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Home-Based Exergaming among Children with Overweight and Obesity:

A Randomized Clinical Trial

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Abstract

Background—Given children's low levels of physical activity and high prevalence of obesity, there is an urgent need to identify innovative physical activity options.

Objective—To test the effectiveness of exergaming (video gaming that involves physical activity) to reduce children's adiposity and improve cardiometabolic health.

Methods—This randomized controlled trial assigned 46 children with overweight/obesity to a 24-week exergaming or control condition. Intervention participants were provided a gaming console with exergames, a gameplay curriculum (1 hr/session, 3 times/week), and videochat sessions with a fitness coach (telehealth coaching). Control participants were provided the exergames following final clinic visit. The primary outcome was body mass index (BMI) z-score. Secondary outcomes were fat mass by dual energy x-ray absorptiometry (DXA) and cardiometabolic health metrics.

Results—Half of the participants were girls, and 57% were African American. Intervention adherence was 94.4%, and children's ratings of acceptability and enjoyment were high. The intervention group significantly reduced BMI z-score excluding one control outlier (intervention [standard error] vs. control [SE]: -0.06 [0.03] vs. 0.03 [0.03], p=0.016) with a marginal difference in intent-to-treat analysis (-0.06 [0.03] vs. 0.02 [0.03], p=0.065). Compared to control, the intervention group improved systolic BP, diastolic BP, total cholesterol, LDL-cholesterol, and MVPA (all p-values < 0.05).

Conclusions—Exergaming at home elicited high adherence and improved children's BMI z-score, cardiometabolic health, and physical activity levels. Exergaming with social support may be promoted as an exercise option for children.

Trial registration—ClinicalTrials.gov, NCT02560493

Keywords

video games; weight loss; exercise; technology; coaching; African Americans

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Nearly 20% of U.S. children ages 6 to 11 years are affected by obesity. Young children with obesity are developing early signs of cardiovascular disease. Declining physical activity during childhood and into adolescence contributes to significant weight gain. Meta-analyses indicate that increasing children's physical activity over a 24-week period significantly reduces BMI z-score and improves cardiometabolic risk factors. However, only 42% of 6–11 year-olds and 8% of 12–15 year-olds meet national physical activity guidelines of 60 minutes of daily moderate-to-vigorous physical activity (MVPA); therefore, identifying enjoyable, sustainable physical activity options is a public health priority.

Exergames (i.e. video games that require physical activity) transform sedentary screen-time into physically active screen-time. Systematic reviews and meta-analyses indicate that players can reach light to moderate intensity physical activity while exergaming. 7-10 However, there are contradictory findings on the extent to which exergames can reduce children's adiposity or improve cardiovascular disease risk factors in the home setting. 11-15 The inconsistency in findings may be that prior home-based trials lacked a theoretical basis and used exergames as the sole tool for physical activity promotion, resulting in sharp declines in exergaming after a few weeks.

The present GameSquad trial used exergaming as one tool within a behavior change intervention that was grounded in social cognitive theory, ¹⁶ which conceptualizes behavioral change as the result of links among behaviors (e.g., exergame play), the environment (e.g., parental and coach support), and psychosocial variables (e.g., self-efficacy and quality of life). Exergames are often played with family members, ¹⁷ and social interaction during group-based exergame play is a key predictor of weight loss. ¹⁸ Exergames encourage exercise through supportive words on the screen like "Flawless" and "Almost" to boost players' self-efficacy (one's belief about personal control ¹⁶), which predicts exercise adherence. ¹⁹ The GameSquad intervention provided social support by requiring children to play with or against a family member or friend and by requiring children and parents to attend telehealth counseling sessions designed to promote self-efficacy and to reduce perceived barriers.

The goal of this parallel randomized controlled trial was to test the effectiveness of the exergaming intervention to reduce adiposity and improve cardiometabolic health in children with overweight and obesity. Given that the intervention was grounded in behavioral theory with the use of social support and telehealth counseling, the primary hypothesis was that children randomized to the exergame intervention would decrease BMI z-score compared to a control group. Secondary hypotheses were that the children in the exergaming intervention would improve cardiometabolic risk factors, ²⁰ body composition (fat mass and bone mineral density), health behaviors (physical activity and diet), ²⁰ and psychosocial health compared to the control group.

