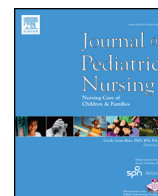




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## Home-exercise Childhood Obesity Intervention: A Randomized Clinical Trial Comparing Print Versus Web-based (Move It) Platforms

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## ABSTRACT

**Purpose:** To compare the impact of adhering to a Mediterranean diet plus mixed physical exercise program (Move-It) implemented by means of printed instructions or via a web-platform (with or without e-mail support) on body composition, physical fitness, and blood pressure.

**Design and Methods:** Randomized clinical trial. Fifty-two overweight or obese Spanish children and adolescents were randomly assigned to the print-based ( $n = 18$ ), Move-It ( $n = 18$ ), or Move-It plus support ( $n = 16$ ) intervention groups. Two-way mixed ANOVA tests were used to compare any changes between the groups in terms of percentage body fat, physical fitness ( $VO_2$ peak), handgrip strength, and systolic and diastolic blood pressure. The measurements were taken before and after a three-month mixed-exercise (aerobic and resistance) and Mediterranean-diet program which was either implemented by means of printed instructions or via a web-platform (with or without e-mail support).

**Results:** No statistical differences were found between groups. However, the results highlighted significant improvements in body fat percentage metrics over time for all three groups (print-based:  $-1.8\%$ , 95%CI  $-3.3\%$  to  $-0.3\%$ ; Move-It:  $-1.8\%$ , 95%CI  $-3.3\%$  to  $-0.3\%$ ; Move-It plus support:  $-2.0\%$ , 95%CI  $-3.7\%$  to  $-0.4\%$ ,  $P < 0.05$ ). We also observed a tendency towards improvement in the  $VO_2$ peak, handgrip strength, and blood pressure variable values 10 min after the exercise-stress test in these three groups.

**Conclusions:** The program improved the body composition, regardless of the way it is implemented.

**Practice Implications:** A mixed physical exercise program lasting for three months, combined with a Mediterranean diet, improves the body composition of children and adolescents with overweight/obesity.

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## Introduction

The notable decrease in physical fitness and muscular strength seen in children and adolescents over the last few decades is contributing to long-term clinical cardiovascular morbidity, and is becoming an even more prominent factor than other established contributory elements such as dislipemia, hypertension, or body mass index (Ortega, Ruiz, & Castillo, 2013; Ortega, Ruiz, Castillo, & Sjostrom, 2008). With the aim of improving body composition and reducing cardiovascular risk in

children and adolescents, many different physical exercise interventions have been trialed. The majority have been conducted in face-to-face groups and in controlled environments (Universities, healthcare centers, etc.), however, physical exercise interventions in an at-home setting (Lisón et al., 2012; Lisón, Bruñó-Soler, Torró, Segura-Ortí, & Alvarez-Pitti, 2017; Showell et al., 2013; Waters et al., 2011) and/or those using a web platform, with or without support (An, Hayman, Park, Duszaj, & Ayres, 2009; Antwi et al., 2012), are rarer.

To the best of our knowledge, no studies have evaluated the efficacy of a mixed physical exercise (aerobic plus resistance modalities) program implemented through a web platform to children and adolescents with overweight or obesity. Thus, the objective of this present study was to evaluate the impact of a combined Mediterranean-diet and mixed physical-exercise web-based program (Move It) with or without support (weekly reminder and motivational e-mails) on body composition, physical fitness, and blood pressure values in these patients.

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## Methods

This randomized clinical trial (NCT03080376) was approved by the Ethics Committee at the Hospital and followed the ethical guidelines for human experimentation, set out in the Declaration of Helsinki. A total of 65 children and adolescents with overweight or obesity aged between 9 and 16 years ( $12.6 \pm 1.7$  years) were consecutively recruited at the hospital pediatric service. The inclusion criteria were that the participants must be patients with overweight or obesity with availability to participate in the program at home via the Internet. Patients with secondary obesity syndromes or with acute illnesses were excluded from the study. Obesity was diagnosed when the body mass index (BMI) exceeded the 95th percentile for the patient's age and sex. Subjects with a BMI between the 85th and 95th percentile of the BMI distribution were defined as overweight. The extent of the excess weight was quantified using Cole's LMS method, which normalizes BMI and its skewed distribution, by expressing it as a standard deviation score (Cole, Bellizzi, Flegal, & Dietz, 2000). Subjects with severe obesity ( $z$ -score  $> 2.5$ ) were excluded because these individuals require specific individualized programs to avoid potential orthopedic problems. None of the subjects were taking any regular medications, nor did they display any clinical manifestations of illnesses. Informed consent acknowledgement was obtained from all of the participants' parents before the study commenced.

Before the trial started, investigator 1, who was not involved in the selection and inclusion of the participants, organized the preparation of numbered, opaque, sealed envelopes containing the patients' group allocation; investigator 2 generated the random sequence using a computerized random number generator. Upon enrolment in the study, 52 participants were randomly assigned to the print-based ( $n = 18$ ), web-based (Move It;  $n = 18$ ), or Move It plus support ( $n = 16$ ) groups. Fig. 1 shows the progression of the participants through the trial.

