Effectiveness of a school-based physical activity intervention on adiposity, fitness and blood pressure: **MOVI-KIDS** study

Vicente Martínez-Vizcaíno,^{1,2} Diana P Pozuelo-Carrascosa,¹ Jorge C García-Prieto,¹ Iván Cavero-Redondo,¹ Montserrat Solera-Martínez,¹ Miriam Garrido-Miguel,¹ Ana Díez-Fernández,^{1,3} Abel Ruiz-Hermosa,¹ Mairena Sánchez-López^{1,4}

ABSTRACT

 Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/ bjsports-2018-099655).

¹Social and Health Care Research Center, Universidad de Castilla-La Mancha, Cuenca, Spain ²Faculty of Health Sciences, Universidad Autónoma de Chile, Talca, Chile ³Faculty of Nursing, Universidad de Castilla-La Mancha, Cuenca, Spain ⁴Faculty of Education, Universidad de Castilla-La Mancha, Cuenca, Spain Correspondence to

Diana P Pozuelo-Carrascosa, Social and Health Care Research Center, Universidad de Castilla La Mancha, Cuenca 16071, Spain; dianap.pozuelo@uclm.es

Accepted 17 December 2018

Check for updates

© Author(s) (or their

employer(s)) 2019. No

commercial re-use. See rights

To cite: Martínez-Vizcaíno V,

Br J Sports Med Epub ahead

of print: [please include Day Month Year]. doi:10.1136/

and permissions. Published

Pozuelo-Carrascosa DP.

García-Prieto JC, et al.

bjsports-2018-099655

Objective To test a physical activity intervention (MOVI-KIDS) on obesity indicators, physical fitness and blood pressure (BP) in children.

Methods A crossover randomised cluster trial was conducted, which comprised 1434 children (4–7 years old) from 21 schools in the provinces of Cuenca and Ciudad Real in the Castilla-La Mancha region of Spain. The intervention consisted of three 60 min sessions/week on weekdays between October 2013 and May 2014. Changes in anthropometric variables, physical fitness and BP parameters were measured. The analyses used were mixed regression models to adjust for baseline covariates under cluster randomisation.

Results There was no significant improvement in overweight/obesity with the intervention compared with the control group in both sexes. Further, the intervention did not alter other adiposity indicators or BP parameters. Improvements in cardiorespiratory fitness were seen in girls (1.19; 95% CI 0.31 to 2.08; p=0.008), but not in boys. Finally, there was an improvement in velocity/agility in both girls (-2.51 s; 95% CI -3.98 to -1.05; p=0.001) and boys (-2.35 s; 95% CI -3.71 to -0.98; p=0.001), and in muscular strength in both girls (0.66; 95% CI 0.03 to 1.28; p=0.038) and boys (1.26; 95% CI 0.03 to 1.28; p<0.001).

Conclusion MOVI-KIDS was not successful in reducing the adiposity and maintained BP levels at previous healthy values in children. The intervention, however, showed significant improvements in cardiorespiratory fitness in girls, and muscular strength and velocity/agility in boys and girls.

Trial registration number NCT01971840; Postresults.

INTRODUCTION

The worldwide increasing prevalence of childhood obesity is a major public health problem.¹ In Castilla-La Mancha, approximately one in every four children in early years of education is overweight (including obesity).² This overweight prevalence is in accordance with data observed in Spain³ and other regions of the world.⁴ The causes of childhood obesity have not been adequately established, although a decline in daily physical activity is widely recognised as one of the main drivers of the situation.

Weight status and, in general, cardiovascular risk factors tend to persist from childhood through adolescence into adulthood.⁶⁷ The stability of these

What are the new findings?

- Schools are a promising place to implement children's physical activity programmes.
- Solid evidence about how a school-based physical activity intervention should be introduced is lacking.

How might it impact on clinical practice in the future?

 MOVI-KIDS, a play-based, non-competitive, physical activity intervention achieved improvements in cardiorespiratory fitness in girls, and muscular strength and motor fitness, which includes speed, agility and coordination of movements, in both girls and boys.

risk factors over a person's lifetime is known as tracking, which might be interpreted as the ability of children's values of cardiovascular risk factors to predict risk into adulthood. Moreover, physical activity patterns and aerobic capacity track moderately well from early childhood to middle childhood.

Cardiorespiratory fitness (CRF) and muscle fitness are associated with cardiovascular disease risk factors in children and adolescents.9 A recent meta-analysis reported that school-based physical activity interventions improve CRF in children,¹⁰ suggesting that it is possible to improve the cardiovascular health of children and adolescents by increasing physical activity. Furthermore, muscular fitness has been associated with better development of bone health and greater insulin sensitivity.

Accordingly, efforts to halt the current obesity crisis should start at young ages, and promotion of physical activity should be key to achieving longterm effectiveness.

Although the need for preventive interventions from early ages is not questioned, evidence about how they should be implemented is lacking.^{11 12} Most systematic reviews¹¹ agree that school-based programmes targeted at increasing physical activity and preventing obesity should include multicomponent strategies that at least involve children's school environment and families. The MOVI intervention (http://www.movidavida.org) is based on a

BMJ

by BMJ.



social ecological model and consists of (a) a school play-based physical activity programme, non-competitive, recreational and suitable for all children; (b) parents' and teachers' involvement in promoting active lifestyles in children and (c) interventions facilitating physical activity at school.

