#### ORIGINAL ARTICLE

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## Effectiveness of MOVI-KIDS programme on health-related quality of life in children: Cluster-randomized controlled trial

Andres Redondo-Tebar<sup>1,2</sup> 
| Abel Ruiz-Hermosa<sup>2,3</sup> | Vicente Martinez-Vizcaino<sup>2,4</sup> | Alberto Bermejo-Cantarero<sup>2,5</sup> | Iván Cavero-Redondo<sup>2,4,6</sup> | Noelia María Martín-Espinosa<sup>7</sup> | Mairena Sanchez-Lopez<sup>2,8</sup> |

<sup>1</sup>Universidad de Granada, PROFITH "PROmoting FITness and Health through Physical Activity" Research Group, Sport and Health University Research Institute (iMUDS), Granada, Spain

<sup>2</sup>Universidad de Castilla-La Mancha, Social and Health Research Center, Cuenca, Spain

<sup>3</sup>Universidad de Extremadura, ACAFYDE research group, Cáceres, Spain

<sup>4</sup>Facultad de Ciencias de la Salud, Universidad Autónoma de Chile, Talca, Chile

<sup>5</sup>Facultad de Enfermería, Universidad de Castilla-La Mancha, Ciudad Real, Spain

<sup>6</sup>Facultad de Enfermería, Universidad de Castilla-La Mancha, Cuenca, Spain

<sup>7</sup>Facultad de Enfermería, Universidad de Castilla-La Mancha, Toledo, Spain

<sup>8</sup>Facultad de Educación, Universidad de Castilla-La Mancha, Ciudad Real, Spain

#### Correspondence

Vicente Martinez-Vizcaino, Centro de Estudios Sociosanitarios, Universidad de Castilla-La Mancha, C/Santa Teresa Jornet s/n, 16071 Cuenca, Spain. Email: vicente.martinez@uclm.es

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**Objective:** To test the effectiveness of an 8-month school-based multicomponent intervention (MOVI-KIDS) in improving health-related quality of life (HRQoL) in schoolchildren.

**Study Design:** A randomized cluster trial was conducted including 1168 children aged 4–6 years who attended 21 schools in two Spanish provinces (Cuenca and Ciudad Real). MOVI-KIDS study is a multicomponent physical activity intervention, which consisted of (i)  $3 \times 60$ -min sessions/week, (ii) educational materials for parents and teachers, and (iii) school playground modifications. The parent's proxy report of the KINDL-R Spanish version (6 subdimensions and a total score), and the KINDL-R self-reported by children (total score) was used to measure HRQoL. Mixed linear regression models were conducted to test differences in each HRQoL dimension between intervention and control groups, controlling for baseline values, cardiorespiratory fitness, and socioeconomic status, by gender.

**Results:** The boys in the intervention group presented better scores on total HRQoL than the control group in both the parent ( $\beta = 1.46$ ; 95% CI: 0.23–2.70) and self-reported ( $\beta = 2.13$ ; 95% CI: 0.53–3.74) versions, as well as on the emotional well-being dimension ( $\beta = 2.43$ ; 95% CI: 0.48–4.36). There was no significant effect of the intervention on physical well-being, self-esteem, family, and friends. In girls, no statistically significant differences were found between those who participated in MOVI-KIDS and those who did not.

**Conclusion:** Our data support gender differences in the effect of MOVI-KIDS, such that while in boys the intervention was successful in increasing total scores of HRQoL, as well as emotional well-being scores, the intervention was not effective in improving girls' HRQoL.

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#### K E Y W O R D S

based physical activity intervention, child, health-related quality of life, programme effectiveness, proxy report, school-based intervention, self-report

## **1** | INTRODUCTION

Health-related quality of life (HRQoL) has been described as an individual's subjective perception of the impact of health status on physical, psychological, and social functioning, also considering the ability to perform appropriate activities according to the age of the individual. It is considered an important marker of health status in children.<sup>1</sup> Previous studies have indicated that regular physical activity (PA) has important physical, psychosocial, and cognitive health benefits for children.<sup>2–4</sup> It is therefore to be expected that PA is a factor influencing the HRQoL of schoolchildren.

