002 |
| Placebo | 12 |  |  |  |
| BMI SDS (difference betw een groups) | | | | |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 10 | -0.12 |  | 0.005 |
| Placebo | 12 |  |  |  |

**Stagi, S; Lapi, E; Seminara, S; Pelosi, P; Greco, P; Capirchio, L; Strano, M; Giglio, S; Chiarelli, F; Martino, M**

**Policaptil Gel Retard significantly reduces body mass index and hyperinsulinism and may decrease the risk of type 2 diabetes mellitus (T2DM) in obese children and adolescents with family history of obesity and T2DM**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The authors and co-authors did not receive any funding to conduct this study. | |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Retrospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval (ethical code 122/2016) w as obtained fromthe Meyer Children’s University Hospital Ethics Committee. Written inf ormed assent/consent  w asobtained from all participants and their parents or guardians. | | |
| Outcomes other than  BMI | Other obesity, lipids, glucose metabolism, blood pressure, behaviors | |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere the presence of severe hyperinsulinism, insulin resistance and MetS and age betw een 8.0 and 14.5 years at the ﬁrst evaluation. Patients w ith obesity and MetS, w ho chose not to take a medication as a mean to reduce w eight and treated only w ith a LGI served as a control group (51 subjects; 24 males, 27 females; median age at study entry 12.4, range 8.2–14.5 years). Inclusion and exclusion criteria and the study protocol of the control group w ere the  same as previously seen for patients. | | |
| Exclusion criteria | Exclusion criteria w ere patients aged <8.0 years or >14.5 years at the ﬁrst evaluation, cognitive impairment, diagnosis of type 1 diabetes, existing syndrome disorders w ith or w ithout cognitive impairment, impaired renal or hepatic function, malabsorption disorders, cancer, patients enrolled in a w eight loss program at the ﬁrst evaluation, endocrine causes of obesity such as hypothyroidism or Cushing disease, and use of medications for w eight loss or any medication that could compromise the study evaluation such as topical or systemic glucocorticoids, anticonvulsant therapy, grow th hormone, sexual steroids or gonadotropin releasing  hormone analogues. | | |
| Group  differences | Patients selected into groups. |  |  |
|  | Metformin | Metformin + Policaptil Gel Retard | LGI Diet |
| Interventions | | | |
|  | Metformin | Metformin + Policaptil Gel Retard | LGI Diet |
| Brief description | subject’s study medication dose w as progressively increased according to a prespeciﬁed algorithm: in Weeks 1 and 2, participants took one tablet (500 mg) daily; thereafter, the dosage w as increased by 500 mg/day every seven days to a maximumdoseof 1500mg/ day(threetablets) | subject’s study medication dose w as progressively increased according to a prespeciﬁed algorithm: in Weeks 1 and 2, participants took one tablet (500 mg) daily; thereafter, the dosage w as increased by 500 mg/day every seven days to a  maximumdoseof 1500mg/ day(threetablets). All patients took three tablets (2175 mg) of the Policaptil Gel Retard bef ore their tw o main meals. | Patients w ith obesity and MetS, w ho chose not to take a medication as a mean to reduce w eight and treated only w ith a LGI served as a  control group |

Outcomes

BMI SDS

24 months

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (w ithin group) | p (vs. control) | p (vs. met + PGR) |
| Metformin | 41 | 2.14 | 0.2 | NS | <0.005 | <0.001 |
| Metformin + Policaptil Gel Retard | 45 | 1.92 | 0.17 | <0.001 | <0.001 |  |
| LGI Diet | 34 | 2.28 | 0.26 | NS |  | NS |

**Wilson, Dm; Abrams, Sh; Aye, T; Lee, Pd; Lenders, C; Lustig, Rh; Osganian, Sv; Feldman, Ha**

**Metformin extended release treatment of adolescent obesity: a 48-week randomized, double-blind, placebo-controlled trial with 48-week follow-up**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | The GPRNis funded by the Elizabeth Glaser Pediatric Research Foun-dation, a program of the Elizabeth Glaser Pediatric AIDSFoundation. The study w as supported by the ElizabethGlaser Pediatric Research Foundation and NIH–supported Clinical Research Cen-ters (Stanf ord University, grant MO1-RR00 070; BaylorCollege of Medicine, grant MO1-RR00188; University of California, San Francisco, grant UL-RR024131-01; Uni-versity of California, Los Angeles, grant  MO1-RR0086 5; Harvard Medical School, grant MO1-RR021 72). Bristol-Myers Squibb provided ac-tive drug (Glucophage XR) and both placebos | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the insti-tutional review boards at each of the 6 centers; inf ormed parentalconsent and subject assent w ere obtained. | |
| Outcomes other  than BMI | Other obesity, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | Adolescents aged 13.00 years to younger than 18 years w ereeligible if they w ere obese (BMI95th percentile for age andsex5) but w eighed less than 136 kg  (the w eight limit for thedual-emission x-ray absorptiometry [DXA] table). | |
| Exclusion criteria | ubjects w ere excluded if they had a previous diagnosis of diabetes mellitus, had ever used a medication to treat diabetes mellitus or insu- lin resistance, had ever used a medication to aid in w eight loss, w ere taking any medications know n to increase metformin lev- els (eg, cimetidine), received recent glucocorticoid therapy, had any identified syndrome or medical disorder predisposing to obesity, had surgical therapy for obesity, had attended a for- mal  w eight loss program w ithin the previous 6 months, admit- ted to significant alcohol use in the past 6 months, had el- evated creatinine ( 1.2 mg/dL [to convert  to micromoles per liter, multiply by 88.4]) or liver enzymes (aspartate amino- transferase or alanine aminotransferase 80 U/L [to convert to microkatals per liter, multiply by 0.0167]) levels, had un- treated disorders of thyroid function, had impaired ambula- tion or mobility, or had ever been pregnant | |
| Group  differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions | | |
|  | Metformin | Placebo |
| Brief description | Up to 2g/day + lifestyle program | Placebo + lifestyle program |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 52 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 27 | -0.9 | 0.5 | 0.03 |
| Placebo | 27 | 0.2 | 0.5 |  |
| BMI SDS |  |  |  |  |
| 52 w eeks | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Metformin | 27 | -0.09 | 0.04 | 0.09 |
| Placebo | 27 | -0.01 | 0.04 |  |

**Yanovski, Ja; Krakoff, J; Salaita, Cg; McDuffie, Jr; Kozlosky, M; Sebring, Ng; Reynolds, Jc; Brady, Sm; Calis, Ka**

**Effects of metformin on body weight and body composition in obese insulin-resistant children: a randomized clinical trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | This study w as supported by the Intramural Research Program of the Eunice Kennedy Shriver NICHD, NIH (Grant Z01-HD-000641), and NCMHD, NIH (both to J.A.Y.), and in part by NIDDK (J.K.). J.A.Y. received a grant from Obecure and has a material transfer agreement w ith Roche for support of other obesity-  medication treatment studies | |
| Country | USA |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the In- stitutional Review Boards of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH, and the Phoenix Area Indian Health Service. Written assent and consent w ere obtained from chil- dren and their parents. The study w as  overseen by a Data and Saf ety Moni- toring Board convened by NICHD. | |
| Outcomes other  than BMI | Other obesity, blood pressure, other labs, lipids, glucose metabolism |  |
| Population | | |
| Inclusion criteria | aged 6–12 years, recruited through new spaperadvertisements and letters to physicians, w ere eligible if they had BMI$95thpercentile according to the Centers for Disease Control and Prevention 2000grow th charts for the United States; w ere prepubertal or early pubertal (de-fined as breast Tanner stage I–III for girls;  testes,8 mL for boys); and hadf asting hyperinsulinemia, defined as fasting insulin$15mU/ mL | |
| Exclusion criteria | Children w ere excluded if they had impaired fasting glucose, w ere diabetic, or reported a diagnosed renal, cardiac, endocrine, pulmonary, or hepatic disease that might alter body w eight. Subjects w ere excluded for baseline creatinine . 1 mg/dL and for alanine aminotransferase (ALT) or aspartate aminotransferase  (AST) that exceeded 1.5 times the upper limit of the laboratory normal range | |
| Group  differences | Randomized |  |
|  | Metformin | Placebo |
| Interventions | | |
|  | Metformin | Placebo |
| Brief Description | Up to 1g/day metformin, w ith lifestyle treatment | Placebo, w ith lifestyle treatment |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Metformin | 53 | -0.11 | -0.16 | -0.05 | 0.02 |
| Placebo | 47 | -0.04 | -0.1 | 0.02 |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Metformin | 53 | -0.78 | -1.54 | -0.01 | 0.006 |
| Placebo | 47 | 0.32 | -0.54 | 1.18 |  |

**Treatment effects on measures of body composition in the TODAY clinical trial**

Study

Identification

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsorship source | w ork w as completed w ith funding from the NIDDK of the National Institutes of Health (grants U01-DK- 61212, U01-DK-61230, U01-DK-61239, U01- DK- 61242, and U01-DK-61254), the National Center for Research Resources (NCRR) General Clinical Research Centers Program (grantsM01- RR-00036 [Washington University School of Medicine], M01-RR-00043-45 [Children’s Hospital Los Angeles], M01-RR-00069 [University of Colorado Denver], M01-RR- 00084 [Children’s Hospital of Pittsburgh], M01-RR-01066 [Massachusetts General Hospital], M01-RR- 00125 [Yale University], and M01-RR-14467 [University of Oklahoma Health Sciences Center]), and the NCRR Clinical and Translational Science Aw ards (grants UL1-RR-024134 [Children’s Hospital of  Philadelphia], UL1-RR- 024139 [Yale University], UL1-RR-024153 [Children’sHospital of Pittsburgh], UL1-RR- 024989 [Case Western Reserve University],  UL1-RR-024992 [Washington University in St. Louis], UL1-RR-025758 [Massachusetts General Hospital], and UL1-RR-025780 [University of Colorado Denver]). | | |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB | The protocol w as approved by an external evaluation com- mittee convened by the NIDDK and the institutional review board of each partici-  patinginstitution.All participants provided both inf ormed parental consent and minor child assent | | |
| Outcomes other  than BMI | Other obesity |  |  |
| Population |  |  |  |
| Inclusion criteria | 10 – 17 years of age, diagnosed w ith type 2 diabetes , 2 years according to American Diabetes Association (ADA) di- agnostic glucose criteria (4), BMI $ 85th percentile, and negative for diabetes autoantibodies (5). Subjects also had to successfully complete a 2 – 6monthpre- randomization run-in period in w hich they demonstrated mastery of standard diabetes education, w ere w eaned from nonstudy diabetes medications, demon- strated tolerance of metformin up to a dose of 1,000 mg tw ice daily but no less than 500 mg tw ice daily, attained glyce- mic control (HbA 1c , 8% [64 mmol/mol] monthly for at least 2 months) on  metfor- min alone, and demonstrated adherence to study medication and visit attendance | | |
| Exclusion  criteria | none noted |  |  |
| Group  differences | Randomized |  |  |
|  | Metformin | Metformin + Rosiglitazone | Metformin + Lifestyle |
| Interventions |  |  |  |
|  | Metformin | Metformin + Rosiglitazone | Metformin + Lifestyle |
| Brief description | metformin, few details provided on actual  implementation | metformin + Rosiglitazone, few details provided on actual  implementation | Metformin plus an intensive lifestyle  program |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI change from baseline |  |  |  |  |  |  |  |  |
|  | 2 years |  |  |  | 6 months |  |  |  |
|  | N | Mean | SE | p (across groups) | N | Mean | SE | p (across groups) |
| Metformin | NR | 1.57 | 0.21 |  | NR | 0.35 | 0.17 |  |
| Metformin + Rosiglitazone | NR | 2.93 | 0.2 | (MR and ML) 0.0002 | NR | 0.7 | 0.17 | (M and MR) <0.0001 |
| Metformin + Lifestyle | NR | 1.52 | 0.2 | (M and ML) 0.0201 | NR | -0.21 | 0.17 | (MR and ML) <0.0001 |

**Bassols 2019**

**Effects of metformin administration on endocrine-metabolic parameters, visceral adiposity and cardiovascular risk factors in children with obesity and risk markers for metabolic syndrome: A pilot study**

Study Identification

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsorship source | The study was supported by grants from the Instituto de  Salud Carlos III, Madrid, Spain (EC10/00252 and PI16/01335 to A.L-B.; CPII17/ 00013 and PI17/00557 to  J.B.; CD15/00162 to S. X.), projects co-funded by FEDER (Fondo  Europeode Desarrollo Regional ) and from the Generalita t  de Catalunya, Barcelon a, Spain (SLT002/1 6/00065 to B. M-P.). |  |  |
| Country | Spain |  |  |
| Methods |  |  |  |
| Design | Randomized controlled trial |  |  |
| Group | Parallel group |  |  |
| IRB |  |  |  |
| Outcomes other than BMI | Other obesity, Lipids, glucose metabolism |  |  |
| Population |  |  |  |
| Inclusion criteria | The inclusion criteria were (all had to be fulfilled): (1) age between 6 and 13 years; (2) pre- puberal or early pubertal (Tanner stage I-II) [ 19 , 20 ]; (3) BMI between 2 SD (97th centile) and 4 SD, for age and sex; (4) fasting insulin levels > 6 mIU/L; 5) visceral-to-subcutaneous fat ratio (magnetic resonance imaging [MRI]) > 90th centile, based on a reference of healthy chil- dren without obesity [ 21 ]; and (6) birth weight above –  1.5 SD and below +1.5 SD for gesta- tional age, to avoid the influence of birth weight deviations on metabolic and cardiovascular risk markers. The BMI of the patient ha  d to be stable (along the same percentile) for the past 3 months prior to inclusion in the trial. | | |
| Exclusion criteria | The exclusion criteria were (any of the following): (1) drug or alcohol abuse during gesta- tion; (2) genetic syndromes; and (3) hypothalamic obesity (previous hypothalamic damage, diagnosis of Prader-Willi syndrome, or side effects of psychotropic drugs). At the time of inclusion: (4) abnormalities in thyroid, liver, or  renal function or in serum electrolytes; (5) known skin allergies; (6) glucose intolerance or type 2 diabetes; (7) chronic illnesses other than obesity; (8) treatment with co rticosteroids, sexual hormones, and drugs that may alter glucose tolerance or insulin sensitivity; (9) acute infections or use of anti-  inflammatory drugs or anti- biotics 2 weeks prior to potential inclusion in the study; (10) medical treatment or other thera- pies aimed at reducing body weight (3 mont  hs prior to potential inclusionin the study). | | |
| Group differences |  |  |  |
| Special populations |  |  |  |
|  | Metformin | Placebo | Overall |
| Interventions | |  |  |
|  | Metformin | Placebo |  |
| Brief description | 850 mg metformin once daily at dinner time for 24  months. | placebo once daily (same manufacturer as metformin) at dinner time for 24  months. |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |  |  |
| Baseline | |  |  | 6 months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (between groups) | N | Mean | SD | p (between groups) | N | Mean | SD | p (between groups) |
| Metformin | 9 | 2.9 | 0.2 | NS | 9 | 2.3 | 0.2 | NS | 9 | 2.3 | 0.2 | NS |
| Placebo | 9 | 2.6 | 0.2 |  | 9 | 2.7 | 0.2 |  | 9 | 2.7 | 0.2 |  |

# Non-Randomized Lifestyle Studies (Priority 3)

**Adam, S; Westenhofer, J; Rudolphi, B; Kraaibeek, Hk**

**Effects of a combined inpatient-outpatienttreatment ofobese children and adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This study w as funded by the Deutsche Angestellten-Krankenkasse (DAK) | |
| Country | Germany |  |
| Methods | | |
| Design | Prospective  cohort study |  |
| Group | Parallel group |  |
| IRB | Written inf ormed consent by the parents or guardians of the children and adoles-cents w as required for study participation | |
| Outcomes other  than BMI | Behaviors |  |
| Population | | |
| Inclusion criteria | For the program, obese children and adolescents aged 8–15 years. Parents and their children have to apply on their ow n initiative for admission to  this therapy program. In addition, for inclusion in this evaluation study, candidates had to be at least 10 years old. | |
| Exclusion criteria | None listed |  |
| Group  differences | None |  |
|  | Control Group | Intervention group |
| Interventions | | |
|  | Control Group | Intervention group |
| Brief description | Waitlist | The treatment program lasts for 1 year and comprises of 2 phases: an initial inpatient therapy for 6 w eeks follow ed by a home-based outpatient treatment of the overw eight children, adolescents, and their families for 10.5 months. The therapy complies w ith the guidelines  of the German Working Group of Obesity in Childhood and Adolescence (AGA). |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Control Group | 75 | 0.27 | 0.9 | <0.05 | <0.05 |
| Intervention group | 162 | -2.21 | 1.99 | <0.05 |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Control Group | 75 | 0.04 | 0.17 | NS | <0.05 |
| Intervention group | 162 | -0.36 | 0.34 | <0.05 |  |