The aim of this paper is to examine the effectiveness of an 8-month school-based multicomponent intervention (MOVI-KIDS) on improving adiposity, physical fitness and blood pressure in 4–7-year-old children.

METHODS

Study design and participants

The MOVI-KIDS study was a crossover randomised cluster trial, which comprised 1604 school children from 21 schools (19 public, two private) located in the provinces of Cuenca and Ciudad Real in the Castilla-La Mancha region of Spain. The study followed recommendations of the CONSORT statement¹³ on cluster randomised trials. In addition, to report the results of the MOVI-KIDS study in this paper, the Consensus on Exercise Reporting Template (CERT)¹⁴ was used.

The study was approved by the clinical research ethics committee of Virgen de la Luz Hospital in Cuenca. Approval from directors and boards of governors was obtained to enlist schools, and all parents of children who were in the third preschool grade (4–5 years) and the first grade of primary school (aged 6–7 years) were invited to participate. Parents were asked to give their written informed consent to allow their child to participate in the study; this consent could be revoked by the parents or children at any time.¹⁵

The MOVI-KIDS intervention

The design of this intervention is based on the social ecological model.¹⁶ This is a theoretical model of behaviour change, in which behaviour is understood as the interaction between the physical and social environment. The intervention was applied in the intervention group (IG) and implemented in three different ways. First, an after-school, play-based and non-competitive physical activity programme, adapted to the children's levels of motor competences (4-6 years old). The programme comprised three 60 min sessions/week on weekdays, including basic sports games, playground games, dance and others activities focusing on developing motor skills. The intensity of sessions was moderate-to-vigorous according to a previous MOVI study in which the oxygen consumption (VO₂) of the games included was measured,¹⁷ and all physical activity sessions started with a warm-up and finished with a cool-down. Second, parents and teachers were involved in the programme promoting active lifestyles in children through the use of reinforcement tools as teaching material like a refrigerator magnet with recommendations for physical activity for children, answering a satisfaction with the programme questionnaire, and accessing the blog (http://movi3kids.blogspot.com.es/) where questions about how to promote active lifestyles were answered. Here parents could see their children's progress and learn how to reinforce healthy lifestyles. Third, environmental interventions were introduced to encourage children to be more active in the playground. These included balance circuits and panels encouraging physical activity during recess, and tyres of different colours and sizes with posters describing how to use them.

The sessions were designed by two physical activity science graduates, and the after-school physical activity sessions were delivered by sports instructors, who had received 2 days of training in order to standardise the way in which the sessions were carried out in all the schools in the study.

Both the IG and control group (CG) continued to receive their standard physical education lessons (1 h/week for preschool children and 2 h/week for first graders).

The first year of the MOVI-KIDS intervention was conducted between October 2013 and May 2014. In the second year (October 2014 to May 2015), the CG became the IG and viceversa. At the end of the first year, approximately 90 sessions of physical activity had been performed in each school.

Study variables and measurements

Measurement procedures have been described extensively elsewhere.¹⁸ In each school, trained researchers measured the variables under standardised conditions.

Anthropometry and body composition

The measurement of *weight* was carried out to the nearest 100 g with children in light clothes and barefoot (Seca 861 scales, Vogel and Halke, Hamburg, Germany). Height was measured using a wall-mounted stadiometer (Seca222, Vogel and Halke) with children barefoot, standing against the wall and their chin parallel to the floor. Both, weight and height were measured twice at a 5 min interval. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in metres. Children were classified as underweight, normal weight, overweight or obese, according to BMI cut-off values proposed by Cole and Lobstein.¹⁹ Waist circumference was determined by the average of three measurements taken with a flexible tape placed at the midpoint between the last rib and the iliac crest at the end of a normal expiration. In addition, the waist circumference/ height index was calculated. Fat mass percentage was obtained with an eight-electrode Tanita Segmental-418 bioimpedance analysis system (TANITA Corporation, Tokyo, Japan). This determination was made twice in the morning, with children shoeless and fasting, after urination and a 15 min rest.

Blood pressure

Diastolic blood pressure (DBP) and systolic blood pressure (SBP) were determined twice at a 5 min interval, after a 5 min resting period, using an automatic BP monitor OMROM-M5-I (Omron Healthcare Europe BV, Hoofddorp, Netherlands) and three different sized cuffs, according to the circumference of the right arm, which were placed 2 cm above the elbow flexure at heart level with the arm supported and children sitting. Two readings were obtained and the mean was used for the analysis.

The mean arterial pressure (MAP) was calculated with the following formula: $DBP + (0.333 \times [SBP-DBP])$.

