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EFFECTS OF A MOTION SENSOR-BASED INTERVENTION IN OBESE ADOLESCENTS: A PILOT RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Aim: the purpose of the present pilot study was to verify the effects of astep goals pedometer interventionon physical activity level and cardiometabolic profile in obese adolescents. **Methods:** The intervention was designedusing a pilot randomized controlled trial with 19 adolescents. The 8-week intervention included following components: (i) pedometer for physical activity self-monitoring; (ii) individualized goal setting; (iii) parent text messages for social support. The primary outcome was physical activity (PA) and secondary outcomes included cardiometabolic profile. The effects of 8-weeks intervention was analyzed using the generalized estimation equation (GEE) method in a gamma repeated-measures model for the outcomes. **Results:** A group–time effect was observed after 8-week for physical activityin intervention group (baseline: 7,553 steps/day [IC95% 6036 to 9446]; (post: 11,138 steps/day [IC95% 9255 to 13403]). **Conclusion:** A 8-week of step goals pedometer interventionwas able to improve the PA but did not cardiometabolic profile in these obese adolescents.

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INTRODUCTION

The worldwide prevalence of overweight and obesity has risen dramatically among children and adolescents and has become one the most serious public health in the world (1). The pediatric obesity has increased from 11 million (1975) to 124 million (2016) ("WHO, 2018). In Brazil 23.7% of adolescents are classified with overweight, which corresponding to approximately 3 million individuals, and of these 7.8% are obesity (ESTATÍSTICA, 2016). Pediatric obesity is associated with the early development of several morbidities both physical, cardiometabolic and psychosocial complications (FRANCO et al., 2016; MCCRINDLE, 2015; SAGAR & GUPTA, 2018; WHITAKER *et al*., 2018) . Franssen et al., 2019 observed that LDL cholesterol, triglycerides, triglyceride-to-HDL cholesterol ratio, glucose, insulin concentrations were higher in obese adolescents compared with lean adolescents. It is well known genetic factors, age, lifestyle (e.g. physical activity level and diet), social and environmental are crucial for the development of obesity (CHAN & WOO, 2010; FAIK *et al.*, 2017).

Longitudinal studies have demonstrated physical activity level decline during adolescence (DUMITH *et al.*, 2011; SILVA *et al*., 2018), which is indirect evidence of a relationship between lack of physical activity and adolescent obesity development. Moreover, researches have pointed out that physical activityparticipationis lower in obese compared with normal-weight adolescents (KIM *et al*., 2012; ROURA *et al*., 2016). Therefore, the physical activity promotion in childhood and adolescent is important to prevent theobesity and its associated risk (RANUCCI*et al*., 2017). According to Lubans *et al*., 2009, motion sensors such as pedometer are promising instruments in interventions aimed at promoting PA, which encourage adolescents to increase their daily step. Suchert *et al*., 2018observed that feedback provided by pedometer increased awareness regarding behavioral choices (daily step),and so promoting increase PA level.However, there are few physical activity program using motion sensors that adopted strategies based in behavior change theories (LUBANS *et al.*, 2015). Therefore, the purpose of the present pilot study was to verify the effects of astep goals pedometer

interventionon physical activity level andcardiometabolic profilein obese adolescents.

MATERIALS AND METHODS

Study design and participants

A pilot randomized controlled trial (RCT) of the ActTeens Programwas conducted with obese adolescents,to evaluate one of strategies this program focused on increasing physical activity.The participants (n = 19)were recruited from a Health Center (Quatiguá, Paraná, Brazil). School,adolescents and their parents/guardians provided informed written consent prior to enrolment. Ethics approval was obtained from the human research ethics committee of the States University of Northen of Parana (nº 2.795.427), and the study protocol was registered with the Brazilian Clinical Trials Registry (RBR-4b7tyd).The design, conduct, and reporting for this RCT adhered to the guidelines of the Consolidated Standards of Reporting Trials (MOHER *et al.*, 2010). Data collection was conducted by trained research assistants, blind to group allocation at the state school where participants studied. The adolescents were randomly assigned to either a control orintervention group using numbers generated by specific software (randomization.com) by an independent research. Participants randomized to the intervention group participated in 8-week motion sensor-based physical activity promotion program and the control group received weekly messages about healthy behavior. Eligible participants were obese adolescents age 12-17 years, who did not have cardiometabolic disease diagnosed and with physical or mental condition, which should enabled their participation in physical activity program as outlined in the participant information and consent form.