**Anderson, Y. C.; Cave, T. L.; Cunningham, V. J.; Pereira, N. M.; Woolerton, D. M.; Grant, C. C.; Cutfield, W. S.; Derraik, J. G.; Hofman, P. F. Effectiveness of current interventions in obese New Zealand children and adolescents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study  Identification |  |  |  |  |
| Sponsorship  source | None noted for study |  |  |  |
| Country | New Zealand |  |  |  |
| Methods | | | | |
| Design | Prospective cohort study |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | Approval from the National Ethics Advisory Committee to treat this study as an audit w as obtained | | |  |
| Outcomes other than BMI | None |  |  |  |
| Population | | | | |
| Inclusion  criteria | Entry criteria w ere children and adolescents aged 3 to 16 years that w ere identified as having a BMI>98th centile (WHO definition of obese), or >91st centile  (over-w eight) w ith significant w eight-re-lated co-morbidities. | | | |
| Exclusion  criteria | None noted. |  |  |  |
| Group  differences | No differences in inclusion  criteria. |  |  |  |
|  | Medical | Medical & Dietitian | Medical & Dietitian & Active Families | Multidisciplinary |
| Interventions | | | | |
|  | Medical | Medical & Dietitian | Medical & Dietitian & Active Families | Multidisciplinary |
| Brief description | ‘Standard’ models of care—medical follow -up by a paediatrician at regular intervals w ith no dietitian input (usually because input w as declined) | Medical follow -up by a paediatrician and dietitian input at regular intervals | Medical follow -up/ dietitian input and Green Prescription (GRx) ‘Active Families’ input. GRx ‘Active Families’ programme is implemented by 14 DHBs across New Zealand and delivered by regional sports trusts. It is a family/w hānau based programme that attempts to encourage healthy lifestyle change in children, adolescents and their families at a community level, addressing both physical activity and nutrition in w eekly  sessions for up to 12 months. | The multi-disciplinary intervention programme involved input from a paediatrician, healthy  lifestyles co-ordinator, dietitian, psychologist, and ‘Active Families’ co-ordinator. The inter- vention involved 8 group sessions at w eekly intervals after baseline assessment, w ith a goal of follow -up for 24 months. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |
| 2.1 Years (average) | | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Medical | 23 | -0.17 | -0.33 | -0.01 | <0.05 | 0.64 |
| Medical & Dietitian | 75 | -0.14 | -0.23 | -0.04 | <0.01 |  |
| Medical & Dietitian & Active Families | 47 | -0.22 | -0.33 | -0.1 | <0.001 |  |
| Multidisciplinary | 145 | -0.13 | -0.2 | -0.07 | <0.001 |  |
| BMI |  |  |  |  |  |  |
| 2.1 Years (average) | | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Medical | 23 | 2.1 | 0.94 | 3.25 | <0.001 | 0.3 |
| Medical & Dietitian | 75 | 1.89 | 1.23 | 2.56 | <0.0001 |  |
| Medical & Dietitian & Active Families | 47 | 1.14 | 0.33 | 1.94 |  |  |
| Multidisciplinary | 145 | 2.01 | 1.53 | 2.49 |  |  |

**Braet, C.; Tanghe, A.; Bode, P. D.; Franckx, H.; Winckel, M. V.**

**Inpatient treatment of obese children: a multicomponent programme without stringent calorie restriction**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | None listed |  |
| Country | Belgium |  |
| Methods |  |  |
| Design | Case-control study |  |
| Group | Parallel group |  |
| IRB | Not listed |  |
| Outcomes other than BMI | Psychosocial, mental health, behaviors |  |
| Population |  |  |
| Inclusion criteria | Children and adolescents ref erred tothe centre by physicians for inpatient treatment because of obesity |  |
| Exclusion criteria | Children w ith Prader Willi syndrome or mental retardation w ere not recruited |  |
| Group differences | No differences |  |
|  | Inpatient Treatment | Waitlist control |
| Interventions |  |  |
|  | Inpatient Treatment | Waitlist  control |
| Brief description | Adapted physical training 4 hours/w eek and "stimulated to exercise for 10 hours/w eek or more) ; dietary change according to  conventional recommendations (30% energy from fat; 15% from protein; 55% from carbs; providing betw een 1500-1800 kcal/day); cognitive behavioral modification (12 w eeks follow ed by problem-solving booster session every w eek) | Waitlist |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Adjusted BMI (percent change) |  |  |  |  |
| 10 months | | | | |
|  | N | Median | Range (Low er Bound) | Range (Upper Bound) |
| Inpatient Treatment | 31 | -48 | -102 | -4 |
| Waitlist control | 35 | 6 | -29 | 27 |
| Weight |  |  |  |  |
| 10 months | | | | |
|  | N | Median | Range (Low er Bound) | Range (Upper Bound) |
| Inpatient Treatment | 31 | -19 | -41 | 2 |
| Waitlist control | 35 | 4 | -11 | 21 |

**Braet, C.; Van Winckel, M.; Van Leeuwen, K.**

**Follow-up results of different treatment programs for obese children**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study Identification |  |  |  |  |  |
| Sponsorship source | None listed |  |  |  |  |
| Country | Beligum |  |  |  |  |
| Methods |  |  |  |  |  |
| Design | Prospective cohort study |  |  |  |  |
| Group | Parallel group |  |  |  |  |
| IRB | Not reported |  |  |  |  |
| Outcomes other than BMI | None |  |  |  |  |
| Population |  |  |  |  |  |
| Inclusion criteria | The children w ere betw een 7 and 16 years of age (mean= 1 1.6 y) and w ere at least 20% overw eight. Subjects w ere free of other  medical problems such as diabetes, or did not suffer from any syndromic obesity | | | | |
| Exclusion criteria | No other medical problems such as  diabetes |  |  |  |  |
| Group differences | Control group w as not treatment-  seeking |  |  |  |  |
|  | Group | Individual | Advice | Camp | Control |
| Interventions |  |  |  |  |  |
|  | Group | Individual | Advice | Camp | Control |
| Brief description | In a group- The outpatient program (group or individual) consisted of an intensive part for the child only, including seven sessions of 90 min (tw ice a month) and seven family  follow -up ses- sions (once a month). | Individually- The outpatient program (group or individual) consisted of an intensive part for the child only, including seven sessions of 90 min (tw ice a month) and seven family  follow -up ses- sions (once a month). | Received the same counseling as all other groups | They received balanced healthy food (1 500 kcal/day) and daily  lifestyle exercises (5 Nday). After- w ards, all families of the summer camp condition w ere requested to attend the monthly follow -up  sessions. | Usual care |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| Percentage w eight loss | | | | | | | | |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | p (w ithin group) | p (across groups) | N | Mean | p (w ithin group) | p (across groups) |
| Group | 45 | -8.84 | <0.001 |  | 45 | -13.08 | <0.001 |  |
| Individual | 48 | -8.34 | <0.001 |  | 48 | -9.84 | <0.001 |  |
| Advice | 57 | NA |  |  | 57 | -6.84 | <0.001 |  |
| Camp | 55 | -15.59 | <0.001 | <0.001 | 55 | -14.67 | <0.001 | NS |
| Control | 54 | NA |  |  | 54 | 2.52 | <0.001 |  |

**Bruyndonckx**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Supported by the University Research Fund (BOF-ID) of the University of Antw erp to Drs Conraads, Vrints, Ramet, Vissers, and Bruyndonckx (grant  24585)and by the Belgian Hypertension Committee Aw ard 2010. | |
| Country | Belgium |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The protocol complied w ith the Declaration of Helsinki, w as approved by the ethics committee of the Antw erp University Hospital, and w as registered at  ClinicalTrials.gov (NCT01461226). All participants and their parents gave their w ritten inf ormed consent. | |
| Outcomes other  than BMI | Other obesity, lipids, blood pressure, glucose metabolism, other (endothelial function, CV fitness) | |
| Population | | |
| Inclusion criteria | 61 individuals betw een the ages of 12 and 18. Inclusion criteria w ere a BMI $ 97th age- and gender-speci fi c percentile for adolescents younger than 16  years and BMI $ 35 for adolescents older than 16 years. | |
| Exclusion criteria | Exclusion criteria w ere an acute orchronic inflammatory process, use of nonsteroidal antiinflammatory orimmunosuppressive drugs, structuralheart disease or  other cardiovasculardiseases, and active malignanthemat ologic disease | |
| Group differences | Quasi-randomized (those just starting a 10 month residential program versus those on the w aitlist) | |
|  | Residential Treatment | Waitlist Control |
| Interventions | | |
|  | Residential Treatment | Waitlist Control |
| Brief description | Inpatient treatment included dietary restriction (1500 – 1800 kcal/day), physical activity, and psychological support under medical  supervision. | Participants on the w aiting list w ere treated by their general practitioner or pediatrician, focusing on caloric restriction and encouragement to participate in  sports activities. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 10 months | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Residential Treatment | 27 | 27.39 | 3.57 | <0.001 |
| Waitlist Control | 21 | 39.1 | 5.26 |  |
| BMI SDS |  |  |  |  |
| 10 months | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Residential Treatment | 27 | 1.55 | 0.53 | <0.001 |
| Waitlist Control | 21 | 2.9 | 0.42 |  |

**Chamay-Weber, C.; Farpour-Lambert, N. J.; Saunders Gasser, C.; Martin, X. E.; Gal, C.; Maggio, A. B.**

**Obesity Management in Adolescents: Comparison of a Low-Intensity Face-to-Face Therapy Provided by a Trained Paediatrician with an Intensive Multidisciplinary Group Therapy**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | This study w as supported by the University Hospitals of Geneva |  |
| Country | Sw itzerland |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the Research Ethics Committee of the HUG and adolescents and their parents provided their consents | |
| Outcomes other than BMI | None |  |
| Population |  |  |
| Inclusion criteria | Adolescents w ith obesity w ere ref erred by paediatricians, general practitioners, school nurses, families or by the staff of the Department of Child and Adolescent of the HUG. Age 11-18 years of age Intensive Group Therapy: i) to have at least one parent w ho can attend the parents’ meetings, ii) to understand and speak French (adolescents and parents), iii) absence of psychiatric or developmental disorders limiting group participation, iv)  absence of orthopaedic condition limiting the participation in physical activity | |
| Exclusion criteria | Less than 5 months follow -up |  |
| Group differences | Patients/Families self select into groups: a) Intensive Group Therapy (family based behavioural therapy conducted by a multidisciplinary team) b)  low -intensity face-to-face therapy, (an out-patient consultation conducted by a paediatrician trained in obesity care) | |
|  | Intensive group therapy | Low Intensity |
| Interventions |  |  |
|  | Intensive group therapy | Low Intensity |
| Brief description | The main goal of the intensive group therapy w as to encourage lifestyle changes over a 1-year period. It consisted of psycho-educative sessions of 90 min w ith a dietician and a psychologist certified in cognitive-behav-ioural therapy, and sessions of 90 min of physical activity w ith a sport teacher specialised in adapted physical education. | Cognitive and behavioural management techniques w ere used to promote lifestyle changes in adolescents and their parents. The mean duration of a visit w as 45 min.  Consultations every 1-3 months. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| End of therapy (5-12 months) | | | | | |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Intensive group therapy | 72 | -0.24 | 0.5 | <0.001 | NS |
| Low Intensity | 159 | -0.2 | 0.5 | <0.001 |  |

**Chen**

**Istart smart**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | NR |  |
| Country | USA |  |
| Methods |  |  |
| Design | Historically controlled trial |  |
| Group | Parallel group |  |
| IRB | The University of California San Francisco Committee on Human Research approved the study |  |
| Outcomes other than BMI | Other obesity, blood pressure, behaviors |  |
| Population |  |  |
| Inclusion criteria | (1) The adult and child self -identified ethnicity as Chinese or of Chinese origin, and they reside in the same household. (2) The child w as able to speak and read English. (3) The child w as in good health, defined as free of an acute or life-threatening disease. (4) Parents w ere able to speak  English, Mandarin, or Cantonese and w ere able to read in English or Chinese | |
| Exclusion criteria | NR |  |
| Group differences |  |  |
|  | iStart Smart | Control |
| Interventions |  |  |
|  | iStart Smart | Control |
| Brief description | iStart Smart Program: Parent-child small group sessions (four times); children attended 8 w eekly 1.5 hour small group sessions and parents attended a single 1 hour parent w orkshop. Medical care w as integrated into the prgram through individualized w eight management supervised by a pediatrician. Programs included educational play-based activities teaching self -efficacy, critical thinking, and problem solving. Each session included 30 min. of  interactive health curriculum and community center staff led 60 min of exercise. | Children in the historical control group had their w eight, height, and blood pressure measured as the same interval as children  in iStart Smart. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |  |  |
|  | T0 |  |  |  | T1 |  |  |  | T2 |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| iStart Smart | 21 | 25.53 | 3.65 | NA | 21 | 25.16 | 3.91 | NA | 21 | 24.53 | 4.2 | 0.004 |
| Control | 20 | 23.17 | 1.22 | NA | 20 | 23.18 | 1.28 | NA | 20 | 23.2 | 1.31 |  |

**Cheng, J. K.; Wen, X.; Coletti, K. D.; Cox, J. E.; Taveras, E. M.**

**2-Year BMI Changes of Children Referred for Multidisciplinary Weight Management**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | The w ork is funded in part by the National Institute on Minor-ity Health and Health Disparities (Grant no. R01MD00396). | |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study protocol w as approved by the human subjectscommittee of Boston Children’s Hospital. | |
| Outcomes  other than BMI | None |  |
| Population | | |
| Inclusion criteria | Overw eight (BMI≥85th and<95th sex- and age-specific percentile based on Centers for Disease Prevention and Control 2000 Grow th Charts) or obese (>95th percentile) children aged 2–18 years w ho w ere ref erred from the CHPCC to the OSA program betw een 2003 and 2009. And had completed at least 2 visits in  the 2 years after ref erral. | |
| Exclusion  criteria | None reported |  |
| Group  differences | Children w ho chose to attend One Step Ahead program vs. those w ho did not (but w ere ref erred). | |
|  | One Step Ahead | Primary Care |
| Interventions | | |
|  | One Step Ahead | Primary Care |
| Brief description | Dieticians provide family-centered nutrition education and teach families practical skills; a physical activity coordinator matches familiesw ith free or low -cost neighborhood exercise programs; a behavioral psychologist evaluates families for maladaptivebehaviors and provides supportive mental health services; a medical social w orker frequentl yassists families w ith acute social support needs. | Seen by their primary care providers for routine w ell child-care annually or more frequently for problem-focused visits (e.g., for w eight related or other issues). CHPCC w ell care visit content is based on the Bright-Futures Guidelines for Health Supervision[7], but no practice-w ide standards existed at the time of this study for obesity assessment, education or  follow -up intervals. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS (Monthly rate of change) | | | | | | | | | | | | | | | | |
|  | 0-6  months |  |  |  | 7-12  months |  |  |  | 13-18  months |  |  |  | 19-24  months |  |  |  |
|  | mean | CI  (low er bound) | CI  (upper bound) | p  (betw een groups) | mean | CI  (low er bound) | CI  (upper bound) | p  (betw een groups) | mean | CI  (low er bound) | CI  (upper bound) | p  (betw een groups) | mean | CI  (low er bound) | CI  (upper bound) | p  (betw een groups) |
| One Step  Ahead | -0.013 | -0.017 | -0.009 | 0.001 | -0.008 | -0.011 | -0.006 | 0.093 | -0.008 | -0.01 | -0.006 | 0.051 | -0.008 | -0.01 | -0.006 | 0.008 |
| Primary  Care | 0.004 | -0.005 | 0.013 |  | -0.005 | -0.008 | -0.003 |  | -0.005 | -0.007 | -0.003 |  | -0.004 | -0.006 | -0.002 |  |

**Cloutier, M. M.; Wiley, J.; Huedo-Medina, T.; Ohannessian, C. M.; Grant, A.; Hernandez, D.; Gorin, A. A. Outcomes from a Pediatric Primary Care Weight Management Program: Steps to Growing Up Healthy**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Supported by the Catherine and Patrick Weldon Donaghue Medical Research Foundation, the Aetna Foundation, and the Hartford Foundation for Public Giving  and Bingham McCutcheon. The authors declare no conflicts of interest. | |
| Country | USA |  |
| Methods | | |
| Design | Historically controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the Institu-tional Review Board of Connecticut Children’s MedicalCenter. | |
| Outcomes  other than BMI | Behaviors |  |
| Population | | |
| Inclusion  criteria | child aged 2-4 years, Hispanicor African American race/ethnicity by self -report (English-or Spanish-speaking), and Women, Inf ants, and Childrenprogram–  eligible and receiving services. | |
| Exclusion  criteria | Dyads w ere excluded if the mother w as aged <18 years, lived outside of the Hartford area, or planned to move out of the area w ithin the next 12 months, or if  the child had special needs (dietary,physical, and/or emotional) that w ould make the intervention inappropriate or BMI <5th percentile. | |
| Group  differences | Same inclusion |  |
|  | Usual care | Intervention |
| Interventions | | |
|  | Usual care | Intervention |
| Brief description | Historical control: height and w eight measurements,calculation of body mass index [BMI] percentile by mostclinicians, and counseling as deemed appropriate by theclinician | Pediatric primary care clinicians used MI techniques (positive affirmation, open-ended questions  w ith reflective listening, collaborative goal setting, and contracting) during regularly scheduled clinic visits over a 12-month period to target 4 specific obesogenic behaviors (milk consumption, juice and sugar-sw eetened beverage consumption, television/screen time, and physical activity). A  w ritten contract, self -monitoring calendar,and telephone follow -up at 5-7 days after the clinic visit  reinf orced the intervention. |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI Percentile |  |  |  |
|  | 12 months |  |  |
|  | N | Mean | P (betw een groups) |
| Usual care | 218 | 8.75 | <0.001 |
| Intervention | 200 | -0.33 |  |

**Danielsson, P.; Bohlin, A.; Bendito, A.; Svensson, A.; Klaesson, S.**

**Five-year outpatient programme that provided children with continuous behavioural obesity treatment enjoyed high success rate**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This study w as funded by the Public Health Services Committee Administration, the Department of Development, Stockholm County Council and the  Samariten Foundation. | |
| Country | Sw eden |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | All families have accepted to be registered in BORIS, and the study w as approved by the Stockholm Regional Ethical Review Board (2007/462-31/2). | |
| Outcomes other  than BMI | Other- Parent BMI |  |
| Population | | |
| Inclusion criteria | Patients aged four to 13 years, ref erred to and treated at the outpatient clinic. Only children w ith obesity and severe overw eight children w ith high risk for  obesity development or comorbidities are accepted for treatment. | |
| Exclusion criteria | NR |  |
| Group differences | To be able to evaluate, the treatment effects in a matched comparison group w ere identified in the National Health Care Register for Childhood Obesity  (BORIS). The comparison group w as matched on date and age at start of treatment, further inclusion criteria w ere treatment in the same healthcare level. | |
|  | Treatment | Comparison |
| Interventions | | |
|  | Treatment | Comparison |
| Brief description | Parent education, group and individual behavior modification, physical activity counseling, visits w ith PCP's,  nurse, dieticians, etc. | Comparison group obtained from  database |