Methods

Participants

Parents were recruited for their child's participation through email, school newsletters, social media, news media, doctors' offices, and community events. Of 96 children whose parents completed an online screening survey, 46 met eligibility criteria and were randomly assigned (see Figure 1). Inclusion criteria included being between the ages of 10 and 12 years, having a BMI percentile ≥85th, living in a household with high-speed internet connection, and having at least one family member or friend willing to play the exergame with the participant for 3 hours/week. Exclusion criteria included being pregnant; having impairments that prevent normal ambulation; or having an indication of cardiac abnormality or previous or current symptoms of cardiovascular disease, musculoskeletal injury, or epileptic seizures. All study procedures were approved by the Pennington Biomedical Research Center Institutional Review Board.

Procedures

Interested parents completed a screening form online followed by a phone screen. Eligible children were scheduled for a screening visit where the child provided written assent and the parent/legal guardian provided written consent. Participants were provided with an accelerometer to wear for 7-days and scheduled a baseline clinic visit to occur at least 8 days later. During the baseline clinic visit, participants returned the accelerometer and underwent study measurements.

The participant was randomly assigned to the GameSquad intervention or a control condition, revealed by an interventionist ("fitness coach") using an opaque sealed envelope after completion of baseline measurements. A biostatistician generated the allocation sequence using biased coin randomization based on the BMI z-score collected at the screening visit to ensure balance across conditions. Participants returned for an end of study clinic visit at Week 24, occurring within 72 to 168 hours following the final gaming session (for intervention participants) to observe cumulative rather than acute effects of the exergaming. All data assessors and investigators were blinded to participant's condition.

Each participant randomized to GameSquad was provided a Kinect® and Xbox 360® gaming console (Microsoft, Redmond, WA), a 24-week Xbox Live subscription, and four exergames (*Your Shape: Fitness Evolved 2012, Just Dance 3, Disneyland Adventures*, and *Kinect Sports Season 2*). Two fitness coaches visited the parent and child at home within 7-days of randomization to deliver and set up the gaming equipment and play the first gaming challenge together.

The GameSquad intervention encouraged participants to meet a goal of 60 minutes/day of MVPA for 24-weeks. Participants were asked to play exergames three days/week with a family member or friend to help them meet this MVPA goal. Each exergaming participant received a booklet that provided a standardized gameplay curriculum to play three challenges each week with increasing intensity, difficulty, and duration (10 min/session in week 1, increasing by 10 min each session and sustained at 60 min/session after week 6). In this booklet, children with parental assistance recorded exergame play start and stop time for

each challenge, which was used to calculate compliance and adherence. The maximum duration of 60 minutes per exergaming session was selected to meet the physical activity guidelines (≥ 1 hour/day physical activity)²¹ and to not exceed screen-time guidelines (≤ 2 hours/day recreational screen-time²² with co-viewing/participation with a parent²³).

The telehealth component consisted of each participant and a parent in the exergaming condition meeting with a fitness coach over videochat via the exergame console, on a weekly basis for the first six weeks and biweekly thereafter. Participants in the GameSquad intervention were provided a Fitbit Zip (Fitbit, San Francisco, California) to wear during the 24-week period. Steps/day were wirelessly uploaded and reviewed by the fitness coach. The fitness coach followed a script for the virtual meetings that reviewed child's steps/day, recorded gameplay data from the child's booklet, and helped the child and parent to create solutions to barriers for physical activity. The script focused on building the child's self-efficacy and social support for physical activity (e.g. "I'm really proud of you"; "Having friends and family can help you stay motivated. What buddies can be physically active with you?").

Participants assigned to the control condition were asked to maintain their normal level of physical activity for 24 weeks and were provided the Xbox console and exergames following their final clinic visit. All participants received \$25 at baseline and \$25 at follow-up to compensate for travel costs.

Measures

Screening—The screening visit included a physical examination by a physician or nurse practitioner including Tanner staging for sexual maturity, height and weight measurement, resting electrocardiogram, and a brief readiness interview to confirm study eligibility. Parents provided child's birth certificate to confirm date of birth and reported child's biological sex, race, and medical history including pre-existing medical conditions.

