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Using Evidence to Recommend Interventions for Long-term Weight Control in Overweight Children

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Abstract

Childhood obesity can lead to later life-threatening conditions that impact negatively on quality of life, morbidity and mortality outcomes. There are a considerable number of research studies, specifically interventions that have been conducted the last 2 decades with overweight children and their families. Yet, there is variability in the methodological rigor of the studies, and some of the more rigorous designs reported in meta-analyses are a challenge to implement in practice. Therefore, nurse practitioners who work with these children find it challenging to make feasible and effective recommendations. This paper describes a method that can be used to evaluate individual interventions that have been found effective for long-term weight control in children and adolescents. The RCTs from a 2009 meta-analysis of interventions for treating obesity in children and adolescents were evaluated for external validity using a generalizability assessment framework by Green and Glasgow. Pediatric nurse practitioners who deal with the complicated health challenges of obesity in children are best positioned to use evidence-based interventions to guide their recommendations to children and families. The framework presented in this paper will help guide their decisions on which interventions should be implemented.

Keywords

intervention; long term weight control; obesity; pediatrics

Introduction

Obesity in childhood is recognized as a major health problem that demands concerted attention from health care providers. Over the past three decades the proportion of overweight children has doubled among 2 to 5-year-olds and tripled among 6 to 19-year-olds.¹ Obesity in children and adolescents has been established as a significant risk factor for premature death, disability, and multiple medical co-morbidities, including cardiovascular diseases, type 2 diabetes, hypertension, and some types of cancer.²⁻³ Obese children are also more likely to develop psychosocial problems that frequently persist into adulthood, such as low self-esteem, social isolation, and depression.⁴ In addition, obesity and its co-morbidities,

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including type 2 diabetes, dyslipidemia, cardiovascular disease, and mental health problems, contribute significantly to U.S. healthcare expenditures. Medical expenses related to obesity were estimated at \$147 billion in 2008.⁵ Hence, the adverse consequences of obesity require effective interventions for prevention and treatment that can be translated into practice.

The development of obesity in childhood involves interactions among multiple factors that may influence diet and physical activity behaviors and increase obesity risk. These include personal (e.g., attitudes, beliefs, cultural experiences, taste preferences), environmental (e.g., homes, schools, community, built environment, food availability and cost), societal (e.g., cultural norms, advertising and food marketing, social networks, technological developments, economics, public policy) and physiological (e.g., appetite and satiety mechanisms and regulation, adipose tissue metabolism, genetic predisposition, intrauterine and pre-gestation to infancy) factors.⁶⁻⁷ The interaction effects of these factors on obesity development, however, remain to be fully elucidated.

Given the significant health and social consequences of childhood obesity, discovery of effective interventions to prevent and treat obesity and overweight children has been a focus of research for the past 25 years. In fact, there has been a considerable number of intervention studies reported in the literature since 1980,⁸⁻⁹ with more than 20 meta-analyses of intervention studies related to childhood obesity prevention and treatment published between 1980 and 2009. Most recently, Luttikuis et al¹⁰ conducted a meta-analysis of interventions for treating obesity in children that included studies conducted from 1985 to May 2008. The authors reviewed and critiqued 64 randomized controlled trials (RCTs) examining the effectiveness of several lifestyle interventions, including dietary, physical activity and/or behavioral therapy, as well as drug interventions for treating obesity in children with a minimum of six months follow-up.

The purpose of this paper is to provide pediatric nurse practitioners with a better understanding of how to evaluate the generalizability of recent RCTs that produced significant long-term weight control (at 12 months or longer post interventions) in children and adolescents¹⁰ and presents the most effective interventions used in the RCTs to guide decisions on which research-based interventions should be implemented. A framework by Green & Glasgow¹¹ was employed to identify the potential for translation of the individual interventions. Table 1 presents the criteria suggested by Green & Glasgow for evaluating generalizability of individual interventions. The RCT is identified as the strongest level of evidence for the evaluation of intervention efficacy.¹² Pediatric nurse practitioners provide health advice and preventive health consultation to children and their parents during regularly scheduled physical examinations, required immunization visits, and illness care. Therefore, these providers are best positioned to use evidence generated from RCTs to guide their recommendations to children and families in clinical practice who are interested in reducing their weight.

