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EVALUATION OF AN INTERVENTION FOCUSING ON CHILDREN TO PROMOTE PHYSICAL ACTIVITY IN THE ENTIRE COMMUNITY: FEASIBILITY, EFFECTIVENESS AND SUSTAINABILITY OVER TIME.

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Evaluation of an intervention focusing on children to promote physical activity in the entire community: Feasibility, effectiveness and sustainability over time.

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Abstract

Regular physical activity during childhood is associated with physical, mental, emotional and social health benefits. The constant practice of physical activity is considered one of the best buys available in public health. Youth that participate in an active lifestyle can achieve greater health when they reach adulthood. The World Health Organization recommends to perform at least 60 minutes per day of moderate to vigorous physical activity for children and adolescents in order to obtain health benefits. However, globally, this level of physical activity is hardly achieved. Children and adolescent who do not reach the recommended levels of physical activity are defined as physically inactive and nowadays physical inactivity constitutes a new type of pandemic. For this reason, the World Health Organization launched a global action plan addressing physical activity with a goal of reducing physical inactivity in children and youth. The plan also included recommendation to improve individual and community health and contribute to the social, cultural and economic development of all nations. Worldwide, children and adolescents spend a significant amount of time in school and for this reason the school represents a fundamental educational setting that can play a pivotal role increasing students' physical activity. Opportunities to be physically active should not be considered purely in relation to when children attend physical education classes but also making physical activity available during the school day, such as physically active lessons, and multicomponent physical activity interventions. Since school-based physical activity interventions are quite numerous, the present thesis focused on interventions delivered during school hours and that integrate small doses of physical activity as part of routine instruction. This type of intervention is called "Active Breaks." Active Breaks consists of brief 5–15 minutes sessions of physical activity led by teachers who introduce short bursts of PA into the academic lesson. In light of this the present thesis aims to evaluate the feasibility, efficacy and sustainability over time of an Active Breaks intervention targeting children to promote physical activity in the entire community.

The research reported here commenced with a systematic literature review including meta-analysis. The intent was to reinforce the existing body of knowledge in studies of physical activity with children and youth (Study 1). The systematic review's findings suggests that Active Breaks had a facilitating effect on children's physical activity levels contributing to reach the 60 minutes per day of moderate to vigorous physical activity recommended and in improving the classroom time on task behaviour. Lasting effects were obtained with the most intense (10 min three times a day for 12 weeks) or longer (10–15 min once a day for 9 months) interventions. Study 2 then stemmed from the literature review and included a pilot feasibility study to test the efficacy, feasibility and sustainability of an Active Breaks intervention for primary school children. This was followed by presentation of a research protocol for a quasi-experimental study: The Imola Active Breaks study (I-MOVE). The I-MOVE (Study 3) is the core feature of the doctoral project and involved a larger sample of children examining various physical, cognitive, mental and health-related quality-of-life outcomes.

The longitudinal component of the I-MOVE study (Study 6: commencing in 2019 and ending in 2021) provided a means to investigate the principal determinants of health-related quality of life (Study 4) and to evaluate the impact of COVID-19 on children's' physical activity levels with a focus on examining gender differences (Study 5).

Finally, Study 6 reports the effect of the Active Breaks intervention on children's' physical and cognitive performance. Active Breaks stimulated improvement in children's working memory and classroom behaviour. Despite disruptions due to the pandemic, Active Breaks proved to be sustainable and play a protective role with regard to physical fitness and weight status. The findings confirm that Active Breaks can be a valid strategy for increasing physical activity levels at school and limiting time spent in sedentary behaviour. The program represents a cost-effective strategy for school settings regardless of age and gender differences and can transform the school into a more dynamic environment for both physical and cognitive health.

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1. Introduction

1.1. Benefits of physical activity

Physical activity (PA) is defined by the World Health Organization (WHO) as any bodily movement produced by skeletal muscles that requires energy expenditure [1].

Thus, PA means any movement that an individual can make in their daily life, during free time, travelling to the workplace or as part of work itself, during school and around the home. Physical activity can be undertaken in many different ways: walking, cycling, actively participating in sports or any active form of recreation (e.g., dance, yoga, tai-chi). Physical activity can also be undertaken at work. All modalities of physical activity can provide health benefits if practiced regularly and if they are of sufficient duration and intensity [2].

To date, many empirical studies, reviews and meta-analysis confirm health benefits related to the practice of PA. These benefits are especially due to the protective role for prevention and management of non-communicable disease (NCD) such as cardiovascular disease, metabolic diseases, neoplastic diseases in particular breast and colon cancer [2-4]. Engaging in regular PA is one of the most important things that people can do to sustain or improve their health. Renowned epidemiologist Jerry Morris defined PA as the “best buy” in public health.

There is also evidence that PA has benefits for mental health [5], and regular exercise can delay cognitive decline [6], contribute to the maintenance of healthy weight [2], and promote general well-being [7].

The 2018 Physical Activity Guidelines Advisory Committee Scientific Report confirmed that regular PA provides a variety of other benefits: promoting better sleep, helping individuals feel better, and making it easier for people to perform their daily tasks [8].

Table 1. Effects of Physical Activity in children, adolescents, adults and older adults
In children and adolescents PA has shown to:
Improve bone health (ages 3 through 17 years)
Improve weight status (ages 3 through 17 years)
Improve cardiorespiratory and muscular fitness (ages 6 through 17 years)
Improve cardio metabolic health (ages 6 through 17 years)
Improve cognition (ages 6 to 13 years)
Reduce the risk of depression (ages 6 to 13 years)

In adults and older adults PA is associated with:
Lower risk of all-cause mortality
Lower risk of cardiovascular disease mortality
Lower risk of cardiovascular disease (including heart disease and stroke)
Lower risk of cardiovascular disease (including heart disease and stroke)
Lower risk of type 2 diabetes
Lower risk of adverse blood lipid profile
Lower risk of cancers of the bladder, breast, colon, endometrium, esophagus, kidney, lung, and stomach
Improve cognition
Reduced risk of dementia (including Alzheimer's disease)
Improved quality of life
Reduced anxiety
Reduced risk of depression
Improved sleep
Slowed or reduced weight gain
Weight loss, particularly when combined with reduced calorie intake
Prevention of weight regain following initial weight loss
Improved bone health
Improved physical function
Lower risk of falls (older adults)
Lower risk of fall-related injuries (older adults)

Note: The Advisory Committee rated the evidence of health benefits of physical activity as strong, moderate, limited, or grade not assignable. Only outcomes with strong or moderate evidence of effect are included in this table. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. JAMA. 2018;320(19):2020-2028. doi:10.1001/jama.2018.14854.