Intervention

The PA intervention was designed to increase the physical activity level guided by the social cognitive theory (SCT) (. The intervention included following components: pedometer for physical activity self-monitoring plus goal setting;parent text messages for social support on behavior change); and weekly messages to support healthy eating and regular PA using WhatsApp Group.Detailed description of intervention components and hypothesized mediators are reported in Supplementary file 1. Strategies used to increase physical activity level of adolescents were pedometer goals setting, where each adolescent received his/her owngoal (based on the number of steps measured at the baseline).

The goals were predetermined by the researcher of way progressive, from the execution of an additional 10% in the first and second week, 15% in the third and fourth week, 20% in the fifth and sixth week, to 25% in the seventh and eighth week over the baseline number of steps (KANTANISTA *et al*, 2017). This intervention had as objective propose a realistic goal setting with aim to achieve at least 10000-11700 steps/day (Tudor-Locke *et al*., 2011). Research assistants sent messages daily for adolescents to encourage achieve and maintenance of the goals.In addition, they also were responsible for sending by WhatsApp® nutrition and physical activity weekly messages for the parents. The control group received the same messages about healthy behavior as intervention adolescents.

Primary Outcome

Physical activity: PA was assessed using pedometer (model Yamax Digi-Walker, SW 700; Tokyo, Japan). Pedometers have been established as a reliable and valid tool formeasuring physical activity for both children and adolescents(ROWE *et al.*, 2004; SCOTT *et al*., 2014; TUDOR-LOCKE *et al.*, 2009).Specifically, a research assistant provided 5-min instructions to inform adolescents about proper wearing of the pedometer and how to note the number of steps/day in the sheet of record. The participants wore the pedometer constantly for 7-day, with the exception of time spent sleeping, swimming, and showering(LUBANS*et al*., 2015).

Secondary Outcomes

Cardiometabolic variables analyzed were glucose, insulin, triglyceride (TG), total cholesterol (TC) and glycated hemoglobin (HbA1c). Blood samples were collected from the antecubital vein in vacuum tubes after 12 hours fasting, at twodifferent moments (baseline and post-intervention), followed the recommendations of the Brazilian Society of Clinical Pathology/Laboratory Medicine. Fasting glucose was measured using the reference enzyme Hexokinase. To determine the fasting insulinwas used by the chemiluminescence method. Total cholesterol (TC) and triglycerides (TG) were analyzed by enzymatic colorimetric method, and glycated hemoglobin was determined using high performance liquid chromatography. Body weight was measured to the nearest 0.1 kg in light clothing without shoes using a portable digital scale (Welmy®, Santa Bárbara do Oeste, São Paulo, Brazil) and height was recorded using a portable stadiometer (Welmy®, Santa Bárbara do Oeste, São Paulo, Brazil). Body mass index (BMI) was calculated using the standard equation (weight [kg]/height $[m]^2$) and its was classified according to World Health Organization data (WHO, 2007). Waist circumference was measured at the midpoint between the last rib and the iliac crest using a steel tape (Sanny®, São Bernardo do Campo, São Paulo, Brazil).

Statistical Analysis

Adolescent´s baseline descriptive characteristics [mean (SD)] were calculated. StudentT-test was used to compare the baseline values between the groups. The effects of 8-weeks intervention wasanalyzed using the generalized estimation equation (GEE) methodin a gamma repeated-measures model for the outcomes. We entered group, time, and the interaction of group × time as independent variables into model. All statistical procedures were performed using SPSS software (version 20.0). Statistical significance was set at $p<0.05$.

RESULTS

Nineteen obese adolescentswere recruited(57.8% female; mean age, 14.84 ± 1.91 years)assessed at baseline (Figure 1). Baseline characteristics of the study sample can be seenin Table 1. There were no differences between the intervention and control groups at baseline. Baseline and 8-week intervention for physical activity and cardiometabolic profile outcomes are presented in Table 2.We observed significant intervention effects for physical activity (step count/day) in the intervention group. Significant difference was found for glucose and insulin in the control group. There were no significant interactions observed betweenthe groups.