Anthropometry—Height and weight were measured on a wall-mounted stadiometer and digital scale, respectively, with the average of two measurements used in analysis. BMI z-score, BMI percentile over 95th, and weight-for-age z-score were calculated based on the child's age, sex, height, and weight based on the 2000 CDC Growth Charts.²⁴

Adiposity—A dual energy x-ray absorptiometry (DXA) scan was completed with a GE iDXA whole-body scanner (GE Medical Systems, Milwaukee, WI) to measure total fat mass and % fat mass. Bone mineral density (BMD; g/cm²) was also calculated for the whole body and by region (trunk, spine, leg). The scans were analyzed with Encore V.13.60.033. All females (n= 21) completed a urine pregnancy test prior to the DXA scan.

Cardiometabolic risk factors—Resting blood pressure (BP) was assessed using a standard sphygmomanometer after the participant rested for 5 min in a quiet room. The average of two systolic and diastolic measurements was used for analysis, and BP percentiles were calculated based on age, sex, and height.²⁵ A blood draw following an 8-hour fast was performed by a trained phlebotomist following standard venipuncture standards. Samples were assessed for total cholesterol, triglycerides, glucose, and high-

density lipoprotein (HDL)-cholesterol. Low-density lipoprotein cholesterol (LDL)-cholesterol was estimated using the Friedewald equation: LDL = total cholesterol – [{triglycerides/5] + HDL].

Physical activity—Physical activity was measured with an Actigraph GT3X+ accelerometer on the right hip (ActiGraph, of Ft. Walton Beach, FL) for 7 days between the screening visit and baseline clinic visit and for 7 days prior to the end of study clinic visit. Accelerometry data were included in the analysis if the participant had data for at least 10 hours/day with at least 4 days/week including one weekend day. Sedentary, light, moderate, and vigorous intensity physical activity were classified based on the criteria of Evenson et al. 26

Dietary intake—Participants completed the National Cancer Institute's Self-administered 24-hour Dietary Recall (ASA24-Kids) on a web-based program, with parental assistance as needed. Total caloric intake and intake of fat, carbohydrates, and protein were examined. Dietary components were examined based on the AHA ideal cardiovascular health metrics. 20

Psychosocial measures—Psychosocial measures were collected using REDCap, a HIPAA-compliant online data capture tool.²⁷ Quality of life was used as a global measure of physical, psychological, and social well-being and measured using the KIDSCREEN-10 index.²⁸ Two instruments were selected to assess tenets of social cognitive theory: the 21-item Friendship Quality Questionnaire was used to measure children's peer support²⁹ and self-efficacy for physical activity was measured using the physical activity portion of the Self-Efficacy for Healthy Eating and Physical Activity measure.³⁰

Acceptability surveys—An acceptability survey adapted from a prior exergaming trial³¹ was emailed to intervention parents for children to complete at weeks 4 and 12 and administered at Week 24 clinic visit. Questions included injuries during game play and intervention enjoyment/acceptability.

Power Calculation

An *a priori* power calculation was used to estimate the sample size needed to detect a significant difference by condition in BMI z-score using a mixed model controlling for significant covariates (e.g. sex, age). The recommendation was for –0.09 BMI z-score change relative to the control group based on prior exergaming ¹⁵ and exercise trials, ⁴ requiring 23 participants/group allowing for up to 10 dropouts. ¹⁸

Statistical Analysis

Age was calculated based on date of birth and baseline clinic visit date. Mixed effects models were used to examine differences by condition in each outcome variable, controlling for baseline value, age, and sex. One participant was designated as lost to follow up after week 3 of the intervention; despite multiple contact attempts by phone, mail, and e-mail, she did not return for follow-up assessment. A total of 45 participants completed the final study visit and were included in intent-to-treat analysis. One control participant decreased BMI z-

score by 3.3 standard deviations below the mean change in the control group. Therefore, analyses were repeated excluding this outlier. For the physical activity models, 34 participants were included who had complete accelerometry data at both timepoints, and these models controlled for average daily wear-time. The α level (2-sided) was set at 0.05. Statistical analysis was conducted using SAS version 9.4 (SAS Institute, Inc).

Results

Study enrollment and data collection occurred from October 2015 – September 2016. Participants were 11.2 ± 0.8 years of age, including 46% girls and 57% African American, 41% White, and 2% other. Tanner stage was 2.6 ± 1.2 (range: 1 to 5). See Table 1 for clinical characteristics of the sample. Parent-reported medical conditions in children included anemia (n=1), asthma (n=6), type 2 diabetes (n=1), and impaired hearing (n=2). Based on the AHA criteria, 20 most children had ideal BP, fasting glucose, and smoking status, whereas 20 had poor or intermediate cholesterol levels, 42 had intermediate physical activity levels (more than 0 but less than 60 min/day), and all children had poor or intermediate diet score.