The 2018 Scientific Report also notes there are immediate benefits of PA in addition to those related to regular PA practiced for months or years [8]. Moreover, PA can also have an effect on brain health. Some of these benefits, such as a reduced state anxiety, improved sleep quality, and improved cognitive functioning occur immediately after a single session of PA. Regular PA improves trait anxiety deep during sleep, and also positively influences different components of executive functioning (including the ability to plan and organize, self-monitoring, inhibit, or facilitate behaviours, initiate tasks, and control emotions). Engaging in PA also benefits cognitive functioning by improving performance on academic achievement and neuropsychological tests (such as those involving mental processing speed, memory) and executive functioning thus lowering the risk of developing cognitive impairment, such as dementia including Alzheimer's disease [9]. These cognitive benefits are evident not only in healthy children and adults but also in people who experience various cognitive impairments including attention deficit hyperactivity disorder (ADHD), schizophrenia, multiple sclerosis, Parkinson's disease, and stroke. Physical activity contributes to reduce symptoms of anxiety in adults and older adults and lowers the risk of developing depression in children and adults.

Physically active adults and older adults are likely to report having a better quality of life. In addition, physically active individuals report that they sleep better. Greater volumes of PA are associated with reduced sleep latency (taking less time to fall asleep), improved sleep efficiency (higher percentage of time in bed actually sleeping), improved sleep quality, and greater amounts of deep sleep. Greater volumes of moderate-to-vigorous PA are also associated with significantly less daytime sleepiness, better sleep quality, and reduced frequency of use of sleep-aid medications [9].

Physical activity should not be confused with exercise, which is a subcategory of PA that is planned, structured, repetitive, and aims to improve or maintain one or more components of physical fitness [1,2]

Physical fitness (PF) is an important issue from a public health perspective, it is in fact a set of attributes that are either health- or skill-related [1,10]. Physical fitness is defined as "the ability to carry out daily tasks with vigour and alertness, without undue fatigue, and with ample energy to enjoy leisure-time pursuits and respond to emergencies" [9]. Physical fitness is associated with reduced all-cause mortality and cardiovascular disease mortality and reduced risk of developing a wide range of chronic diseases, such as Type 2 diabetes and hypertension. The health-related components of PF are:

- **cardiorespiratory fitness** that is the ability to perform large-muscle, whole-body exercise at moderate-to-vigorous intensities for extended periods of time.
- **musculoskeletal fitness** that is the integrated function of muscle strength, muscle endurance, and muscle power to enable performance of work.
- **flexibility** the range of motion available at a joint or group of joints.
- **balance** the ability to maintain equilibrium while moving or while stationary.
- **speed** the ability to move the body quickly.

Physical fitness and PA are closely related and both provide important key indicators of health outcomes [11-13].

Physical activity not only plays a fundamental role in the mental, cognitive and physical health in everyone but also in sociability and interpersonal skills. This is because PA provides people with a chance to have fun, enjoy the outdoors, socialize and share activities with other individuals and not just as a means of improving one's own health.

When theoretical frameworks such as social cognitive theory [14], the theory of planned behaviour [15] or a focus on the affective or emotional response to exercise and PA are considered, individuals are more likely to adhere to a prescribed routine for exercise [16]. This is because when people experience genuinely good feelings following exercise, they are more likely to be physically active on a regular basis and maintain their motivation to exercise. This has the effect of improving their self-efficacy as a person who exercises routinely perceives that they can competently execute the task (exercise) with positive benefits [16]. This creates a linkage between effort, skill and the desired outcomes. These close linkages suggest that self-efficacy and emotional responses may be important variables with regards to why people choose to adhere to rigorous exercise routines (the perceived benefits outweigh the costs). Therefore, it is important to address positive affective responses and consider the fun part of PA and exercise when creating guidelines [1,17-19].

1.2 Physical activity recommendations for children and adolescents

There is a constant growth of interest in the benefits perceived through PA determined by age. For this reason recommendations and guidelines, both from the WHO and U.S. Department of Health and Human Services, are categorized based on age [8].

To date, many literatures highlight how both children and adolescents are in an important stage of life during which time their motor skills dramatically improve (i.e., hand-eye coordination, athletic ability, and physical stature). When children and adolescents regularly engage in PA, they can learn and adopt positive lifestyle behaviours, which in turn build the foundations for life-long health and well being [9]. Youth that participate in an active lifestyle can achieve greater health when they reach adulthood [9]. The more recent WHO Guidelines on PA and sedentary behaviour, updating those published in 2010, provide evidence-based public health recommendations for adults, older adults, children, adolescents, on the amount of PA (frequency, intensity and duration) required to provide health benefits and mitigate health risks [20].

Intensity of PA also plays a role in health benefits. Some activities are of a higher intensity than others because they require more energy output during exercise. Generally, the intensity of PA is categorized as light, moderate, or vigorous. Energy expenditure is expressed by multiples of the metabolic equivalent of task (MET), where 1 MET is the rate of energy expenditure while sitting at rest. Below is a breakdown of the MET levels associated with different intensities of activity:

- **Light-intensity activity** is non-sedentary waking behaviour that requires less than 3.0 METs; examples include: walking, cooking activities, or light household chores.
- **Moderate-intensity activity** requires 3.0 to less than 6.0 METs; examples include: walking briskly, playing doubles tennis, or raking leaves in the yard.
- **Vigorous-intensity activity requires** 6.0 or more METs; examples include: jogging, shoveling snow, or participating in a strenuous fitness class [8].

The different types of PA are divided into three categories:

1. **Aerobic activities** involve large muscle groups in dynamic activities that result in substantial increases in heart rate and energy expenditure. Running, hopping, skipping, jumping rope, swimming, dancing, and bicycling are all examples of aerobic activities. Aerobic activities improve cardiorespiratory fitness and strengthen skeletal muscles [21].
2. **Muscle-strengthening activities** make muscles do more work than usual during activities of daily life. This is called *overload* and strengthens the muscles. Muscle-strengthening activities can be unstructured and part of play, such as playing on playground equipment, climbing trees, and playing tug-of-war. Or they can be structured, such as lifting weights or working with resistance bands.
3. **Bone-strengthening activities** produce a force on the bones of the body that promotes bone growth and strength. This force is commonly produced by impact with the ground. Running, jumping rope, basketball, tennis, and hopscotch are all examples of bone-strengthening activities. Bone-strengthening activities can also be aerobic and muscle strengthening. Table 2 shows how type of PA can be divided based on a child's age.