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| --- | --- | --- | --- | --- | --- |
| Outcomes | | | | | |
| BMI SDS (Change relative  to TAU) | | | | | |
|  | 5  years |  |  |  |  |
|  | n | Mean | SD | p (w ithin  group) | p (betw een groups) |
| Treatment | 110 | 4-6 years (-1.2); 7-10 years (-1.0) 11-  13 years(-0.6) | 0.8 (for all groups) | 4-6: p=0.01 | p<0.001 all groups, betw een specific age groups: p<0.05 |
| Comparison | 103 | 4-6 years (-0.8) 7-10 years (-0.8) 11-  13 years (-0.3) | 4-6 years (0.6) 7-10 years (0.5) 11-  13 years (0.1) |  |  |

**Eliakim, A; Friedland, O; Kowen, G; Wolach, B; Nemet, D**

**Parental obesity and higher pre-intervention BMI reduce the likelihood of a multidisciplinary childhood obesity program to succeed--a clinical observation**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Not indicated |  |
| Country | Israel |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not indicated |  |
| Outcomes  other than BMI | Other obesity |  |
| Population | | |
| Inclusion  criteria | Children and adolescents attending the obesity clinic age 6-16 |  |
| Exclusion  criteria | None of the subjects had an organic cause for his/her obesity, and none of the subjects received any medication that w ould interfere w ith grow th or w eight  control (e.g. corticosteroids, thyroid hormone). | |
| Group  differences | Control group are those w ho w ere unable to participate in structured program |  |
|  | Control | Intervention |
| Interventions | | |
|  | Control | Intervention |
| Brief description | unable to participate in our structured program either because of other obligations during the time of the training sessions, or due to transportation difficulties, served as controls. The control subjects w ere ref erred to an ambulatory pediatric nutritional consult at least once every 3 months, and w ere instructed to perform  physical activity three times per w eek on their ow n. | All subjects and parents w ere invited together for a series of four evening lectures (childhood obesity, general nutrition, therapeutic nutritional approach for childhood obesity, and exercise and childhood obesity) during the first 3 months of the program. The lectures w ere given by the  physicians and dietitians of the Child Health and Sports Center. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Control | 37 | 0.6 | 0.1 | <0.05 | 37 | 1.4 | 0.3 | <0.05 |
| Intervention | 77 | -1.1 | 0.3 |  | 77 | -1.3 | 0.3 |  |
| BMI Percentile |  |  |  |  |  |  |  |  |
|  | 6 months |  |  | 12 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Control | 37 | 0.5 | 0.3 | <0.05 | 37 | 0.5 | 0.7 | <0.05 |
| Intervention | 77 | -2.6 | 0.5 |  | 77 | -4.7 | 0.8 |  |

**Eliakim, A; Kaven, G; Berger, I; Friedland, O; Wolach, B; Nemet, D**

**The effect of a combined intervention on body mass index and fitness in obese children and adolescents - a clinical experience**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Israel |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes  other than BMI | Other obesity, behaviors |  |
| Population | | |
| Inclusion  criteria | Children and adolescents seen in the obesity clinic |  |
| Exclusion  criteria | None of the subjects had an organic cause for his/her obesity and none received any medication w hich w ould interfere w ith grow th or w eight control (e.g.  corticosteroids, thyroid hormone). | |
| Group  differences | Control group are those w ho could not participate. |  |
|  | Control | Combined intervention |
| Interventions | | |
|  | Control | Combined intervention |
| Brief description | A group of 25 obese children and adolescent w ho w ere follow ed in our obesity clinic and w ere unable to participate in our dietary and exercise programme due to other obligations during the time of the training sessions and because of transportation difficulties served as controls. The control subjects w ere ref erred to an outpatient nutritional consultation at least once every 3 months and w ere  instructed to perform physical activity three times per w eek on their ow n. | All subjects and parents w ere invited together for a series of four evening lectures (childhood obesity, general nutrition, therapeutic nutritional approach for childhood obesity, and exercise and childhood obesity) during the first 3 months of the programme. Subjects received a balanced hypocaloric diet, and participated in a tw ice-w eekly training programme (1 h  per training session). |

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| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 3 months |  |  |  |  |
|  | n | Mean | SD | p (w ithin group) | p (betw een groups) |
| Control | 25 | 25.6 | 1.4 | <0.05 | <0.05 |
| Combined intervention | 177 | 25.4 | 0.3 | <0.05 |  |

**Endevelt, R.; Elkayam, O.; Cohen, R.; Peled, R.; Tal-Pony, L.; Michaelis Grunwald, R.; Valinsky, L.; Porath, A.; Heymann, A. D. An intensive family intervention clinic for reducing childhood obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Israel |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Both participants and their parents signed an inf ormed consent and an agreement to take part in the program; the study w as approved by the local ethics  committee | |
| Outcomes other  than BMI | Other obesity |  |
| Population | | |
| Inclusion criteria | Children aged 5 to 14 years w ho w ere defined as overw eight or obese. And w ho previously failed at least 2 other w eight loss attempts. In- Inclusion in the study required family physician re- ferral and the w illingness and commitment of the children and their parents to long-term participa- tion in the intervention  program. | |
| Exclusion  criteria | No additional |  |
| Group  differences | "Only children (and their families) from the inter-vention group w ho had participated in at least 85%of the meetings, including the physical activityclasses, w ere included in the analysis." | |
|  | Intervention | Comparison |
| Interventions | | |
|  | Intervention | Comparison |
| Brief description | Parents’ education groups for nutrition and healthy behavior, children's individual therapy, and  physical activity groups for 6 months | The comparison group consisted of children aged 5 to 14 years, from the same MHS regions, w ho according to their computerized records w ere overw eight or obese during the same time period and w ere  matched (using a frequency matching method) to the intervention group by baseline BMI z scores. |

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| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| Post-Intervention | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Intervention | 100 | 1.74 | 0.8 | 0.019 |
| Comparison | 943 | 1.95 | 0.4 |  |

**Gortmaker, S. L.; Polacsek, M.; Letourneau, L.; Rogers, V. W.; Holmberg, R.; Lombard, K. A.; Fanburg, J.; Ware, J.; Orr, J. Evaluation of a primary care intervention on body mass index: the Maine Youth Overweight Collaborative**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Evaluation of the MYOC intervention w as supported by the CDC (Prevention Research Centers Grant U48DP000 064), by the Maine Health Access Foundation,  and Harvard Catalyst for Dr. Ware’s time. | |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study received institutional re-view board approval by the Committee on Human Subjectsat the Harvard School of Public Health (Boston, MA) | |
| Outcomes  other than BMI | None |  |
| Population | | |
| Inclusion  criteria | 2-18 years |  |
| Exclusion  criteria | None |  |
| Group  differences | Unclear |  |
|  | MYOC | Control |
| Interventions | | |
|  | MYOC | Control |
| Brief description | Key change components of the MYOC intervention included: (1) approximately one 1.5-day learning session (for the practice team to attend) every 6 months; (2) 4–6 minutes during each w ell-child visit for the healthcare provider to deliver the 5210 healthy habits message to promote self -management skills, and set goals;  (3) 5 minutes during each w ell-child visit for another practice team member (e.g., medical assistant or nurse) to measure height and w eight for BMI; (4) tw o 30- minute meetings per month to assess team progress and discuss partnerships  w ith community and state organizations; (5) one to tw o 1-hour conf erence calls per month; and 6) a 1-hour site visit every few months | Intervention sites had been participating in MYOC since November 2004, w hereas control sites started to implement the intervention in September 2006. Our focused efforts at the start of phase 2 allow ed us to compare patient grow th trajectories from intervention sites to patient grow th trajectories in sites w here no intervention had yet occurred. Lagged design. |

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| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS  Intervention Effect |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | >50th<=85th |  |  |  | >85th<=95th | |  |  |  |  | >95th |  |  |  |  |
|  | N | Mean | CI  (low er bound) | CI  (upper bound) | p (across  groups) | N | Mean | CI  (low er bound) | CI  (upper bound) | p (across  groups) | N | Mean | CI  (low er bound) | CI  (upper bound) | p (across  groups) |
| MYOC | 278 | 0.002 | -0.0034 | 0.0084 | 0.41 | 130 | 0.0067 | -0.0013 | 0.15 | 0.1 | 161 | 0.0008 | -0.0061 | 0.0077 | 0.81 |
| Control | 228 |  |  |  |  | 85 |  |  |  |  | 104 |  |  |  |  |

**Hinchman, J.; Beno, L.; Mims, A.**

**Kaiser Permanente Georgia's Experience with Operation Zero: A Group Medical Appointment to Address Pediatric Overweight**

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| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None mentioned, but all w ork for Kaiser Permanente |  |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other  than BMI | Other obesity |  |
| Population | | |
| Inclusion criteria | 11-17 years participating in O.Z. and matched control |  |
| Exclusion criteria | None |  |
| Group differences | None |  |
|  | Operation Zero | Control |
| Interventions | | |
|  | Operation Zero | Control |
| Brief description | O.Z. includes w eekly one-hour appointments for tw o months (the core program), follow ed by another four appointments at three-month intervals (the After-O.Z. program), for a maximum group of 15 patients and their parents.O.Z. is a family-based intervention that requires one parent or  guardian to participate in each session and at home. | Usual care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 1 years |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Operation Zero | 24 | 1.22 | 2.8 | <0.05 | NS |
| Control | 18 | 1.6 | 2.29 | <0.05 |  |

**Lipana, L. S.; Bindal, D.; Nettiksimmons, J.; Shaikh, U. Telemedicine and face-to-face care for pediatric obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None reported |  |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other  than BMI | Behaviors |  |
| Population | | |
| Inclusion criteria | All children seen in the telemedicine or FTF clinic. |  |
| Exclusion  criteria | None |  |
| Group  differences | Population attending each clinic differs. |  |
|  | Face to Face | Telemedicine |
| Interventions | | |
|  | Face to Face | Telemedicine |
| Brief description | Telemedicine and in-person consultations consisted of interdisciplinary evaluations provided by a general pediatrician w ith additional training and  expertise in childhood w eight management and a registered dietician | Telemedicine and in-person consultations consisted of interdisciplinary evaluations provided by a general pediatrician w ith additional training and  expertise in childhood w eight management and a registered dietician |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| Slow ed w eight gain, maintenance, or reduction | | | |
| Unclear (Outcomes) | | | |
|  | N | Mean | P (betw een groups) |
| Face to Face | 63 | 44 | NR |
| Telemedicine | 49 | 69 |  |

**Marild, S.; Gronowitz, E.; Forsell, C.; Dahlgren, J.; Friberg, P.**

**A controlled study of lifestyle treatment in primary care for children with obesity**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | We are gratef ul for grants from the Västra Göta-landsregion supporting the study as primaryfunding source: Research Council, Västra Göta-landsregionen,  Sw eden, [http://w](http://w/) w w.vgregion.se/sv/Vastra-Gotalandsregionen/startsida/. We alsothank Sahlgrenska University Hospital for financialsupport. | | |
| Country | Sw eden |  |  |
| Methods | | | |
| Design | Prospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | This study w as approved by the Ethical Committeeof Göteborg University (registered as Ö348-03), andinf ormed consent w as obtained from the parents of all  participants. | | |
| Outcomes  other than BMI | Other obesity, lipids, glucose metabolism, other labs. | |  |
| Population | | | |
| Inclusion  criteria | 8-13 year old children. Theyw ere eligible if they had obesity in accordance w iththe IOTF criteria and no ongoing or previous treat-ment for obesity at registration  for the study. | | |
| Exclusion  criteria | None |  |  |
| Group  differences | None. Partially randomized. |  |  |
|  | Nurse-Dietician treatment (NTD) | Nurse-dietician-physiotherapist treatment (NDPT) | Non-intervention |
| Interventions | | | |
|  | Nurse-Dietician treatment (NTD) | Nurse-dietician-physiotherapist treatment  (NDPT) | Non-intervention |
| Brief description | 12 visits over 12 months (8 visits w ith the nurse and 4 w ith the RD). Ten sessions w ere in an individual setting, and tw o  w ere arranged as group meetings w ith cooking and advice about buying food. | This programme w as designed to put a special emphasis on physical activity. A physiotherapist substituted for the nurse in the NDT programme at 4 of the 12 monthly appointments. | Historical control. Ref erral notes w ere sent to the clinic in Göteborg for treatment of children w ith obesity. Ref errals usually came from school- based health care, w here no treatment w as possible. Valid inf ormation about age, sex, and clinic-measured w eight and height w as mandatory at ref erral. At the start of treatment, usually after at least 1 year, w eight  and height w ere recorded again. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 12 months |  |  |  |
|  | N | Mean | SD | p (vs control) |
| Nurse-Dietician treatment (NTD) | 27 | -0.33 | 0.3 | 0.002 |
| Nurse-dietician-physiotherapist treatment (NDPT) | 28 | -0.36 | 0.3 | 0.0005 |
| Non-intervention | 138 | -0.14 | 0.3 |  |
| BMI |  |  |  |  |
|  | 12 months |  |  |  |
|  | N | Mean | SD | p (vs control) |
| Nurse-Dietician treatment (NTD) | 27 | -0.39 | 1.9 | 0.002 |
| Nurse-dietician-physiotherapist treatment (NDPT) | 28 | -0.46 | 2.1 | 0.0007 |
| Non-intervention | 138 | 0.99 | 2.07 |  |

**Nemet, D.; Levi, L.; Pantanowitz, M.; Eliakim, A.**

**A combined nutritional-behavioral-physical activity intervention for the treatment of childhood obesity--a 7-year summary**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Israel |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes  other than BMI | Other obesity |  |
| Population | | |
| Inclusion  criteria | Children and adolescents 6-16 years follow ed in the obesity clinic |  |
| Exclusion  criteria | None of the subjects had an organic cause for his/her obesity, and none of them received any medication that may interfere w ith grow th or w eight control (e.g.,  corticosteroids, thyroid hormone replacement) | |
| Group  differences | Controls w ere those "unable to participate" |  |
|  | Intervention | Control |
| Interventions | | |
|  | Intervention | Control |
| Brief description | Children participated for up to a year. They had monthly visits to dietitian for first 6 months. The level of parent vs. child participation depended on the age of the child. Children received inf ormation sheets.Children w ere given a balanced reducing diet 30% below reported caloric intake on dietary recall or 15% below estimated required intake. Children participated in tw ice w eekly exercise sessions w ith  coaches and told to exercise 30-45 minutes once/w eek on their ow n. | The control subjects w ere ref erred to an ambulatory nutritional consult at least once every 3 months, and w ere instructed to perform physical activity three times per w eek on their ow n. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 3  months |  |  |  |  | 6  months |  |  |  |  | 12  months |  |  |  |  |
|  | N | Mean | SD | p (w ithin  group) | p (betw een  groups) | N | Mean | SD | p (w ithin  group) | p (betw een  groups) | N | Mean | SD | p (w ithin  group) | p (betw een  groups) |
| Intervention | 749 | 25.1 | 0.1 | <0.05 | NR | 359 | -1.3 | 0.1 | <0.05 | NR | 147 | 24.7 | 0.3 | <0.05 | NR |
| Control | 67 | 26.4 | 0.8 | NS |  | 67 |  |  |  |  | 54 | 27.5 | 0.8 | <0.05 |  |

**Nowicka, P; HÃ¶glund, P; Pietrobelli, A; Lissau, I; Flodmark, Ce Family Weight School treatment: 1-year results in obese adolescents**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | None reported |  |
| Country | Sw eden |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Signed inf ormed consent w as obtained from bothchildren and parents. Ethical approval w as obtain-ed from the Regional Ethical Review Board  atthe University of Lund | |
| Outcomes other than  BMI | None |  |
| Population |  |  |
| Inclusion criteria | Obese adolescents 12-19 years ref erred for treatment. At least one of thechild’s parents had to be w illing to participate intreatment and be able to  communicate in Sw edishw ithout help from an interpreter. | |
| Exclusion criteria | None |  |
| Group differences | None |  |
|  | Intervention | Control |
| Interventions |  |  |
|  | Intervention | Control |
| Brief description | A structured intervention program based on systemic family therapy and solution-focused therapy. 4 group meetings over 1 year. Each meeting w as 4 hours (nutrition, physical activity, behavior). Each family met briefly w ith a pediatric nurse/pediatrician during each meeting as  w ell. | Waiting list |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
|  | 1 year |  |  |
|  | N | Mean | P (betw een groups) |
| Intervention | 65 | 3.21 | NS |
| Control | 23 | 3.3 |  |

**Nuutinen, O.**

**Long-term effects of dietary counselling on nutrient intake and weight loss in obese children**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | Finnish Culture Foundation, the Juho Vainio Foundation, and the Foundation of the Finnish Dietetic Association | |
| Country | Finland |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other than BMI | Behaviors |  |
| Population |  |  |
| Inclusion criteria | Children 6-16 years w ith relative body w eight >120%. |  |
| Exclusion criteria | NR |  |
| Group differences | Conventional treatment had low er w eight |  |
|  | Intensive treatment | Conventional treatment |
| Interventions |  |  |
|  | Intensive treatment | Conventional treatment |
| Brief description | Individual monthly physician treatment, OR behaviors modification including group sessions. | Usual treatment by school nurse. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| Relative w eight loss |  |  |  |  |  |  |  |  |
|  | 1 year |  |  |  | 2 years |  |  |  |
|  | N | Mean | p (w ithin group) | p (across groups) | N | Mean | p (w ithin group) | p (across groups) |
| Intensive treatment | 29 | 16.2% | <0.001 | NR | 29 | 12.8% | <0.001 | NR |
| Conventional treatment | 16 | NR | NS |  | 16 | 7.3% | NS |  |