Method

The methodology for this evaluation consisted of 2 phases. The first phase was an in-depth review of studies included in a recent meta-analysis¹⁰ on interventions for treating obesity in children. In the second phase we applied an evaluation framework suggested by Green and Glasgow to assess the generalizability of the selected interventions.

As each of the 64 studies in the Luttikuis meta-analysis was reviewed, only those RCTs that demonstrated significant change in at least one of the following: body mass index (BMI), weight, waist circumference, percentage overweight, or body fatness, at 12 months or longer post interventions, compared with control conditions were chosen for the present paper.

RCTs were excluded if they used self-reported weights and heights or if they contained incomplete information about intervention components and/or outcome assessments. A summary of the six RCTs included in this paper is presented in Tables 2 and 3.

A Summary of the Findings in the Meta-Analysis

The majority of the RCTs included in the meta-analysis by Luttikuis et al¹⁰ failed to show long-term significant weight improvement. However, of the 64 RCTs in the meta-analysis, six showed significant long-term weight improvement. These six RCTs (four were lifestyle intervention trials and two were drug trials) demonstrated significant effects in treating obesity in children or adolescents with a minimum of 12 months follow-up. Four were implemented in the U.S. and two in Israel and Canada. The RCTs tested lifestyle interventions that were family-based, targeted overweight or obese (BMI>85th percentile) children and adolescents, involved parents, and used multi-component interventions. The drug trials, along with behavioral modification intervention, targeted adolescents with severe obesity (BMI>97th percentile). The primary outcome measures in all of these RCTs were weight, BMI, percent overweight, percent body fat, and waist circumference.

Translation of Evidence from the Meta-Analysis into Practice

Green and Glasgow¹¹ and Glasgow et al¹³ provide a useful framework for assessing the relevance, applicability, and generalizability of research focused on treating overweight and obesity in children. Unlike the meta-analytic procedures, which focus on assessing the internal validity of interventions [internal validity is the extent to which differences identified between randomized groups are a result of the intervention being tested]¹⁴; Green and Glasgow's criteria address external validity. External validity is defined as the extent to which the results of a study can be generalized beyond the sample to the "real world" population¹⁵⁻¹⁶ and therefore be most useful for translation into practice. Although similar to, these criteria go beyond the traditional critiquing model used to assess the validity of a study to provide the reader with a way to decide whether the findings will work in their setting with their patients/clients. The following components are the framework guided by Green and Glasgow¹¹ for evaluating the generalizability of the RCTs:

1. Populations and settings (e.g., target population, recruitment methods, participation rate, and representativeness of participants and settings);
2. Program implementation (e.g., levels of delivery expertise, program components, and adaptation of the program);
3. Outcomes for decision making (e.g., significant change in BMI, moderators, program cost, quality of life, and adverse consequences);
4. Maintenance and institutionalization (e.g., long-term effects, attrition, and dropouts).

The following section discusses how to evaluate the generalizability of the selected RCTs using the framework mentioned above.

Assessment of Generalizability of the Selected RCTs

1. Populations and Settings

When a nurse is considering whether an individual study should be applied to his/her clients and setting, he/she needs to ask the following questions: a) Who is the targeted population?, b) What are the eligibility criteria for participants?, c) Where were the data collected?, d) What is the percentage of those who participated?, and e) Is the intervention adaptable for

different settings? It is important to review the individual studies to evaluate whether they describe these characteristics as well as how similar they are to the clients and setting.

The intended population for all six RCTs from the meta-analysis used as an exemplar from which to base recommendations for practice was children or adolescents who were overweight or obese. The target of the RCTs using lifestyle interventions was an overweight (BMI > 85th percentile) or obese (BMI > 95th percentile) child; however, parental involvement varied across studies and included either being targeted for weight loss with their child together or in a role supporting their child. The RCTs testing drug therapy targeted only severely obese adolescents (BMI > 97th percentile).