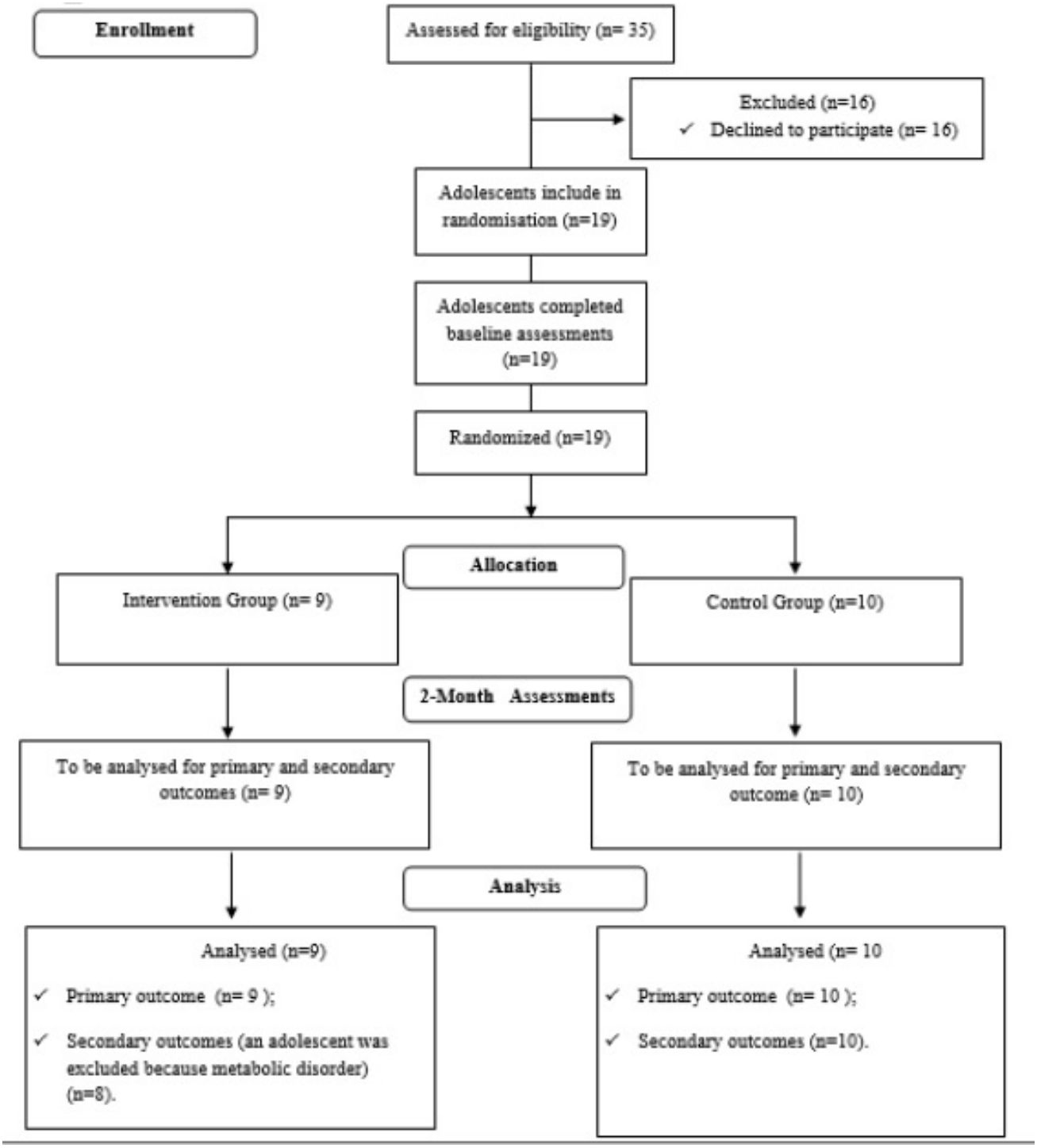

Figure 1. Flow participants through of study

Table 1. Baseline characteristics of the study sample. Mean (SD)

	Intervention Group (n=9)	Control Group (n=10)	Total (n=19)
Age (years)	14.8 (1.7)	14.8 (2.1)	14.8 (1.9)
Height (cm)	162.1 (4.6)	164.7 (9.5)	163.4 (7.5)
Weight (kg)	84.6 (9.2)	85.5 (15.3)	85.1 (12.4)

obese adolescentsis limited.The present study showed that the 8-week ofpedometer intervention proved to be effective in significantly increasing thephysical activity (steps/day). These findings expand knowledge and adds value on the strategies (i.e. pedometers, goal setting and social support) which should implemented when the objective is stimulus to practice PA in obese adolescents. Moreover, positive effects on PA might be due to motivational aspects as autonomy (free choice relating to when, what type, and with whom he/she wants to be physically active), self-monitoring own PA levels, pedometers feedback function (self- awareness) and social comparison ('peer competition') (SCOTT *et al.*, 2018; SUCHERT *et al.*, 2018). Consistent with our results, Staiano et al. (2017) observed an increased daily steps in adolescents who received individualized step goals. Considering the cardiometabolic profile, our results did not report any changes in the