Adherence to exergaming sessions (completed vs. expected minutes/week) was 94.4% and compliance (completed vs. expected days/week) was 88.5%. At the readiness interview, 10 parents reported concerns that space at home was insufficient for exergame play; ultimately 19 children played the exergames in a living room, 2 in the child's bedroom, and 1 in a family gaming room. Reported reasons for non-compliance included schoolwork, sports practice, and being sick. Compliance to videochat sessions was 92.7%, and 9.8% of these sessions instead occurred over the phone due to faulty internet connection. Telehealth sessions averaged 14.5 ± 5.2 minutes in length. Among those randomized to the intervention group, two children reported an injury during gameplay (bruise to the ankle or wrist).

Primary Outcome

Compared to the control group, the intervention group significantly reduced BMI z-score when the outlier was excluded (intervention [standard error] vs. control [SE]: -0.06 [0.03] vs. 0.03 [0.03], p=0.016) and marginally reduced BMI z-score in intent-to-treat analysis (-0.06 [0.03] vs. 0.02 [0.03], p=0.065).

Secondary Outcomes

Compared to the control group, the intervention group improved systolic BP percentile (-5.0 [5.1] vs. 10.9 [5.0], p = 0.036), diastolic BP percentile (-7.4 [4.3] vs. 8.3 [4.2], p = 0.017), total cholesterol (-7.1 [3.5] vs. 6.7 [3.5] mg/dL, p = 0.011), and LDL-cholesterol (-4.9 [3.1] vs. 7.4 [3.1] mg/dL, p = 0.010). There was a significant reduction in weight z-score favoring the intervention group (p = 0.049). There was no intervention effect for change in fat mass, % fat mass, BMD, glucose, or HDL-cholesterol. The intervention group gained half as much fat mass (0.8 ± 0.5 kg) compared to the control group (1.7 ± 0.5 kg). Findings were similar with the outlier excluded. See Table 2.

The intervention group engaged in significantly more min/d of MVPA (3.6 [3.4] vs. -7.8 [3.2], p=0.028) compared to the control group at Week 24. The change by condition in total

caloric intake did not reach significance (-297 [215] vs. 279 [200] kcal/day, p = 0.069). Baseline self-reported energy intake (1894 ± 881 kcal/day) aligned with recommended dietary guidelines for this age group.³² The intervention group consumed significantly fewer carbohydrates (-44.6 [25.6] vs. 45.5 [23.7] g/day, p=0.017). Findings were similar with the outlier excluded. The intervention group improved self-efficacy towards physical activity compared to the control group (-44.6 [25.6 vs. 45.5 [23.7], p = 0.01). There was no difference by condition in quality of life or peer support.

Intervention Acceptability

Children reported playing exergames primarily with a parent (n=12), alone (n=6), or with siblings or someone else (n=4). Children's favorite game was *Kinect Sports* (n=18) followed by *Just Dance 3* (n=3) and *Your Shape: Fitness Evolved 2012* (n=1). The majority of children found the exergaming acceptable and enjoyable (see Supplemental Table 1), and 19 children rated the physical intensity of playing the exergames as moderate to hard. Children reported wearing the Fitbit every day or just about every day (n=19), a few times a week (n=2), or every now and then (n=1). Twenty children were moderately to extremely satisfied with the Fitbit and two were slightly satisfied. Half of the children reported buying additional games during the intervention, but these games were primarily non-active games (10 of the 14 games purchased).

Discussion

This 24-week home-based exergaming intervention reduced BMI z-score and improved cardiometabolic health among children with overweight and obesity. These results expand upon a home-based exergaming trial that effectively reduced BMI z-score and body fat over a 6-month period. By contrast, three trials that provided children with exergames to play at home did not change children's adiposity or physical activity levels; 11–13 one potential explanation for lack of effectiveness may be the rapid decline in children's exergame play after the first few weeks of intervention. The present GameSquad intervention retained excellent adherence for children's exergaming (94% over 24-weeks) by employing social support including regular videochats with a fitness coach and a gaming curriculum and step tracker to motivate children's physical activity.