Inclusion and exclusion criteria for subject recruitment and the recruitment processes were described in each of the RCTs. BMI was the most common variable used as an inclusion criterion. Random allocation procedures were described in the RCTs. Allocation to intervention or control was concealed in one RCT using lifestyle interventions conducted by Golan et al¹⁷ and in all drug trials. Allocation concealment is a process of preventing all individuals involved in the recruitment processes from knowing to which group a participant will be allocated before entering the study.¹⁸ In the drug trials, all participants and expertise delivering the interventions were blinded to group assignment and treatments; however, the RCTs using lifestyle intervention were non-blinded.

Sample size and dropout rates were presented in all of the RCTs. Power calculations were also presented. Most RCTs using lifestyle interventions consisted of small sample sizes. Of the six RCTs, more than 75% of the enrolled participants completed the trials; suggesting that the interventions were palatable to the participants and the procedures were feasible. There was, however, no report on the number of staff participating in any of the included RCTs which could be an issue for some clinical settings who would choose to implement these programs. Outpatient and weight loss clinics were the primary settings in which the RCTs were conducted. There is as yet no evidence that any of the interventions used in the selected RCTs would be successful in other types of settings such as community and school settings.

There were no statistically significant differences in demographic and social factors between participants and those who declined or dropped out in any of the included RCTs. Of the four RCTs with lifestyle intervention, three were conducted in the U.S. and one in Israel. Both drug trials were conducted in the U.S.; however, the trial by Chanoine et al¹⁹ was also conducted in Canada. There was limited diversity in the study populations, and overall lacked inclusion of American Indian, Hispanic, and African American children who have higher rates of obesity than white. It is important to note that limited representativeness of the study populations can limit the use of interventions because individuals from other ethnic groups may respond differently to the interventions. In addition, younger children including preschoolers were not included in any of the RCTs. Most participants in the drug trials were white and female; however, the authors reported no significantly different treatment effects associated with gender or ethnic origin.

2. Program Implementation

Additional essential elements to be considered for translation include program components and intensity, as well as whether certain skills and special training are required to deliver the intervention. Nurse practitioners should ask: a) How well were the program components and intensity described in the individual studies?, b) Does the program consist of multiple components, high intensity, and long term approach?, and c) Does the program require special training or high-skilled staff to deliver? Components, intensity, and length of interventions can result in generalizability. It is expected that interventions with less

components and intensity, requiring fewer resources, demanding less staff expertise, and allowing for greater flexibility are more likely to be adopted.

The various intervention components and intensity of the six RCTs were well described, and the outcomes of the interventions were evaluated and presented on the range of implementation variations of the individual RCTs. This would make it easier to replicate, or adapt, the interventions outside of the study. The lifestyle interventions were family-based and consisted of dietary, physical activity and behavioral modification interventions. Dietary intervention emphasized increasing healthy eating and decreasing high energy dense foods. Physical activity intervention emphasized increasing physical activity and decreasing sedentary activity. Behavioral modification interventions varied across the studies, including cognitive-behavioral intervention (i.e., self monitoring and stimulus control), problem-solving approaches, lifestyle knowledge and skills, and coping techniques. Parental involvement included praising the child's healthy behavior, eliminating food as a reward, determining what foods were offered, offering only healthy food options, removing temptations from the child's environment, and modeling healthy behaviors. The drug trials also provided behavioral modification strategies related to diet and exercise for the participants. The drug trial conducted by Berkowitz et al²⁰ provided stress management and social support to the participants in both treatment and control groups. The lifestyle interventions and drug therapy consisted of multiple contacts. The duration of lifestyle interventions ranged from 5 to 12 months. In the drug trials, interventions ranged from 48 to 54 weeks.

Most interventions used in all RCTs were implemented at the individual level; therefore, the information at the setting-level implementation was limited. Two RCTs, one using lifestyle interventions¹⁷ and another using drug trial²⁰, modified the lifestyle program to fit their settings or participants. For instance, Golan and colleagues¹⁷ reported that the program content used in the parents and children group was modified to fit the children in the group. None of the RCTs required specific training to deliver intervention. All drug trials and the RCT using lifestyle intervention conducted by Savoye et al²¹ employed several different types of expertise, such as dietitian, psychologist, and physician, to deliver the programs, suggesting that an interdisciplinary team would be more effective in translating these interventions into the practice setting than a single discipline practitioner. The protocols used for outcome measurements in the six RCTs were standardized according to national or international criteria, such as criteria for overweight or obesity in children, and changes in BMI z scores were based on the CDC age- and sex-specific tables.