Although the positive relationship between PA and biopsychosocial health has been evidenced in children,<sup>2,5,6</sup> school-based PA interventions including HRQoL as an endpoint are scarce and their results inconclusive.<sup>7,8</sup> Thus, while some studies have reported that school-based PA programmes are effective in improving several domains of HRQoL, such as psychological well-being,<sup>9–12</sup> autonomy,<sup>9,13</sup> and parent relation<sup>9,13</sup> or school,<sup>12</sup> other studies have found no effect.<sup>14–19</sup> As far as we know, only two studies have been conducted on children of preschool age,<sup>17,19</sup> a critical period to initiate health promotion strategies.<sup>20</sup>

Furthermore, studies of PA programmes' effectiveness on healthy schoolchildren's HRQoL have shown no gender-specific results<sup>9–19</sup> and have not included covariates that may affect this relationship (e.g., cardiorespiratory fitness<sup>21</sup> or socioeconomic status<sup>22</sup>). Thus, given that both PA levels<sup>23,24</sup> and HRQoL scores<sup>25</sup> are different in boys and girls, there are reasons to believe that the effect of PA programmes on HRQoL could be different for each gender and may also be affected by confounders. In addition, recognizing gender inequalities and taking into account the gender perspective are useful to explore differences that exist between genders in society, providing key information necessary to guide policy and decision-makers and to advance the achievement of gender equality, especially when designing health promotion strategies.<sup>26,27</sup>

Thus, the aim of this study was to examine the effectiveness of MOVI-KIDS, an eight-month school-based multicomponent intervention, on improving HRQoL in 4- to 7-year-old schoolchildren.

## 2 | METHODS

## 2.1 | Study design and participants

The MOVI-KIDS study (ClinicalTrials.gov NCT01971827) was a cluster-randomized trial, which followed the recommendations of the CONSORT statement in this field.<sup>28</sup> The sample comprised 1604 children attending 21 schools (19 public and 2 state co-funded) in the Spanish provinces of Cuenca and Ciudad Real.<sup>29</sup> Each school was randomly assigned to either the intervention group (IG; 11 schools) or the control group (CG; 10 schools), using the StatsDirect statistical package. The CONSORT 2010 extension to cluster-randomized trials and the Consensus on Exercise Reporting Template (CERT)<sup>30</sup> were used to report the results of this study.

The study protocol was approved by the Clinical Research Ethics Committees of the "Virgen de la Luz" Hospital in Cuenca and the General University Hospital of Ciudad Real, both in Spain. Approval from the directors and boards of governors was obtained to recruit from the schools, and all parents whose children were in the third grade of preschool (aged 4–5) and the first grade of primary school (aged 6–7) were invited to participate. To avoid contamination, when more than one school met the inclusion criteria and were in the same locality, only one was invited to participate in the study. Written informed consent for participation was required from the children's parents, which could be revoked at any point by either the parents or the child.

# 2.2 School-based physical activity intervention

The MOVI-KIDS intervention was conducted between October 2013 to May 2014. The MOVI-KIDS programme is a multidimensional intervention based on the social-ecological model, which is a theoretical model of behavior change, i.e., the interaction between the physical and the social environment.<sup>31</sup> The intervention was carried out in the IG and was applied in three different ways. The first one was the non-competitive PA programme based on after-school games, which were adapted to the motor

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competence levels of the children (aged 4-7). The programme included three 60-min sessions per week focusing on developing motor skills (e.g., basic sport games, playground games, or dance), which began with a warmup and ended with a cool-down and had a moderate-tovigorous intensity, according to a previous MOVI study.<sup>32</sup> A total of 76 PA sessions were conducted in each school. All activities were implemented by monitors with technical qualifications in physical activity and sports, specifically engaged and adequately trained for the programme. A detailed description of the games can be found in the programme manual.<sup>33</sup> The second one was that the programme involved the children's parents and their teachers-i.e., using reinforcement tools, such as teaching material with children's PA recommendations, asking questions, or checking their children's progress through the programme blog in order to promote and reinforce healthy PA lifestyles. Finally, the third one was to introduce environmental interventions that could encourage children to be more active in the playground (fixed and mobile equipment, such as balance and jump circuits and colored tires).

