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Combined use of a wristband and a smartphone to reduce body weight in obese children: randomized controlled trial

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Summary

Background: Technological instruments may help control paediatric obesity.

Objective: We tested whether a personalized programme based on the energy expenditure obtained from a wristband (WB) and the energy intake obtained from a smartphone application (APP) is superior to a standard approach at promoting weight loss.

Methods: We performed a randomized controlled trial in obese children aged 10–17 years. The experimental (EXP) and control (CTR) groups were given a low-energy diet and a prescription for physical activity. The EXP group was equipped with a WB and an APP and given personalized feedback every 7 days. The main outcome was weight loss at 3 months.

Results: The mean (standard deviation) *z*-score of body mass index at the enrollment was 2.20 (0.47) in the EXP ($n = 16$ out of 23) and 2.09 (0.34) in the CTR group ($n = 14$ out of 20) of children who completed the trial. The mean (95%CI) difference in weight loss at 3 months was 0.07 kg (95%CI: 2.81 to 2.96) for EXP vs. the CTR.

Conclusion: A personalized lifestyle programme based on a WB and an APP was not superior to a standard lifestyle programme at promoting weight loss in obese children.

Keywords: children, obesity, remote sensing technology, smartphone.

Introduction

The prevalence of paediatric obesity is rapidly increasing (1). Both low-energy expenditure (EE) and high-energy intake (EI) are contributing to this phenomenon (2). However, obesity is much more than a positive energy balance, because it has important genetic, psychological, behavioural and environmental roots (2).

Randomized controlled trials (RCT) have shown that obese children may lose weight by lifestyle interventions (3). However, the results obtained in the real-life setting are largely unsatisfactory (4). Most children own smartphones and prefer to learn using electronic media (5). Such instruments may help children control obesity. Specific smartphone applications (APP) and short messaging services (SMS) may be useful to promote healthy eating and physical activity (PA) (6). Besides the intrinsic interest of children for electronic gadgets, the possibility of obtaining frequent feedback makes these instruments potential means for promoting weight loss (7). APP and SMS have been shown to be able to induce short-term behavioural changes in adults (8,9). However, the effectiveness of mobile health technology (m-health) to promote weight loss is equivocal in children (10–13). APP-based tracking of food consumption has been associated with positive changes in the dietary behaviour of obese children (14). A recent review reported increases of PA and self-monitoring in the absence of relevant changes of body mass index (BMI) (10). Importantly, PA was always self-reported, posing a problem of measurement validity. Accelerometers allow an objective assessment of PA and are the most practical means for evaluating EE (15). We decided to objectively assess PA-incorporating accelerometers in an m-health technology weight loss programme designed for obese children.

The aim of the present study was therefore to test whether a personalized lifestyle programme, built by experts on the basis of the EE data obtained by a wristband (WB) incorporating an accelerometer and the EI data obtained by a smartphone APP, was superior to a standard lifestyle change programme at promoting weight loss in obese children.

Subjects and methods

Trial design

We performed a parallel arm RCT.

Participants

Participants were recruited at the Obesity Clinic of the V. Buzzi Paediatric Hospital (Milan, Italy). The inclusion criteria were essential obesity with BMI ≥95th percentile (16), age ≥10 and ≤17 years and Caucasian ethnic group. The exclusion criteria were genetic/syndromic obesity, psychiatric disease and any condition compromising the ability to walk.

Interventions

Interventions common to the experimental and control groups

At recruitment (T0), indirect calorimetry (IC) was performed in thermo-neutral conditions, using an open-circuit indirect calorimeter (Vmax 29 Encore, Yorba Linda, CA, USA), from 8 to 10 AM, after a 12-h fast and at least 24-h free of structured PA. At T0, a Mediterranean diet was given to all participants. The energy content of the diet was obtained by subtracting 200–500 kcal day^{-1} from the estimated total EE. According to Butte *et al.* we considered 200 kcal day^{-1} as the lowest energy gap usable in children to prevent weight gain (17). Total EE was estimated from resting EE measured by IC taking into account the age and the level of PA (18).

All participants were encouraged to practise 1 h day^{-1} of moderate to vigorous PA, to minimize sedentary time by reducing screen time (<2 h day^{-1}) (19) and to follow the Mediterranean diet during the 3 months study period. Participants were subsequently randomized in the experimental (EXP) and control (CTR) group.