Allocation concealment was preserved from all the research personnel throughout the study and investigators assessing the outcomes were blinded to the group allocations. The study took place at the Pediatric Department (Obesity and Cardiovascular Risk Unit), from March 2017 to May 2017.

### Exercise Programs

Before commencing the intervention, the participants and their parents attended two sessions (delivered by pediatricians at the hospital) to educate them about the benefits of the Mediterranean diet and show them how the exercise program should be carried out. Details of the diet intervention (Mediterranean diet) are described in a previous work (Lisón et al., 2012).

The physical exercise intervention consisted of a training circuit with increasing intensity, comprising an aerobic activity (brisk walking) (Cebolla i Martí, Álvarez-Pitti, Guixeres Provinciale, Lisón, & Baños, 2015) interspersed with ten muscular strength exercises that recruit the main muscle groups, to be performed at low intensity with a high number of repetitions (Lisón et al., 2012). The intervention programmed 60 sessions distributed over three months, with five weekly sessions of 60 min each. All the subjects performed the same exercise program, but they accessed it in two different ways. The print-based group used a written guide, as described in the study carried out by Lisón et al. whereas the Move It group accessed the exercise program via an online web platform (Fig. 2; <https://www.youtube.com/watch?v=Fnlk4Ckhpic>). The Move It plus support group accessed the same online web platform as the Move It group, but additionally received weekly reminder and motivational e-mails according to each individual's specific compliance. In the two conditions based on the web platform the participants could choose the backdrop, avatar, and even the music for each exercise session.

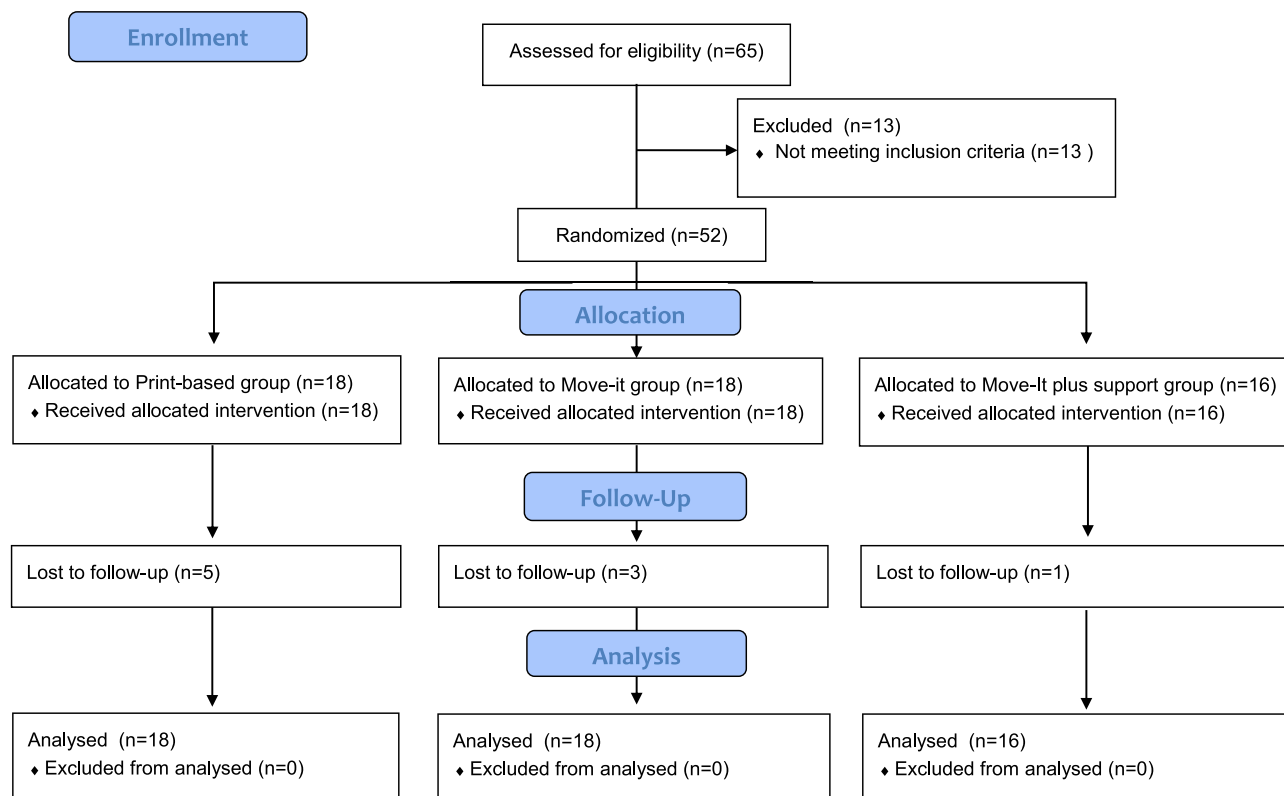


Fig. 1. A schematic diagram indicating the movement of the study-subjects through the study's allocation, intervention-delivery, and analysis stages.

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