Table 2. Type of Physical Activity Based on Developmental Age

Type of Physical Activity	Preschool-Aged Children	School-Aged Children	Adolescents

Moderate– intensity aerobic	Games such as tag or follow the leader Playing on a playground Tricycle or bicycle riding Walking, running, skipping, jumping, dancing Swimming Playing games that require catching, throwing, and kicking Gymnastics or tumbling Games such as tag or follow the leader Playing on a playground Tricycle or bicycle riding Walking, running, skipping, jumping, dancing Swimming Playing games that require catching, throwing, and kicking Gymnastics or tumbling	Brisk walking Bicycle riding Active recreation, such as hiking, riding a scooter without a motor, swimming Playing games that require catching and throwing, such as baseball and softball	Brisk walking Bicycle riding Active recreation, such as kayaking, hiking, swimming Playing games that require catching and throwing, such as baseball and softball House and yard work, such as sweeping or pushing a lawn mower Some video games that include continuous movement
Vigorous– intensity aerobic		Running Bicycle riding Active games involving running and chasing, such as tag or flag football Jumping rope Cross-country skiing Sports such as soccer, basketball, swimming, tennis Martial arts Vigorous dancing	Running Bicycle riding Active games involving running and chasing, such as flag football Jumping rope Cross-country skiing Sports such as soccer, basketball, swimming, tennis Martial arts Vigorous dancing

Note: Some activities, such as bicycling or swimming, can be moderate or vigorous intensity, depending upon level of effort. For preschool-aged children, aerobic activities listed can be either moderate or vigorous intensity. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. JAMA. 2018;320(19):2020-

2028. doi:10.1001/jama.2018.14854

As previously noted, PA in children and adolescents provides numerous health benefits: improved physical fitness (cardiorespiratory and muscular fitness), cardio-metabolic health (blood pressure, dyslipidaemia, glucose, and insulin resistance), bone health, cognitive outcomes (academic performance, executive function), mental health (reduced symptoms of depression); and reduced adiposity. For these reasons the WHO recommends that children and adolescents from 5 to 17 years of age perform an average of 60 minutes per day of moderate to vigorous-intensity (MVPA), in a week and vigorous-intensity aerobic activities, and those that strengthen muscle and bone, should be incorporated at least 3 days a week [20].

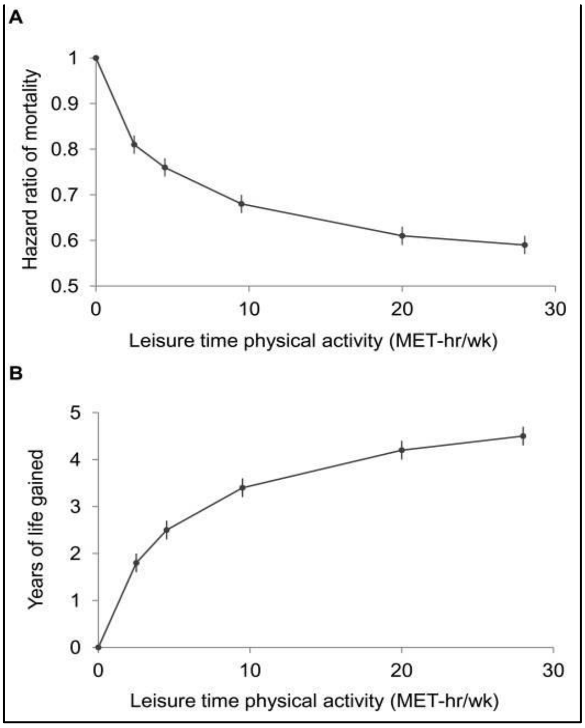
Also the US PA guidelines suggest that children from 6 to 17 years of age should engage at least 60 minute per day of MVPA and as part of their 60 minutes or more of daily PA, children and adolescents should include bone-strengthening PA on at least 3 days a week [9]. Canada also provides 24-Hour movement guidelines on PA for children and youth (ages 5-17). These guidelines are in line with previous ones regarding type, intensity, and frequency of PA suggesting that participants practice several hours of varied structured and unstructured light physical activities [22].

1.3 Physical Inactivity versus Sedentary Behaviour

As previously mentioned, there are numerous PA recommendations that exist around the world. Despite substantial evidence and numerous guidelines, levels of physical inactivity, particularly in children and adolescents, are very high. The WHO defined physical inactivity (PI) as non-achieving of the PA guidelines (60 minutes per day). This has prompted some to consider PI as a new type of pandemic [23,24]. This is because PI is a risk factor for premature mortality and several NCDs [9]. For example, a study by Lee et al. (2008) estimated that PI caused 6%–10% of premature mortality, coronary heart disease, Type 2 diabetes, breast cancer and colon cancer [25]. A more recent publication in 2016 [26] focused entirely on PA, and reported an estimated 5.3 million deaths per year due to PI. The same report underlined the effect of PI on dementia [27], pointing to the large health-care costs of inactivity [28], additional health risks from excessive sitting, and, most importantly, the observation that PA is not improving worldwide, despite an increased number of countries having a national PA policy or plan [29].

A study by Katzmarky et al. (2021) [30] recently evaluated the effect of PI on NCD burden in low, middle and high income countries. The study suggests that PI is responsible for a significant global health burden: a total of 7.2% and 7.6% of all-cause and cardiovascular disease deaths, respectively, are attributable to PI. Furthermore, the same study indicates that the proportion of NCD attributable to PI range from 1.6% for hypertension to 8.1% for dementia. Across low, middle, and high-income countries there was a trend of increasing in the adjusted population attributable risk (PARs). Latin American and Caribbean countries and high-income Western and Asia Pacific countries, followed by countries in Central Asia, the Middle East and North Africa had the highest NCD burden associated with PI. Countries in sub-Saharan Africa, Oceania and East and Southeast Asia have the lowest NCD burden associated with PI. Globally, PI is estimated to cost INT$ 54 billion in direct health care, in 2013, of which 57% is incurred by the public sector and an additional INT$ 14 billion is attributable to lost productivity [28]. However, even low amounts of MVPA reduce the risk of all-cause mortality. Figure 2 shows that there are large benefits when a person moves from being inactive to being insufficiently active.

Figure 2 Leisure time physical activity of moderate to vigorous intensity and mortality



Moore SC, Patel AV, Matthews CE. Leisure time physical activity of moderate to vigorous intensity and mortality: a large pooled cohort analysis. PLoS Med. 20129 (11):e1001335. doi:10.1371/journal.pmed.1001335

A recent European study monitored the PA levels of children and adolescents, using objective instruments such as accelerometers (Table 3) [31]. The data shows that more than two-thirds of European youth can be categorized as insufficiently active. Table 3 shows that the prevalence of sufficiently active children is lower among youth living in Southern Europe (23%) compared to those living in Northern Europe (31%). In particular, the prevalence of adequately active children was higher in Northern (31%), intermediate in Central (26%), and significantly lower in Southern Europe (23%)[31].

Table 3 Prevalence (95% CI) for being categorized as sufficiently physically active by European region, country and age group.

