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Family Intervention for Obese/ Overweight Children Using Portion Control Strategy (FOCUS) for Weight Control: A Randomized Controlled Trial

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Abstract

Nutritional counseling for children with obesity is an important component of management. This randomized controlled trial was conducted to compare change in body mass index (BMI) z score after 6 months. Children 8 to 16 years with a BMI greater than the 85th percentile were randomized to standard of care nutrition counseling versus intervention with standard nutrition counseling including portion control tool training for the family. Measures were completed at baseline, 3 months, and 6 months. Fifty-one children were randomized to control and 48 to intervention. Mean age was 11 years (SD = 2.2). Mean BMI z score was 2.7 (SD = 0.4). Forty-five percent were male (n = 45). Follow-up at 6 months was 73.7% (73/99). Although no differences were seen between the groups, there was a significant decrease in BMI z score between baseline and 6 months within each group.

Keywords

pediatric, obesity, management, nutrition, portion size

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Introduction

Obesity has become an increasing public health problem. In adults, the prevalence of obesity has increased from 13.4% to 30.9% from 1960 to 2000 in the United States.[1,2] By 2010, the prevalence of obesity in the United States was reported to be 35.5% in adult men and 35.8% in adult women.[3] In Canada, less than 10% of people were obese in all provinces in 1985; in 2000, no province had less than 10% obese individuals, and 5 provinces reported an obesity prevalence in excess of 20%.[4] Data from the Canadian Community Health Survey in 2014 showed that 20.2% of Canadian adults were obese.[5] In the United States, the prevalence of obesity among children was estimated at 17% in 2003 and 2004.[6] A World Health Organization study estimated that the prevalence of obesity in European children aged 6 to 9 years was 6% to 31% in boys and 5% to 21% in girls depending on the country.[7] Early intervention is especially important since high body mass index (BMI) levels in childhood are strongly correlated with risk of obesity as an adult, and can also have adverse effects on adult health.[8]

As the prevalence of pediatric obesity has increased, so has the trend toward increasing portion sizes.[9] The portion sizes of readymade foods that are sold for immediate consumption have increased by 200% to 500% over recent years.[10,11] This is relevant, since portion size has been demonstrated to correlate with the number of calories ingested by a person at a meal.[9,12] Studies have shown that most people are unable to accurately estimate

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portion sizes[13-15] and cannot accurately estimate their energy intake.[16,17]

A previous randomized controlled trial demonstrated that a portion control tool can induce weight loss in obese adults with type 2 diabetes and also decrease their diabetes medication requirements.[18] Whether the same tool can be efficacious in children is unknown. Furthermore, in pediatric populations, there is evidence that family-based interventions for healthy lifestyles are just as important, if not more, than interventions that focuses on the child alone. Parenting practices have been shown to affect children's eating behaviors and can therefore influence a child's weight.[19] Interestingly, focusing on parental education alone has also been shown to have a greater reduction in a child's weight compared with interventions involving children alone.[20] Studies have demonstrated that weight loss interventions in obese children need to focus on parental involvement and not the child exclusively.[21-23]

The purpose of this study was to assess the effect of a family intervention using a portion control tool on BMI *z* score in children. The randomized controlled trial was designed to evaluate a previously studied portion control system[18] (calibrated plate and bowl) compared to standard nutrition counseling in reducing BMI *z* score after a 6-month period in obese and overweight children.

Methods

Study Population

Participants were recruited between July 2009 and December 2013 from the Calgary, Alberta, Canada, area using posters and advertising in clinics at the Alberta Children's Hospital, community physician offices, pharmacies, and health clinics.

Participants were included if they were age 8 years to 16 years and had a BMI ≥85th percentile for age and gender. Participants were excluded from the study if they were currently taking a weight loss medication, enrolled in any organized weight loss programs or exercise programs, consumed more than 30% of all meals at restaurants (making it difficult to bring the portion control tool), had a history of gastrointestinal disorder, psychiatric illness under the care of a physician, Cushing's syndrome, hypothalamic or genetic etiology of obesity, uncontrolled or untreated thyroid disease, a current diagnosis of cancer, history of an eating disorder such as bulimia or anorexia nervosa, any surgery in the past 3 months, any surgery planned in the ensuing 6 months, or any other chronic illness that could affect weight change.