Experimental intervention

Participants randomized to the EXP group were given a WB and an APP for all the duration of the study (3 months). The aim of the WB was to measure EE and that of the APP was to measure EI.

The WB (E3, Empatica, Italy) is made of (i) a tri-axial accelerometer detecting movement; (ii) a photoplethysmograph measuring heart rate; (iii) two electrodes evaluating galvanic skin response; and (iv) an infrared thermometer measuring cutaneous temperature. The WB was cross-validated against IC in obese children (20). The participants were asked to wear the WB from awakening to bedtime for at least 5 days per week. The data recorded by the WB were uploaded daily at bedtime to the manufacturer's web server using a secure connection. Data were processed by a proprietary algorithm, which estimates EE in MET (metabolic equivalent for oxygen consumption) on a minute basis. The estimated activity is associated with the corresponding MET value (Figure S1). Because the WB is not water resistant, the investigators performed a phone call asking whether and for how long water sports had been practised. The EE data obtained by the WB were made available daily to the study researchers on a purposely developed secure web platform together with the EI data obtained by the APP.

The APP (MeTeDa srl, Italy) is a database allowing real-time recording of food consumption. It contains a visual database of foods and three portion sizes (small, medium and large) for each food. The information on the energy and nutrient content of the foods normally shown by the APP was not available to the participants. The participants were asked to enter the raw foods into the APP immediately or shortly after their consumption. The data recorded by the APP were uploaded daily at bedtime to the manufacturer's web server using a secure connection. The EI data obtained from the APP were made available daily to the study researchers on a secure web platform together with the EE data obtained from the WB. The study dietitian checked daily that the food consumption data were entered regularly.

Specific sessions (2 h per five participants) were performed to train the children/families to use the system. A manual describing the WB/APP could be downloaded, and a help line was available during the study.

The information obtained from the web platform was used by a team of paediatric endocrinologists, sports medicine doctors and dietitians to develop personalized lifestyle programmes following the indications of the American Academy of Pediatrics and other Medical Associations (18,19,21–24) (Figure S1). Such information consisted in EE expressed in METS (per minute, hour, day and week) and EI in kcal (per day and week) and nutrient intake expressed as grammes and percentage of energy (per day and week). On the basis of the recordings made in the preceding 7 days, a weekly feedback on the

adequacy of the diet and PA was sent to the EXP group via SMS (Figure S1).

Each SMS addressed the compliance to the diet, the energy gap, the sedentary time, the PA level and the quality of the diet and gave suggestions on how to reach each of these five goals (Figure S1). A positive feedback was included in the SMS every time a participant reached at least one goal, with specification of the reached goal(s). Twelve SMS per participant were sent during the study.

No interventions were administered in addition to those described previously. Compliance was defined as wearing WM and using APP more than or equal to 5 days per week.

Control intervention

At T0 participants, randomized to the CTR group received only the Mediterranean diet and instruction to practise PA and minimize sedentary activity to follow during the 3 months study period (19). No other interventions were delivered during the study period.

Outcomes

The main outcome was the between-group difference in weight change, defined as the difference between body weight at 3 months and at the baseline. The secondary outcome was the between-group difference in BMI change, defined as the difference between BMI (standard deviation scores [SDS]) at 3 months and at the baseline. Ancillary outcomes were the changes in energy and macronutrients, defined as the difference between the values recorded at 3 months and the baseline using the APP in the EXP group and a food diary in the CTR group (25). Further ancillary outcomes were the changes in the level of commitment to the intervention, burden of the child with the intervention, satisfaction with the intervention, burden of the parents with the intervention, awareness on the importance of lifestyle changes and change of habits using the intervention.

Measurements

Body weight and height were measured following standard guidelines at the baseline, 1-, 2- and 3-month follow-up visits. SDS of BMI were calculated using Italian reference data (16). The energy and nutrient intake at 1 and 3 months were evaluated using a food diary (25) in the CTR group and the APP in the EXP group. The level of commitment to the intervention, the burden of the child with the intervention, the satisfaction with the intervention, the burden of the parents with the intervention, the awareness on the importance of lifestyle changes and the change of habits were evaluated at 1 and 3 months using a five-level Likert scale (0, very low; 1, low; 2, medium; 3, high; and 4, very high).