European region	Overall region	Country	Region Children (2–9.9y)	Adolescents (≥10–18 y)
North (n = 28,988)	31 (29,34)	Norway	37 (26, 49)	34 (32,37)
		Sweden	33 (28,39)	38 (31,44)
		Denmark	32 (24,41)	29 (21,37)
		Finland	25 (11,38)	29 (15,43)
		Estonia	28 (23,32)	40 (29,52)
		UK	31 (21,40)	30 (27,32)
Central (n = 9287)	26 (20,32)	France	N/A	28 (23,33)
		Germany	33 (28,38)	24 (10,38)
		Austria	N/A	34 (27,40)
		Swiss	38 (25,51)	43 (37,48)
		Belgium	18 (10,26)	20 (16,23)
		Hungary	22 (19,25)	38 (31,46)
South (n = 9222)	23 (20,27)	Portugal	25 (21,29)	24 (19,29)
		Spain	25 (21,28)	33 (29,37)
		Italy	N/A	21 (17,26)
		Malta	N/A	14 (10,19)
		Cyprus	13 (9,16)	N/A
		Greece	N/A	27 (22,33)

Note: All prevalence estimates are adjusted for sex, age, wear time, country, season, study year and ActiGraph models. Study used as cluster variable in all models to obtain robust variance estimations.
Steene-Johannessen J, Hansen BH, Dalene KE, et al. Variations in accelerometry measured physical activity and sedentary time across Europe - harmonized analyses of 47,497 children and adolescents. Int J Behav Nutr Phys Act. 2020;17(1):38

Sedentary behaviours are becoming more and more frequent, also in these target age groups (5 – 17), suggesting that this will soon become a public health issue [32]. Sedentary behaviour is defined as any waking behaviour characterized by an energy expenditure of 1.5 METS or lower while sitting, reclining, or lying. Most desk-based office work, driving a car, and watching television provide examples of sedentary behaviours; these can also apply to those unable to stand, such as wheelchair bound individuals.

A recent systematic review suggests that increasing PA and decreasing sedentary behaviour may enhance health in children and adolescents. Likewise, decreasing sedentary behaviour may also have a positive effect on depression, satisfaction with life and happiness in children and adolescents [33]. However, when describing a sedentary lifestyle, any behaviour is considered, even those involving use of computer screens (i.e., recreational use of computers and television viewing). Indeed, this type of behaviour is considered the most prevalent and pervasive sedentary behaviour in

developed countries. Prolonged screen time has been associated with unhealthy outcomes such as increased risk of Type 2 diabetes, cardiovascular disease, all-cause mortality, and depressive symptoms in children and adolescents [34,35].

A growing body of evidence suggests there is a negative association between sedentary behaviour and health outcomes. For this reason, it is increasingly important to include concerted recommendations regarding sedentary behaviours, especially for children and youth. As the research literature shows, higher amounts of sedentary behaviours are associated with poor health outcomes including increased adiposity, poorer cardio-metabolic health, fitness, behavioural conduct/pro-social behaviour; and reduced sleep duration [9]

A compilation of evidence on the role of sedentary behaviours has prompted, for the first time, the 2020 WHO recommendations to include guidelines on sedentary behaviour [36]. The WHO guidelines recommend that: children and adolescents should limit the amount of time spent being sedentary, particularly the amount of recreational screen time. [20]. Unlike the WHO guidelines, which are very general those issued by Canada provide greater detail regarding sedentary behaviour: no more than 2 hours per day of recreational screen time and limited sitting for extended periods [32].

Using these guidelines and recognizing the public health implications of PI in children and youth, the WHO launched its first campaign “The Global Action Plan on Physical Activity 2018–2030” to address sedentary behaviours. The campaign includes four strategic objectives (i.e., create an active society, active environment, active people, and active system) along with 20 policy actions to achieve a 15% relative reduction in the global prevalence of PI in adults and adolescents by 2030.The mission of the WHO campaign is to ensure that all people have access to safe and exercise-enabling environments, providing people with diverse opportunities to be physically active in their daily lives. The goals of the campaign will provide the foundation to improve individual and community health and contribute to the social, cultural and economic development of all nations: More active people for a healthier world [37]. In particular, the third sustainable development goal is precisely focused on good health and well-being aiming to reduce one third premature mortality from non-communicable diseases using the vehicles of prevention and treatment to promote mental health and well-being.

2. The Role of School in Promoting Healthy Activity

2.1 The role of school in promoting physical activity

Increasingly, there is growing interest regarding the importance of exposure to PA opportunities during childhood. This emphasis takes into account that health behaviours established during early life are more likely to persist or remain part of a person's behavioural repertoire from childhood to adulthood [38]. Healthy lifestyles are established early in life and influenced by families, schools, community organizations, health care providers, faith-based institutions, government agencies, and even the media [9].

Taking into account the alarming situation of PI and sedentary behaviour previously discussed, it should be apparent that there is a tremendous need to invest in the promotion of PA, especially in children. This effort must take into account as many settings as possible including utilizing schools. Globally, children and adolescents spend a significant amount of time in school. As a result, educational settings have the potential to increase student PA making them ideal venues for conducting health promotion interventions [39-41]. Importantly, schools provide access to health promotion activities regardless of age, gender, race, or nationality. Because they are inclusive, they can include children from different backgrounds, those from lower socioeconomic strata, and racial/ethnic backgrounds without distinction.

The European Commission's Council (2013) indicates that schools are responsible for the promotion and facilitation of physically active school days. Indeed, schools cannot achieve their primary educational mission if students are not healthy and fit [42]. As a result, schools are widely considered as important institutions for the promotion of PA and fitness in children and adolescents [38].

Promotion of PA among children and adolescent should be a primary concern for schools, especially because the school setting plays not only an important role in promoting PA participation and but also in teaching children about the benefits of PA from an health point of view.

Opportunities to be physically active should not be considered purely in relation to when children attend physical education (PE) classes but also consider when children are not in school (i.e., before and after school) or during vacation time [38]. Because schools are so inclusive and can make PA education part of their curriculum, school-based interventions are likely to have better reach and avoid health inequalities.

The U.S. Centers for Disease Control and Prevention (CDC) suggest schools should invest in multicomponent programs including PE classes, making PA available during the school day, before and after school. Such programs should include properly trained staff and reinforce family/community involvement. The school setting is a key environment for PA promotion through different opportunities including PE classes, before and after school programs, recess programming, active school travel, classroom-based PA such as physically active lessons, and multicomponent physical activity interventions [43,44].

Teachers in primary and secondary schools play a fundamental role in the promotion of PA and school wellness. Their efforts can be coupled with family members and guardians all of whom can facilitate change to healthy and dynamic lifestyles. Finally, community involvement promotes the maximum use of school and community facilities within and beyond the school day [45].

Despite evidence pointing to a prominent role for schools in promoting health in particular through the promotion of PA, to date schools are mainly characterized by sedentary habits [46,47].

The American Heart Association suggests that children and adolescent should perform 30 minutes of MVPA every day during school hours; however the hours designated for PE are the only ones guaranteeing a minimum amount of PA. This, unfortunately, is insufficient to achieve both the recommended 60 minutes of MVPA per day and 30 minutes during school days, respectively [39]. Recently, Grao et al. conducted a 3-year longitudinal study designed to assess the impact of PA and sedentary behaviour on health indicators ("UP&DOWN study"). In addition, the study also identified the psycho-environmental and genetic determinants of PA in a sample of Spanish children and adolescents. The authors found that less than 10% of students spent half of recess or PE class time on MVPA [48]. Grao]

These findings comport with the recent literature suggesting that European school children spend very little school time engaged in MVPA and large amounts in SB [49-51] In the United Kingdom and Canada, primary school children spend 62%–70% of their school-time in SB and 9%–16% of their school-time in MVPA, respectively [52,53]. These and related findings suggest that the current school settings might not generate a sufficient amount of PA in children and adolescents.