The present study observed meaningful improvements in children's systolic and diastolic BP, total cholesterol, and LDL-cholesterol. These results align with observations that 24 weeks of physical activity intervention can induce measurable changes in children's cardiometabolic health.⁵ These improvements in cardiometabolic risk factors were achieved with a BMI z-score difference of 0.08 units, which is similar in magnitude to a 24-week home-based exergaming intervention among 322 10–14 year-olds with overweight and obesity¹⁵ and to a systematic review on lifestyle obesity treatments for children.⁴ There is no direct evidence on what BMI z-score change constitutes a clinically meaningful change, with an expert panel suggesting a reduction of –0.20 to 0.25 BMI z-score³³ and other studies indicating –0.15 BMI z-score reduction.³⁴

There were no significant treatment effects on DXA-measured body composition including fat mass, % fat mass, or BMD, though the intervention group gained half as much fat mass

compared to the control group. The lack of statistical significance may be because the study was powered to detect differences in BMI z-score but not these secondary outcomes. By contrast, a prior 12-week lab-based, supervised exergaming study (180 min/week of exergaming) in 41 adolescent girls aged 14 to 18 years significantly reduced abdominal subcutaneous adipose tissue and increased BMD in the trunk and spine, compared to a self-directed care control condition. The present trial focused on children 10–12 years of age; as indicated in the present data and others, children (especially girls) accumulate fat mass during this peripubertal period as sexual maturation induces hormonal, biological, and behavioral changes that contributes to fat accumulation. Therefore, a focus on attenuating fat gain (rather than fat loss per se) may be a reasonable approach in the peripubertal age range. While the intervention did not change bone density, the potential detrimental relationship of fat mass on bone development in children warrants further attention as evidence indicates that adults with higher fat mass have lower BMD.

The children's baseline MVPA ($35 \pm 18 \text{ min/day}$) did not meet physical activity guidelines (60 min/day)²¹ and was lower than accelerometry data from a nationally representative sample of children ages 6-11 years (95 min MVPA/day) and 12-15 years (45 min MVPA/ day). 6 Intervention participants' overall MVPA increased by 11 min/day over the control group between baseline and week 24, and children remained engaged with the intervention across the 24-week period. A change of 11 min/day of MVPA after 6-months of intervention is important given the ages of 10 to 12 years are typically characterized by a rapid decline in MVPA.⁶ This magnitude of change aligns with a prior trial of exergaming in a physical education (P.E.) classroom that increased children's MVPA by 9 minutes/session compared to standard P.E., ³⁸ though the trial was small (n=4). One study of 60 children observed 6 min/day increase in vigorous physical activity and no difference in moderate vigorous physical activity following 10-weeks of home-based exergaming, though this change did not significantly differ from the wait-list control group. 12 By contrast, other studies observed no change in daily MVPA after three³⁹ to six months^{11,15} of in-home exergaming, though exergaming use dramatically declined in the first few weeks in trials that did provide additional support for MVPA. 11,39

Self-efficacy towards physical activity significantly improved during the intervention, aligning with prior exergaming trials that improved youths' self-efficacy. ⁴⁰ Dietary intake also changed, with the intervention consuming marginally fewer calories and fewer carbohydrates compared to the control group. This finding aligns with a 24-week exergaming intervention in which the intervention group reduced self-reported daily energy intake from snack food compared to a passive video game control group, though the change was not statistically significant. ¹⁵ The findings also align with a systematic review indicating adolescents with obesity did not change or reduced energy intake following acute bouts of exercise. ⁴¹

Two adverse events (bruising) were reported in the GameSquad trial, which is similar to prior exergaming studies reporting minor bruises, hand lacerations, and back pain. 42,43 Prolonged or overly aggressive play has produced injuries in prior exergaming case studies. However, a study comparing injury rates during running vs. exergaming observed 2.44 injuries per 100 hours of running vs. no injuries during 201 hours of exergaming. 44 No

exergaming-related serious adverse events have been reported in systematic reviews. 43,45 Future trials should report on adverse events to inform recommendations for exergame play, 8 including proper endurance and strength training. 46

A unique aspect of the GameSquad intervention was the inclusion of fitness coaches, who provided telehealth counseling complemented with real-time monitoring of steps/day using a commercially available step tracker. While the fitness coaches were research staff members with bachelor degrees in kinesiology, the coaching role could be fulfilled by a variety of para-professionals or lay health providers. In other words, this home-based intervention could be deployed by a variety of entities if adequate social support and structure are provided to the children and families. A key driver of intervention success is the child's active engagement within the behavior change intervention.⁴⁷ Telehealth directly involves the child in communicating, monitoring, and counseling on exercise. As exercise counseling becomes integrated into primary care delivery, telehealth should be further explored to deliver tailored exercise counseling and support to children with obesity.