Written informed consent was obtained for each participant and parent/guardian. The study (E-22161) was approved by the Conjoint Health Research Ethics Board (University of Calgary, Calgary, Alberta). The trial was registered at ClinicalTrials.gov (NCT00881478).

Study Protocol

At baseline, participants were asked to complete a 3-day food intake record for the dietician to review and a medical history form (including previous diagnosis of diabetes, hypertension, or dyslipidemia; dietary and medical interventions that they have previously attempted to manage their obesity; current exercise and activities [eg, time spent using computers or watching the television], and current medications).

Participants were randomly assigned to the control or intervention group. A computer-based random number sequence generator was used to create the random allocation. Sequentially numbered sealed envelopes were used to conceal the sequence until participants were assigned. The random allocation sequence was generated by a research assistant, while enrollment and assignment of participants to groups was done by the research coordinator. Participants and care givers were not blinded to the intervention since they were instructed on use of the portion control tools.

Both groups received a 1-hour session of standard nutrition counseling from a registered dietitian regarding healthy eating habits, appropriate portion sizes, and based on the Canada Food Guide. The intervention group received an additional 10 to 15 minutes counseling on how to use a calibrated dinner plate and breakfast cereal bowl for the child and adults in the family as a means of dietary portion control.

The portion control tool used was a commercially available dinner plate and breakfast bowl that has been previously described.[18] A child plate and adult male and female plates were available. Each had markings for carbohydrates, proteins, cheese, sauce, and the remainder for vegetables. The cereal bowl has markings for different caloric densities of cereal and is designed to measure a 200-calorie portion of cereal with ½ cup of milk (any type). Participants were instructed to use the calibrated plate at the largest meal of the day and the cereal bowl when cereal was consumed at breakfast.

The duration of the study was 6 months (Figure 1). Height, weight, waist circumference, and blood pressure were measured at baseline, 3 months, and 6 months. Blood samples were taken at baseline and 6 months including fasting: cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides, insulin, glucose, total adiponectin, high-molecular-weight adiponectin, and alanine aminotransferase. A 75-gram oral glucose tolerance test was also completed.

All participants were asked to refrain from starting any weight loss medication, other weight loss programs, or special diets during the trial period. Monthly phone

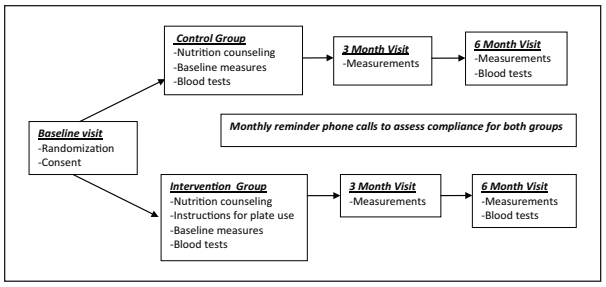

Figure 1. Diagram of study protocol.
Measurements included height, weight, waist circumference, and blood pressure. Blood tests were done fasting and included the following: total cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides, insulin, glucose, total adiponectin, high-molecular-weight adiponectin, and alanine aminotransferase. A 75-gram oral glucose tolerance test was also completed.

contact from the research coordinator was used to assess compliance of using the portion control system in the intervention group and following dietitian recommendations in both groups.

Outcome Measures

Measures were completed at baseline, 3 months, and 6 months. Weight was measured in clothed participants with no jackets or shoes using a calibrated scale (Seca, Germany). Height was measured using a wall-mounted, calibrated stadiometer (Holtain Limited, Britain). Waist circumference was measured using the technique described by Douketis et al.[24] A measuring tape was used to assess waist circumference midway between the lower costal margin and the iliac crest at the end of a normal expiration. Blood pressure was measured with a calibrated, automated machine and using the average of 2 measurements (Dinamap V100, GE Medical Systems, Milwaukee, WI). Fasting lipids, glucose, and alanine aminotransferase were analyzed using the Roche Cobas 6000 (Roche Diagnostics, Indianapolis, IN), and insulin was analyzed using the Abbott Architect (Abbott Diagnostics, Abbott Park, IL). Total adiponectin and high-molecular-weight adiponectin was analyzed using an ELISA kit (Alpco Diagnostics, Salem, NH).