2.2 School-based physical activity interventions

WHO defined school as," that place or social context in which people engage in daily activities in which the factors environmental, organizational and personal interact with each other to influence health and well-being." This means that schools should take on the onus of promoting health, a privileged setting for endowing young people with a favourable culture to health, capable of affecting their attitudes and lifestyles.

The purpose of school-based PA interventions is to increase students' ability to engage in MVPA daily while increasing the duration of weekly MVPA. The goal is for children and adolescents to reach the recommended levels of PA and achieve the indicated health benefits. School-based interventions target simultaneously children at risk and children not at risk for future chronic disease. When structured properly, they can increase both knowledge and behaviour conducive to healthier lifestyles thereby increasing the reach of these interventions [2].

During the school day there are many opportunities to increase levels of PA with numerous opportunities to engage students in different places and times. For instance, recess and lunch breaks are valuable opportunities to promote both structured and unstructured PA. Children and adolescents can be active for at least 40% of lunch-time and recess, however, some reviews have demonstrated that many young people, especially girls, spend the majority of break-time in sedentary behaviours [54,55]. Physical activity and sports activities organized by the school are valid strategies they can be offered before or after school in both competitive and non-competitive environments and are often offered in all grades of education. Promoting small dose of PA during the day is another viable strategy to increase movement and energize the brain. Such strategies include the use of energizers (i.e., short physical activity breaks conducted in the classroom) and integrating PA to assist learning in other curriculum areas (e.g., math and science) [56,57].

Schools can also offer PA opportunities before, during or after the school day as part of intramural and interscholastic sports programs. Schools can also promote initiatives such as walkability or sustainable mobility in order to improve students' PA levels. Hillis et al. propose the following summary regarding possible school-based interventions (see Table 4) [58].

Table 4. Comprehensive school physical activity program recommendations

Component	**Description and Recommendations**
Physical education	Provide 150 minutes/week of PE for elementary schools • Provide 225 minutes/week of PE for secondary schools • Students are physically active for at least 50% of PE lesson time • Provide quality PE that is enjoyable and teaches students movement and behavioural skills in PE
Physical activity during	Provide students with chances to be active during recess and lunch-time

school	• Provide playground markings, access to equipment and organized activities during break-times • Integrate physical activity into the classroom to assist learning in other curriculum areas (e.g. mathematics and science) and to break up sitting time (e.g., energizers)
Physical activity before and after school	Offer a variety of intramural activities before and after school that are both competitive and non-competitive in nature • Promote active transportation to school (i.e., walking and riding to school)
Staff involvement	Provide appropriate and on-going professional training in physical activity instruction for staff members • Provide wellness programs for staff members that encourage them to role model physical activity • Encourage staff members to be active with students in PE and school sport
Family and community engagement	Involve family member and guardians as volunteers in PE and school sport • Involve family members and guardians in evening and weekend special events • Establish joint-use and shared-use agreements with community organizations to encourage use of school facilities before and after school

Hills AP, Dengel DR, Lubans DR. Supporting public health priorities: recommendations for physical education and physical activity promotion in schools. *Prog Cardiovasc Dis*. 2015;57(4):368-374

A recent systematic review [59] examined multiple types of school-based PA-related interventions and concluded they had very little impact on overall time spent in MVPA. Likewise, the same review indicated programs also have little impact on time spent sedentary. However, new evidence is emerging with regard to specific school-based interventions that address the whole-school environment and incorporate PA throughout the school day suggesting these types of intervention may have the strongest effect on time spent in MVPA [59].

All of these factors increasingly point toward the need for an intervention that primarily involves the school staff and that is effective, feasible and sustainable over time. For this reason the aim of the following doctoral thesis is to highlight the feasibility, effectiveness and sustainability of a prospective classroom-based intervention.

3. Study 1 Evaluation of School-based Interventions involving Active Breaks in Primary Schools: A Systematic Review and Meta-Analysis

This systematic review was published in the Journal of Sport and Medicine in Science, Elsevier.

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Overview

A growing number of studies report that regular physical activity (PA) during childhood is associated with physical, mental, emotional and social health benefits [1,2]. This includes systematic reviews, which confirm the importance of Moderate to Vigorous Physical Activity (MVPA) in school-aged children in order to obtain health benefits [3,4].
Considering that children spend many hours at school, the classroom provides an ideal setting to promote children's PA, since it gives access to children regardless of age, ethnicity, gender and socio-economic status.
Since school-based PA interventions are quite numerous, the present study focused on interventions delivered during school hours and that integrate small doses of PA as part of routine instructions. As a first step, I conducted a literature review, with the intent to reinforce the existing body of knowledge in this field of study by investigating the effects of AB school-based interventions on PA levels, classroom behavior, cognitive functions, and academic performance in primary school children.

3.1 Introduction

To begin with, naturalistic observational studies have provided evidence of dose-response relations, indicating that the more PA, the greater the health benefits. Experimental studies have shown that even modest amounts of PA can have health benefits in high-risk young people (e.g., obese persons) [3]. As stated earlier, WHO recommends 60 min per day of

MVPA for children and adolescents in order to obtain health benefits; [5] however, globally, this level of PA is rarely achieved [6,7,8].

Previous systematic reviews have shown that classroom-based PA can have a positive impact on PA level [9], classroom behaviour [9,10], cognitive functioning and academic achievement [11]. Several mechanisms might explain the effects of PA on cognitive functioning and academic performance. First, acute PA causes the release of neurotransmitters, which increase physiological arousal and attention levels, consequently enhancing cognitive performance. Second, continuous aerobic PA is thought to enhance angiogenesis and neurogenesis in areas of the brain involving memory and learning functions [9,11,12]. Improvements in executive functioning and attentional processes may, in turn, be associated with better academic performance of preadolescent children [13].

Among the possible interventions to implement PA in a classroom setting, Active Breaks (ABs) has been proposed by several authors [9,10]. Active Breaks consists of 5–15 minute sessions of MVPA led by teachers who introduce short bursts of PA into the academic lesson. Active Breaks can be implemented in any school context, as the program does not require special spaces, equipment or trained personnel. Studies of ABs in school settings report high levels of sample heterogeneity, varied intervention characteristics and diffuse outcomes. As a result, the present systematic review outlines AB effects on PA levels, classroom behaviour, cognitive functioning and academic achievement of primary school children. Unlike previous systematic reviews, this includes AB interventions carried out exclusively in the classroom, as an integral part of curricular instruction. Classrooms are at the centre of school activity, where children spend considerable time sitting. All schools have classroom even those without outdoor spaces and gyms. Furthermore, the review includes only primary schools, since at this age children are more receptive to learning and adopting healthy practices and behaviours.