**Nuutinen, O.; Knip, M.**

**Weight loss, body composition and risk factors for cardiovascular disease in obese children: long-term effects of two treatment strategies**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This study w as supported by research grants from the Finnish Cultural Foundation, the Juho Vainio Foundation, and the Foundation of the Finnish Dietetic  Association. | |
| Country | Finland |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Ethics Committee of the University of Oulu approved this study. Inf ormed parental consent w as obtained after the goals and treatment procedures of the study  had been explained | |
| Outcomes  other than BMI | Other obesity, lipids, glucose metabolism |  |
| Population | | |
| Inclusion  criteria | Age 6-15 w ith body w eight >120%. |  |
| Exclusion  criteria | No additional |  |
| Group  differences | Sequential, but group visits had higher baseline w eight. |  |
|  | Individual | Group |
| Interventions | | |
|  | Individual | Group |
| Brief description | During the first year, each child in the individually treated group (Group I), together w ith his or her parents, had five nutrition counseling sessions w ith the nutritionist. The main emphasis in dietary counseling w as on reducing refined foods and increasing fiber-rich foods in the child's diet. Dietary counseling w as based on the nutritional shortcomings identified in the first food records kept by the  children and/or their parents | ehavior-modification program (Group II) included seven group sessions. During the first year, each group included tw o to four children of the same age and tw o to eight parents. |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| Weight (kg) |  |  |  |  |  |  |  |  |  |  |
|  | 1 year |  |  |  |  | 2 years |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Individual | 16 | 63.6 | 18 | NS | NS | 16 | 71 | 18.1 | <0.001 | NS |
| Group | 12 | 73.7 | 20 | NS | NS | 12 | 82.9 | 23 | <0.001 | NS |

**Reinehr, T.; Kersting, M.; Alexy, U.; Andler, W.**

**Long-term follow-up of overweight children: after training, after a single consultation session, and without treatment**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship  source | Not listed |  |  |
| Country | Germany |  |  |
| Methods |  |  |  |
| Design | Retrospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | Not reported |  |  |
| Outcomes other  than BMI | None |  |  |
| Population |  |  |  |
| Inclusion criteria | Patients at the clinic or taking part in DONALD (a longitudinal study), aged 6-15 years | | |
| Exclusion criteria | Children requiring treatment are excluded from the DONALD study. | |  |
| Group differences | Very different baseline BMI |  |  |
|  | No intervention | Single consultation | Training |
| Interventions |  |  |  |
|  | No intervention | Single consultation | Training |
| Brief description | "All the overw eight children in  the DONALD study" | Children unable to participate in the  Obeldicks training program | One-year program of physical exercise, nutrition education, and behavior  therapy including individual psychologic care of the child and his/her family. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 1  year |  |  |  |  |  | 2  years |  |  |  |  |  |
|  | N | Mean | Range (Low er  bound) | Range (Upper  bound) | p (w ithin  group) | p (across  groups) | N | Mean | Range (Low er  bound) | Range (Upper  bound) | p (w ithin  group) | p (across  groups) |
| No intervention | 100 | -0.02 | -0.6 | 0.5 | NS | NR | 100 | -0.05 | -0.66 | 0.89 | NS | NR |
| Single  consultation | 66 | -0.06 | -1 | 0.73 | NS |  | 66 | 0.04 | -0.74 | 0.75 | NS |  |
| Training | 81 | -0.38 | -2.28 | 0.53 | <0.001 |  | 81 | -0.3 | -2.1 | 0.46 | <0.001 |  |

**Reinehr, T; Kleber, M; Toschke, Am**

**Lifestyle intervention in obese children is associated with a decrease of the metabolic syndrome prevalence**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | TR received grant support fromof the German ‘Competence Net Obesity,’ w hich is supported by the German Federal Ministry of Education and Research (grant number 01 GI0839) and by Sandoz Pharmaceuticals GmbH. AMT received grant support from of the German ‘Competence Net Obesity,’ w hich is supported by  the German Federal Ministry of Education and Research (grant number 01 GI0839). | |
| Country | Germany |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The local ethics committee of the University of Witten/Herdeckeapproved this study. Written inf ormed consent w as obtained fromall children and their parents  prior to study start | |
| Outcomes  other than BMI | Blood pressure, lipids, glucose metabolism |  |
| Population | | |
| Inclusion  criteria | We examined 288 obese children aged 10–16 years completingthe outpatient 1-year lifestyle intervention “Obeldicks” at differ-ent treatment centers in North-  West Germany (Datteln, Dortmund,Marl, Herne, and Gelsenkirchen). | |
| Exclusion  criteria | Childrennot finishing the intervention, w ith endocrine disorders, famil-ial hyperlipidemia or syndromal obesity w ere excluded from thestudy. | |
| Group  differences | The control group comprised of 186 obese children w ith 1 yearfollow -up, w ho w ere not treated w ith the lifestyle intervention.All these children did not participate in the intervention programbecause they lived too far aw ay and had no means of transport | |
|  | Lifestyle | Control |
| Interventions | | |
|  | Lifestyle | Control |
| Brief description | Briefly, this outpatient intervention pro-gramisbasedonphysicalactivity,nutritione ducation,an dbe haviortherapy including the individual psychological care of the childand his or her family. An interdisciplinary team of pediatri- cians, diet-assistants, psychologists, and exercise physiologists w asresponsible for the training. | All obese children and their parents not participating in the lifestyle intervention  w ere advised in a 15 min consultation as to  a suitable diet, the necessary physical exercise and behavior patterns. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS (Change relative to TAU) | | | | | |
|  | 1 year |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| Lifestyle | 288 | 2.26 | 0.54 | <0.001 | <0.001 |
| Control | 186 | 2.58 | 0.44 | <0.001 |  |

**Reybrouck, T.; Vinckx, J.; Van den Berghe, G.; Vanderschueren-Lodeweyckx, M.**

**Exercise therapy and hypocaloric diet in the treatment of obese children and adolescents**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | None listed |  |
| Country | Belgium |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Consent w as obtained from the parents after nature of the treatment had been explained to them. | |
| Outcomes other than  BMI | None |  |
| Population |  |  |
| Inclusion criteria | Obese children and adolescents 3.9 to 16.4 years |  |
| Exclusion criteria | No additional |  |
| Group differences | Unclear |  |
|  | Diet and Exercise | Diet only |
| Interventions |  |  |
|  | Diet and Exercise | Diet only |
| Brief description | in addition to keeping the same low calorie diet w ere instructed to perform a daily  physical exercise program | low calorie diet of 800 to 1 OOO kcal per day, w hich w as caref ully  explained by a dietician |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percent overw eight |  |  |  |  |
|  | 4 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Diet and Exercise | 14 | -25.5 | 13.5 | <0.05 |
| Diet only | 11 | -15.8 | 10.5 |  |

**Schwartz, R. P.; Hamre, R.; Dietz, W. H.; Wasserman, R. C.; Slora, E. J.; Myers, E. F.; Sullivan, S.; Rockett, H.; Thoma, K. A.; Dumitru, G.; Resnicow, K. A. Office-based motivational interviewing to prevent childhood obesity: a feasibility study**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identif ication |  |  |  |
| Sponsorship source | This study w as supported by the Cen-ters for Disease Control and Prevention, the GenentechFoundation for Grow th and Development, the Ameri-can Dietetic Association Foundation, the American Di-etetic Association, the Health Resources and Services Ad-ministration Maternal and Child Health Bureau,  MeadJohnson Nutritionals, and the American Academy of Pe-diatrics | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Prospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | The study w as approved by the institutional review boardsof the American Academy of Pediatrics, the Centers for Dis-ease Control and Prevention (CDC),  Morehouse School of Medi-cine, the Indian Health Service, and Wake Forest UniversitySchool of Medicine | | |
| Outcomes other  than BMI | Behaviors |  |  |
| Population | | | |
| Inclusion criteria | Criteria included the child being aged 3 to 7 years, being a patient seen at a w ell-child care visit w ith a BMI for age and sex at the 85th percentile or greater but below the 95th percentile or at the 50th percentile or greater but below the 85th percentile w ith at least 1 parent’s BMI being 30 or greater. Patients and  families w ere required to speak the English language and have a w orking telephone. | | |
| Exclusion criteria | Children in foster care, institutions, or group care w ere excluded, as w ere children w ith chronic medical disorders. | | |
| Group  differences | None |  |  |
|  | Control | Minimal | Intensive |
| Interventions | | | |
|  | Control | Minimal | Intensive |
| Brief description | Standard care | Motivational interview ing by physician only | Motivational interview ing by physician and RD. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI Percentile |  |  |  |  |
|  | 6 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Control | 19 | -0.6 | 2.4 | 0.85 |
| Minimal | 27 | -1.9 | 2 |  |
| Intensive | 15 | -2.6 | 2.8 |  |

**Sousa, P; Fonseca, H; Gaspar, P; Gaspar, F**

**Controlled trial of an Internet-based intervention for overweight teens (Next.Step): effectiveness analysis**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This w ork w as funded by Fundação para a Ciênciae a Tecnologia (PTDC/DTP- PIC/0769/ 2012) and supported by the Poly-technic Institute of Leiria, Portugal,  and the Department of Paediatrics ofthe at Hospital de Santa Maria, Lisbon, Portugal. | |
| Country | Portugal |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | This study w as approved by the Ethical Committee for Healthand funded by the Foundation for Science and Technology(PTDC/ DTP- PIC/0769/ 2012) in 2012. | |
| Outcomes  other than BMI | Other obesity, psychosocial, behavior, blood pressure |  |
| Population | | |
| Inclusion  criteria | Obese adolescents from a paediatric obesityclinic (Portugal), aged betw een 12 and 18 years (BMI percen-tile≥95th), w ith Internet access of at least once a  w eek (inclu-sion criteria). | |
| Exclusion  criteria | Exclusion criteria w ere the presence of severepsychopathology, inability to communicate in w riting, preg-nancy or having been proposed for bariatric surgery. | |
| Group  differences | None |  |
|  | Next Step | Control |
| Interventions | | |
|  | Next Step | Control |
| Brief description | e-therapeutic platform (Next.Step), w hich included a diverseset of resources, such as educational resources (videos, bro-chures, menus, w eekly tips, access to other links), self - monitoring (food, w eight and physical activity records), socialsupport (chats, discussionf orums and personalized messages), interactive training modules (self -assessmentquizzes, making their ow n diets) and motivational tools (per-sonal goals planning, treatment progression  registry, positivereinf orcement). | he control group follow ed the standard clinical treatmentprotocol, w hich includes individual visits to the paediatrician,dietician and exercise physiologist. These adolescents joined aw aiting list to access Next.Step in the short run |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 24 w eeeks | | | | | |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Next Step | 25 | -0.04 | 0.12 | 0.11 | 0.852 |
| Control | 46 | -0.05 | 0.13 | 0.036 |  |

**Spieth, Le; Harnish, Jd; Lenders, Cm; Raezer, Lb; Pereira, Ma; Hangen, Sj; Ludwig, Ds A low-glycemic index diet in the treatment of pediatric obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | This study w as supported by grants from the Chil-dren’s Hospital League, Boston, Mass, and the Charles H. HoodFoundation, Boston, Mass. Dr Lenders w as supported by grantT32 DK07703, and Dr Ludw ig w as supported by grant 1K08DK02440 from the National Institute of Diabetes and Diges-tive and Kidney  Diseases, Bethesda, Md. | |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes  other than BMI | Other obesity |  |
| Population | | |
| Inclusion  criteria | Children attending Optimal Weight for Life Program (mean age 10) |  |
| Exclusion  criteria | Cushing Syndrome, hypothyroidism, hypothalamic disease, diabetes mellitus or an obesity-associated genetic syndrome, or those concurrently follow ing a very  low -energy diet) | |
| Group  differences | Tw o different teams. |  |
|  | Low -GI diet | Reduced Fat Diet |
| Interventions | | |
|  | Low -GI diet | Reduced Fat Diet |
| Brief description | The low -GI diet w as designed to obtain the low est glycemic response possible w hile providing adequate dietary carbohydrates, satisfying all nutritional recommendations for children, and maintaining palatability. Specific macronutrient goals w ere 45% to 50% carbohydrate, 20% to 25% protein, and 30% to 35% fat. All patients received dietary and lifestyle counseling. Patients  also received problem-focused behavior therapy w hen ref erred to psychologist. | Balanced, hypoenergetic reduced-fat diet. Recommendations w ere tailored on an individual basis to incorporate an energy restriction of approximately 1042kJ (250 kcal) to 2084 kJ (500 kcal) per day compared w ith usual energy intake.  Specific macronutrient goals w ere 55% to 60% carbohydrate, 15% to 20% protein, and 25%to 30% fat. All patients received dietary and lifestyle  counseling. Patients also received problem-focused behavior therapy w hen ref erred to psychologist. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI (Unadjusted) |  |  |  |  |  |
| Variable (mean 4.2-4.3 months) | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Low -GI diet | 64 | -1.53 | -1.94 | -1.12 | <0.001 |
| Reduced Fat Diet | 43 | -0.06 | -0.56 | 0.44 |  |

**Tanas, R.; Marcolongo, R.; Pedretti, S.; Gilli, G.**

**A family-based education program for obesity: a three-year study**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None reported |  |
| Country | Italy |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Aninf ormed oral consent w as obtained from children's par-ents/caregivers bef ore enrolment. The study w as approvedby the Ethics Committee of Ferrara | |
| Outcomes other  than BMI | None (for both groups) |  |
| Population | | |
| Inclusion criteria | Caucasian overw eight andobese children and adolescents, aged 3 to 18 years, w ith af ollow up of at least one year. | |
| Exclusion criteria | Children w ith secondary obesity and psychiatric problems w ere excluded. | |
| Group  differences | Children w ere "matched for age, gender, parents BMI and follow -up time". | |
|  | Therapeutic education program (TEP) | Dietary therapy |
| Interventions | | |
|  | Therapeutic education program (TEP) | Dietary therapy |
| Brief description | Initial education and assessment session, therapeutic education session for parents in small groups, single  family group assessment. | It includes a complete clinical assessment, an advice onphysical activity and a prof essional dietetic consultationw ith diet prescription; the follow up schedule is the sameas in the study  group, but w ithout telephone follow -up. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
| 3 years (unclear) | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Therapeutic education program (TEP) | 85 | -0.44 | 0.7 | <0.01 |
| Dietary therapy | 105 | -0.01 | 0.5 |  |

**Taveras, E. M.; Perkins, M.; Anand, S.; Woo Baidal, J. A.; Nelson, C. C.; Kamdar, N.; Kwass, J. A.; Gortmaker, S. L.; Barrett, J. L.; Davison, K. K.; Land, T. Clinical effectiveness of the massachusetts childhood obesity research demonstration initiative among low-income children**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship source | This study w as supported by the Centers for Disease Control and Prevention (CDC) National Center for Chronic Disease Prevention and HealthPromotion (Aw ard no.: U18DP003370). Dr. Taveras is supported by grant K24 DK10589 from the National Institute of Diabetes and Digestive and Kidney Diseases. This study w as supported by the Centers for Disease Control and Prevention (CDC) National Center for Chronic Disease Prevention and HealthPromotion (Aw ard  no.: U18DP00337 0). Dr. Taveras is supported by grant K24 DK10589 from the National Institute of Diabetes and Digestive and Kidney Diseases. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Prospective  cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | We received a w aiver of inf ormed consent from theMassachusetts Department of Public Health to use longitudinal elec-tronic health record data | |  |
| Outcomes other  than BMI | None |  |  |
| Population | | | |
| Inclusion criteria | All w ell children aged 2 to 12 years receiving care at the three FQHCs and residing in the community w ere eligible. Children w ith BMI>85th percentile w ere  eligible for ref erral to the Healthy Weight Clinics. | | |
| Exclusion  criteria | Children w ith severe chronic health conditions (e.g., con-genital and chromosomal anomalies) w ere excluded. | |  |
| Group  differences | None |  |  |
|  | MA-CORD #1 | MA-CORD #2 | Treatment as usual |
| Interventions | | | |
|  | MA-CORD #1 | MA-CORD #2 | Treatment as  usual |
| Brief description | Unable to implement full program | Intervention componentsaimed to improve primary and secondary prevention of childhoodobesity and included (1) advanced training to FQHC staff on clinicalquality improvement and obesity prevention, assessment, and man-agement;  (2) computerized, point-of-care decision support tools forclinicians on obesity management; (3) implementation of multidisci-plinary w eight management programs w ithin the FQHCs, e.g.,Healthy Weight Clinics; (4) integrating CHWs into the primary careand Healthy Weight Clinic teams; and (5) FQHC environmentalchanges to support behavior change modification. | FQHC w ith usual treatment |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS (Change relative to TAU) | | | | | |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| MA-CORD #1 | 111 | -0.02 | -0.16 | 0.12 | NS |
| MA-CORD #2 | 1368 | -0.16 | -0.21 | -0.12 | <0.0001 |
| Treatment as usual | 2286 |  |  |  |  |