Statistical Analysis

Sample Size. The primary outcome of this study was change in BMI *z* score. A sample size of 88 individuals (44 per arm in the study) would have an 80% power to detect a difference in BMI *z* score of 1.5 between the intervention group and the control group. This sample size assumes a standard deviation in the BMI *z* score of 2.5. Given an anticipated dropout rate of 20% and an anticipated rate of 5% of families that would include

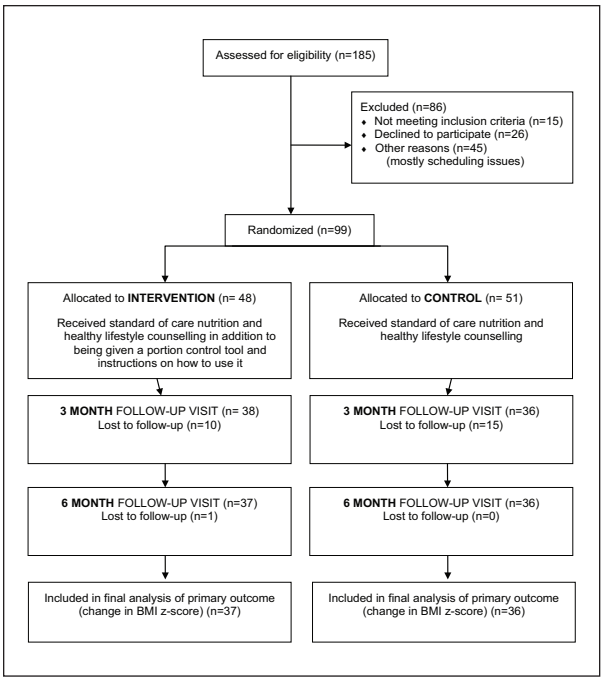

Figure 2. Diagram of patients included in the study.

siblings where only one could be analyzed to preserve sample independence, the enrollment target was set at 116 patients (58 in each arm). Over a 4-year period, a total of 99 participants were enrolled. Recruitment was discontinued when a dedicated pediatric weight management clinic became available at the Alberta Children's Hospital as an option for families.

Data were analyzed using an intention-to-treat (with last observation carried forward for missing data) and per-protocol analysis (≥80% compliance with recommendations as measured by self-report from monthly research coordinator phone calls). If multiple siblings were enrolled, then only one per family was randomly selected for analysis to avoid any cluster effects and maintain sample independence. The mean change in BMI *z* scores was compared between the 2 groups using a paired *t* test with a significance level α of .05. Paired *t* test was also used for comparing the change in continuous variables from baseline and 6 months between the control and intervention groups.

Results

Patient Characteristics

A total of 99 subjects were enrolled with 45% male (n = 45), mean age of 11 years (SD = 2.2), BMI of 29.1 kg/m^2 (SD = 5.6), BMI *z* score 2.7 (SD = 0.4). There were 51 children in the control group and 48 children in the intervention group (Figure 2). There were no significant differences between the 2 groups at baseline (Table 1).

Table 1. Baseline Characteristics[a].

Characteristic	Intervention (Portion Control Tool), n = 48	Control, n=51
Gender	25 Males/23 females (52.08% male)	20 Males/31 females (39.21% male)
Age (years)	11.50 (2.15)	10.90 (2.33)
Age groups	10 years and under: n = 18; over 10 years: n = 30	10 years and under: n = 26; over 10 years: n = 25
BMI (kg/m^2)	29.80 (5.63)	28.53 (5.67)
BMI percentile	98.75 (0.93)	98.74 (0.97)
BMI z score	2.74 (0.42)	2.69 (0.35)
Waist circumference (cm)	95.63 (14.17)	93.37 (14.14)
Systolic BP (mm Hg)	120.08 (10.61)	119.26 (10.05)
Systolic BP percentile	80.61 (19.89)	82.58 (19.67)
Systolic BP z score	1.14 (0.89)	1.22 (0.90)
Diastolic BP (mm Hg)	68.56 (6.74)	66.62 (4.53)
Diastolic BP percentile	64.83 (18.61)	62.78 (16.39)
Diastolic BP z score	0.45 (0.59)	0.35 (0.46)
Fasting insulin (pmol/L)	148.02 (121.51)	105.64 (71.16)
Fasting glucose (mmol/L)	5.20 (0.38)	5.07 (0.30)
Glucose at 2-hour OGTT (mmol/L)	5.67 (1.18)	5.64 (0.80)
ALT (U/L)	25.58 (16.67)	22.26 (10.52)
Total cholesterol (mmol/L)	4.40 (0.77)	4.19 (0.79)
Triglycerides (mmol/L)	1.19 (0.53)	1.22 (0.59)
HDL (mmol/L)	1.15 (0.28)	1.27 (0.37)
LDL (mmol/L)	2.71 (0.72)	2.36 (0.66)
Total adiponectin (ng/mL)	1.97 (1.35)	2.14 (1.33)
High-molecular-weight adiponectin (ng/mL)	1.73 (1.57)	1.22 (1.32)