In summary, it is important to carefully review the nature of individual interventions for their components, strategies, intensity, and duration that produce effective results to ensure their validity and to determine whether the interventions fit with clients, resources, and time.

3. Outcomes for Decision Making

To make rational decisions about which individual interventions should be chosen for clients, nurses need to ask the following questions: a) Do the interventions lead to a significant decrease in BMI and clinical relevance?, b) What is the effect size?, c) What are the program costs?, and d) Are quality of life and adverse consequences related to the interventions presented?

The six RCTs demonstrated significant effects in treating obesity (significant reduction in at least one of the anthropometric measures including BMI, body weight, percent body weight, percent body fat, and waist circumference) in children or adolescents after 12 months follow-up. In addition, the lifestyle intervention RCT by Savoye et al²¹ indicated significant clinical improvement in total cholesterol, and serum insulin in the participants at 6 and 12

months follow-up; and the drug trial by Berkowitz et al²⁰ reported that significant clinical improvement in high-density and low-density lipoprotein cholesterol, serum insulin and serum glucose was observed in the participants at 12 months follow-up. To properly assess intervention effectiveness, the primary analysis of the RCTs was performed by intention to treat (all participants included in the analysis according to original group allocation, and follow-up was maximized regardless of program attendance). The design, program implementation strategies, and report were robust and followed the CONSORT (CONsolidated Standards of Reporting Trials) statement, providing the practitioners with more confidence about the rigor of the design and ultimately the findings. The impact of potential covariates in moderating and mediating the effects of treatment was included in the analyses of the RCTs which helps one think about what specific types of patients may benefit more or less (e.g., male, female) from an intervention. The potential covariates included age, gender, race, socioeconomic, and family structure; however, these did not affect the efficacy of the treatments.

All RCTs were designed with adequate power, indicating that any significant or non-significant findings were likely to be valid. Four of six RCTs were developed from findings of pilot studies.²⁰⁻²³ Savoye et al²¹ reported that the program was previously tested in a nonrandomized pilot study and demonstrated significant lowering in BMI over two years. All drug trials had been tested in obese adults, as well as in adolescents who were similar to those intended to receive the intervention for obesity treatment; weight changes were positive, and no major safety concerns were raised in the participants.

All six RCTs showed positive outcomes in treating obesity in children. A multi-site drug trial conducted in the U.S. and Canada¹⁹ evaluated the treatment effects across centers and found no significant differences. An overall effect size of lifestyle interventions over control conditions in children at 12 years of age or older was -0.14 on BMI standard deviation score, BMI-SDS (95% CI: -0.18. to -0.10, $Z = 7.11$, $p < .00001$) and -3.27 kg/m² on absolute BMI (95% CI: -3.38 to -3.17, $Z = 60.10$, $p < .00001$) at 12 months follow-up.¹⁰ Among children under 12 years of age, the effect size at six months follow-up was -0.06 (95% CI: -0.12 to -0.01, $Z = 2.14$, $p = .03$) on BMI-SDS in the parent-focused group intervention over the control conditions.¹⁰ However, the difference in BMI reduction was no longer significant at 12 months follow-up although decreases in BMI-SDS remained. It is important to note that the effects of interventions on child weight reduction may vary depending on the differences in child metabolism, nutritional needs, and growth and psycho-social development which were not measured in the RCTs throughout childhood. The overall reduction in initial BMI and fat-mass found in drug trials was more than 10%. Berkowitz et al²⁰ reported an average of 7.8 kg reduction in initial BMI in the participants treated with sibutramine in combination with behavior therapy at 6 months follow-up; however, the role of behavior therapy intervention on weight improvement was not evaluated. Therefore, the effects of behavior therapy on BMI reduction could not be determined. Future studies should evaluate the effects of behavior therapy in combination with drug therapy on weight improvement.