Limitations

While there was sufficient power to detect a difference in the primary outcome, the study would have benefited from a larger sample size to reduce variability. Videochat compliance was objectively captured by the fitness coach, but gaming adherence and compliance were reliant on the child and parental report at each gaming session. Coach monitoring at each videochat may have reduced memory recall bias but social desirability bias is possible. It is not possible to isolate specific intervention components (e.g. time spent in MVPA during exergaming vs. other activities, the role of coach and parental support) that contributed to the difference in BMI z-score and cardiometabolic health. Therefore, future research should examine these influences to identify the most effective strategies to achieve clinically meaningful improvements in children's adiposity and cardiometabolic health. Finally, future trials should conduct follow-up assessments to test for the sustainability of exergame play following the end of the intervention as well as potential sustained effects on children's cardiometabolic health and health behaviors.

Conclusion

Interactive gaming coupled with telehealth fitness counseling was an acceptable, effective tool to foster physical activity in children with obesity who are in need of sustainable physical activity options.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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management, analysis, or interpretation of the data; the preparation, review, or approval of the manuscript; or the decision to submit the publication.

Abbreviations

AHA American Heart Association

BMC bone mineral conten

BMD bone mineral density

BMI body mass index

BP blood pressure

DXA dual energy x-ray absorptiometry

HDL high-density lipoprotein

LDL low-density lipoprotein

MVPA moderate-to-vigorous physical activity

SE standard error

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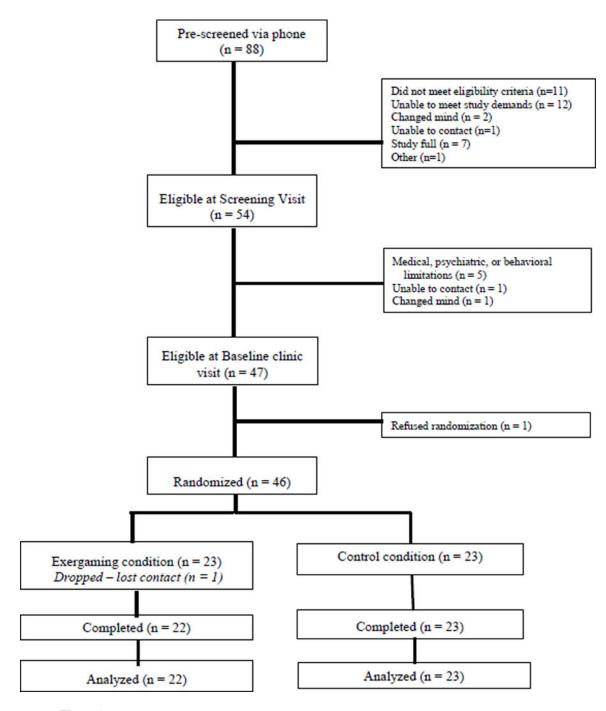


Figure 1. CONSORT Participant Flow for the GameSquad Trial.

 Table 1

 Baseline Body Composition and Cardiometabolic Risk Factors Overall and By Intervention Assignment.