Abbreviations: BMI, body mass index; BP, blood pressure; OGTT, oral glucose tolerance test; ALT, alanine aminotransferase; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
[a]Values expressed as mean (standard deviation). There were no significant differences in the baseline characteristics between the control and intervention group.

Follow-up at 6 months was 73.7% (73/99) with 37 subjects remaining in the intervention group and 36 subjects in the control group (Figure 2).

Adherence to Study Protocol

Families were contacted monthly by phone and asked about compliance with recommendations made by the dietitian around food choices and portion sizes. In the intervention group, the families were also asked about compliance with using the portion control tool. Participants were considered compliant if they reported following their plan at least 80% of the time in the past month. Overall, the compliance during the 6 months was 67.7% (SD = 25.6) with the intervention group compliance at 64.0% (SD = 25.5) and the control group at 71.5% (SD = 25.5).

Primary Outcome

No significant difference in change in BMI *z* score at 6 months was seen between the groups when analyzing those that had baseline and 6 month measures (Table 2). With an intent-to-treat analysis (last value carried forward for missing data), no significant differences in change in BMI *z* score was seen between the groups. Using a per-protocol analysis of those that were compliant at least 80% of the time, the change in BMI *z* score also was not significantly different. Although no differences were seen between the groups, within each group, there was a significant decrease in BMI *z* score between baseline and 6 months. For those that completed the study to 6 months, the change in BMI *z* score for the intervention group (n = 37) was −0.15 ($P = .005$), and in the control group (n = 36) the change in BMI *z* score was −0.10 ($P = .015$).

Secondary Outcomes

No significant difference in changes in anthropometric measures and laboratory markers was seen at 6 months between the 2 groups when analyzing those that had baseline and 6-month measures (Table 2). With an

Table 2. Change Between Baseline and 6 months (for Those That Had Values at Both Time Points)[a].

Characteristic	n	Intervention (Portion Control Tool)	n	Control	*P*	Confidence Interval
Weight (kg)	37	2.55 (5.16)	36	2.67 (5.00)	.92	−2.49, 2.25
BMI (kg/m^2)	37	0.02 (1.64)	36	0.14 (1.52)	.74	−0.86, 0.61
BMI *z* score	37	−0.15 (0.30)	36	−0.10 (0.22)	.42	−0.17, 0.07
Waist circumference (cm)	36	−3.09 (19.2)	36	1.94 (18.4)	.26	−13.87, 3.80
Systolic BP percentile	36	−6.17 (23.1)	36	−8.89 (23.75)	.62	−8.30, 13.75
Diastolic BP percentile	37	−3.42 (24.67)	36	−6.27 (21.64)	.60	−8.05, 13.76
Fasting insulin (pmol/L)	32	4.39 (104.25)	32	44.51 (132.18)	.18	−99.60, 19.38
Fasting glucose (mmol/L)	31	0.003 (0.31)	34	0.05 (0.71)	.74	−0.32, 0.23
2-Hour OGTT (mmol/L)	30	0.023 (1.21)	33	−0.07 (1.69)	.79	−0.65, 0.84
ALT (U/L)	32	−2.85 (6.01)	34	−0.85 (9.02)	.30	−5.79, 1.80
Total cholesterol (mmol/L)	31	−0.16 (0.48)	32	−0.19 (0.48)	.83	−0.21, 0.26
Triglycerides (mmol/L)	31	0.028 (0.49)	32	−0.098 (0.51)	.32	−0.13, 0.38
HDL (mmol/L)	31	0.034 (0.18)	32	0.028 (0.17)	.90	−0.08, 0.09
LDL (mmol/L)	31	−0.21 (0.42)	32	0.17 (0.44)	.71	−0.26, 0.18
Total adiponectin (ng/mL)	35	−0.082 (1.56)	34	0.30 (1.69)	.33	−1.17, 0.40
High-molecular-weight adiponectin (ng/mL)	35	−0.088 (0.91)	34	0.059 (1.17)	.56	−0.65, 0.36