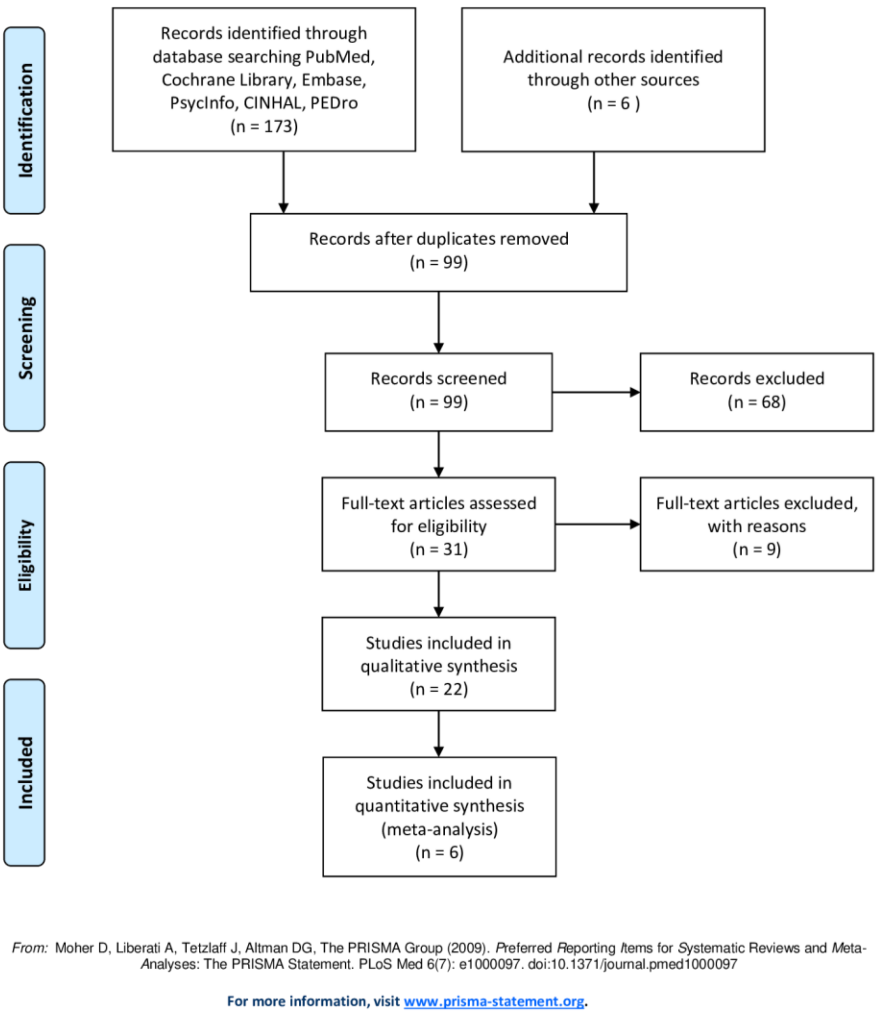
3.2 Material and Methods

The systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. The protocol is registered in the International Prospective Register of Systematic Reviews (PROS-PERO; registration no. CRD420181185 available from https://www.crd.york.ac.uk/prospero/display_record.php Record ID=118568). The following PICO (Patients, Interventions, Comparators and Outcomes) question was developed, addressing the primary search objective, through the following search terms: (P) children attending primary school, aged 6–13 years, (I) active break intervention, (C) active learning, theoretical lesson about PA or no intervention, and (O) PA levels, classroom behaviour, academic achievement and cognitive functioning. Electronic databases that were searched, with no time restriction and up to 30 April 2019, included: Medline, Cochrane Library, Embase, Psycinfo, CINHAL, and PEDro. Search strategies (strings adapted to the different databases) used the following keywords and terms: "(Active breaks OR activity break OR brain break) AND (Primary school OR elementary school) AND (Children OR Child) AND (Classroom break OR movement break OR lesson break AND (Physical activity OR Exercise)." Inclusion criteria were: 1) Articles written in English; 2) AB interventions carried out inside the classroom; 3) Study population in primary school; 4) Association between ABs and PA levels, cognitive or academic achievements or behaviour outcomes; and 5) Original primary data. Exclusion criteria included: 1) Articles not relevant to the research topic; 2) AB interventions carried out outside the classroom; 3) Kindergarten and older classroom age groups; and 4) Study protocol or other papers without original data. The review included a grey literature search for retrieving other papers and hand searches of key conference proceedings, journals, professional organizations' websites and guideline clearing houses. In accordance with this type of snowball technique, the review examines references cited in primary papers to identify additional relevant papers. In addition, the author contacted investigators and relevant study authors, seeking information about unpublished or incomplete studies [14]. Three independent and blind investigators screened and checked all the titles and abstracts retrieved in order to select pertinent items. In certain cases, where there were doubts about a study's relevance, the investigators assessed the eligibility of the study by reading the full text of the article. Two researchers then independently and blindly assessed the risk of bias, using the "Cochrane Tool for Quality Assessment" for Randomized Controlled Trials (RCTs) [15] and the "Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) tool for observational studies [16]. Any disagreement between the quality scores separately assigned by the blind reviewers was resolved through discussion and, if necessary, a third blind reviewer served as tiebreaker. The Cochrane Tool for Quality Assessment analyses seven bias categories for studies classified as RCT: (1) random sequence generation, (2) allocation concealment (concerning bias of selection and allocation), (3) selective reporting for reporting bias, (4) blinding of participants and personal (performance bias due to knowledge of the allocated intervention), (5) blinding of outcome assessment for detection bias, (6) incomplete outcomes data for bias in attrition, and another category (7) called “other bias” based on the probable bias not covered in the other categories. Each category results in a value of high, low or unclear (when the authors did not provide enough evidence about the bias category) risk of bias. The author provided a score to convert the Cochrane risk of bias tool to AHRQ (Agency for Healthcare Research and Quality) standards (Good, Fair and Poor). The STROBE statement is a 22-item tool specifically designed to evaluate the quality of observational studies. Eighteen items are the same in the three different checklists and five questions (items 6, 8, 13-15) are differently formulated for each study design: (1) Cohort study, (2) Case report study, (3) Cross sectional study. STROBE does not provide ways to clearly define a score in order to rate the quality of a study. As a general rule, the higher the score, the higher the quality of the study. The author decided to use cut-offs for three levels of scoring: 0–14 as poor quality, 15–25 as intermediate quality and 26–33 as good quality of the study [17]. First, the author conducted a descriptive analysis of the studies, focusing on the following characteristics: author, country, study design, population, type, intensity and frequency of intervention, outcomes, number of experimental (EG) and control (CG) groups, results, and stratifying studies based on their different outcomes. After this step, the author performed separate meta-analyses for the different investigated variables, including studies comparable for measurement instruments and statistical methods. If possible, the author compared values between pre-post intervention and EG vs CG. When this was not feasible, the author used only post-intervention values. The author analyzed statistical heterogeneity to test the robustness of matching the studies for meta-analysis, evaluating heterogeneity by the use of graphic forest plots and by calculating the I2 statistic, which represents the percentage of the variance in effect estimates that is caused by heterogeneity rather than by sampling bias (chance). An I2 statistic ≥50% was used as the threshold for indicating substantial heterogeneity. If the author found less than five studies analysing one topic or studies that were substantially heterogeneous, the author used a random-effects model in accordance with the Cochrane Handbook for Systematic Reviews of Interventions [18], following the method of DerSimonian and Laird to compute the random-effects estimates for the corresponding statistics [19]. The author carried out meta-analyses using the RevMan pro-gram (Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014), and computed forest plots to graphically show effect estimates with 95%CIs for the single trials selected for meta-analysis and pooled results.