Physical fitness

Cardiorespiratory fitness (CRF) was evaluated using the Course Navette test (20 m shuttle run test), a valid and reliable measure of maximal aerobic capacity in children,²⁰ and performed using the Léger protocol.²¹ Velocity/agility was measured using the 4×10 m shuttle run test. Two attempts were made with an interval of 5 min, and only the best attempt was considered. Lastly, *muscular strength* was measured using the standing long jump, which measured explosive lower body strength, and for this analysis, relative strength [standing long jump (cm)/weight (kg)] was used.



Figure 1 Flow chart of trial participants. CG, control group; IG, intervention group.

Socioeconomic level

Data for the familiar socioeconomic level were gathered using self-reported occupation and education questions answered by both the father and mother. An index of socioeconomic level was calculated using data on the parent's education and occupation.²²

Statistical analyses

The sample size was estimated to show differences between the CG and the IG of 2% (α error of 0.05 and statistical power of

0.80) in BMI at the end of the first year. The estimated sample size was 140 children per group; this figure was multiplied by an inflation factor for cluster-randomised trials,²³ which was estimated at 1.13 using measurements from previous studies on BMI.²⁴ In order to examine subgroup differences (ie, sex, age or socioeconomic level) under the same conditions and estimating a 15% dropout rate, the minimum sample size was estimated to be 1600 children (800 for each group). Data are described by mean (SD) or percentages. Intervention effects were estimated, by sex, using mixed linear and logistic regression models, with

Table 1 Characteristics of the study sample

	Intervention g	roup	Control group	
Characteristics	Boys (n=317)	Girls (n=302)	Boys (n=402)	Girls (n=413)
Age (years)	5.32±0.62	5.38±0.64	5.31±0.59	5.39±0.62
BMI (kg/m ²)	15.97±2.46	15.89±2.56	15.85±2.33	15.68±2.37
BMI (z-score)	0.23±1.44	0.16±1.38	0.17±1.39	0.06±1.35
Fat mass (%)	19.84±5.39	20.26±6.74	19.92±4.76	20.15±6.11
Waist circumference (cm)	56.09±6.17	55.65±6.56	55.88±5.72	54.89±5.91
Waist circumference(cm)/ height (cm) index	0.48±0.05	0.48±0.05	0.48±0.04	0.48±0.04
SBP (mm Hg)	102.32±10.24	100.93±9.67	103.01±10.59	101.91±9.9
DBP (mm Hg)	61.57±8.85	62.14±8.75	61.86±7.63	63.39±8.6
MAP (mm Hg)	75.15±8.59	75.06±8.31	75.58±7.9	76.23±8.44
20 m SRT (stages)	1.94±1.5	1.68±1.16	1.71±1.30	1.41±0.96
CRF (VO ₂ max estimate)	49.39±3.37	49.02±3.1	49.37±3.13	48.77±3.07
Velocity/agility (se)	16.78±2.29	17.37±1.90	16.96±2.17	17.55±2.29
Muscular strength (cm/kg)	4.51±1.29	4.52±1.24	4.54±1.27	4.43±1.15

Results are shown as mean+SD.

 P values for all comparisons between intervention and control schoolchildren, by sex, were >0.056.

BMI, body mass index; CRF, cardiorespiratory fitness.; DBP, diastolic blood pressure; MAP, mean arterial pressure; SBP, systolic blood pressure; SRT, shuttle run test.

adjustment for baseline outcomes, and with age, socioeconomic level, weight status and cluster factor school as covariates. The effect estimates for the quantitative outcome variables describe the difference between the mean change in the IG and the mean change in the CG. The effect estimates for binary outcome variables were obtained from logistic regression models and are presented as odds ratios with 95% CIs. To identify a possible clustering effect of data in schools, the intercluster correlation coefficient was calculated.²⁵

In addition, two exploratory analyses (not included in the registered study protocol) were conducted to assess the effectiveness of MOVI-KIDS intervention by weight status categories and by school grade categories (preschooler or school children).

All analyses were performed with Stata version 14.0 (Statacorp, College Station, Texas, USA).

RESULTS

Of the 2407 children invited to participate in the MOVI-KIDS study, 1604 (66.6%) agreed. Of these, 1434 children including 719 boys (50.1%) and 715 (49.9%) girls, had valid data for both measurements (baseline and at the end of the first year of the intervention) (figure 1). These data were used for the analysis. No differences in age, sex or BMI between children who had valid data and those who did not were found. Descriptive baseline characteristics (mean \pm SD) of the study sample are presented in table 1. No statistically significant differences were found between the intervention and control children for any baseline characteristic.

Changes in obesity markers, physical fitness and blood pressure parameters

Table 2 presents data on outcomes at baseline and follow-up, as well as the adjusted differences, between IG and CG, at the end of the first year of the MOVI-KIDS intervention.

No statistically significant changes in overweight/obesity prevalence were found in either girls or boys. Similarly, no significant changes were seen in the underweight prevalence in either sex.

The same was found for the changes in fat mass percentage, waist circumference and BMI in the IG, in both girls and boys.

The intercluster correlations were <0.11, indicating a low level of clustering within the IG and CG.