**Tripicchio, G. L.; Ammerman, A. S.; Neshteruk, C.; Faith, M. S.; Dean, K.; Befort, C.; Ward, D. S.; Truesdale, K. P.; Burger, K. S.; Davis, A. Technology Components as Adjuncts to Family-Based Pediatric Obesity Treatment in Low-Income Minority Youth**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | Funding for this study w as provided by the HealthcareFoundation of Greater Kansas City, the Greater KansasCity YMCA, and FITNET. | | |
| Country | USA |  |  |
| Methods | | | |
| Design | Prospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | The Institutional Review Boardat the University of Kansas Medical Center approved allstudy procedures. | | |
| Outcomes other  than BMI | Behavior |  |  |
| Population | | | |
| Inclusion criteria | Children w ereref erred and eligible to enroll if they had a BMI‡85thpercentile, w ere 2–18 years of age, and did not have adiagnosis that w ould make participation in a group settingdifficult w ithout individualized support (e.g., severe autismspectrum disorder). At least one parent had to agree toattend  program sessions and complete measures. | | |
| Exclusion criteria | No additional |  |  |
| Group  differences | None- Rolling randomization |  |  |
|  | FBBG | TECH1 | TECH2 |
| Interventions | | | |
|  | FBBG | TECH1 | TECH2 |
| Brief description | In-person 12-w eek family based behavioral  group (FBBG) treatment | FBBG plus a digital tablet equipped w ith  a fitness app (FITNET) | FBBG and FITNET, plus five individually tailored TeleMed  health-coaching sessions delivered via Skype |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI SDS (Model 1) |  |  |  |  |  |  |
| 12 w eeks | | | | | | |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| FBBG | 14 | -0.05 | -0.13 | 0.03 | 0.25 | NS |
| TECH1 | 16 | -0.006 | -0.13 | 0.12 | 0.92 |  |
| TECH2 | 18 | -0.09 | -0.14 | -0.05 | <0.001 |  |

**Tucker, S. J.; Ytterberg, K. L.; Lenoch, L. M.; Schmit, T. L.; Mucha, D. I.; Wooten, J. A.; Lohse, C. M.; Austin, C. M.; Mongeon Wahlen, K. J. Reducing pediatric overweight: nurse-delivered motivational interviewing in primary care**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | Funding w as provided by the Mayo Clinic Patient Education Research Committee, Mayo Clinic Nursing Research Committee, and Small Grants Program sponsored by the Mayo Clinic Center for Translational Science Activities. The authors acknow ledge the financial support and her encouragement of Dr. Jill  Sw anson, Consultant and Chair of Community Pediatric & Adolescent Medicine | |
| Country | USA |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Review and approval of human subjects research w erereceived from the Institutional Review Board (IRB) prior tolaunching any study aspects. | |
| Outcomes other  than BMI | Behaviors |  |
| Population | | |
| Inclusion criteria | To be eligible for the study, children had to be 4 – 18 year olds, at the 85 – 95th BMI percentile, and presenting for a w ell-child visit. | |
| Exclusion criteria | Children w ith significant co-morbidities and those presenting for acute care concerns w ere excluded to reduce conf ounding factors and to avoid interference w ith treating acute problems. Additional exclusion criteria included: (1) taking any type of birth control including Depo Provera injections, oral steroids, seizure medications, antidepressants, or medications that affect appetite; (2) pregnancy at time of enrollment or during the study; (3) a diagnosis of any mental health  problems (Autism, ADHD, MR etc.); (4) follow ing any special diets; and (5) non-English speaking or significant language barriers. | |
| Group  differences | None, all control then all intervention |  |
|  | Control | Intervention |
| Interventions | | |
|  | Control | Intervention |
| Brief description | Both groups w ere offered SC during their w ell-child visit. SC included providing a print out  and review of BMI and BMI percentile. | MI around 5-2-1-0 plus standard care w ith a nurse w ith phone  and in office follow up |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |  |  |  |  |  |  |
|  | 6  months |  |  |  |  |  | 12  months |  |  |  |  |  |
|  | N | Mean | Median | Range (low er) | Range (upper) | p (across groups) | N | Mean | Median | Range (low er) | Range (upper) | p (across groups) |
| Control | 57 | 0.3 | 0.3 | -3.1 | 2.4 | 0.05 | 57 | 0.5 | 0 | -1.8 | 3.5 | 0.08 |
| Intervention | 68 | 0 | 0 | -2.2 | 2.5 |  | 68 | 0.1 | 0 | -3.6 | 3.1 |  |

**Tyler, D. O.; Horner, S. D.**

**A primary care intervention to improve weight in obese children: A feasibility study**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This w ork is supported w ith grant funding from the Na-tional Institutes of Health, National Institute of NursingResearch (R21 NR09853). | |
| Country | USA |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the university’s Institu-tional Review Board and by administrators (i.e., schoolsuperintendent, school principals) for  both participatingschool districts. | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids, psychosocial, |  |
| Population | | |
| Inclusion criteria | Eligibility criteriaw ere w eight status (BMI95thpercentile), child age betw een 8 and 12 years, ability tospeak and read English (both parent and  child), havetransportation to the clinic, and w illing to participate. | |
| Exclusion criteria | Exclusion criteria included health conditions that w ould prohibit participation in the intervention either because of the nature of the child’s health problem (e.g., severe mental retardation, metabolic or genetic conditions, such as diabetes or Prader–Willi syndrome) that w ould require highly specialized  care, or the inability to participate (e.g., severe conduct disorder). | |
| Group  differences | None |  |
|  | Treatment | Control |
| Interventions | | |
|  | Treatment | Control |
| Brief description | five NWM intervention visits, w hich consisted of nurse-delivered counseling that  focused on w eight-relatedbehaviors. The nurse intervener used brief negotia- tion techniques based on MI principles and strategies | The compari-son group made four clinic visits: one at baseline for datacollection and w eight management inf ormation and thenthree  subsequent visits for data collection only |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 25 w eeks (Time 3) | |  |  | 37 w eeks (Time 4) | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Treatment | 27 | 2.17 | 0.36 | NS | 25 | 2.18 | 0.36 | NS |
| Control | 20 | 1.99 | 0.33 |  | 18 | 1.98 | 0.36 |  |

**Uysal, Y; Wolters, B; Knop, C; Reinehr, T**

**Components of the metabolic syndrome are negative predictors of weight loss in obese children with lifestyle intervention**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | Thomas Reinehr received grant support from of the GermanMinistry of Education and Research (Obesity netw ork: grantnumber 01 01GI1120A and 01GI  1120B) and by Hexal AG. | |
| Country | Germany |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The local ethics committee of the University of Witten/Herdeckeapproved this study. Written inf ormed consent w as obtained fromall subjects and their  parents according to the declaration of Helsinki | |
| Outcomes other  than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |
| Population |  |  |
| Inclusion criteria | Caucasian children, obese, median age 11.1 years old |  |
| Exclusion criteria | Smokers and children w ith endocrine, genetic, or metabolicdisorders, or on medical therapy w ere excluded from the study | |
| Group differences | No lifestyle are those w ho declined to participate |  |
|  | Lifestyle Intervention | No intervention |
| Interventions |  |  |
|  | Lifestyle Intervention | No intervention |
| Brief description | outpatient intervention program is based on physical activity, nutrition education, and behavior therapy  including the individual psychological care of the children and their family | Those w ho declined to participate because of  lack of time or lack of motivation. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |
|  | 1 year |  |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Lifestyle Intervention | 484 | 2.25 | 1.89 | 2.61 | <0.001 | NR |
| No intervention | 533 | 2.48 | 2.13 | 2.83 | 0.018 |  |

**Van Helst**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | Financial support w as provided by the University of  Littoral. |  |
| Country | France |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | All procedures w ere performed in accordance w ith the ethical standards of the Helsinki Declaration of 1975 as revised in 1983 and the European Good  Clinical Practices. | |
| Outcomes other than  BMI | Blood pressure |  |
| Population |  |  |
| Inclusion criteria | Eligibility criteria included BMI >97th percentile, age betw een 7 and 17 years, nonsyndromic obesity, and normal clinical examination, that is, normal  grow th and normal psychomotor development | |
| Exclusion criteria | None described |  |
| Group differences | No differences |  |
|  | Control | Treatment |
| Interventions |  |  |
|  | Control | Treatment |
| Brief description | Controls received normal care of a specialist physician in pediatrics. | Treatment consisted of a unique program of physical activity that emphasized playing games. Activity sessions w ere offered once per w eek, 2 h each session, for 12 months.  Physical activity w as complemented w ith health education. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SD | p (vs control) |
| Control | 37 | 30.8 | 4.6 | <0.05 |
| Treatment | 37 | 30 | 6.1 |  |

**Videira-Silva, A.; Fonseca, H.**

**The effect of a physical activity consultation on body mass index z-score of overweight adolescents: results from a pediatric outpatientobesity clinic**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship  source | None reported |  |
| Country | Portugal |  |
| Methods |  |  |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | This study w as approved by theresearch ethics committee of the Faculty of Medicine of the University of Lisbon, Portugal (271/2016), and is in accordance  w ith the 1964 Helsinkideclaration and its later amendments or comparable ethical standards | |
| Outcomes other  than BMI | Other obesity |  |
| Population |  |  |
| Inclusion criteria | Overw eight adolescents(BMI≥p85) aged 10–17 |  |
| Exclusion criteria | Clinical files from patients w ith mental disorders, con-ditions leading to inability to perform regular PA and/orinvolvement in other w eight loss programs,  w ere notconsidered for analysis. | |
| Group differences | PA consultation is "optional" |  |
|  | PAc | STc |
| Interventions |  |  |
|  | PAc | STc |
| Brief description | Optional for those follow ed at the clinic. Additionally to the PA levelassessment and behavior change, the PA consultationaims to adjust  PA and exercises (type, intensity, andtechnique) to the individual patient clinical condition,personality, and pref erences. | Standard  clinic care |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SE | p (w ithin group) | p (betw een groups) |
| PAc | 198 | -0.12 | 0.3 | <0.0001 | <0.05 |
| STc | 198 | -0.05 | 0.29 | <0.0001 |  |
| BMI |  |  |  |  |  |
|  | 6 months |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| PAc | 198 | -0.15 | 1.8 | 0.21 | <0.05 |
| STc | 198 | 0.27 | 1.79 | 0.038 |  |

**Wald, E. R.; Moyer, S. C.; Eickhoff, J.; Ewing, L. J. Treating childhood obesity in primary care**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | This study w as supported by a grant from the Agency of Healthcare Research and Quality. | |
| Country | USA |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the Health Sciences Institutional Review Board of the University of Wisconsin–Madison | |
| Outcomes other  than BMI | Other obesity |  |
| Population | | |
| Inclusion criteria | (a) w ere betw een the ages of 9 and 12 years w ith a body mass index (BMI) ≥95th percentile for age and gender and (b) had a parent/caregiver w ill-ing to  participate in the program and attend all sessions. | |
| Exclusion criteria | Children w ere excluded from participation in the pro-gram in the rare instance that they had a severe medical condition that required aggressive treatment of their obesity (eg, pseudotumor cerebri, severe sleep apnea, significant endocrinologic abnormalities) or cognitive impairments that prevented them from fully  participat-ing in the treatment (ie, being unable to read and/or w rite at a grade level needed to do the homew ork assignments that w ere part of the program). | |
| Group  differences | None |  |
|  | Quasi-Control | Intervention |
| Interventions | | |
|  | Quasi-Control | Intervention |
| Brief description | Wait 3-4 months bef ore beginning treatment. Then  same as Intervention | The 8-w eek group inter - vention focused on adopting a healthy lifestyle w ith attention to  dietary and physical activity behaviors. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
| 15 w eeks | | | | | |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Quasi-Control | 23 | -0.03 | 0.12 | 0.492 | NR |
| Intervention | 55 | -0.1 | 0.16 | <0.001 |  |

**Warschburger, P.; Fromme, C.; Petermann, F.; Wojtalla, N.; Oepen, J.**

**Conceptualisation and evaluation of a cognitive-behavioural training programme for children and adolescents with obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | Germany |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other  than BMI | Psychosocial |  |
| Population | | |
| Inclusion criteria | At least 9 years old, IQ in normal range, percentage overw eight at least 20% |  |
| Exclusion  criteria | None |  |
| Group  differences | None |  |
|  | Experimental Group | Control Group |
| Interventions | | |
|  | Experimental Group | Control Group |
| Brief description | e used self-monitoring, contract-management,stimulus-control, modelling, eating-management and rein-forcement principles. Over six sessions the children andadolescents learned to understand  w hy they had becomeoverw eight and w hat they could do to lose w eight and feelbetter. | Muscle relaxation training- They received a calorie- reduced diet and took part in an exercise  programme for obese children and adolescents. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percentage overw eight |  |  |  |  |
| 6 months (?) | | | | |
|  | N | Mean | SD | p (betw een groups) |
| Experimental Group | 121 | -15.47 | 13.32 | <0.01 |
| Control Group | 76 | 14.03 | 10 |  |

**Yoshinaga, M.; Sameshima, K.; Miyata, K.; Hashiguchi, J.; Imamura, M.**

**Prevention of mildly overweight children from development of more overweight condition**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None |  |
| Country | Japan |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other  than BMI | Other obesity, lipids, blood pressure |  |
| Population | | |
| Inclusion criteria | 6-11 year olds w ith % relative body w eight >=35% |  |
| Exclusion criteria | None |  |
| Group differences | Treatment group w ere those clinically indicated from the screening |  |
|  | Treating | Screening |
| Interventions | | |
|  | Treating | Screening |
| Brief description | If the family doctor determined that thestudent’s overw eight should be treated, the student couldchoose to attend the treatment program. 20 minute lesson from  pediatrician, nutritional program. | School nurses screened all children (from 6 to 11 years old)in elementary school. Children screened could visit their family doc-  tors if they chose to. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Change in BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Treating | 40 | -0.9 | 1.9 | <0.0001 |
| Screening | 240 | 1 | 1.3 |  |

**Bailey-Davis 2019**

**Feasibility of enhancing well-child visits with family nutrition and physical activity risk assessment on body mass index**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Identification |  |  |  |
| Sponsorship source | Geisinger Clinical Innovations and Geisinger Obesity In-stitute provided support for the project. |  |  |
| Country | USA |  |  |
| Methods |  |  |  |
| Design | Prospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | This project was reviewed by the Geisinger In-stitutional Review Board and approved asIRB# 2013-0304. |  |  |
| Outcomes other than BMI | None |  |  |
| Population |  |  |  |
| Inclusion criteria | Intervention group participants included children who hada baseline WCV at an intervention clinic between 1 No-vember 2013 and 31 October 2014 with weight andheight data (BMI screening) and a completed FNPA as-sessment and a second (1-year follow-up) WCV withheight and weight data within 10–18 months of baseline.The non-respondent group participants were childrenfrom the same clinics as intervention participants andFNPA assessments were offered but not completed atbaseline. Non-exposed group participants includedchildren who completed a baseline WCV at a non-intervention clinic with weight and  height data between1 November 2013 and 31 October 2014 and had follow-up WCVs within the described timeline earlier. Partici-pants were aged 2–9 years at baseline. | | |
| Exclusion criteria | Children diagnosed with type 1 diabetes or cancer were excluded |  |  |
| Group differences | . At baseline,on average, the intervention children significantly differedfrom the non-respondent and the non-exposed childrenin age, BMIz-score and weight category (allP’s≤0.05).Intervention and non-exposed children also significantlydiffered in medical assistance and race/ethnicity (allP’s≤0.05). Among children aged 2–5, intervention chil-dren significantly differed from non-respondent and non-exposed children in age, BMIz-score and weight cate-gory (allP’s≤0.05). Additionally, children aged 2–5inthe intervention and non-exposed groups significantly dif-fered by sex, medical assistance and race/ethnicity. Incontrast,  among children aged 6–9, the intervention andnon-respondent groups significantly differed in age(P≤0.01), and the intervention and non-exposed  groupdiffered in medical assistance and race/ethnicity (allP’s≤0.0001) | | |
| Special populations |  |  |  |
|  | FNPA Risk Assessment | Non-exposed | Overall |
| Interventions | |  |  |
|  | FNPA Risk Assessment | Non-exposed |  |
| Brief description | The intervention was initiatedwith an automated email generated 10 days prior to ascheduled WCV via the  patient portal (at home). The emailincluded a link to the FNPA risk assessment. The health system’s programming enabled automatedFNPA risk assessment data collection; integration ofthese data with BMI screening data into the EHR inreal-time; and display as clinical decision support. Thissupport included responses for each FNPA item, thesummary score, talking points for promoting health andreducing risk, and printable educational materials. Pro- viders were trained to use motivational interviewing andgoal setting to counsel parents on the FNPA topicsand  provide tailored feedback with educational mate-rials. Educational materials. | Non-exposed participants were derived from six clinicswhere FNPA was not  available nor were providers trainedon the intervention |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 1 year |  |  |  |
|  | N | Mean | SD | p (between groups) |
| FNPA Risk Assessment | 2724 | 0.07 | 0.63 | 0.392 |
| Non-exposed | 3324 | 0.13 | 0.63 |  |

**Coles 2018**

**Breaking barriers: Adjunctive use of the Ontario Telemedicine Network (OTN) to reach adolescents with obesity living in remote locations**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | The author(s) disclosed receipt of the following financial sup-port for the research, authorship, and/or publication of thisarticle: J.H. is supported by the SickKids University ofToronto Mead Johnson Chair in Nutritional Science, whichprovides unrestricted funds for research. | |
| Country | Canada |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study was approvedby the Research Ethics Board at The Hospital for SickChildren. Written consent was obtained directly fromall adolescents in the study. | |
| Outcomes other than BMI | Psychosocial |  |
| Population |  |  |
| Inclusion criteria | adolescents(12–18 years of age) living with severe and complexobesity, and their families, within Ontario, Canada.Severe and complex obesity were defined as  having aBMI percentile greater than or equal to the 99th per-centile for age and sex, or a BMI greater than or equalto the 95th percentile for age and sex with significantweight-related comorbidities | |
| Exclusion criteria | None noted |  |
| Group differences | Both OTN and non-OTN patients had similar ages,body weights, BMIs and income levels at baseline(Table 1). On average, OTN patients attended 4.86visits in  addition to their in-person sessions. Patientsreceiving OTN lived approximately 62 km further fromthe hospital compared to non-OTN patients (p=0.002)(Table 2). | |
|  | OTN | Comparison |
| Interventions |  |  |
|  | OTN | Comparison |
| Brief description | STOMP + telemedi-cine visits were offered as an option 6 months followingenrolment in the programme. All patients were offered the option of telemedicineappointments to supplement their “in-person” medicalvisits to the programme. The OTN includes the use ofPersonal Video Conferencing (PCVC) and Guestlink | STOMP is a two year intensive programmeproviding quality collaborative care to adolescents(12–18 years of age) living with severe and complexobesity, and their families, within Ontario, Canada. Adolescents and fam-  ilies were offered education and support through indi-vidual and group sessions. All sessions were held face-to-  face for the first 6 months of the programme, as theinitial curriculum consists of interactive group sessionsand are attended in person. Following this, individualsreceived ongoing regular support from HCPs (dieti-tians, exercise counsellors, social workers and psychol-ogists) at frequencies varying from weekly to monthlyover the two year period. Patients also attended in-personmedical visits with the physician every 6 months  formonitoring of their height and weight. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
| 6 months | | | | |
|  | N | Mean | SE | p (across groups) |
| OTN | 50 | 0.08 | 0.03 | 0.215 |
| Comparison | 50 | 0.08 | 0.02 |  |