3.3 Results

The author found 179 studies from the databases searched and through hand searches. Papers were published from 2002 to 2019; 80 studies were excluded because they were duplicates, and an additional 68 were excluded following abstract and/or title review. After this step, the author judged 31 records as relevant, 9 of which were subsequently excluded after a detailed full-text reading (ABs were not carried out inside the classroom and/or the monitored parameters did not match the inclusion criteria). The finally systematic review included 22 articles that fully met the eligibility criteria (Figure 1).

Figure 1 PRISMA diagram of the selection of studies



Tables 1 to 4 show the characteristics of the selected studies: six out of 22 were declared by the author as RCTs [20-25] and 16 were observational studies [26-41]. A majority of the studies were conducted in the US (n: 12, 54.5%), with a smaller number conducted in the UK and Canada (both with n:2, 9.1%), and even fewer conducted in Australia, Germany, Macedonia, Netherland, Poland and Switzerland (all represented by n: 1, 4.5%). The sample sizes for the different studies varied from a low of 21 children [31] to 4599 children [25]. Ages of the children ranged between 6 and 12 years. The AB time ranged from 3–5 minutes [21,36,39] to a maximum of 20 minutes, [34] with a total dose varying from 10 minutes a week [22,28,41] to 30 minutes a day [20,35]. In most of the studies the overall daily time dedicated to ABs was 10–15 minutes. Among the 22 studies, the author identified 4 domains in relation to the specified outcomes. Many studies analyzed multiple outcomes, and thus were included in several of the following four primary outcomes: 1) Physical Activity outcomes: 11 studies (50.0%), 2) Classroom Behaviour outcomes: 11 studies (50.0%), 3) Cognitive Functioning outcomes: 5 studies (22.7%), and 4) Academic Achievement outcomes: 4 studies (18.1%). Table 1 reports the main characteristics and results of the studies with PA level as the primary outcome, stratified into three secondary outcomes: "MVPA levels" monitored with accelerometers [20,23,24,25,27], "Step count" monitored with accelerometers or pedometers [22,28,29,38,41], and "Performance/fitness levels" measured with standardized fitness test and/or self-administered questionnaires [23,35,41]. Three of these studies included BMI as additional outcome [20,23,35]. Of the five studies investigating MVPA levels, three reported statistically significant improvements, in terms of total MVPA (after AB interventions lasting from 9 to 24 weeks). In particular, one study evaluated the pre-post changes in the EG [27] and two compared the MVPA differences between EG and CG [20,23]. Whitt-Gloveret al. found, after an 8-week intervention with a control group that performed the same intervention three months later, increasing percentages of MVPA and LMPA (Light to Moderate Physical Activity) with significant differences between EG and CG only for LMPA ($p < 0.05$) [25].

Watson et al. found the same trend of increasing MVPA after a 6-week intervention, but without significant differences between EG and CG [24]. Drummy et al. found that time spent in MVPA increased also during the weekend, showing an effect of AB intervention on out of school activities [20]. Of the five studies investigating the steps count, three reported statistically significant improvements in EG compared with CG, following an intervention lasting five days, 12 weeks [38], and 9 months [28], respectively. Among these studies, Erwin et al. were the only investigators who monitored results three months post-intervention, finding an improvement in step count in the subsequent follow-up. The same authors also compared results in relation to the teacher's compliance, showing that children who were managed by high fidelity teachers significantly improved their steps count, in contrast with classrooms led by teachers less adherent to the AB intervention (i.e., low vs. high fidelity) and with CG ($p < 0.01$) [28].

Fedewa et al. compared steps count between two AB groups, one with only AB exposure and one with AB exposure combined with academic exercises. The authors reported that children with only ABs increased their steps count over time, compared to children with ABs + academic exercises in movement ($p < 0.01$)[29]. Stewart et al. examined the effect of ABs in relation to children's age (school grades: 1,3,5), showing that steps count increased with age [41]. Three studies analysed the effect of AB interventions on performance/fitness levels, including energy consumption parameters. Katz et al. observed an improvement in terms of abdominal, upper limbs and trunk extensors strength, with significant differences in EG compared with CG following a 6-month AB intervention of 30 minutes a day ($p < 0.001$)[35]. van den Berg et al., after a 9-week intervention with 10 minutes of AB/day, found no significant differences between EG and CG in aerobic capacity (Vo2max) and self-perception profile (athletic component) [23]. Stewart et al. compared energy consumption during a 5-day intervention of 10–11 minutes a day, in children of different school grades (1,3,5). Although older children consumed more Kcals, the total energy expenditure was similar (from 6.2 to 6.4 METs), with little evidence of age differences [41].

Three of the studies examining PA as an outcome also took into account BMI changes. The AB interventions, lasting, respectively 9 weeks [23] and 12 weeks [20], did not significantly alter the children's BMI, while Katz et al., after a 9-month intervention, observed a significant, small and counterintuitive decrease of BMI in the CG ($p < 0.05$) [35]. Table 2 reports the main characteristics and results of studies with classroom behaviour as an outcome, evaluated by different tools: seven out of 11 studies used the "Time on Task" (TOT) observation technique (http://ug-pal.weebly.com/time-on-task.html) that measures the average time in which students are engaged or not in learning, during a lesson [24,25,30,32,33,36,38]. Two studies [21,39] used the APAS questionnaire to measure the child's attitudes, beliefs, and self-efficacy toward PA [42]. The remaining two studies used non-standardized scales: one based on a brief teacher survey [27], and the other based on annual reports of the school (Independent School District ISD work social skills tool)[35]. The majority of these studies reported that the proposed AB interventions significantly improved classroom behaviour in EG compared with CG.