## 2.3 | Process evaluation

Monitors recorded attendance and adverse effects at each session. Children who attended at least 80% of the sessions received gifts with the programme logo to increase adherence to MOVI-KIDS. Telephone and email contact was maintained with the monitors to obtain monthly updates on children's attendance to quantify possible drop-outs and to find out the reasons for them, and programme progress. Also, they were invited to two meetings at the beginning and 3 months later. In addition, a quarterly visit was made to the centers to evaluate how the programme was going and to carry out satisfaction surveys. Finally, satisfaction with the programme was assessed 4 months after the start of the intervention by means of a questionnaire for parents and schoolchildren.

Physical education lessons (one 45-min session a week for the preschool children, and two 45-min sessions a week for the first graders) were maintained for both the IG and CG.

## 2.4 | Study variables

Baseline (September 2014) and follow-up (June 2015) measurements were collected at the schools by trained researchers. The measurement procedures are extensively described elsewhere.<sup>29</sup> These were:

Health-related quality of life (HRQoL) was assessed using the Spanish language versions of the KINDL-R self-report and parent's proxy-report questionnaire (referring to the previous week),<sup>34</sup> which has good validity, reliability, and an easy-quick way to fill it by children under 7 years old.<sup>35,36</sup> Cronbach's alpha was calculated for the dimensions of the KINDL-R at baseline (0.80) and the follow-up (0.83), indicating high internal consistency.<sup>37</sup> KINDL-R children self-report contains 12 items in which the average score was transformed into a scale from 0 to 100 obtaining only a total score HRQoL.<sup>38</sup> KIND-R parent's proxy report is distributed in six dimensions (physical well-being, emotional wellbeing, self-esteem, family, friends, and school) and a total score HRQoL. Each dimension average scores were transformed into a scale from 0 to 100 points, making it possible to obtain also a total score HRQoL.<sup>38</sup> Higher scores indicate better HROoL.<sup>38</sup>

*Socioeconomic status* was assessed using self-reported occupation and education questions completed by parents. An index of socioeconomic status was calculated based on parents' education and occupation levels, according to the Spanish Society of Epidemiology scale procedures, which classifies family socioeconomic status into five categories; these five levels were collapsed for our analyses into lower-upper lower, lower middle and upper middle-upper.<sup>39</sup>

*Weight* and *height* were measured twice, using SECA-821 and SECA-222, respectively (Vogel and Halke), and following standardized procedures. *Body mass index (BMI)* was calculated by dividing the means of weight (Kg) by height (m<sup>2</sup>). *Body fat mass percentage* was estimated using the TANITA BC-418 body composition analyzer (TANITA Corp).

*Physical fitness* was assessed using three tests included in the Alpha-Fitness Test Battery.<sup>40</sup> Cardiorespiratory fitness was measured using the 20-meter shuttle run test, muscle strength was evaluated by the standing long jump test, and speed agility was obtained through the 4x10meter shuttle run test.

## 2.5 | Statistical analyses

In MOVI-KIDS, the ad hoc sample size was not estimated to show differences between CG and IG in BMI, which was the primary outcome of this study. The details of the sample size have been described elsewhere.<sup>41</sup> In brief, the estimated sample size was 140 children per group, which was multiplied by an inflation factor for cluster-randomized trials. Thus, the minimum sample size was estimated to be 1600 children (800 for each group). Data are described by means and standard deviations or percentages. Differences between groups in age, anthropometry, body composition, fitness components, and HRQoL variables were tested using t-tests. Qualitative variables associations were tested with the chi-square test. Intervention effects were estimated with mixed linear regression models, with adjustment for each baseline outcome, with cardiorespiratory fitness, socioeconomic status as covariates, and school as a cluster factor, by gender. Effect estimates (ß) describe the differences between the mean change in IG and mean change in CG, adjusted by covariates, with 95% confidence intervals (CI). The analyses were performed on an intention-to-treat basis.