Sample size

Sample size was calculated on the basis of the main outcome (weight change). When we designed the RCT, a systematic review had estimated a weight loss of 1.5 kg as the mean effect that could be obtained with computer-based interventions in adults (26). In the absence of data for children, we took this as a plausible and clinically relevant estimate for the effect of the present intervention in children. With a common standard deviation of the difference of 1.6 kg, 20 subjects per group give a power of 80% to detect a mean difference of −1.5 kg at an alpha level of 0.05 (Student's *t*-test).

Randomization

The participants were randomly allocated to one of the two treatment groups following simple randomization procedures. The randomization was performed using the ralloc module for the Stata software (Stata Corporation, College Station, TX, USA).

Blinding

The RCT was unblinded because of the nature of the interventions.

Statistical analysis

Continuous data are reported as means and standard deviations (SD). Discrete data are reported as the number and percentage of subjects with the characteristic of interest. The comparison of weight change (weight at 3 months–weight at baseline) in the EXP vs. the CTR group was performed using Student's *t*-test as pre-specified by the study protocol. The analyses of secondary outcomes were performed using random effects generalized linear models (REGLM). REGLM for continuous variables used a Gaussian family and an identity link. REGLM for ordinal variables, i.e. those measured on Likert scales, used an ordinal family and a logit link. All REGLMs included the following predictors: (i) time (discrete: 0 = baseline or 1 month depending from the outcome; 1 = 3 months); (ii) treatment (discrete, 0:CTR; 1:EXP); 3) a treatment * time interaction (discrete * discrete); and (iv) the baseline value of the outcome (continuous). Each participant was

modelled as random effect. Statistical analysis was performed using Stata 14.1 (Stata Corporation, College Station, TX, USA).

Ethical approval

The protocol was approved by the local Ethical Committee, and the parents of the children gave their written informed consent. No compensation was given.

Results

Flow of the participants during the study

Figure 1 depicts the flow of the participants during the study. Eighty-four children and adolescents followed as outpatients at our Obesity Clinic were evaluated for inclusion into the study starting from 1 March 2015. Eleven children were excluded because of violation of the inclusion criteria, and 30 declined to participate. The remaining 43 children were consecutively enrolled into the study from 1 to 30 April 2015. Twenty-three of them were randomized to the EXP treatment and 20 to the CTR treatment. One child from the CTR group withdrew the consent immediately after randomization. Twelve participants were lost to follow-up, seven in the EXP group and five in the CTR group. The trial ended on 31 July 2015. All the planned 12 SMS/ participant were successfully delivered, and the reception of all the SMS was confirmed by the participants.

Baseline characteristics of the children

Table 1 gives the baseline characteristics of the 14 CTR and 16 EXP children who completed the trial. Despite the similar BMI, the EXP group was heavier than the CTR group. Although this difference was obtained via a randomization process and can therefore be considered a product of chance, it is large enough [10.8 kg (95%CI: 1.37 to 23.1)] that we took it into account when we performed the analysis of the main outcome using the REGLM. Table S1 compares the baseline anthropometric features of the children who were lost to follow-up with those of the children who completed the trial. The two groups had similar features.

Main outcome

Considering the 16 EXP children and the 14 CTR children who completed the trial, the difference in weight change was −0.06 kg (95%CI: 3.29 to 3.14) for the EXP vs. the CTR group ($p = 0.96$, Student's t-test). A somewhat less imprecise but still low estimate of the effect size was obtained from the REGLM correcting for baseline weight. Such difference was in fact 0.07 kg (95%CI: 2.81 to 2.96, $p = 0.96$) corresponding to weight changes of 0.72 kg (95% CI: 1.39 to 2.83) in the CTR and 0.79 kg (95%CI: 1.18 to 2.76) in the EXP group (Table S2).

Secondary outcome

The difference in BMI change was 0.01 kg (95%CI: 0.15 to 0.18) SDS for the EXP vs. the CTR group ($p = 0.87$, REGLM) corresponding to BMI changes of −0.04 kg (95%CI: 0.16 to 0.08) SDS in the CTR and −0.03 kg (95%CI: 0.14 to 0.09) EXP in the CTR group (Table S1).