For the physical fitness parameters, improvements were seen in both boys and girls. In boys, compared with controls, the time of the velocity/agility test decreased (-2.51s; 95% CI -3.98 to -1.05; p=0.001) while muscular strength increased (0.66; 95% CI 0.03 to 1.28; p=0.038). These improvements in velocity/agility (-2.35s; 95% CI -3.71 to -0.98; p=0.001) and muscular strength (1.26; 95% CI 0.03 to 1.28; p<0.001) were similar in girls. In addition, CRF (assessed by 20 m shuttle run test [SRT]) was significantly improved in girls (1.19; 95% CI 0.31 to 2.08; p=0.008) but not in boys (0.96; 95% IC; -0.13 to 2.05; p=0.083).

The intervention did not alter BP parameters (SBP, DBP and MAP) in either boys or girls.

Subgroup analyses by weight status categories at baseline (online supplementary table 1) showed similar results in adiposity, physical fitness and blood pressure, with better results achieved in children of normal weight.

In addition, a subgroup analysis by school grade categories (preschool or school children) showed no beneficial changes in BP, adiposity or physical fitness parameters (online supplementary table 2).

Process evaluation

Compliance and satisfaction with the programme

Of 1604 parents who gave written informed consent, 1490 (92.9%) completed the questionnaire evaluating their children's sociodemographic variables. Of 1604 children who agreed to participate in the programme, a total of 1434 (89.4%) attended both measurements and more than 75% of the physical activity sessions (children assistance was recorded daily).

To measure satisfaction with the programme activities, 369 out of 504 participating children (73.2%) and 366 (72.6%) of their parents completed a questionnaire (online supplementary files 3 and 4). In this questionnaire, 90.1% of the children stated that they liked attending MOVI-KIDS, and felt happy playing with their peers who attended the programme. In addition, 93.2% of the parents stated that their children had fun with the activities developed and 87.1% stated that the programme had improved the relationships of their children with classmates.

Adverse outcomes

No injuries or other adverse events occurred during the physical activity sessions, or during the health and physical examinations.

DISCUSSION

There is no consistent evidence that physical activity interventions reduce adiposity or improve physical fitness at early ages. Our data show that the MOVI-KIDS intervention did not significantly reduce adiposity indexes. However, it significantly improved motor and muscular fitness in children aged 4–7 years, and CRF (20 m SRT) in girls but not in boys.

Several systematic reviews have examined the effectiveness of interventions in preventing overweight and obesity in preschool children. Waters *et al*²⁶ reported a slightly positive effect in a meta-analysis including eight studies, in which interventions were mostly based on both diet and physical activity. Wang *et al*¹² reported that school-based physical activity programmes which include home and community components are beneficial for prevention of childhood obesity. However, evidence provided by the latest community-based studies is controversial. The Ballabeina study,²⁷ a multidimensional school-based intervention

 Table 2
 Changes in adiposity, fitness and blood pressure from baseline to 8 months' follow-up among intervention versus control schoolchildren, by sex