All analyses were performed using Stata version 16.0 (StataCorp. 2019. *Stata Statistical Software: Release 16.* College Station, TX: StataCorp LLC). Statistical significance was set at 0.05.

### 3 | RESULTS

A total of 2407 children from 21 schools were invited to participate and 1604 (66.6%) parents gave written consent allowing their children to participate in the study (1299 from the IG and 1108 from the CG). Of these, 1447 (51.69% boys) children had complete data on HRQoL (610 from the IG and 837 from the CG). Finally, both measures baseline and endpoint were taken for a total of 1168 children (430 from the IG; and 738 from the CG), and these data were used for the analysis (Figure 1).

Table 1 presents the descriptive baseline characteristics of the study sample. No differences were found in baseline outcome variables between the intervention and control groups, except for the boys in the CG, who presented a higher percentage of low socioeconomic status and scored better on the total score of the children's self-report HRQoL, while the girls in the IG scored better on cardiorespiratory fitness and the HRQoL friends' dimension.

Table 2 shows the comparison of changes in HRQoL dimensions in the intervention versus control group, by gender. The boys in the IG presented better scores on total HRQoL than the CG in both the parents' ( $\beta = 1.46$ ; 95% CI: 0.23–2.70; p = 0.020) and self-reported ( $\beta = 2.13$ ; 95% CI: 0.53–3.74; p = 0.009) versions, as well as on the emotional well-being dimension ( $\beta = 2.43$ ; 95% CI: 0.48–4.36; p = 0.014). There was no significant effect of the intervention on physical well-being, self-esteem, family, and friends. In girls, no statistically significant differences were found. The comparison of changes in HRQoL dimensions in the intervention versus control group for the total sample is shown in (Table S1).

According to the process evaluation, the children attended more than 75% of the PA sessions of the programme, and no injuries or problems occurred during the physical examinations or during the PA programme. Forty-three (10%) children withdrew from the program because of the following reasons: changes of residence, incompatibility with other activities, and incompatibility with the parents' schedule. In terms of satisfaction, 95.2% of parents reported they were quite or fully satisfied with the programme, whereas 90.1% of the children enjoyed the intervention and were happily playing with their peers who attended the programme.

## 4 | DISCUSSION

This study aimed to test the effectiveness of a one-schoolyear multicomponent intervention consisting of a recreational non-competitive PA programme in improving HRQoL in schoolchildren, by gender, using both selfreported measures and parents' proxy reports. The results revealed that MOVI-KIDS improved the HRQoL of boys, whereas no effectiveness was found in girls.

The benefits of school-based PA interventions in HRQoL are a debatable issue. While a recent systematic review<sup>42</sup> and previous intervention studies<sup>9–12</sup> have reported that school PA programmes can improve both total and emotional dimensions of HRQoL, other interventions<sup>14-19</sup> have found no significant effects. Several explanations have been proposed for this inconclusive evidence, such as the heterogeneity of the studies with respect to the ages of participants, instruments of HRQoL assessment, and design of interventions (type, duration, intensity, and frequency). In general, the interventions seem to be effective on HRQoL when they are delivered by qualified professionals<sup>10–13</sup> and focus not only on the volume but also on the type of activities,<sup>9,10,13</sup> i.e., favoring cooperation and teamwork, self-esteem, and increasing perceived motor proficiency.