**Derwig 2019**

**Child-Centred Health Dialogue for primary prevention of obesity in Child Health Services - a feasibility study**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | This project was funded by The Swedish research Council for Health, Working life and Welfare (FOrTe), region Skåne and Föreningen Mjölkdroppen Helsingborg. | |
| Country | Sweden |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study was planned and carried out in compliance with the ethical princi-ples of the Declaration of Helsinki. Approval was obtained from the regional ethical review Board in lund (2015/223). | |
| Outcomes other than  BMI | None |  |
| Population |  |  |
| Inclusion criteria | In total, 203 children participated in Child-Centred Health Dialogue while 582 children received usual care. (all children received usual care). Between June 2015 and June 2016 nurses working at the intervention CHCs invited all 4-year-olds to par-ticipate in CCHD. Children identified with overweight and obesity and their caregivers or other important family members were invited to the targeted part of CCHD, Family Guidance, taking place 1–3 weeks after the universal 4-year health visit.  "overweight" was not defined in the methods as far as I can tell. | |
| Exclusion criteria | None noted |  |
| Group differences | Matched on age; usual care much higher BMI SDS |  |
|  | Intervention | Usual care |
| Interventions |  |  |
|  | Intervention | Usual care |
| Brief description | hild-Centred Health Dialogue CCHD is a structured child-centred  health dialogue that consists of two parts: (1) a universal part directed to all 4-year-olds and their caregiver visiting CHS and (2) a targeted  part for families where the 4-year-old is identified with overweigh | Usual care involved a 4-year health visit to all 4-year-olds where nurses were recommended to talk with caregivers about the child’s eating habits and physi-cal activity. The professionals were aware of the importance of promoting health lifestyles, but they did not receive any  specific training regarding over-weight prevention as was provided in CCHD. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS |  |  |  |  |
|  | 1 year |  |  |  |
|  | N | Mean | SD | p (between groups) |
| Intervention | 194 | 0.01 | 1.42 | NS |
| Usual care | 582 | 0.05 | 0.44 |  |

**Hagman 2020**

**Promising results from an implemented treatment model for paediatric obesity**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | The review of medical files, analyses and evaluation of the implementation was partly financially supported by the Stockholm County Council | |
| Country | Sweden |  |
| Methods |  |  |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Ethical approval was obtained from the Ethics Committee in Stockholm, Sweden (No. 2014/1422-31/2) |  |
| Outcomes other than BMI | Blood pressure, glucose metabolism, lipids, other labs |  |
| Population |  |  |
| Inclusion criteria | Included in this study were all children between 6 and 12.9 years of age who were referred to and started the explicit weight loss treatment programme  described below during 1 January 2008-31 December 2014 in any of the six outpatient paediatric clinics in Stockholm County Council that have implemented the action plan. The control group was children (n = 3012) receiving obesity treat - ment at outpatient paediatric clinics (n = 46) from different parts of Sweden that  have not implemented the model. | |
| Exclusion criteria | no additional |  |
| Group differences | Data were retrieved from The Swedish Childhood Obesity Register BORIS, and the same dates of treatment initiation and the same inclusion and exclusion criteria were applied. | |
|  | Treatment | Control |
| Interventions |  |  |
|  | Treatment | Control |
| Brief description | Group activities for parents and children separately, followed by individual meetings with parents/child together. Parents had 90 min. group sessions weekly for 7 weeks including peer support and structured discussions to help them support child lifestyle goals. In parallel with the parental group sessions, children partici - pated in educational and physical  activities with emphasis on giv - ing the children positive experiences. Both the parental and child group sessions followed the same themes, After the group sessions, all families continued with individual treatment including visits to a medical doctor one to two times per year, visits to a nurse four to five times per year and for those who required, visits to a  dietician and/or physiotherapist. The visits lasted 30-60 minutes | Treatment of childhood obesity in Sweden comprises behavioural lifestyle modi-fication, and may be delivered differently, for exampleto the whole family or parents only. |

|  |  |  |  |
| --- | --- | --- | --- |
| Outcomes |  |  |  |
| BMI SDS |  |  |  |
|  | 2 years |  |  |
|  | N | Mean | P (between groups) |
| Treatment | 750 | -0.31 | <0.0001 |
| Control | 3012 | -0.23 |  |

**Tucker 2019**

**Evaluation of a Primary Care Weight Management Program in Children Aged 2(-)5 years: Changes in Feeding Practices, Health Behaviors, and Body Mass Index**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | Blue Care Network of Michigan and We Are For Children, LLC. |  |
| Country | USA |  |
| Methods |  |  |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | All study procedures were approved by the Spectrum Health Institutional Review Board, and writtenconsent was obtained from all parents participating in the research |  |
| Outcomes other than  BMI | Behaviors, other (sleep) |  |
| Population |  |  |
| Inclusion criteria | Participants were comprised of families with children aged 2–5 years who attended one of thefour participating primary care pediatric offices. BMI> 85th percentile (overweight), or a rapid BMI increasesuch that2 BMI percentile lines were crossed during the past year on a standard CDC growthchart, excluding the 5th percentile | |
| Exclusion criteria | None noted. |  |
| Group differences | At baseline, patient behavioral measures were similar between treatment and control groupsfor sleep, physical activity, and screen time, but not for FNPA, which was  higher/healthier amongcontrols (p= 0.002) | |
|  | Physician health-behavior counseling | Usual care |
| Interventions |  |  |
|  | Physician health-behavior counseling | Usual care |
| Brief description | The study intervention included two primary components: (1) physician-familyhealth behavior conversations during well-child visits, and  (2) four monthly visits with a RDN toevaluate, educate, and implement improved feeding habits and nutritional choices. A third  optionalcomponent of the intervention included counseling sessions with a social worker to help familiesovercome barriers to change,  such as food security, family relationships, and general parentingstrategies | Usual medical care |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI SDS Change |  |  |  |  |
| 6 months | | | | |
|  | N | Mean | SD | p (across groups) |
| Physician health-behavior counseling | 53 | -0.13 | 0.42 | 0.332 |
| Usual care | 66 | -0.05 | 0.4 |  |

# Non-Randomized Pharmaceutical Studies (Priority 4)

**Aa, Mp; Hoving, V; Garde, Em; Boer, A; Knibbe, Ca; Vorst, Mm**

**The Effect of Eighteen-Month Metformin Treatment in Obese Adolescents: comparison of Results Obtained in Daily Practice with Results from a Clinical Trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None listed |  |
| Country | The Netherlands |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | The Medical EthicalCommittee of the St. Antonius Hospital, Nieuw egein/Utre-cht, the Netherlands, approved the RCT study protocol andw ritten inf ormed  consent w as obtained from participants (ifapplicable) and parents. | |
| Outcomes other  than BMI | Glucose metabolism |  |
| Population | | |
| Inclusion criteria | Thepatients in the daily clinical practice group w ere included ifthey w ere aged 10–16 years at start of metformin therapy, w ereobese (defined as BMI standard deviations score (BMI-SDS)>2.3), and had a follow -up time of at least 18 months. The inclusion criteria for thepatients in the RCT w ere age 10–16 years,  obesity (defined asBMI-SDS>2. 3), insulin resistance (defined as HOMA-IR≥3.4), and being of Caucasian origin. | |
| Exclusion criteria | Retrospective chart review : Patients w ere excluded if they had type 2 diabetes mellitus. |  |
| Group  differences | Daily clinical practice group: higher proportion boys. Marginally higher height (p=0.08). Higher fasting glucose, fasting insulin, HOMA-IR. Marginally higher  A1c. | |
|  | Clinical practice group | Trial group |
| Interventions | | |
|  | Clinical practice group | Trial group |
| Brief description | The daily clinical practice group consisted of patientsw ho w ere treated off label w ith metformin in the  pedi-atric obesity outpatient clinic . Metformin 1000 mg 2x/d or if GI effects 500 mg 2x/d or 1000 mg 1x/d. Also multidisciplinary lifestyle intervention program | the RCT group, consisted of thepatients of the  metformin arm of a RCT on metformin versusplacebo in obese children. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
| 18 months | | | | | |
|  | N | Median | IQR (low er bound) | IQR (upper bound) | p (betw een groups) |
| Clinical practice group | 19 | -0.36 | -2.1 | 1.58 | 0.686 |
| Trial group | 23 | 0.22 | -2.87 | -1.27 |  |
| BMI SDS |  |  |  |  |  |
| 18 months | | | | | |
|  | N | Median | IQR (low er bound) | IQR (upper bound) | p (betw een groups) |
| Clinical practice group | 19 | -0.15 | -0.54 | 0.05 | 0.99 |
| Trial group | 23 | -0.12 | -0.5 | 0.08 |  |

**Harden, K. A.; Cowan, P. A.; Velasquez-Mieyer, P.; Patton, S. B.**

**Effects of lifestyle intervention and metformin on weight management and markers of metabolic syndrome in obese adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | None reported |  |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | All individuals hadpreviously signed a clinic repository consent form. Approval ofthe Institutional Review Board of the University of Tennessee Health Science  Center w as obtained prior tobeginning data collection | |
| Outcomes  other than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |
| Population | | |
| Inclusion  criteria | 11-to18-year-olds thatw ere obese w hohad at least a 6-month follow -up visit. |  |
| Exclusion criteria | Exclusion criteria included: youth diagnosed w ith type 1 diabetes mellitus, hypopituitarism, Prader–Willi syndrome, uncontrolled hypothyroidism, postorgan  transplantation; individuals w ho w ere seen in the clinic but not speciﬁcally treated for w eight management; or youth w ho w ere receiving antiobesity medications other than metformin | |
| Group  differences | Group clinically determined, metformin group much higher w eight, and 32% (vs 0% in control) had diabetes. | |
|  | Metformin | Nonmetformin |
| Interventions | | |
|  | Metformin | Nonmetformin |
| Brief description | The lifestyle interventions provided to all participants included: diet analysis, dietary counseling, ﬁtness assessment and exercise counseling w ith access to a ﬁtness facility, family support sessions, and behavioral counseling. Weight loss medications utilized included metformin. Subjects w ere classiﬁed as being in the metformin group if they  received metformin for at least 2 months. | The lifestyle interventions provided to all participantsincluded: diet analysis, dietary counseling, fitness assess-ment and exercise counseling w ith access to a fitnessfacility, family support sessions, and behavioral counsel-ing. Received no metformin. |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| Relative BMI |  |  |  |  |  |  |  |  |  |  |
|  | 6 months |  |  |  |  | Last visit |  |  |  |  |
|  | N | Mean | SD | p (w ithin group) | p (betw een groups) | N | Mean | SD | p (w ithin group) | p (betw een groups) |
| Metformin | 37 | 188.16 | 1.74 | NS | <0.05 | 37 | 187.27 | 1.74 | <0.05 | <0.05 |
| Nonmetformin | 26 | 179.77 | 2.07 | NS |  | 26 | 180.19 | 2.07 | NS |  |

**Juarez-Lopez, C.; Klunder-Klunder, M.; Madrigal-Azcarate, A.; Flores-Huerta, S.**

**Omega-3 polyunsaturated fatty acids reduce insulin resistance and triglycerides in obese children and adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | CONACYT and the Government of the State of Campechef unded this project, Grant CAMP-2006-C01-29017 | |
| Country | Mexico |  |
| Methods | | |
| Design | Cluster randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | Prior to the study, ethical clearance w as obtained from Campeche State research ethics committees and school authorities in accordance w ith the Declaration of  Helsinki. w e obtained inf ormed consent from the children and their parents to perform an open-label trial in w hich the assignment of treatment w as based on the school the child attended | |
| Outcomes  other than BMI | Other obesity, blood pressure, lipids, glucose metabolism |  |
| Population | | |
| Inclusion  criteria | Children in 5th and 6th grades w ith obesity and insulin resistance | |
| Exclusion  criteria | Children and adolescentsw ith type 2 diabetes w ho w ere attending a formalw eight loss program or w ho had identified syndromesthat predisposed them  to obesity w ere excluded. | |
| Group  differences | They call this "randomized", but they assigned schools to medications. I'm leaving it in Priority 4. | |
|  | Metformin | Omega-3 |
| Interventions | | |
|  | Metformin | Omega-3 |
| Brief description | 500 mg metformin 12 w eeks. In the Met-assigned schools, the dose w as 250mg for the ﬁrst 2w k (one-half of a 500-mg tablet; Dabex Merck Metformin, 500mg, lot M64547), and  from w eek 3 to the end of the study, they received 500mg daily (one tablet). The ingestion of metformin w as indicated  w ith breakfast | 1.8 g omega 3 PUFA 12 w eeks. Intheω3-assignedschools,thecapsulesusedcontained 600mg of PUFA ω-3, [(360mg of eicosapentaenoic acid (20:5 n-3) and 240mg of docosahexaenoic acid (22:6 n-3)] (Omega-3 Prime Fitness®, Lot 1205051).  Eachparticipantreceivedthreecapsulesdaily(1.8g/d), ingesting one w ith each meal of the day. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 12 w eeks |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Metformin | 98 | -0.27 | -0.53 | -0.01 | 0.127 |
| Omega-3 | 103 | -0.55 | -0.81 | -0.3 |  |

**Krzystek-Korpacka, M.; Patryn, E.; Kustrzeba-Wojcicka, I.; Chrzanowska, J.; Gamian, A.; Noczynska, A.**

**The effect of a one-year weight reduction program on serum uric acid in overweight/obese children and adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | The research w as supported by Wroclaw Research Center EITq under the project ‘‘Biotechnologies and advanced medical technologies – BioMed’’ (POIG  01.01.02-02-003/08-00) financed from the European Regional Development Fund (Operational Programme Innovative Economy, 1.1.2). | |
| Country | Poland |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study protocol w as approved by the Medical Ethics Committeeof our University and w as in accordance w ith the Ethical Standardsstated in the Helsinki  Declaration of 1975. Inf ormed consent w asobtained from the study participants and their parents | |
| Outcomes other than BMI | Other obesity, glucose metabolism, lipids, other labs |  |
| Population | | |
| Inclusion criteria | otherw ise healthy children and adolescents (10–17 years old) w ho w ere overw eight (n=27) or obese (n=86) | |
| Exclusion  criteria | Exclusion criteria w ere as follow s: central nervous system diseases, genetic disorders, Cushing’s syndrome, grow th hormone deficiency, insulinoma,  hypothyroidism and iatrogenic obesity. | |
| Group  differences | Baseline differences not reported separately by condition. How ever the subset given metformin: "In addition, a subgroup of 31 participants diagnosed w ith abnormalities in insulin and/or carbohydrate metabolism (insulin-resistance, hyperinsulinism, impaired fasting or post-prandial glucose) w ere administered metformin (2=500 mg). " | |
|  | Diet/exercise | Diet/exercise + metformin |
| Interventions | | |
|  | Diet/exercise | Diet/exercise + metformin |
| Brief description | Intensive physical activity and a hypocaloric diet (1500 kcal), devised individually for each study participant based on the recommendations of the American Heart Association Nutrition Committee | In addition, a subgroup of 31 participants diagnosed w ith abnor-malities in insulin and/or carbohydrate metabolism (insulin-resis-tance, hyperinsulinism, impaired fasting or post-prandial glucose)w ere administered metformin (2=500  mg). |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI% (Females) |  |  |  |  |  |
| 1 year |  |  |  |  |  |
| N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Diet/exercise | -4.5 | -7.6 | -1.4 | <0.05 | 0.131 |
| Diet/exercise + metformin | -9.3 | -15.6 | -3 | <0.05 |  |
| BMI% (Males) |  |  |  |  |  |
| 1 year |  |  |  |  |  |
| N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Diet/exercise | 2.1 | -2.2 | 6.4 | <0.05 | 0.031 |
| Diet/exercise + metformin | -5.7 | -11.7 | 0.4 | 0.052 |  |