With regard to potential adverse outcomes, there are no reports of safety assessment and potential adverse outcomes in the RCTs with lifestyle interventions. However, both of the drug trials assessed medication adherence, safety, and adverse outcomes. Increase blood pressure and pulse rate, as well as ventricular premature complexes and extrasystoles have been reported as adverse outcomes in sibutramine; gastrointestinal tract adverse effects such as oily stool, nausea, and asymptomatic gall stones were indicated in orlistat. The authors argued that gall stones development was caused by excess or rapid weight loss, not orlistat.¹⁹ No significant effects of adverse outcomes from drug trials impacted weight loss in the participants. The reporting of adverse or unexpected outcomes serves as a protection to the

population; and nurses should consider the extent of the adverse outcomes when making a decision about whether an intervention should be chosen for dissemination.

It is also important to know about program cost in order to make a decision about what interventions nurses could apply. Although none of the RCTs systematically estimated program costs, the potential cost of interventions could be estimated based on types and length of the interventions, types and number of expertise needed to deliver the interventions, types and number of settings for an intervention to be delivered, the necessary of transportations, and types and amount of equipment needed. The program cost can vary significantly from one setting to another depending on resources available in those settings.

4. Maintenance and Institutionalization

Assessing the sustainability of an intervention's impact on child weight provides an indicator of program utility. Considering the maintenance and institutionalization of the interventions, nurses should ask the following questions: a) Are data reported on longer term effects, at least 12 months following treatment?, b) Are data on attrition by condition reported?, and c) Are analyses conducted of the representativeness of those who drop out?

All six RCTs monitored and evaluated the program effects on the individuals for at least one year. Weight improvement was sustained by the individuals who completed the interventions at a minimum of 12 months post intervention. Attrition figures were presented in all RCTs. Study withdrawals and drop-out rates were evaluated and included in the analyses. The drop-out rates at the end of the RCTs with lifestyle interventions and drug therapies ranged from 11% to 33%, and 28% to 35%, respectively. The baseline characteristics among participants who withdrew from the studies or dropped out were described in all RCTs, but they were similar to those of the completers. Missing data were handled and imputation analyses were reported in all RCTs.

Note: A summary of rating criteria using Green & Glasgow's framework for the six selected RCTs is available and can be emailed to readers upon request.

Implications and Recommendations for Practice

This paper addressed and utilized the Green and Glasgow framework to evaluate the external validity of the promising six RCTs from a 2009 meta-analysis of interventions for treating obesity in children and adolescents to make recommendations for effective long-term weight control interventions to pediatric nurse practitioners. Evidence from this review demonstrated that family-based, lifestyle interventions with a behavioral modification aimed at changing diet and physical activity patterns can provide significant and clinically meaningful weight reduction in both children and adolescents compared to standard care in the long term, for at least 12 months follow-up. In severely obese adolescents, consideration should be given to the use of either orlistat or sibutramine, combined with behavioral therapy; however, such therapy needs to be carefully weighed against the potential for adverse effects.

Interventions that address key elements related to childhood obesity, including diet, physical activity, and lifestyle patterns, show promising long term weight control. The recommendations for effective long-term weight control interventions for overweight and obese children drawn from this review include the following:

1. Dietary intervention should emphasize healthy eating, such as increasing fruits and vegetables and decreasing high energy-dense foods.

2. Physical activity intervention should focus on increasing physical activity and reducing sedentary behaviors.
3. Behavioral modification intervention should include cognitive-behavioral intervention, problem-solving approaches, lifestyle knowledge and skills, and coping techniques.
4. Family-based interventions with parental involvement should be encouraged as they have produced significant effect in reducing weight gain in children and adolescents.
5. A drug therapy combined with behavioral modification intervention in relation to diet and physical activity appears to be effective in weight control in severely obese adolescents (BMI > 97th percentile).
6. Child body weight and BMI should be monitored and followed up for at least 12 months after any intervention.
7. Attrition is a common problem in weight control trials. To minimize attrition, nurses may need to provide additional support and encouragement with regular contact and opportunities for the child/adolescent/family to pose questions about challenges they encounter. The use of email or a practice website could be used as a mechanism for regular communication. In addition, program duration and delivery method (e.g., on-site or remote contacts) may need to be modified to fit with clients' needs.