Our data show a mixed effect. In boys, the data corroborate that our intervention improved the total HRQoL scores and emotional well-being scores, while, in girls, no significant improvement was found. The lack of studies examining the gender differences in the effect of PA on HRQoL makes it impossible to compare our results with previous evidence, although a previous study conducted only with girls<sup>10</sup> was effective in improving HRQoL. Two possible reasons to explain the gender differences observed in our study could be: the higher baseline HRQoL scores of girls in the IG compared with boys; and the lower level of girls' participation in the activities planned, as previous studies indicated,<sup>43</sup> girls are less involved in plays than boys. Despite our intervention being designed in line with the interests of both boys and girls (which were considered by interviewing the participants themselves,



FIGURE 1 Flow chart of trial participants. CG-control group; IG-intervention group

#### **TABLE 1** Characteristics of the sample

	Intervention gro	oup	Control group	
	Boys $(n = 324)$	Girls ( $n = 286$ )	Boys $(n = 424)$	Girls ( $n = 413$ )
Characteristics				
Age (years)	5.31 (0.63)	5.37 (0.63)	5.33 (0.59)	5.37 (0.63)
Socioeconomic status $(n, \%)$				
Lower—Upper lower	88, 27.76	80, 27.59	145, 35.45*	120, 30.15
Lower middle	145, 45.74	144, 49.66	170, 41.56	177, 44.47
Upper middle—Upper	84, 26.50	66, 22.76	94, 22.98	101, 25.38
Anthropometry and body composition				
Weight (kg)	21.80 (4.92)	21.26 (4.88)	21.56 (4.80)	21.02 (4.55)
Height (cm)	115.83 (5.99)	114.94 (5.90)	116.04 (6.16)	115.07 (6.13)
Body mass index (kg/m <sup>2</sup> )	16.10 (2.61)	15.90 (2.52)	15.86 (2.34)	15.69 (2.36)
Body fat mass (%)	20.16 (5.82)	20.30 (6.67)	19.93 (4.79)	20.26 (6.26)
Fitness components				
Cardiorespiratory fitness (20-m shuttle run, stage)	2.16 (1.47)	1.90 (1.12)**	1.98 (1.25)	1.62 (0.94)
Muscle strength (standing broad jump, cm)	96.88 (19.93)	88.39 (16.02)	96.12 (19.49)	87.13 (19.96)
Speed agility (4×10, s)	16.83 (2.33)	17.42 (1.93)	16.95 (2.20)	17.60 (2.32)
Health-related quality of life				
Physical well-being	85.43 (13.20)	84.29 (12.56)	85.51 (12.86) <sup>a</sup>	83.01 (14.30)
Emotional well-being	82.35 (12.43)	84.83 (11.76) <sup>a</sup>	84.13 (12.69)	84.41 (12.30)
Self-esteem	75.69 (15.34)	79.98 (14.89) <sup>a</sup>	75.68 (16.47)	77.89 (14.92) <sup>a</sup>
Family	82.65 (12.80)	84.39 (11.98)	82.77 (12.58)	83.91 (12.59)
Friends	85.65 (12.56)	88.32 (10.89)* <sup>,a</sup>	85.51 (12.89)	86.05 (12.92)
School	82.78 (13.48)	86.55 (11.87) <sup>a</sup>	82.21 (14.07)	86.28 (11.22) <sup>a</sup>
Total score parents	82.42 (09.02)	84.68 (08.40) <sup>a</sup>	82.65 (09.61)	83.57 (09.02)
Total score children <sup>b</sup>	82.01 (11.09)	82.09 (11.74)	84.52 (11.12)*	83.47 (11.34)

*Note*: Results are shown as means and standard deviations, except for socioeconomic status, which is presented as percentage. The values of the *p* indicate significant differences in intergroup (intervention vs. control) by gender (\*p < 0.05; \*\*p < 0.001).

<sup>a</sup> Superscript indicates differences intragroup (boys vs. girls) in health-related quality of life (p < 0.005).

<sup>b</sup> Health-related quality of life children self-report.

their teachers, and families at the beginning of the study), the girls might have engaged less with the sessions, as described in other research.<sup>44–46</sup> This lower engagement might be responsible for the non-effectiveness in girls since, as has been described in the literature, a positive effect of school-based PA intervention programmes on HRQoL could be explained by an increase in levels of PA.<sup>8</sup> Therefore, future PA interventions should take into account the preferences and interests of girls in their design since they may be a good strategy to improve their HRQoL. Moreover, they should be delivered by PA professionals who can implement didactic strategies of female empowerment to involve girls in the activities.