**Marques, P.; Limbert, C.; Oliveira, L.; Santos, M. I.; Lopes, L.**

**Metformin effectiveness and safety in the management of overweight/obese nondiabetic children and adolescents: metabolic benefits of the continuous exposure to metformin at 12 and 24 months**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | None reported |  |
| Country | Portugal |  |
| Methods |  |  |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other than BMI | Glucose metabolism, lipids |  |
| Population |  |  |
| Inclusion criteria | Patients w ere eligible if they w ere overw eight/ obese (BMI≥ 85th/95th percentile for age and sex, respectively) and w ith ages betw een 8 and  17 years. | |
| Exclusion criteria | The exclusion criteria included: previous diagnosis of diabetes mellitus or use of medication to treat insulin resistance/losing w eight; present or past exposure to glucocorticoids, oral contraceptives or any medication that could interfere w ith w eight; medical disorders predisposing to obesity or insulin resistance such as polycystic ovary syndrome, other endocrinopathies or genetic syndromes; liver or renal dysfunc-tion  (aspartate/alanine aminotransferases or gamma-glutamyl transferase > 1.5 times the upper limit of normal; serum creati-nine > 1.5 mg/dL). | |
| Group differences | Metformin w as initiated in patients w ith BMI-SDS>2 and HOMAIR >3. Metformin group had higher w eight, height, BMI, BMI z-score | |
|  | Lifestyle intervention | Metformin |
| Interventions |  |  |
|  | Lifestyle intervention | Metformin |
| Brief description | Both groups w ere submitted to lifestyle intervention in order to optimize dietary intake and stimulate physical activity. Dietary and nutritional education w as provided by an experienced nutritionist, w ho emphasized the need for reduction or avoidance of calorie- dense and nutrition-poor foods. Moderate physical exercise, on a daily basis and w ith the duration of 30–60 min, w as promoted by the nutritionist and the pediatric endocrinologist in each patient visit. Patients w ere observed every 3 months by these tw o health prof essionals. | Metformin w as initiated in patients w ith BMI-SDS>2 and HOMAIR >3. An initial daily dose of 0.5 g w as usually used, w ith increments to a maximum daily dose of 2 g, based on the clinician’s judgment and the patient’s tolerance. Both groups w ere submitted to lifestyle intervention in order to optimize dietary intake and stimulate physical activity. Dietary and nutritional education w as provided by an experienced nutritionist, w ho emphasized the need for reduction or avoidance of calorie-dense and nutrition-poor foods. Moderate physical exercise, on a daily basis and w ith the duration of 30–60 min, w as promoted by the nutritionist and the pediatric endocrinologist in each patient visit. Patients w ere observed  every 3 months by these tw o health prof essionals. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |
| 12 months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Lifestyle intervention | 38 | -0.2 | 0.5 | 0.141 | 21 | -0.1 | 0.5 | 0.069 |
| Metformin | 36 | -0.4 | 0.5 |  | 16 | -0.5 | 0.8 |  |
| BMI |  |  |  |  |  |  |  |  |
| 12 months | |  |  | 24 months | |  |  |  |
|  | N | Mean | SD | p (betw een groups) | N | Mean | SD | p (betw een groups) |
| Lifestyle intervention | 38 | 0 | 3.1 | 0.082 | 21 | 1.3 | 2.5 | 0.097 |
| Metformin | 36 | -1.3 | 3.2 |  | 16 | 1.3 | 5.3 |  |

**Ryder, J. R.; Kaizer, A.; Rudser, K. D.; Gross, A.; Kelly, A. S.; Fox, C. K.**

**Effect of phentermine on weight reduction in a pediatric weight management clinic**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Dr Ryder is supported by an individual training grant from NIH/NHLBI (F32-HL127851). Dr Rudser and Kaizer are supported, in part, by the National Center  forAdvancing Translational Sciences/NIH (UL1TR000114). The other authors received nof unding for this project | |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | This study w as approved by the University of Minnesota Institutional Review Board. |  |
| Outcomes  other than BMI | Blood pressure |  |
| Population | | |
| Inclusion criteria | Patients in the phentermine plus SOC group w ere included if they w ere additionally prescribed phentermine at a dose of 15mg per day for w eight loss and had at least one follow -up visit. The SOC-only group w as selected using an identical range of baseline age (11.9–17.7 years) and BMI (31–58kg m−2) to that of the phentermine plus SOC group in an effort to establish a w ell-matched comparison group. Patients w ere allow ed to contribute data to both groups if they ﬁrst  started on SOC and then later additionally initiated phentermine treatment w hile still receiving SOC. | |
| Exclusion  criteria | Patients w ere excluded if they w ere taking any other medication w ith w eight-altering properties (either gain or loss) and those w ho underw ent bariatric surgery. | |
| Group  differences | Clinically determined groups |  |
|  | Phentermine + Standard Care | Standard Care |
| Interventions | | |
|  | Phentermine + Standard Care | Standard Care |
| Brief description | All patients w ere treated w ith SOC lifestyle modiﬁcation therapy, w hich included nutrition and exercise counseling supported by behavioral modiﬁcation strategies. The SOC w as delivered by a multidisciplinary team including a registered dietitian, physical therapist, pediatric psychologist and pediatrician w ho specializes in childhood obesity. Patients w ere seen approximately every 4 w eeks, although some more  frequently and some less frequently, depending on their need. Patients in the phentermine plus SOC group  w ere included if they w ere additionally prescribed phentermine at a dose of 15mg per day for w eight loss and had at least one follow -up visit. | All patients w ere treated w ith SOC lifestyle  modification therapy,w hich included nutrition and exercise counseling supported bybehavioral modification strategies. |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes | | | | | | | | | | |
| BMI SDS (Change relative to  SOC) |  |  |  |  |  |  |  |  |  |  |
|  | 3  months |  |  |  |  | 6  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Phentermine + Standard Care | 20 | -0.06 | -0.1 | -0.01 | 0.01 | 11 | -0.09 | -0.16 | -0.02 | 0.019 |
| Standard Care | 171 |  |  |  |  | 96 |  |  |  |  |
| BMI (Change relative to SOC) | | | | | | | | | | |
|  | 3  months |  |  |  |  | 6  months |  |  |  |  |
|  | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) | N | Mean | CI (low er  bound) | CI (upper  bound) | p (across  groups) |
| Phentermine + Standard Care | 20 | -1.14 | -1.76 | -0.51 | <0.001 | 11 | -1.57 | -2.78 | -0.36 | 0.011 |

|  |  |  |
| --- | --- | --- |
| Standard Care | 171 | 96 |

**Stagi, S.; Ricci, F.; Bianconi, M.; Sammarco, M. A.; Municchi, G.; Toni, S.; Lenzi, L.; Verrotti, A.; de Martino, M.**

**Retrospective Evaluation of Metformin and/or Metformin Plus a New Polysaccharide Complex in Treating Severe Hyperinsulinism and Insulin Resistance in Obese Children and Adolescents with Metabolic Syndrome**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | The authors and co-authors did not receive any funding to conduct this study. | |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Retrospective cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | Ethical approval (ethical code 122/2016) w as obtained fromthe Meyer Children’s University Hospital Ethics Committee. Written inf ormed assent/consent  w asobtained from all participants and their parents or guardians. | | |
| Outcomes other than  BMI | Other obesity, lipids, glucose metabolism, blood pressure, behaviors | |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria w ere the presence of severe hyperinsulinism, insulin resistance and MetS and age betw een 8.0 and 14.5 years at the ﬁrst evaluation. Patients w ith obesity and MetS, w ho chose not to take a medication as a mean to reduce w eight and treated only w ith a LGI served as a control group (51 subjects; 24 males, 27 females; median age at study entry 12.4, range 8.2–14.5 years). Inclusion and exclusion criteria and the study protocol of the control group w ere the  same as previously seen for patients. | | |
| Exclusion criteria | Exclusion criteria w ere patients aged <8.0 years or >14.5 years at the ﬁrst evaluation, cognitive impairment, diagnosis of type 1 diabetes, existing syndrome disorders w ith or w ithout cognitive impairment, impaired renal or hepatic function, malabsorption disorders, cancer, patients enrolled in a w eight loss program at the ﬁrst evaluation, endocrine causes of obesity such as hypothyroidism or Cushing disease, and use of medications for w eight loss or any medication that could compromise the study evaluation such as topical or systemic glucocorticoids, anticonvulsant therapy, grow th hormone, sexual steroids or gonadotropin releasing  hormone analogues. | | |
| Group  differences | Patients selected into groups. |  |  |
|  | Metformin | Metformin + Policaptil Gel Retard | LGI Diet |
| Interventions | | | |
|  | Metformin | Metformin + Policaptil Gel Retard | LGI Diet |
| Brief description | subject’s study medication dose w as progressively increased according to a prespeciﬁed algorithm: in Weeks 1 and 2, participants took one tablet (500 mg) daily; thereafter, the dosage w as increased by 500 mg/day every seven days to a maximumdoseof 1500mg/ day(threetablets) | subject’s study medication dose w as progressively increased according to a prespeciﬁed algorithm: in Weeks 1 and 2, participants took one tablet (500 mg) daily; thereafter, the dosage w as increased by 500 mg/day every seven days to a  maximumdoseof 1500mg/ day(threetablets). All patients took three tablets (2175 mg) of the Policaptil Gel Retard bef ore their tw o main meals. | Patients w ith obesity and MetS, w ho chose not to take a medication as a mean to reduce w eight and treated only w ith a LGI served as a  control group |

Outcomes

BMI SDS

24 months

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | N | Mean | SD | p (w ithin group) | p (vs. control) | p (vs. met + PGR) |
| Metformin | 41 | 2.14 | 0.2 | NS | <0.005 | <0.001 |
| Metformin + Policaptil Gel Retard | 45 | 1.92 | 0.17 | <0.001 | <0.001 |  |
| LGI Diet | 34 | 2.28 | 0.26 | NS |  | NS |

**Lentferink 2018**

**Long-term metformin treatment in adolescents with obesity and insulin resistance, results of an open label extension study**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Identification |  |  |  |  |
| Sponsorship source | We would like to acknowledge ZonMw for funding our study |  |  |  |
| Country | Netherlands |  |  |  |
| Methods |  |  |  |  |
| Design | Prospective cohort study (RCT plus open label extension) |  |  |  |
| Group | Parallel group |  |  |  |
| IRB | Thestudy protocol was approved by the Medical EthicalCommittee of the St. Antonius Hospital, Nieuwegein/Utrecht, the Netherlands. From all participants/parents awritten informed consent was obtained at start RCT. Allstudy procedures were in accordance with the  Declarationof Helsinki and the Medical Research Involving HumanSubjects Act (WMO) of the Netherlands. | | |  |
| Outcomes other than  BMI | Glucose metabolism, blood pressure, lipids, other obesity, psychosocial, other  (fitness) |  |  |  |
| Population |  |  |  |  |
| Inclusion criteria | Didn't state original criteria from RCT. For this extension: metformintherapy was only offered to participants who still sufferedfrom obesity (defined as body mass index  standarddeviation score (BMI-sds > 2.3))27, and IR (defined asHomeostasis Model Assessment for Insulin Resistance(HOMA-IR)≥3.4). | | | |
| Exclusion criteria | TSDM, PCOS, endocrine disorders treated with corticosteroids, height <1.3 SD from target, syndromal disorders, pregnancy, alcohol use, impaired renal function,  impaired hepatic function, insufficient Dutch | | | |
| Group differences | Study-arms differed significantly for HOMA-IR, but notfor BMI or BMI-sds. Participants were predominantlyfemale and in pubertal (Tanner 2–4) or postpubertal(Tanner  5) stages. The observed Tanner stages differedsignificantly between the study-arms. | | | |
|  | MM (Metformin RCT + Extension) | MP (Metformin RCT + No  Met Extension) | PM (Placebo RCT + Met  Extension) | PP (Placebo RCT + No  Met Extension) |
| Interventions |  |  |  |  |
|  | MM (Metformin RCT + Extension) | MP (Metformin RCT + No  Met Extension) | PM (Placebo RCT + Met  Extension) | PP (Placebo RCT + No  Met Extension) |
| Brief description | FCT: 18 months treatment with metformin. Extension: In contrast to the RCT nospecific supervised physical training program was offered.Similar to the RCT,  participants on metformin therapyreceived immediate-release metformin 500 mg  tablets inan increasing dosing regimen, with a maximum of twotablets twice daily in the fourth week. | Metformin during RCT, declined for open-label extension | Placebo during RCT, Metformin in open- label extension | Placebo during RCT, declined for open-label extension |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |  |  |  |  |  |
| 18 months (end of  RCT) | |  |  |  | 36 months (end of  OLE) | |  |  |  |  |
|  | N | Mea n | CI (lower bound) | CI (upper bound) | p (across groups) | N | Mea n | CI (lower bound) | CI (upper bound) | p (across groups) |
| MM (Metformin RCT +  Extension) | 5 | 0.1 | -0.5 | 0.2 | 0.241 | 5 | 0.3 | -0.6 | 0.6 | 0.619 |
| MP (Metformin RCT + No Met  Extension) | 14 | -0.3 | -1.3 | 0.2 |  | 14 | -0.2 | -1.4 | 0.7 |  |
| PM (Placebo RCT + Met  Extension) | 6 | -0.2 | -0.4 | 0.2 |  | 6 | -0.2 | -0.4 | 0.3 |  |
| PP (Placebo RCT + No Met  Extension) | 6 | 0.1 | -0.5 | 0.2 |  | 6 | 0.1 | -0.4 | 0.4 |  |
| BMI |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 18 months (end of  RCT) | |  |  |  | 36 months (end of  OLE) | |  |  |  |  |
|  | N | Mea  n | CI (lower  bound) | CI (upper  bound) | p (across  groups) | N | Mea  n | CI (lower  bound) | CI (upper  bound) | p (across  groups) |
| MM (Metformin RCT + Extension) | 5 | 1.3 | -3.1 | 2 | 0.161 | 5 | 3.4 | -2.9 | 7.3 | 0.716 |
| MP (Metformin RCT + No Met  Extension) | 14 | -1.4 | -4.5 | 3.3 |  | 14 | -0.6 | -4.1 | 10.3 |  |
| PM (Placebo RCT + Met Extension) | 6 | 0.8 | -1.8 | 3.4 |  | 6 | 1.3 | -0.6 | 6.4 |  |
| PP (Placebo RCT + No Met  Extension) | 6 | 1 | -1.2 | 2.4 |  | 6 | 2.9 | -0.7 | 3.9 |  |

# Surgical Studies (Priority 5)

**Gothberg, G.; Gronowitz, E.; Flodmark, C. E.; Dahlgren, J.; Ekbom, K.; Marild, S.; Marcus, C.; Olbers, T. Laparoscopic Roux-en-Y gastric bypass in adolescents with morbid obesity--surgical aspects and clinical outcome**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Primary funding source: Research council, Västra Götalandsregionen, Sw eden. Additional fund-ing source: Fru Mary von Sydow 's foundation, Gothenburg,  Sw eden. | |
| Country | Sw eden |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | Not reported |  |
| Outcomes other  than BMI | Psychosocial |  |
| Population | | |
| Inclusion criteria | For surgery: Consent to undergo surgical treatment- Aged 13–18 years- BMIZ40 orZ35 kg/m2w ith comorbidity (type 2 diabetes,sleep apnea, joint pain, and high blood lipids)- Pubertal Tanner stage4III and passed peak height grow thvelocity Controls: During the recruitment period, 81 adolescents (43% boys)  w ereselected from the Childhood Obesity Register in Sw eden (BORIS) asconventional treatment controls | |
| Exclusion criteria | Surgery: Severe or insufficiently treated psychiatric disorder- Ongoing drug abuse- Obesity due to syndromes, monogenic disease, or brain injury- Reluctance  to undergo long-term follow -up | |
| Group  differences | Clinically determined |  |
|  | Surgery (Adolescents) | Controls |
| Interventions | | |
|  | Surgery (Adolescents) | Controls |
| Brief description | gastric bypass surgery after completion of comprehensive w eight program; surgery at one  of three specialist pediatric units in Sw eden | conventional treatment controls selected from the Childhood  Obesity Register in Sw eden |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| Percent w eight change |  |  |  |  |  |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Surgery (Adolescents) | 81 | -32 | -35 | -30 | NR |
| Controls | 81 | 3 | 0 | 7 |  |

**Inge, T. H.; Courcoulas, A. P.; Jenkins, T. M.; Michalsky, M. P.; Helmrath, M. A.; Brandt, M. L.; Harmon, C. M.; Zeller, M. H.; Chen, M. K.; Xanthakos, S. A.; Horlick, M.; Buncher, C. R.**

**Weight Loss and Health Status 3 Years after Bariatric Surgery in Adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | Supported by grants from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (U01DK072493 and UM1DK0724 93 to Dr. Inge, UM1DK095710 to Dr. Buncher, UL1TR000077-04 to Cincinnati Children's Hospital Medical Center, UL1RR025755 to Nationw ide  Children's Hospital, M01-RR00188 to Texas Children's Hospital/Baylor College of Medicine, UL1RR024153 and UL1TR000005 to the University of Pittsburgh,  and UL1TR000165 to the University of Alabama, Birmingham). | |
| Country | USA |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The protocol and data and saf ety monitoring plans w ere approved by the institutional review board at each institution | |
| Outcomes other  than BMI | Glucose metabolism, blood pressure, other labs |  |
| Population | | |
| Inclusion criteria | 13-19 years old, other criteria based on surgery criteria |  |
| Exclusion criteria | No additional |  |
| Group  differences | Patients chose surgery type |  |
|  | Gastric Bypass | Sleeve Gastrectomy |
| Interventions | | |
|  | Gastric Bypass | Sleeve Gastrectomy |
| Brief description | Roux-en-Y gastric bypass | Sleeve gastrectomy |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 3 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Gastric Bypass | 125 | -15 | -17 | -14 | <0.05 |
| Sleeve Gastrectomy | 48 | -13 | -15 | -11 |  |

**Inge, T. H.; Laffel, L. M.; Jenkins, T. M.; Marcus, M. D.; Leibel, N. I.; Brandt, M. L.; Haymond, M.; Urbina, E. M.; Dolan, L. M.; Zeitler, P. S. Comparison of Surgical and Medical Therapy for Type 2 Diabetes in Severely Obese Adolescents**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | Multiple NIH |  |
| Country | USA |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | he TODAY and Teen-LABS protocols w ere ap-proved by the institutional review boards of each participat-ing institution. Participants provided w ritten  inf ormed paren-tal consent and child assent. | |
| Outcomes other  than BMI | Other obesity, glucose metabolism, blood pressure, lipids, other labs |  |
| Population | | |
| Inclusion criteria | 30 Teen-LABS partici-pants w ith type 2 diabetes at the time of surgery, TODAY participants (irrespec-tive of treatment group assignment) w ere frequency matchedto the 30 Teen-LABS participants w ith type 2 diabetes using thef ollow ing matching characteristics: baseline age (13-18 years),race, sex, ethnicity,  and baseline BMI (>35). | |
| Exclusion criteria | None |  |
| Group differences | Different cohorts, but frequency matched |  |
|  | Teen-LABS | TODAY |
| Interventions | | |
|  | Teen-LABS | TODAY |
| Brief description | 24 underw ent Roux-en-Y gastric bypass and 6 underw ent vertical sleeve gastrectomy | metformin |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI |  |  |  |  |  |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Teen-LABS | 30 | -15.1 | -17.3 | -13 | <0.001 |
| TODAY | 63 | 1.3 | -0.2 | 2.8 |  |