Abbreviations: BMI, body mass index; BP, blood pressure; OGTT, oral glucose tolerance test; ALT, alanine aminotransferase; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
[a]Values expressed as mean (standard deviation).

intent-to-treat analysis (last value carried forward for missing data), no significant differences in anthropometric measures and laboratory markers was seen between the groups. Using a per-protocol analysis of those that were compliant at least 80% of the time, there were no significant differences between the groups at 6 months for change in anthropometric measures and laboratory markers.

Adverse Events

No adverse events or unintended effects were noted in either group.

Discussion

Various interventions have been studied for the treatment of pediatric obesity with variable success.[25] In this current randomized controlled trial, no significant difference was seen in the change in BMI *z* score between the intervention and control groups after 6 months in children with overweight and obesity. Although no differences were seen between the groups, each group did have a significant decrease in BMI *z* score between baseline and 6 months, which indicates that the nutritional counseling in addition to the regular follow-up in the study resulted in weight loss for the children. In this group of obese/overweight children, the use of portion control tool failed to replicate the finding in an adult study, which found that this portion control tool was more effective for weight reduction in those with type 2 diabetes and obesity and that the portion control tool also enabled patients with type 2 diabetes to decrease their hypoglycemic medications.[18]

The differences in findings between these 2 studies could be due to the participants involved. For example, there are differences in food consumption behavior between children and adults. Children often have little control over the food that is available to them in the home, how food is prepared, and when meal times are offered. In order to address the family impact in this study, parents were also given adult-specific portion control plates in the intervention group and were counseled on healthy eating habits for the entire family. However, the role of the family in the eating habits of the child may have influenced levels of adherence to the protocol when compared to the adult study.

A limitation of this study was the short duration of 6 months. The adult study was also 6 months in duration.[18] This may have limited the ability to see long-term changes in BMI *z* score in this population. Since the study participants were recruited from clinics at the Alberta Children's Hospital, community physician offices, pharmacies, and health clinics, the population may have been biased toward children that would be seeking medical attention. Compliance with using the portion control tool was not optimal and this may also have limited the effect on change in BMI *z* score in children, although the compliance was similar to the previous study by Pedersen et al,[18] which did show

differences. The frequency of in-person contact in this study was also a limitation. Phone calls were conducted monthly to assess compliance, but regular monthly office visits may have improved compliance and effect of the intervention. Adherence was not specifically collected for the child and the parent since the phone calls were made to the parent and they were asked to comment on the overall family adherence. In addition, parental anthropometric measures were not captured in this study; it would have been interesting to note these characteristics, whether parents experienced weight loss during the trial period, and whether changes in parental BMI was associated with changes in their child's BMI.

Conclusion

In our study, addition of a portion control tool to standard nutritional counseling did not result in a significant change in BMI *z* score after 6 months compared to standard nutrition counseling. Nutritional counseling for families did result in improvement in BMI *z* score over a 6-month period, but there remains a need for simple, adjunctive, practical tools that can assist families in weight management when they have children who are overweight and obese.

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Author Contributions

JH: contributed to conception and design; contributed to acquisition, analysis, and interpretation; drafted manuscript; critically revised manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

SDP: contributed to conception and design; contributed to interpretation; critically revised manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

HV: contributed to design; contributed to acquisition, analysis, and interpretation; critically revised manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

AN: contributed to conception and design; contributed to analysis and interpretation; critically revised manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

CH: contributed to conception and design; contributed to acquisition, analysis, and interpretation; critically revised manuscript; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

Authors' Note

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Declaration of Conflicting Interests

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