To our knowledge, this is the first study on the effectiveness of a school-based PA intervention on HRQoL in schoolchildren by gender, controlling for cardiorespiratory fitness and socioeconomic status, also including parents' and children's perceptions of HRQoL, which gives greater robustness to our findings. Despite the strengths of the study, it does have several limitations. First, a major limitation of this study is that PA was not measured before and after the intervention, and it is therefore impossible to know whether the increase in PA levels is the cause of the improved HRQoL. Second, the 20-meter shuttle run test used did not have enough sensitivity, in fact, an appropriate adapted version for children under 6 years of age was validated in 2014 in which the initial speed is 6.5 km/h and increasing 0.5 km/h every minutemen. Third, Kiddy-KINDL-R self-report can only estimate a total HRQoL score, not allowing for a comparison of parents' and children's perceptions by dimensions. Furthermore, although the self-report children's version has been translated to Spanish according to a standardized translation and backtranslation process, no validity study has been conducted on children of this age in the Spanish population, so the findings should be treated with caution. Fourth, even

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	Baseline		After intervention		Difference betwee intervention and b	n after aseline	Effect estimate	
Health-related quality of life	Intervention group	<b>Control group</b>	Intervention group	Control group	Intervention group	Control group	Beta <sup>a</sup> (95% CI)	<i>p</i> Value
Boys	n = 324	<i>n</i> = 424	n = 222	n = 374				
Physical well-being	85.43 (13.20)	85.51(12.86)	85.94(12.59)	83.14~(15.03)	0.51	-2.37	2.12 (-0.63-4.86)	0.131
Emotional well-being	82.35 (12.43)	85.43(12.69)	85.11 (12.25)	83.29 (12.53)	2.76	-2.14	2.43 (0.48-4.36)	0.014
Self-esteem	75.69 (15.34)	84.13(16.47)	76.60 (16.61)	75.54 (15.65)	0.91	-8.59	0.75(-1.72-3.21)	0.553
Family	82.65 (12.80)	82.35(12.58)	83.16 (11.82)	81.71 (12.87)	0.51	-0.64	1.11(-0.86-3.08)	0.268
Friends	85.65 (12.56)	75.68 (12.89)	85.59 (12.99)	84.65~(12.86)	-0.06	8.97	$0.87 \left(-1.01 - 2.75\right)$	0.362
School	82.78 (13.48)	75.69(14.07)	82.99 (13.29)	80.43(13.27)	0.21	4.74	1.15(-0.83-3.13)	0.255
Total score parents	82.42 (09.02)	82.77(09.61)	83.20 (09.27)	81.48(09.56)	0.78	-1.29	1.46 (0.23–2.70)	0.020
Total score children <sup>b</sup>	82.01 (11.09)	82.65 (11.12)	83.66(10.70)	82.26 (10.87)	1.65	-0.39	2.13 (0.53-3.74)	0.009
Girls	n = 286	n = 413	n = 208	n = 364				
Physical well-being	84.29 (12.56)	83.01(14.30)	83.68 (13.16)	82.74(14.19)	-0.61	-0.27	0.25 (-2.12-2.63)	0.833
Emotional well-being	84.83 (11.76)	84.41(12.30)	83.76 (13.50)	83.81 (12.19)	-1.07	-0.60	0.30 (-1.63-2.23)	0.761
Self-esteem	79.98(14.89)	77.89(14.92)	80.15(16.04)	77.55 (16.07)	0.17	-0.34	0.79(-1.80-3.38)	0.548
Family	84.39~(11.98)	83.91(12.59)	83.52 (12.51)	82.60(12.83)	-0.87	-1.31	0.93 (-1.05-2.92)	0.356
Friends	88.32~(10.89)	86.05(12.92)	88.29 (11.28)	86.39(12.43)	-0.03	0.34	0.26(-1.55-2.06)	0.780
School	86.55 (11.87)	86.28(11.22)	86.29~(12.41)	85.01(11.84)	-0.26	-1.27	0.98(-1.08-2.99)	0.358
Total score parents	84.68(08.40)	83.57 (09.02)	84.30 (09.33)	83.00(09.46)	-0.38	-0.57	0.60 (-0.73-1.93)	0.378
Total score children <sup>b</sup>	82.09 (11.74)	83.47(11.34)	83.36(11.15)	$84.15\ (10.30)$	1.27	0.68	-0.62 (-2.22-0.99)	0.451
<i>Note:</i> Results are shown as mea The values of the <i>p</i> in bold indic	ns and standard deviations. cate significant differences be	etween intervention and	l control group ( $p < 0.05$ ).					