**Manco, M.; Mosca, A.; De Peppo, F.; Caccamo, R.; Cutrera, R.; Giordano, U.; De Stefanis, C.; Alisi, A.; Baumann, U.; Silecchia, G.; Nobili, V. The Benefit of Sleeve Gastrectomy in Obese Adolescents on Nonalcoholic Steatohepatitis and Hepatic Fibrosis**

|  |  |  |  |
| --- | --- | --- | --- |
| Study  Identification |  |  |  |
| Sponsorship  source | None listed |  |  |
| Country | Italy |  |  |
| Methods | | | |
| Design | Prospective  cohort study |  |  |
| Group | Parallel group |  |  |
| IRB | In accordance w ith the recommendations of the EthicsCommittee at the Bambino Gesù Children’s Hospital that ap-proved the study protocol (NCT 02564679), it w as designedas a prospective pilot investigation; patients w ere not as-signed randomly to treatment groups. Written informed consentw as obtained from  parents/legal guardians and patients. | | |
| Outcomes  other than BMI | Other obesity, blood pressure, lipids, glucose metabolism, other labs, psychosocial | |  |
| Population | | | |
| Inclusion criteria | Inclusion criteria included: age 13-17 years; BMI≥35 kg/m2;biopsy-proven NAFLD; failure to achieve 10% w eight lossusing lifestyle intervention alone during the prior 6 months;w illingness and motivation to adhere to treatment recom-mendations; clear understanding of risks and benefits deriv-ing from medical  treatment and surgery, including lifestylecommitment in case of LSG; and dedicated family relativesw illing to serve as caregivers. | | |
| Exclusion criteria | Exclusion criteria included: genetic obesity; any endocrineor systemic disease, except metabolic abnormalities related to obesity; severe gastroesophageal  reflux disease and/oresophagitis; large sliding hiatal hernia (>5 cm) or paraesophagealhernia type III; psychiatric disorder; previous gastrointestinalsurgery; and  use of recreational drugs and/or alcohol abuse(>140 g/w k) | | |
| Group  differences | Clinically  determined |  |  |
|  | Sleeve Gastrectomy | Intragastric w eight loss device | Lifestyle |
| Interventions | | | |
|  | Sleeve Gastrectomy | Intragastric w eight loss device | Lifestyle |
| Brief description | Laparascopic sleeve gastrectomy | GWLD con-sisted of balloons placed in the stomach for 3 months (ObalonGastric Balloon [OGB; Obalon Therapeutics Inc., Carlsbad,California] in patients aged≤14 years and/or w ith a BMIbetw een 35 and 38 kg/m2) or 6 months (BioEnterics intragastricballoon [BIB; Orbera,  Apollo Endosurgery, Austin, Texas] inpatients>14 years old and/or w ith a BMI>38 kg/m2). | Lifestyleintervention program (NSWL) consisting of a diet tailored tothe individual’s requirements and physical  exercise |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percent change in BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | p (w ithin group) | p (across groups) |
| Sleeve Gastrectomy | 20 | -20.6 | <0.05 | NS |
| Intragastric w eight loss device | 20 | -3.2 | NS |  |
| Lifestyle | 22 | -1.9 | NS |  |

**O'Brien, Pe; Sawyer, Sm; Laurie, C; Brown, Wa; Skinner, S; Veit, F; Paul, E; Burton, Pr; McGrice, M; Anderson, M; Dixon, Jb Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | The study w as funded by grantNHMRC-GA05-38 4215 from the National Health andMedical Research Council. The laparoscopic adjust-able gastric bands used in the study w ere provided by the manuf acturer, Allergan. The Centre for ObesityResearch and Education receives an unrestricted re-search support  grant from Allergan. | |
| Country | Australia |  |
| Methods | | |
| Design | Randomized controlled trial |  |
| Group | Parallel group |  |
| IRB | The study w as approved by the human ethics committees of Monash University, the Royal Children’s Hospital, and the Avenue  Hospital,inaccordancew iththeguidelinesoftheNationalHealthandMedical Research Council of 1999, as revised in 2007. Participants and their parents w ere inf ormed of the 2 study groups and consented to randomization to either treatment program. | |
| Outcomes other  than BMI | Other obesity, blood pressure, glucose metabolism, lipids |  |
| Population | | |
| Inclusion criteria | ligibilitycriteria included age betw een 14 and 18years; body mass index (BMI; calcu-lated as w eight in kilograms divided byheight in meters squared) greater than35; identifiable medical complicationssuch as hypertension, metabolic syn-drome, asthma, back pain; physicallimitations such as an inability to playa sport, difficulties w ith activities of daily living; or psychosocial difficul-ties such as isolation or low self -esteem, subject to bullying that stemsfrom obesity and evidence  of attemptsto lose w eight by lifestyle means formore than 3 years. | |
| Exclusion  criteria | We excluded 3 applicants w ith intellectualdisabilityan d1w ithPrader Willi syndrome |  |
| Group  differences | Randomized |  |
|  | Gastric Banding | Lifestyle |
| Interventions | | |
|  | Gastric Banding | Lifestyle |
| Brief description | Participants in the gastric bandinggroup had the procedure performedw ithin a month of randomization. TheLAP-BAND Adjustable Gastric Band-ing system (Allergan, Irvine, Califor-nia) w as used in all cases. | program of reduced energy intake, increased activity |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |
| BMI SDS |  |  |  |  |  |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Gastric Banding | 25 | -1.08 | -1.31 | -0.86 | <0.001 |
| Lifestyle | 25 | -0.23 | -0.39 | -0.05 |  |
| BMI |  |  |  |  |  |
|  | 2 years |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (across groups) |
| Gastric Banding | 25 | -12.7 | -14.2 | -11.3 | <0.001 |
| Lifestyle | 25 | -1.3 | -2.9 | -0.4 |  |

**Olbers, T.; Gronowitz, E.; Werling, M.; Marlid, S.; Flodmark, C. E.; Peltonen, M.; Gothberg, G.; Karlsson, J.; Ekbom, K.; Sjostrom, L. V.; Dahlgren, J.; Lonroth, H.; Friberg, P.; Marcus, C.**

**Two-year outcome of laparoscopic Roux-en-Y gastric bypass in adolescents with severe obesity: results from a Swedish Nationwide Study (AMOS)**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship  source | The primary funding source w as from Va ¨stra Go ¨talandsregionen [http://w](http://w/) w w.vgregion.se/sv/Vastra-Gotalandsregionen/startsida/ and Stockholm County  Councils, Sw edish Board of Health and Wellfare | |
| Country | Sw eden |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The regional ethics committee approved the study protocol |  |
| Outcomes  other than BMI | Other obesity, lipids, blood pressure, glucose metabolism, other labs |  |
| Population | | |
| Inclusion criteria | For surgery: Age 13–18 years.- BMIX40 orX35 kg m2w ith comorbidity (type 2 diabetes, sleepapnea, joint pain and high blood lipids).- Pubertal Tanner stage4III and passed peak height grow th velocity. We identified a matched adolescent group from the Sw edish ChildhoodObesity Treatment Register (BORIS)6at the end of the recruitment periodof surgical subjects. Eighty-one adolescents (43% boys) w ere selected asconventional treatment comparisons using the same  inclusion andexclusion criteria as for the adolescents undergoing surgery. | |
| Exclusion  criteria | For surgery: Insufficiently treated psychiatric disorder.- Ongoing drug abuse.- Obesity due to syndromes or monogenic disease as clinically assessed(50% had  the MC4 receptor sequenced) or brain injury. | |
| Group  differences | Conventionally treated adolescents had a somew hat low er BMI than surgically treated adolescents at baseline (BMI 42.0 vs 45.5, respectively), and corresponding values for BMI s.d. score w ere 3.9 vs 4.1. The proportion of males w as 35% in both surgical groups and 43% in conventionally treated adolescents. The mean body w eight at inclusion w as 133kg in the adolescent surgery group and 124kg in conventionally treated adolescents. Mean ages w ere 16.5 years for adolescents undergoing surgery and  15.8 years for the conventionally treated adolescents |  |
|  | Surgery Adolescents | Controls |
| Interventions | | |
|  | Surgery Adolescents | Controls |
| Brief description | gastric bypass (after participation in at least 1 year of comprehensive w eight loss program) | conventional tx (individualized or family-based counseling and CBT on diet &PA; low -calorie diets and drugs (metformin, orlistat, or sibutramin)  if clinically indicated) |

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| --- | --- | --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |  |  |
| BMI |  |  |  |  |  |  |
|  | 1 year |  |  |  |  |  |
|  | N | Mean | CI (low er bound) | CI (upper bound) | p (w ithin group) | p (across groups) |
| Surgery Adolescents | 81 | -15.3 | -16.6 | -14 | <0.0001 | <0.05 |
| Controls | 81 | 0.4 | -0.6 | 2.2 | NS |  |

**Olbers, T; Beamish, Aj; Gronowitz, E; Flodmark, C-E; Dahlgren, J; Bruze, G; Ekbom, K; Friberg, P; Gothberg, G; Jarvholm, K; Karlsson, J; Marild, S; Neovius, M; Peltonen, M; Marcus, C**

**Laparoscopic Roux-en-Y gastric bypass in adolescents with severe obesity (AMOS): a prospective, 5-year, Swedish nationwide study**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | TO, EG, KJ, AJB, C-EF, CM, KE, PF, JD, GG, GM, JK, and SM w ere supported by grants from Vastra Gotaland Region, the Sw edish Research Council (521- 2012-319 and 2013-3770 [to GB]), the Sw edish Governmental Agency for Innovation Systems (2013-01339), the Mrs Mary von Sydow Foundation, the  Sw edish Heart and Lung Foundation, the Sw edish Childhood Diabetes Foundation, Stockholm County Council, and the National Board of Health and Welfare. TO and CM w ere supported by grants from the Sw edish Order of Freemasons Children’s Foundation, Stiftelsen Goteborgs Barnhus, and Stiftelsen Allmanna Barnhuset. AJB has received funding from the Royal College of Surgeons of England in the form of a clinical research fellow ship. MN w as supported by a grant from the Sw edish Research Council. MN and GB w ere supported by an aw ard from the US National Institute of Diabetes, Digestive, and Kidney  Diseases (National Institutes of Health; number R01DK105948). | |
| Country | Sw eden |  |
| Methods | | |
| Design | Prospective cohort study |  |
| Group | Parallel group |  |
| IRB | The study w as conducted according to the Declaration of Helsinki w ith the approval of the Gothenburg regional ethics committee (523–04) | |
| Outcomes other  than BMI | Glucose metabolism, lipids, blood pressure, other labs, psychosocial |  |
| Population | | |
| Inclusion criteria | Eligibility criteria w ere: age 13–18 years, BMI ≥ 40, or ≥35 kg/m2 w ith comorbidity (e.g. T2DM, dyslipidaemia, metabolic syndrome), pubertal Tanner stage  >III, height grow th velocity beyond peak, and at least 1 year in a formal, conventional w eight loss programme. | |
| Exclusion criteria | Major exclusion criteria included severe psychiatric disorder, ongoing drug abuse, obesity secondary to brain injury, and syndromic or monogenic obesity | |
| Group  differences | Sequentially matched for BMI age and sex |  |
|  | Adolescents w ith RYGB | Control Adolescents |
| Interventions | | |
|  | Adolescents w ith RYGB | Control Adolescents |
| Brief description | All eligible adolescents presenting w ith severe obesity to three specialised paediatric  obesity treatment units w ere offered assessment for surgery upon fulfilling inclusion criteria. | A matched conservatively treated adolescent control group w as  identif ied from the Sw edish Childhood Obesity Treatment Register (BORIS) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| BMI |  |  |  |  |
|  | 2 years |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Adolescents w ith RYGB | 81 | 32.3 | 6.3 | <0.001 |
| Control Adolescents | 72 | 44.6 | 9.5 |  |

**Pedroso, F. E.; Gander, J.; Oh, P. S.; Zitsman, J. L.**

**Laparoscopic vertical sleeve gastrectomy significantly improves short term weight loss as compared to laparoscopic adjustable gastric band placementin morbidly obese adolescent patients**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | None listed |  |
| Country | USA |  |
| Methods |  |  |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Study approved by IRB of Columbia University Medical Center and Morgan Stanley Children's Hospital. | |
| Outcomes other  than BMI | Lipids, glucose metabolism |  |
| Population |  |  |
| Inclusion criteria | Not stated - retrospective chart review of all patients at Morgan Stanley Children's Hospital - LAGB and VSG registries of the Center for Adolescent  Bariatric Surgery since 2006. Age range 12.7-21.4, meets other criteria for bariatric surgery. | |
| Exclusion criteria | None listed |  |
| Group differences | Patient selected. |  |
|  | LAGB | VSG |
| Interventions |  |  |
|  | LAGB | VSG |
| Brief description | laparascopic adjustable gastric banding + visits w ith pediatric  endocrinologist, nutritionist, psychologist, exercise specialist | Laparoscopic vertical sleeve gastrectomy + visits w ith pediatric  endocrinologist, nutritionist, psychologist, exercise specialist |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| % BMI Loss |  |  |  |  |
|  | 12 months |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| LAGB | 111 | -12.6 | 9 | <0.0001 |
| VSG | 21 | -25.9 | 9.9 |  |

**Ryder, J. R.; Gross, A. C.; Fox, C. K.; Kaizer, A. M.; Rudser, K. D.; Jenkins, T. M.; Ratcliff, M. B.; Kelly, A. S.; Kirk, S.; Siegel, R. M.; Inge, T. H. Factors associated with long-term weight-loss maintenance following bariatric surgery in adolescents with severe obesity**

|  |  |  |
| --- | --- | --- |
| Study  Identification |  |  |
| Sponsorship source | Dr Fox receives salary support for her role as a site principal investigator for NovoNordisk Pharmaceuticals. The other authors have nofinancial relationships relevantto this article to disclose. Dr Rudser and Mr Kaizer are supported in part by theNational Center for  Advancing Translational Sciences/NIH (UL1TR000114). The otherauthors received no funding for this project |  |
| Country | USA |  |
| Methods | | |
| Design | Retrospective cohort study |  |
| Group | Parallel group |  |
| IRB | Study procedures w ere approved by the Cincinnati Children’s Hospital Medical Center Institutional Review Board. |  |
| Outcomes other  than BMI | None (for comparison group) |  |
| Population | | |
| Inclusion criteria | Inclusion criteria for FABS-5+ consisted of: any individual ⩽21 years of age w ho underw ent bariatric surgery at this institution betw een May 2001 and  February 2007 | |
| Exclusion criteria | xclusion criteria consisted of anyone unable to complete self -report forms due to developmental delayor death prior to long-term study visit |  |
| Group  differences | No statistical tests noted but BMI appears higher in surgery compared to non-surgical comparison group. "Despite attempts to recruit a similar comparison  group, baseline differences w ere apparent as the surgical group tended to be older, heavier, w ere more likely to be diabetic and have prehypertension or hypertension" | |
|  | Comparison | Surgical |
| Interventions | | |
|  | Comparison | Surgical |
| Brief description | a non-surgical comparisongroup w as recruited from the multi-component, family-based PWM(pediatric w eight management) program | Roux-en-Y  gastric bypass surgery |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percent change in BMI |  |  |  |  |
|  | 5+ years |  |  |  |
|  | N | Mean | SD | p (betw een groups) |
| Comparison | 30 | 10.3 | 20.6 | NR |
| Surgical | 50 | -29.6 | 13.9 |  |

**Henfridsson 2019**

**Five-year changes in dietary intake and body composition in adolescents with severe obesity undergoing laparoscopic Roux-en-Y gastric bypass surgery**

|  |  |  |
| --- | --- | --- |
| Study Identification |  |  |
| Sponsorship source | AMOS is funded by the Swedish Research Council(521-2012-319), Vinnova:SwedenInterventionBureauGrant(2013-01339), Swedish Heart and Lung Foundation, Research Council of Vä s t r aGötalands Re-gionen(VGFOUREG-307531), and the Swedish Freemason Child foundation, Gothenburg. | |
| Country | Sweden |  |
| Methods |  |  |
| Design | Case-control study |  |
| Group | Parallel group |  |
| IRB | Informed written consent was obtained from both the adolescents and their parents or guardians. | |
| Outcomes other than BMI | Other obesity, behaviors |  |
| Population |  |  |
| Inclusion criteria | Inclusion criteria were BMI≥40or≥35 with obesity-related co-morbidity. | |
| Exclusion criteria | Exclusion criteria included obesity due to brain injury or monogenetic disease, ongoing drug abuse, or unstable psychiatric disease . | |
| Group differences | Adolescents undergoing LRYGB were older and with higher weight and BMI than the controls at baseline | |
|  | LRYGB | Comparison |
| Interventions |  |  |
|  | LRYGB | Comparison |
| Brief description | Laparoscopic gastric bypass surgery | Nonsurgical treatment from BORIS registry |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcomes |  |  |  |  |
| Percent change in BMI |  |  |  |  |
|  | 5 years |  |  |  |
|  | N | Mean | SD | P Value |
| LRYGB | 85 | -28.6 | 12.6 | <0.001 |
| Comparison | 62 | 9.9 | 18.9 |  |