It is important that nurse practitioners have a clear understanding of how the interventions worked and evaluate whether the interventions are feasible and relevant to their particular settings, clients, culture, resources, and staff before using them. Advanced practice nurses should integrate the potential benefit and harm from an intervention guided by the US Preventive Services Task Force²⁴ with the client's values and preferences for therapy. In addition, when reviewing the literature nurse practitioners need to assess the generalizability of individual interventions. Translation of research-based interventions into practice requires evidence with adequate external validity.¹¹ Guidelines developed by Green & Glasgow can help to evaluate and prioritize those interventions with the greatest likelihood of being efficacious.

According to the criteria for research translation,¹¹ these six RCTs showed partial evidence of external validity and contextual relevance. The limitations found in these RCTs include a lack of: 1) robustness of intervention effects across different populations, setting levels, and delivery staff; 2) program cost estimation; and 3) replicability of the findings across settings. In summary, there is a continuing need for RCTs that address obesity treatment in certain subgroups of children such as African Americans, American Indians, and Hispanics; children in families with low socioeconomic status; and young children. An estimation of program cost is also important for translation decisions of nurse practitioners and policymakers. However, this review highlights the need for an effort to increase the reporting of external validity that will enhance evaluation of generalizability and promote research translation. These six RCTs have made a valuable contribution to the literature on the treatment of childhood obesity and their findings can be very useful and effective when used in primary care settings with children, adolescents and families who are seeking long-term solutions the challenge of overweight and obesity.

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Table 1**Key Elements for Evaluating Generalizability Suggested by Green & Glasgow**

Key Elements of Generalizability	Criteria	Sample Questions
Populations and Settings	<ul style="list-style-type: none"> • Target population • Recruitment and selection criteria • Sample size • Participation rates • Characteristics of participants/non-participants 	<ul style="list-style-type: none"> • Who is the targeted population? • What are the eligibility criteria for participants? • What is the percentage of those who participated?
Program Implementation	<ul style="list-style-type: none"> • Program type/components • Program intensity and duration • Program level/location • Number and levels of staff 	<ul style="list-style-type: none"> • How well were the program components and intensity described in the individual studies? • Does the program consist of multiple components, high intensity, and long term approach? • Does the program require special training or high-skilled staff to deliver?
Outcomes for Decision Making	<ul style="list-style-type: none"> • Intervention outcomes (i.e., quality of life, weight loss) • Program costs • Adverse consequences 	<ul style="list-style-type: none"> • Do the interventions lead to a significant decrease in BMI and clinical relevance? • What is the effect size? • What are the program costs? • Are quality of life and adverse consequences related to the interventions presented?
Maintenance and Institutionalization	<ul style="list-style-type: none"> • Percent attrition • Program sustainability • Duration of follow-up 	<ul style="list-style-type: none"> • Are data reported on longer term effects? • Are data on attrition by condition reported?