<sup>a</sup> Intervention effects were estimated with mixed linear regression models, with adjustment for each baseline health-related quality of life variable, sex, cardiorespiratory fitness, socioeconomic status, and cluster factor school.

<sup>b</sup> Health-related quality of life children self-report.

TABLE 2 Changes in health-related quality of life dimensions from baseline to 8 month follow-up between intervention versus control group, by gender

though the intervention lasted 8 months, the results were evaluated immediately after the end of the intervention, so an evaluation of the long-term results was also needed. Fifth, since the intervention was designed according to a social-ecological model, changes in the school or community that might have happened due to our intervention could not be reasonably achieved in this short-term. Such changes, however, may have an influence on the general health status of the children. Moreover, external factors such as the economy or the country's policies included in the model were not assessed, and therefore associations between the variables studied in each domain of the social-ecological model and children's HRQoL directly or indirectly cannot be analyzed. Sixth, although the response rate was relatively high, it should be taken into account that a non-negligible percentage of invited schoolchildren (more than 30%) did not participate in this study, which may influence the generalizability of the results. In addition, given the small sample size, subgroup analyses based on categories of adherence or parents' socioeconomic status were not conducted.

To conclude, the boys who participated in the schoolbased PA intervention obtained higher scores on emotional well-being through the MOVI-KIDS intervention, according to the perception of parents. Furthermore, parents' and children's self-reported perceptions resulted in higher scores for the boys on the total HRQoL score. Thus, promoting PA in school settings, following the interests of schoolchildren, especially those of girls, must be a priority for educational policies in early ages to improve the HRQoL of schoolchildren.

## 5 | PERSPECTIVE

Promoting PA in school settings, since children spend a significant amount of time sitting in classrooms most of the day during the week, should be a priority for educational policies at an early age since it could improve their HRQoL. In this regard, more studies are needed to assess the effectiveness of PA programmes. These programmes could be aimed at increasing the amount of PA, as it has been described that physical exercise programmes can increase PA,<sup>11,14</sup> and this in turn could be a mediator between physical exercise programmes and improvements in HRQoL in children. On the other hand, the PA programmes may focus on promoting social and psychological factors (social interaction, improvement of perceived motor competence, for example), closely associated with HRQoL.<sup>47</sup> Finally, the activities should be conducted by professionals considering both girls' and boys' preferences and motivations and using pedagogical strategies to involve more girls in the exercise sessions.

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#### **CONFLICT OF INTEREST**

The authors declare they have no conflict of interest statement.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

#### ORCID

Andres Redondo-Tebar b https://orcid. org/0000-0001-5920-6159 Abel Ruiz-Hermosa b https://orcid. org/0000-0002-5127-0591 Vicente Martinez-Vizcaino b https://orcid. org/0000-0001-6121-7893 Alberto Bermejo-Cantarero b https://orcid. org/0000-0001-6463-5556 Iván Cavero-Redondo b https://orcid. org/0000-0003-2617-0430 Noelia María Martín-Espinosa b https://orcid. org/0000-0002-1298-6976 Mairena Sanchez-Lopez b https://orcid. org/0000-0002-0217-0623

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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