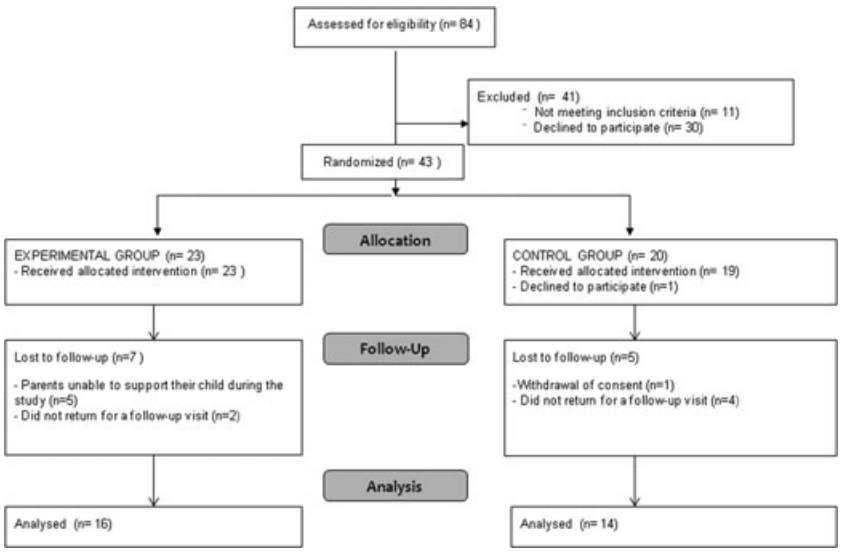

Figure 1 Flow of patients during the study.

Table 1 Measurements of the randomized children who terminated the trial

	CTR		EXP	
	N	%	*N*	%
Male gender	8/14	57.1%	11/16	68.8%
Age (years) (mean, SD)	12.4	2.2	12.6	1.7
Weight (kg) (mean, SD)	71.1	16.4	82.0	16.2
Weight (SDS) (mean, SD)	2.05	0.65	2.47	0.46
Height (m) (mean, SD)	1.57	0.11	1.66	0.11
Height (SDS) (mean, SD)	0.65	1.19	1.40	0.80
BMI ($kg\,m^{-2}$) (mean, SD)	28.6	2.6	29.6	3.3
BMI (SDS) (mean, SD)	2.09	0.34	2.20	0.47
Mother's BMI (SDS) (mean, SD)	26.19	5.78	25.88	3.73
Father's BMI (SDS) (mean, SD)	30.35	4.11	29.21	4.35
Mother's education				
Primary school	1/14	7.1%	0/16	0.0%
Middle school	5/14	35.7%	2/16	12.5%
High school	3/14	21.4%	13/16	81.2%
University	5/14	35.7%	1/16	6.2%
Father's education				
Middle school	7/14	50.0%	4/16	25.0%
High school	5/14	35.7%	10/16	62.5%
University	2/14	14.3%	2/16	12.5%
Mother does physical activity				
Never	0/14	0.0%	3/16	18.8%
Rarely	2/14	14.3%	2/16	12.5%
Sometimes	3/14	21.4%	3/16	18.8%
Often	5/14	35.7%	4/16	25.0%
Regularly	4/14	28.6%	4/16	25.0%
Father does physical activity				
Never	3/14	21.4%	4/16	25.0%
Rarely	2/14	14.3%	1/16	6.2%
Sometimes	4/14	28.6%	2/16	12.5%
Often	3/14	21.4%	1/16	6.2%
Regularly	2/14	14.3%	8/16	50.0%

CTR, control group; EXP, experimental group; SD, standard deviation; SDS, standard deviations scores (Italian growth charts, reference 16).

Ancillary outcomes

The difference in energy change was significantly higher in the EXP than in the CTR group even if the relative contribution of the macronutrients to such change was similar in the two groups (Table S2). Because there were not between-group differences either in weight or BMI, it is possible that this difference is due to the different instruments employed to assess EI in the EXP (APP) and the CTR (food diary) group. There was no between-group difference in the change of commitment, burden, satisfaction, awareness and habits (Table S2).

Compliance

The average APP use was 24 out of 30 days and 11 out of 30 days for the WB. Only one child reached the goal of wearing the WB and using the APP for at least 5 days per week. The change in weight was not associated with the number of days of use of the APP (Spearman's $\rho = -0.07$, $p = 0.53$) and WB (Spearman's $\rho = 0.22$, $p = 0.41$). The only technical difficulty reported was the inability to download the APP for 3 out of 16 subjects.

No harms were reported.