	Baseline		After intervention		Effect estimate		
Changes	Intervention Group	Control Group	Intervention Group	Control Group	Estimate* (95% CI)	P value	ICC
Boys	n=317	n=402	n=317	n=402			
Adiposity							
Fat mass percentage	19.84±5.68	19.92±5.93	19.67±5.21	19.30±5.21	-0.53 (-2.19 to 1.13)	0.530	0.09
Waist circumference (cm)	56.09±5.92	55.88±5.92	57.08±6.59	56.93±6.75	1.50 (–0.23 to 3.22)	0.089	0.07
Ratio waist circumference (cm)/ height (cm)	0.48±0.04	0.48±0.04	0.48±0.05	0.48±0.05	-0.01 (-0.02 to 0.01)	0.422	0.07
BMI (kg/m ²)	15.96±2.39	15.85±2.39	16.10±2.45	16.02±2.45	-0.31 (-0.87 to 0.24)	0.268	0.11
BMI (z-score)	0.23±1.41	0.17±1.41	0.28±1.43	0.21±1.43	0.06 (-0.30 to 0.42)	0.753	0.13
% Overweight/obesity	18.93	17.16	19.62	19.15	1.18 (0.98 to 1.45)	0.085	0.00
% Underweight	18.61	20.65	15.46	16.91	1.12 (0.89 to 1.40)	0.342	0.00
Physical fitness							
CRF (VO ₂ ml/min/kg)	49.85±5.23	49.58±5.66	50.81±5.51	51.19±5.80	0.54 (-4.77 to 5.85)	0.842	0.01
20 m SRT (stages)	1.94±2.08	1.71±2.30	3.01±2.16	3.00±2.34	0.96 (-0.13 to 2.05)	0.083	0.04
Velocity/agility† (s)	16.78±3.79	16.96±4.30	15.69±4.10	16.18±4.76	-2.51 (-3.98 to -1.05)	0.001	0.12
Muscular strength‡ (cm/kg)	4.68±1.63	4.62±1.77	4.61±1.52	4.59±1.64	0.66 (0.03 to 1.28)	0.038	0.01
Blood pressure parameters							
SBP (mm Hg)	102.32±27.78	103.01±32.60	104.53±19.86	105.18±22.91	-5.42 (-13.41 to 2.56)	0.183	0.04
DBP (mm Hg)	61.57±22.68	61.86±26.66	61.32±19.76	61.98±23.16	-5.51 (-12.53 to 1.52)	0.124	0.02
MAP (mm Hg)	75.15±24.10	75.58±28.40	75.73±19.24	76.38±22.53	-5.51 (-12.02 to 0.99)	0.097	0.03
Girls	n=302	n=413	n=302	n=413			
Adiposity							
Fat mass percentage	20.26±7.60	20.15±8.12	20.52±7.02	20.15±7.29	-0.37 (-2.18 to 1.43)	0.685	0.10
Waist circumference (cm)	55.65±6.53	54.89±6.68	56.03±6.51	56.06±6.63	1.50 (-0.52 to 3.52)	0.146	0.05
Ratio waist circumference (cm)/ height (cm)	0.48±0.05	0.48±0.05	0.47±0.05	0.47±0.06	-0.00 (-0.02 to 0.01)	0.229	0.12
BMI (kg/m ²)	15.90±2.48	15.68±2.49	16.06±2.51	15.87±2.51	-0.16 (-0.77 to 0.45)	0.603	0.03
BMI (z-score)	0.16±1.45	0.06±1.49	0.19±1.35	0.13±1.37	0.23 (-0.09 to 0.55)	0.165	0.07
% Overweight/obesity	23.18	20.82	22.18	20.10	1.00 (0.83 to 1.21)	0.971	0.02
% Underweight	19.87	23.49	16.22	19.85	1.18 (0.96 to 1.46)	0.123	0.02
Physical fitness							
CRF (VO ₂ ml/min/kg)	49.43±4.97	48.07±5.91	49.47±5.69	49.21±6.58	2.78 (-1.68 to 7.24)	0.222	0.11
20 m SRT (stages)	1.68±2.17	1.41±2.53	2.45±2.37	2.21±2.75	1.19 (0.31 to 2.08)	0.008	0.08
Velocity/agility† (s)	17.36±4.16	17.55±4.82	16.24±4.90	16.78±5.80	-2.35 (-3.71 to -0.98)	0.001	0.17
Muscular strength‡ (cm/kg)	4.37±1.77	4.33±1.98	4.40±1.68	4.33±1.88	1.26 (0.03 to 1.28)	<0.001	0.02
Blood pressure parameters							
SBP (mm Hg)	100.93±24.81	101.91±29.33	103.00±20.42	102.30±23.89	-1.09 (-9.05 to 6.87)	0.788	0.05
DBP (mm Hg)	62.14±25.00	63.39±29.74	62.50±17.57	62.75±20.69	1.29 (-5.94 to 8.51)	0.727	0.02
MAP (mm Hg)	75.07±24.66	76.23±29.36	76.00±18.16	75.93±21.43	0.45 (-6.19 to 7.10)	0.894	0.05

Data are reported as mean ±SD.

*Effect estimate describes difference between mean change in intervention group and mean change in control group, adjusted by age, gender, socioeconomic level, weight status and cluster factor school. For binary outcome variable (% overweight/obesity and % underweight), effect estimate obtained from logistic regression models with same adjustments and expressed as OR.

†Lower values indicate better results.

#Muscular strength reported as long jump test (cm)/weight (kg).

BMI, body mass index; CRF, cardiorespiratory fitness; DBP, diastolic blood pressure; ICC, intercluster correlation coefficient; MAP, mean arterial pressure; SBP, systolic blood pressure; SRT, shuttle run test.

in migrant preschool children from Switzerland, decreased mean body fat percentage and improved aerobic fitness; however, the IDEFICS study,²⁸ a 2-year multicomponent community-oriented programme for preventing childhood obesity in preschool children, had no effect on indicators of body fatness. However, these studies are not entirely comparable to ours, since the Ballabeina study specifically targeted a migrant population, and the IDEFICS study included a sample of children with a wide age range (2–10 years). Studies testing the effectiveness of physical activity on reducing BP are scarce, and their results are controversial. Although an improvement in BP levels associated with objectively measured regular physical activity has been reported,²⁹ our MOVI-KIDS intervention failed to improve BP. In addition, previous MOVI interventions,^{24 30} and others,^{31 32} have reported no effect on BP. Several reasons might explain these negative findings. The first is related to difficulties in measuring BP in field trials including healthy children. Moreover, similar to a study in which adiposity

Original article

acted as a mediator in the association between cardiorespiratory fitness and BP in preschool children,³³ our intervention, although improving physical fitness, did not reduce BP, possibly because no changes in adiposity occurred. A direct association between BP and adiposity indexes has been repeatedly reported.^{34 35}

A Cochrane systematic review by Dobbins *et al*³⁶ concluded that a longer study period is needed in school-based physical activity interventions to achieve any effect on CRF. However, our intervention failed to improve CRF in boys, even though it lasted for one academic year. These gender differences might be due to the lower values obtained in the 20 m SRT baseline measurements in girls, who might therefore show greater improvements. Furthermore, the narrow range of values that the preschool children showed in the 20 m SRT might suggest a lack of sensitivity to CRF changes. In view of the inability to find differences between IG and CG, it seems reasonable to assume that if the intervention improves the speed/agility test, in parallel, CRF also improves in boys.