Table 2

A Summary of Characteristics of the Lifestyle RCTs Reviewed in this Paper

Authors	Participants	Intervention Components	Intervention Duration	Findings
Epstein et al ²²	41, 8 to 12 years old, obese (BMI > 85th percentile) children and their parents Ethnicity: Caucasians and minority (not described) Setting: U.S.	Family-based Dietary (Traffic Light Diet*) and increased healthy foods or reduce high energy-dense foods), physical activity, and behavior modification of eating and physical activity *Foods are categorized on the basis of their calorie and nutrient content. Green foods come from the fruit and vegetable groups. Yellow foods are higher in energy density than green foods, (fat = 2–5 g or sugar 10–25% calories/serving). Red foods are higher in energy density than yellow or green foods (fat > 5 g or sugar >25% calories/serving). Many red foods come from the fats, oils, and sweets groups and are to be used sparingly. Modified foods from the fats, oils, and sweets groups are considered to be red foods.	5 months Follow-up: at 6, 12, and 24 months	- Significantly different reduction, between increased healthy foods and reduce high energy-dense foods groups at 12- and 24- month follow-up, in child mean zBMI (-0.26 ± 0.15 vs. -0.21 ± 0.17 and -0.27 ± 0.41 vs. -0.11 ± 0.21 units, respectively; $p < .05$), and percent overweight (-18.4 ± 9.3 vs. -13.5 ± 14.1 and -14.2 ± 18.6 vs. -3.0 ± 16.7, respectively, $p < .05$)
Epstein et al ²³	90, 8 to 12 years old obese (BMI > 85th percentile) children and their parents Ethnicity: Not described Setting: U.S.	Family-based Dietary (Traffic Light Diet) physical activity (increased physical activity or decreased sedentary behaviors), and behavior modification of eating and physical activity Low and high doses for the decrease sedentary or increase physical activity group were 10 or 20 h/wk of targeted sedentary behaviors, or the equivalent energy expenditure of 16.1 or 32.2 km per week, respectively.	6 months Follow-up: at 12 and 24 months	- Significantly different decrease, from baseline to six months and 2 years across groups, in mean percent overweight (-25.5 ± 10.6 % and -12.9 ± 17.0%, respectively) and percent body fat (-6.4 ± 3.2 % and -2.0 ± 4.4, respectively)
Golan et al ¹⁷	32, 6 to 11 years old, overweight (BMI > 85 th percentile based on the international acceptable definition of child overweight, age-sex- specific) children Ethnicity: Not described Setting: Israel	Family-based Healthy eating, increase in daily physical activity, decrease in sedentary behaviors (<3 h/d) and self-monitoring of food intake and activities. Parent training in coping techniques, feeding style, and problem solving	6 months Follow-up: at 6 and 18 months	- Significantly different changes from baseline to 18-month follow-up, between parents-only and parent-child groups, in child percent overweight (-9.5% vs. -2.4%) and BMI z score (-0.4 vs. -0.1 units)
Savoye et al ²¹	209, 8 to 16 years old, overweight (BMI > 95 th percentile) children Ethnicity: Non-Hispanic white, Non-Hispanic black, and Hispanic Setting: U.S.	Family-based Bright body weight management program (exercise 50 min twice a week, nutrition education 40 min a week, and behavior modification class 40 min a week). Behavior modification class emphasizes self-awareness, coping skills, and parent modeling healthy behaviors	12 months Follow-up: at 6 and 12 months	- Significantly different changes from baseline to 12-month follow-up, between the weight management and control groups, in mean BMI (-1.7 vs. +1.6, $p < .001$) and percent body fat (-4% vs. +2.0%, $p < .001$)

Table 3

A Summary of Characteristics of the Drug Trials Reviewed in this Paper

Authors	Participants	Intervention Components	Intervention Duration	Findings
Berkowitz et al ²⁰	82, 12 to 16 years old obese (2 units over the mean 95 th percentile $\leq$ BMI $\leq$ 44 based on age and sex) adolescents Ethnicity: White, Black, and Other (not described) Setting: 33 U.S. weight loss clinics	10 mg/day of sibutramine or placebo for 12 months; participants who had not lost $> 10\%$ of initial BMI after 6 months received 15 mg of sibutramine Both groups also received the same behavior therapy for lifestyle modification	12 months Follow-up: weekly visit for 2 weeks, then every 2 weeks until week 12, and monthly visits through the end of the program (1 year)	- Significantly different reduction, between sibutramine and placebo groups at month 6, in mean body weight (-7.8 ± 6.3 kg vs. -3.2 ± 6.1 kg), waist circumference (-8.2 ± 6.9 cm vs. -2.8 ± 5.5 cm), and BMI z score (-0.2 ± 0.2 vs. -0.1 ± 0.1), $p \leq .001$ - Significantly different decrease, between orlistat and placebo groups, in mean BMI (-0.55 vs. $+0.31$, $p = .001$), and waist circumferences (-1.33 cm vs. $+0.12$ cm, $p < .05$) at week 54
Chanoine et al ¹⁹	539, 12 to 16 years old obese (2 units over the mean 95 th percentile $\leq$ BMI < 44 based on age and sex) adolescents Ethnicity: White, Black, and Other (not described) Setting: 32 centers in the U.S. and Canada	120 mg of orlistat or placebo for 3 times/day Both groups also received general guidelines for diet, exercise and behavioral modification.	54 weeks Follow-up: every 2 weeks for the first 4 months, then every month and 2 months through the end of the program	