	Overall (n = 46)	Intervention (n = 23)	Control (n = 23)
Anthropometry			
BMI, z-score	2.08 (0.44)	2.06 (0.46)	2.10 (0.42)
BMI, % over 95th	120.6 (22.4)	120.8 (26.3)	120.5 (18.4)
Weight, z-score	2.29 (0.66)	2.28 (0.69)	2.29 (0.65)
DXA			
Fat mass, kg	29.8 (9.6)	30.4 (11.6)	29.3 (7.4)
Fat mass, %	43.1 (4.9)	42.0 (5.9)	44.1 (3.4)
BMD whole body, g/m ²	1.0 (0.1)	1.0 (0.1)	1.0 (0.2)
Trunk	0.9 (0.1)	0.9 (0.2)	0.8 (0.1)
Spine	0.9 (0.2)	0.9 (0.2)	0.9 (0.1)
Leg	1.1 (0.2)	1.1 (0.2)	1.0 (0.1)
CV Risk Factors			
SBP, %	40.0 (23.2)	36.4 (11.6)	43.7 (25.9)
DBP, %	60.9 (20.1)	58.5 (17.8)	63.3 (22.4)
Cholesterol, mg/dL	160.6 (37.2)	154.1 (36.8)	167.0 (37.3)
HDL-Cholesterol, mg/dL	50.1 (9.1)	48.9 (9.1)	51.3 (9.2)
LDL-Cholesterol, mg/dL	94.4 (30.5)	89.4 (31.2)	99.3 (29.6)
Triglycerides, mg/dL	80.7 (50.2)	79.1 (49.1)	82.3 (52.4)
Glucose, mg/dL	89.2 (5.3)	89.7 (4.8)	88.8 (5.8)
Physical Activity	(n = 45)	(n = 23)	(n = 22)
MVPA, min/day	35.1 (17.8)	35.0 (17.8)	35.1 (18.3)
Dietary Intake	(n = 42)	(n = 20)	(n = 22)
kcal/day	1801.8 (887.3)	1700.0 (905.4)	1894.4 (881.2)

Note. Mean value (standard deviation).

Table 2

Change in Body Composition and Cardiometabolic Risk Factors from Baseline to Week 24 By Intervention Assignment.

	Intent to Treat $(n = 45)$			Without Outlier $(n = 44)$		
	Intervention Adjusted Mean Difference	Control Adjusted Mean Difference	p value	Intervention Adjusted Mean Difference	Control Adjusted Mean Difference	p value
Anthropometry						
BMI, z-score	-0.06 (0.03)	0.02 (0.03)	0.065	-0.06 (0.03)	0.03 (0.03)	0.016
BMI, % over 95th	-2.2 (1.1)	0.6 (1.1)	0.098	-2.1 (1.1)	0.9 (1.1)	0.070
Weight, z-score	-0.10 (0.05)	0.04 (0.05)	0.049	-0.09 (0.05)	0.07 (0.04)	0.022
DXA						
Fat mass, kg	0.8 (0.5)	1.7 (0.5)		0.9 (0.5)	1.8 (0.5)	
Fat mass, %	-0.5 (0.4)	-0.3 (0.4)		-0.5 (0.4)	-0.3 (0.4)	
BMD whole body, g/cm ²	0.03 (0.01)	0.03 (0.01)		0.03 (0.01)	0.03 (0.01)	
Trunk, g/cm ²	0.03 (0.01)	0.03 (0.01)		0.03 (0.01)	0.04 (0.01)	
Spine, g/cm ²	0.04 (0.01)	0.04 (0.01)		0.04 (0.01)	0.04 (0.01)	
Leg, g/cm ²	0.04 (0.01)	0.03 (0.01)		0.04 (0.01)	0.03 (0.01)	
CV Risk Factors						
SBP, %	-5.0 (5.1)	10.9 (5.0)	0.036	-4.8 (5.1)	11.3 (5.1)	0.033
DBP, %	-7.4 (4.3)	8.3 (4.2)	0.017	-7.4 (4.4)	8.5 (4.4)	0.018
Cholesterol, mg/dL	-7.1 (3.5)	6.7 (3.5)	0.011	-6.8 (3.6)	7.1 (3.6)	0.011
HDL-Cholesterol, mg/dL	-1.9 (1.4)	-0.7 (1.3)		-0.7 (1.4)	-1.9 (1.4)	
LDL-Cholesterol, mg/dL	-4.9 (3.1)	7.4 (3.1)	0.010	-4.6 (3.1)	7.8 (3.1)	0.010
Triglycerides, mg/dL	-3.0 (6.9)	1.4 (6.7)		-2.9 (6.9)	1.0 (6.9)	
Glucose, mg/dL	0.5 (1.1)	0.4 (1.1)		0.5 (1.1)	0.5 (1.1)	
Physical Activity						
MVPA, min/day	3.6 (3.4)	-7.8 (3.2)	0.028	3.4 (3.4)	-8.0 (3.3)	0.023
Dietary Intake						
kcal/day	-297.2 (215)	269.5 (200.0)	0.069	-316.4 (211.3)	215.6 (200.4)	0.084

Note. Adjusted estimates (standard error) from mixed effect models controlling for age, sex, baseline value, and accelerometer wear-time (for physical activity only). P values < 0.20 are reported.