Strong evidence supports an inverse association between muscular fitness and cardiometabolic risk factors.^{37 38} Our intervention, as did a previous MOVI intervention,³⁰ significantly improved muscular strength as measured by standing long jump tests. This finding is important because high muscular strength has been associated with higher insulin sensitivity and even cognition in children and adolescents.^{39 40}

Several interpretations may explain why our intervention did not result in the hypothesised outcomes. First, it should be highlighted that fitness changes may be the mediator between physical activity and body composition. Indeed, it seems reasonable to expect that positive changes in physical fitness will trigger a chain of future physiological and behavioural improvements. An additional consideration is related to the social ecological framework underlying our intervention, in which participation from different social levels generates dynamics that trigger changes in processes whose efficacy cannot be assessed in the short term. Finally, because our intervention did not target overweight children, but a school-based population in which underweight and overweight/obesity rates were similar, a reduced effectiveness on modifications of body composition is expected. This may explain the differences observed between previous MOVI interventions^{24 30} and our study. However, we should not underestimate the importance of improvements in physical fitness in children, since it has been suggested that small changes in motor fitness⁴¹ and muscle strength⁴² are associated with substantial improvements in cardiovascular risk factors. Therefore, it seems reasonable to continue recommending the introduction of physical activity interventions in the after-school programme. In populations such as ours, in which the obesity crisis is growing, these interventions should be targeted at improving cardiovascular health through improvements in physical fitness, since it has been consistently shown⁴³ that small improvements in children's fitness are accompanied by significant improvements in cardiovascular health.

This study has some strengths that should be highlighted. First, this was a recreational, non-competitive intervention suitable for all children, except for those with serious disabilities. Second, the intervention was carried out under standardised conditions, since structured training and a written plan of activities was developed for each session. Third, the intervention took place in schools, so it did not exclude any children by sex, ethnic group or physical condition. There was also a high participation rate. Fourth, the sustainability, generalisability and reproducibility of the programme were high, because MOVI-KIDS was a simple, standardised and inexpensive intervention, and it did not modify the school curriculum. Fifth, our study included only objective endpoints with highly rigorous measures, so the intervention was tested more critically than in studies which used self-reported endpoints.⁴⁴

Limitations

There are seven key limitations to our study:

- 1. Although the intervention lasted for 8 months, outcomes were assessed immediately after the intervention ended, thus a long-term endpoint assessment is needed.
- 2. The results of this study on blood pressure and body composition were not positive, perhaps because the dose and/or the intensity of physical activity were insufficient. Although the oxygen consumption in the games included in the intervention has been measured in a previous MOVI intervention in prepubertal children,¹⁷ the characteristics of intensity of games could be age-dependent.
- 3. Anthropometrics, BP and physical fitness measurements were not blinded to the intervention allocation; hence, we cannot exclude a possible bias in the assessment of effectiveness. However, it should be noted that our study included only objective endpoints with highly reproducible measures, so the intervention was tested more rigorously, and weight, fat mass percentage, and BP measurements were made with automatic digital devices, thereby reducing observer errors.
- 4. It has been suggested that, in children, compulsory interventions are more effective,⁴⁵ but the high participation rate in our study ensured a similar compliance to a mandatory intervention.
- 5. As suggested earlier, because the intervention was designed under a social ecological model scheme, some school or community changes that might have occurred because of our intervention could not reasonably be achieved within this short time frame, although such changes would influence children's overall health status and, obviously, adiposity status.
- 6. An important limitation of this study is that physical activity patterns of the participants were not controlled during the intervention. Presumably, the programme was more effective in less active children. In addition, the daily amount and intensity of physical activity was objectively measured by accelerometry only in a subsample. The lack of information about physical activity patterns, intensity and daily amount of activity is another important limitation of this study.
- 7. Another potential limitation is that the prevalence of children who were overweight/obese in our study was lower than in other European populations, thus the expected effect should also be lower.

CONCLUSIONS

The MOVI-KIDS, a play-based non-competitive physical activity intervention, failed to significantly reduce both adiposity indexes and BP levels in children aged 4–7 years. However, this intervention significantly improved CRF in girls, and muscular strength and motor fitness, which includes speed, agility and coordination of movements, in both boys and girls. These physical fitness improvements help to prevent cardiovascular disease, since they are associated with improvements in cardiometabolic risk factors. Additionally, as fitness levels tend to persist from childhood through adolescence to adulthood, results from MOVI-KIDS suggest that this type of intervention might yield both short- and long-term cardiometabolic benefits.

18 a randomised cross-over cluster trial to assess the effectiveness of MOVI-KIDS on preventing obesity in pre-schoolers. BMC Public Health 2015;15:176.