Discussion

We tested whether a personalized lifestyle programme, built by experts on the basis of the EE data obtained from a WB and the EI data obtained from an APP, was superior to a standard programme based on diet and exercise at promoting weight loss in obese children. We found a modest and comparable increase in weight and a modest and comparable decrease in the *z*-score of BMI in the two groups. Our results are in keeping with those of other RCTs showing that smartphones alone are not very effective in reducing BMI in obese children (12–14).

Our study has some strength as compared with the available studies. Firstly, we performed objective measurements of EE using a WB (27). Data obtain from WB were used to construct personalized SMS trying to overcame the limit of SMS based on self-monitoring of lifestyle behaviours, which showed no efficacy on weight loss in paediatric patients (11). Secondly, we integrated the EE from the WB with the EI from the APP using a specific web platform. This allowed the study dietitian to daily check the quality of data entry and the study team to deliver the suggestions. Thirdly, the personalized feedback was built using the most recent recommendations (18,19,20–24). In this respect, it is noteworthy that a recent review of the most popular APPs for weight loss has shown that they are suboptimal in the domain of scientific coverage and accuracy (28).

Lastly, our system was conceived to play an educational role, acting like a sort of personal health coach, empowering the child and his or her family on matters of health and nutrition.

Our study has nonetheless some limitations. Firstly, it was performed on a small sample of children. The minimal difference in weight that we were searching for to declare the experimental system effective was in fact relatively high and lowly variable. The reason

why we choose a relatively high and lowly variable effect size is that we thought that the time and effort required by the experimental system needed a clearly relevant effect size to be justified. Every child randomized to the EXP group had in fact to receive 12 SMS and such feedbacks involved the daily work of the team. Secondly, the study suffered from a substantial loss of children during follow-up. This fact, which is unfortunately common to most weight loss studies, lowered the precision of the estimate of the effect size that we were searching for.

We can imagine different reasons why the experimental system failed to work. Firstly, the overall use of the system was unsatisfactory. While the APP was used frequently, the WB was not. This happened despite the fact that the APP was not designed to take children specifically into account. The high compliance to the APP was not unexpected in view of the great interest of children towards smartphones (11). The participants may have not liked to wear the WB and/or to be monitored even if the degree of discomfort was reportedly similar in the EXP and CTR groups. This possibility is supported by a recent study showing that wearing an accelerometer may produce negative emotions in children, also because of an increased risk of being bullied (29). Secondly, most parents declared that they did not devote enough time in the study activities. It is of interest that five out of seven parents of the EXP participants who left the trial declared that they were unable to support their children during the weight loss programme. Thirdly, the lack of face-to-face interaction between the child, family and the study team may be partly responsible for the negative result (30). Lastly, the fear of being evaluated and the fact that the behaviour could be judged by the parents and/or clinicians may have influenced the compliance.

We think that our experimental device could be improved by reducing the dimensions of the WB, making it more attractive for children and introducing a WB software-based alerting children when they have been inactive for too long.

In conclusion, a personalized lifestyle programme, built by experts on the basis of the EE data obtained from a WB and the EI data obtained from an APP, was not superior to a lifestyle programme to induce weight loss in obese children. The present RCT suggests that children are not a good target population for the experimental system. We believe that such system warrants a further validation in adults, and we are currently recruiting obese adults to perform an RCT similar to that described in this report. We tested a purposely developed system, and our results are clearly not generalizable to other m-health systems. We do not think that our findings should discourage researchers in the field of m-health technology.

Conflict of interest

No conflict of interest was declared.

Authors' contribution

CM and GVZ co-designed and co-coordinated the study. CM wrote the first draft of the manuscript. DC, LS, FP and BB performed the data collection. GB performed statistical analysis and revised the manuscript.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1. Description of the personalized lifestyle programme.
Table S1. Anthropometric measurements of the children who competed the trial and of those who were lost to follow-up. Abbreviations: SD = standard deviation; SDS = standard deviation scores (Italian growth charts).
Table S2. Changes in the main outcome (weight), secondary outcome (z-score of BMI) and ancillary outcomes (energy and macronutrients).
Table S3. Changes in the ancillary outcomes level of commitment to the intervention, burden of the child with the intervention, satisfaction with the intervention, burden of the parents with intervention, awareness on the importance of lifestyle changes, and change of habits using the intervention. All variables were measured on a 5-level Likert scale (1= very low; 2 = low; 3 = medium; 4 = high; 5 = very high).