Table 2. Effect of physical activity intervention on primary and secondary outcomes in obese adolescents

Variables	Intervention			Control			
	Baseline Mean (95% CI)	8-week Mean (95% CI)	Time[b], P	Baseline Mean (95% CI)	8-week Mean (95% CI)	Time[b], P	Group*Time[c], P
Physicalactivity(steps/day)	7,553 (6,036 to 9,446)	11,138 (9,255 to 13,403)	<0.001	8,066 (5,874 to 11,075)	8,079 (5,733 to 11,384)	0.98	0.48
Total cholesterol(mg/dl)	168.8 (150.1 to 189.9)	179.7 (158.6 to 203.6)	0.39	159.2 (142.2 to 178.2)	170.8 (158.2 to 184.3)	0.13	0.40
Triglycerides (mg/dl)	114.0 (79.5 to 163.3)	111.1 (76.7 to 161.2)	0.89	85.0 (66.0 to 109.4)	95.90 (75.4 to 121.9)	0.26	0.50
Glucose (mg/dl)	86.0 (79.2 to 93.3)	89.1 (76.2 to 104.1)	0.74	87.7 (83.0 to 94.6)	83.8 (78.9 to 88.9)	0.02	0.62
Insulin(µUI/mL)	18.0 (15.4 to 20.9)	20.3 (16.2 to 25.4)	0.19	13.2 (10.6 to 16.3)	15.2 (12.6 to 18.4)	0.003	0.05
HbA(mg/dl)	5.1 (4.8 to 5.4)	5.2 (4.9 to 5.5)	0.39	5.0 (4.9 to 5.2)	5.1 (4.9 to 5.4)	0.10	0.78
BMI ($kg \cdot m^{-2}$)	32.6 (30.3 to 34.1)	32.3 (31.2 to 33.4)	0.71	31.3 (29.2 to 33.5)	31.3 (29.1 to 33.6)	0.96	0.57
WC (cm)	97.9 (91.9 to 104.3)	96.9 (92.6 to 104.1)	0.39	93.5 (89.2 to 98.0)	93.8 (88.5 to 99.3)	0.80	0.32

[b] Within-group change over time; [c] Group–time interaction from intervention baseline; BMI: body mass index; WC: waist circumference; HbA: Glycosylated hemoglobin.

concentrations of total cholesterol, triglycerides, glucose, insulin and glycated hemoglobin for experimental group after 8-week intervention.Thus, a possible explanation for this absence of changes may be due to intensity of the PA. According to Tarp, Child, White(2018), time spent in physical activity with increasing intensity is favorably associated with cardiometabolic risk markers in youth irrespective of bout-duration. Thus, this author supports the recommendation of high intensity intermittent activity patterns for cardiometabolic benefits in young people. The intervention was not successful in reducing adolescents BMI and WC. Likewise, Currie*et al*., 2017not found improvement in BMI z-score after 7-week physical activity intervention in obese adolescents. The absence of BMI effect may reflect intervention duration, intensity of individuals participation, shift in body composition from fat to muscle, and/or the absence of an accompanying reduction in energy intake(CROUTER, SALAS, & WIECHa, 2017). In summary, using pedometers plus individualized setting goals and social support as strategies was enough to enhance the PA (steps/day) in these obese adolescents. However, some limitations should be pointed out: the small sample size,a characteristic of pilot studies; the pedometer output do not distinct the different intensities of PA, which would have added value on the interpretation of the results; and the lack of control over eating behavior. Strengths of this study include the randomized controlled trial design, objective measurements of physical activity as well as a focus on a population at high risk – obese adolescents.

Conclusion

Results indicate that 8-week of step goals pedometer intervention promoted increasing physical activity. The addition of a pedometer plus step goals based on baseline values was able to improve PA but did not cardiometabolic profile. Future researches including larger samples and longer duration interventions are necessary. Moreover, further investigation should evaluate the effects of specific tools and strategies to effectively promote physical activity, improve cardiometabolic profile and weight loss in obese adolescents.

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