Acknowledgements The authors thank the schools, families and children for their enthusiastic participation in the study. We thank all membership of the Cuenca Study who helped to make this study possible. Contributors DPP-C, VM-V and IC-R conceptualised and designed the study with

the support of JCG-P and MS-L. VM-V drafted the initial manuscript and together with DPP-C, IC-R and MS-L approved the final manuscript as submitted. DPP-C, IC-R, MS-L. MG-M and VM-V designed the data collection instruments, and coordinated and supervised data collection. DPP-C, IC-R, VM-V, MS-M, MG-M, AD-F, AR-H and MS-L were involved in the analysis and interpretation of data and reviewed the manuscript, approving the final manuscript as submitted.

Funding This study was funded by the Ministry of Economy and Competitiveness-Carlos III Health Institute and FEDER funds (FIS PI12/00761). Additional funding was obtained from the Research Network on Preventative Activities and Health Promotion (RD12/0005/0009). DPP-C (FPU14/01370) and MG-M (FPU15/03847) are recipients of a predoctoral fellowship by the Spanish Ministry of Education, Culture and Sport. IC-R is supported by a postdoctoral grant (FPU13/01582) from Universidad de Castilla-La Mancha, Spain.

Competing interests None declared.

Patient consent Not required.

Ethics approval The study protocol was approved by the clinical research ethics committee of Hospital Virgen de la Luz of Cuenca. All children and their parents consented to participate in the study after receiving oral and written information about the study objectives and procedures.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Data will not be shared, because in this database much of the data do not refer to this article. Data will be available to those authors who need it, by contacting us.

REFERENCES

- Kumar S, Kelly AS. Review of childhood obesity: from epidemiology, etiology, and comorbidities to clinical assessment and treatment. Mayo Clin Proc 2017;92:251-65.
- Martinez Alfonso J, Pozuelo-Carrascosa DP, Solera-Martinez M, et al. Estudio de 2 seguimiento de la prevalencia de delgadez y sobrepeso de una cohorte de escolares de 4 a 6 años de Castilla-La Mancha. Nutr Hosp 2016;33:1299-304.
- 3 Pérez-Farinós N, López-Sobaler AM, Dal Re MÁ, et al. The ALADINO study: a national study of prevalence of overweight and obesity in Spanish children in 2011. Biomed Res Int 2013;2013:163687.
- de Onis M, Blössner M, Borghi E. Global prevalence and trends of overweight and 4 obesity among preschool children. Am J Clin Nutr 2010;92:1257-64.
- 5 Karnik S, Kanekar A. Childhood obesity: a global public health crisis. Int J Prev Med 2012;3:1-7.
- Singh AS, Mulder C, Twisk JW, et al. Tracking of childhood overweight into adulthood: 6 a systematic review of the literature. Obes Rev 2008;9:474-88.
- 7 Juhola J, Magnussen CG, Viikari JS, et al. Tracking of serum lipid levels, blood pressure, and body mass index from childhood to adulthood: the Cardiovascular Risk in Young Finns Study. J Pediatr 2011;159:584-90.
- 8 Jones RA, Hinkley T, Okely AD, et al. Tracking physical activity and sedentary behavior in childhood: a systematic review. Am J Prev Med 2013;44:651-8.
- 9 Ortega FB, Ruiz JR, Castillo MJ, et al. Physical fitness in childhood and adolescence: a powerful marker of health. Int J Obes 2008;32:1-11.
- 10 Pozuelo-Carrascosa DP, García-Hermoso A, Álvarez-Bueno C, et al. Effectiveness of school-based physical activity programmes on cardiorespiratory fitness in children: a meta-analysis of randomised controlled trials. Br J Sports Med 2018;52:1234-40.
- Wang Y, Cai L, Wu Y, et al. What childhood obesity prevention programmes work? A 11 systematic review and meta-analysis. Obes Rev 2015;16:547-65.
- 12 Wang Y, Wu Y, Wilson RF, et al. AHRQ Comparative effectiveness reviews. childhood obesity prevention programs: comparative effectiveness review and meta-analysis. Rockville (MD: Agency for Healthcare Research and Quality (US), 2013.
- 13 Schulz KF, Altman DG, Moher D. CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010;63:834-40.
- 14 Slade SC, Dionne CE, Underwood M, et al. Consensus on Exercise Reporting Template (CERT): explanation and elaboration statement. Br J Sports Med 2016;50:1428-37.
- World Medical Association Declaration of Helsinki. ethical principles for medical 15 research involving human subjects. JAMA 2013;310:2191-4.
- 16 Bronfenbrenner U. Ecological systems theory. Jessica Kingsley Publishers, 1992.
- García-Prieto JC, Martinez-Vizcaino V, García-Hermoso A, et al. Energy expenditure in 17 playground games in primary school children measured by accelerometer and heart rate monitors. Int J Sport Nutr Exerc Metab 2017;27:467-74.
 - Martínez-Vizcaino V, Mota J, Solera-Martínez M, et al. Rationale and methods of

- Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for 19 thinness, overweight and obesity. Pediatr Obes 2012;7:284-94.
- 20 Ruiz JR, Castro-Piñero J, España-Romero V, et al. Field-based fitness assessment in young people: the ALPHA health-related fitness test battery for children and adolescents. Br J Sports Med 2011;45:518-24.
- 21 Léger LA, Mercier D, Gadoury C, et al. The multistage 20 metre shuttle run test for aerobic fitness. J Sports Sci 1988;6:93-101.
- Chilet-Rosell E, Álvarez-Dardet C, Domingo-Salvany A. Use of Spanish proposals for 22 measuring social class in health sciences. Gac Sanit 2012;26:566-9
- Donner A, Klar N. Design and analysis of cluster randomization trials in health research. Arnold: London, England, 2000.
- 24 Martínez Vizcaíno V, Salcedo Aguilar F, Franquelo Gutiérrez R, et al. Assessment of an after-school physical activity program to prevent obesity among 9- to 10-year-old children: a cluster randomized trial. Int J Obes 2008;32:12-22.
- Eldridge SM, Ukoumunne OC, Carlin JB. The intra-cluster correlation coefficient in 25 cluster randomized trials: a review of definitions. Int Stat Rev 2009;77:378-94
- Waters E, de Silva-Sanigorski A, Hall BJ, et al. Interventions for preventing obesity in children. Cochrane Database Syst Rev 2011:CD001871.
- 27 Puder JJ, Margues-Vidal P, Schindler C, et al. Effect of multidimensional lifestyle intervention on fitness and adiposity in predominantly migrant preschool children (Ballabeina): cluster randomised controlled trial. BMJ 2011;343:d6195.
- De Henauw S, Huybrechts I, De Bourdeaudhuij I, et al. Effects of a community-28 oriented obesity prevention programme on indicators of body fatness in preschool and primary school children. Main results from the IDEFICS study. Obes Rev 2015;16(Suppl 2):16-29.
- 29 de Moraes AC. Carvalho HB. Siani A. et al. Incidence of high blood pressure in children - effects of physical activity and sedentary behaviors: the IDEFICS study: high blood pressure, lifestyle and children. Int J Cardiol 2015;180:165-70.
- 30 Martínez-Vizcaíno V, Sánchez-López M, Notario-Pacheco B, et al. Gender differences on effectiveness of a school-based physical activity intervention for reducing cardiometabolic risk: a cluster randomized trial. Int J Behav Nutr Phys Act 2014;11:11.
- Strong WB, Malina RM, Blimkie CJ, et al. Evidence based physical activity for school-31 age youth. J Pediatr 2005;146:732-7.
- 32 Kelley GA, Kelley KS, Tran ZV. The effects of exercise on resting blood pressure in children and adolescents: a meta-analysis of randomized controlled trials. Prev Cardiol 2003:6:8-16.
- 33 Pozuelo-Carrascosa DP, Sánchez-López M, Cavero-Redondo I, et al. Obesity as a mediator between cardiorespiratory fitness and blood pressure in preschoolers. J Pediatr 2017;182:114-9.
- 34 Martín-Espinosa N, Díez-Fernández A, Sánchez-López M, et al. Prevalence of high blood pressure and association with obesity in Spanish schoolchildren aged 4-6 years old. PLoS One 2017;12:e0170926.
- Gopinath B, Baur LA, Garnett S, et al. Body mass index and waist circumference 35 are associated with blood pressure in preschool-aged children. Ann Epidemiol 2011:21:351-7.
- 36 Dobbins M, Husson H, DeCorby K, et al. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. Cochrane Database Syst Rev 2013:CD007651.
- 37 Cohen DD, Gómez-Arbeláez D, Camacho PA, et al. Low muscle strength is associated with metabolic risk factors in Colombian children: the ACFIES study. PLoS One 2014:9:e93150
- 38 Díez-Fernández A, Sánchez-López M, Gulías-González R, et al. BMI as a mediator of the relationship between muscular fitness and cardiometabolic risk in children: a mediation analysis. PLoS One 2015;10:e0116506.
- 39 Benson AC, Torode ME, Singh MA. Muscular strength and cardiorespiratory fitness is associated with higher insulin sensitivity in children and adolescents. Int J Pediatr Obes 2006;1:222-31.
- 40 Smith JJ, Eather N, Morgan PJ, et al. The health benefits of muscular fitness for children and adolescents: a systematic review and meta-analysis. Sports Med 2014:44:1209-23
- 41 Twisk JW, Kemper HC, van Mechelen W. Tracking of activity and fitness and the relationship with cardiovascular disease risk factors. Med Sci Sports Exerc 2000;32:1455-61.
- 42 Grøntved A. Ried-Larsen M. Møller NC. et al. Muscle strength in vouth and cardiovascular risk in young adulthood (the European Youth Heart Study). Br J Sports Med 2015;49:90-4.
- 43 Kriemler S, Zahner L, Schindler C, et al. Effect of school based physical activity programme (KISS) on fitness and adiposity in primary schoolchildren: cluster randomised controlled trial. BMJ 2010:340:c785.
- Byers T. On the hazards of seeing the world through intervention-colored glasses. Am 44 J Clin Nutr 2003;78:904–5.
- 45 Connelly JB, Duaso MJ, Butler G. A systematic review of controlled trials of interventions to prevent childhood obesity and overweight: a realistic synthesis of the evidence. Public Health 2007;121:510-7.

7