Grieco et al. compared two EGs distinguished by PA levels (MVPA and LMPA) with two CGs, one engaged in game activity and one attending a standard lesson, finding that the EGs significantly increased the TOT, compared to the CGs [33]. Grieco et al. analysed TOT pre-post changes by BMI category, showing that BMI did not interact with TOT in the active condition (EG), while, in the inactive condition (CG), time spent on task was reduced as the BMI increased [32]. Only Katz et al. did not report significant differences between EG and CG in classroom behaviour after AB intervention [36]. Table 3 reports the main characteristics and results of the five studies with cognitive functioning as an outcome. Four studies [23,25,37,40] tested children's' attention function using the d2 test, which assesses five components: processing speed, focused attention, concentration performance, attention span and accuracy [43]. Only two studies found a positive effect of AB intervention in most of the d2 components, [26,37] while van den Berg et al. did not observe any significant interaction [23]. Interestingly Schmidt et al., compared a CG with three different EGs, one group with only ABs, one with combined ABs and cognitive exercises, and one with only cognitive exercises. The authors concluded that cognitive engagement, and not ABs, was the crucial factor to increase focused attention and enhance processing speed [40]. van den Berget al. used the Fluency task tool, as proposed by Mulder et al. [44] to test the effect of AB on semantic memory retrieval performance, children's inhibitory performance (using the Stroop Color-Word Task) [45] and three attentional networks including alerting (i.e., achieving and maintaining an alert state), orienting (i.e., selection of information from sensory input), and executive control (i.e., resolving conflict among responses) using the short version of the Attention Network Task. [46,47]. The authors did not find intervention effects on any of these cognitive performance tests [23]. Howie et al. tested the executive functions by the Trail Making Test (TMT) [48] and working memory by the Digit Recall Test [49] in relation to the duration of ABs (5, 10, 15 min). The authors found that executive function and working memory did not significantly change in any duration of AB groups and CG [34]. Table 4 reports the main characteristics and results of the four studies with academic achievement as an outcome, particularly Math and Reading abilities, using different standardized tools to assess Math skills (Westwood One Minute Test [50], Timed Math Test [51], Fast Bridge Learning Math Test [52]), and Reading (Fast Bridge Reading Standardized Assessment [52], and Wheldall Assessment of ReadingTest [53]). Two of these studies reported no intervention effects for math and reading skills [24,31]. Fedewa et al. found a significant improvement only in reading scores for the AB group compared with the academic AB group, depending, however, on school grade [29]. Howie et al. found that the math scores were higher in the groups engaged in ABs lasting at least 10 and 20 minutes, compared with the CG [34].

Table 1 Studies included in the review: physical activity outcomes.

Study	Country	Study design	Intervention	Outcomes	Sample	Results
Carlson et al., 2015 (27)	Montana, USA	Cohort	Active breaks, 10 min, every day, 24 weeks	MVPA (accelerometer)	EG: 1192 No CG mean age: 8.8 ±1.5	Pre-post changes in EG EG**:** +2.3 min/day spent in MVPA, p<0.01
Drummy et al., 2016 (20)	Ireland, UK	RCT	Active breaks, 10 min, 3 per day, 12 weeks	MVPA (accelerometer) BMI	N: 107 EG: 54 CG: 53 age: 9-10	Pre-post changes, EG *vs* CG **MVPA**: EG **(**+9.9 min/day) *vs* CG (-0.5 min/day), p<0.05 **BMI**: EG (-0.1) vs CG (0), no significant differences
van den Berg et al., 2019 (23)	Netherlands	RCT	Active breaks ("Just Dance"), 10 min, every day, 9 weeks	MVPA (accelerometer)	N: 312 EG: 144 CG: 168	Pre-post changes, EG *vs* CG **MVPA** differences at follow up: EG (23.8 min/day) *vs* CG (20.6 min/day), p<0.05
				Performance / fitness (Shuttle run	N: 512 EG: 263 CG: 249	**Performance/fitness level** Vo2max: EG (+0.9

				test, Harter's self-perception profile questionnaire)		ml/Kg/min) *vs* CG (+0.7 ml/Kg/min), no significant differences Self-perception profile (athletic): no significant differences
				BMI	N: 488 EG: 250 CG: 238 age: 9-10	**BMI** No significant differences between EG and CG
Watson et al., 2019 (24)	Australia	RCT	Active breaks, 5 min, 3 per day, 6 weeks	MVPA (accelerometer)	N: 289 EG: 90 CG: 199 age: 8-10	Pre-post changes, EG *vs* CG Linear regression analysis revealed no significant improvement in MVPA following AB intervention
Whitt-Glover et al., 2011 (25)	California, USA	RCT	Active breaks 10 min, every day 8 weeks	MVPA LMPA (accelerometer)	N: 4599 EG: 4 schools CG: 3 schools age: grade 3, 4, 5	Pre-post changes, EG *vs* CG MVPA: EG (+16%), no significant differences LMPA: EG (+51%), $p<0.05$
Erwin et al., 2011 (28)	Kentucky, USA	Cohort	Active breaks 10-15 min, every day, 9 months	Step count (pedometer)	N: 106 EG divided in 2 groups by compliance of teacher CG	Pre-post changes, EG *vs* CG EG-compliant teacher (steps: + 841) *vs* EG-no compliant teacher (steps: -145) *vs* CG (steps: -237), $p<0.01$

					mean age 10.1±0.9	Improvements were maintained at a distance of 3 months from the end of the intervention (post follow-up)
Fedewa et al., 2018 (29)	Kentucky, USA	Cohort	1st group: Only active breaks, 2nd group: Academic based movement breaks 10 min, every day 9 months	Step count (pedometer)	N: 460 EG-active breaks: 284 EG-academic movement breaks: 176 age: grade 3, 4, 5	Pre-post changes between two different intervention groups Multilevel-growth model analysis revealed gains in step count with small to moderate effect size (0.33) in children with only active breaks, compared with those with academic-based movement breaks, p<0.01
Mahar et al., 2006 (38)	North-Carolina, USA	Cohort	Active breaks ("Energizers") 10 min, every day, 12 weeks	Step count (pedometer)	N: 243 EG: 135 CG: 108 mean age: 9.1±0.9	Differences at follow up, EG *vs* CG EG (5587 steps) *vs* CG (4805 steps), p<0.05 Moderate effect size: 0.49
Murthag et al., 2013 (22)	Ireland, UK	RCT	Active breaks, 10 min, every day, 5 days	Step count (pedometer)	N: 90 EG: 39 CG: 51 mean age: 9.3±1.4	Pre-post changes, EG *vs* CG EG (-297 steps) *vs* CG (-1222 steps), p<0.05

Stewart et al., 2004 (41)	Netherlands	Cohort	Active breaks ("Take ten") 10-11 min, every day, 5 days	Step count (accelerometer) Performance / fitness (accelerometer)	N: 71 divided in 3 groups by school grade EG-grade1 EG-grade3 EG-grade5 age: grade 1, 3, 5	Comparison between school grades at follow up **Steps:** EG-grade1 (2931 steps) *vs* EG-grade3 (3443 steps) *vs* EG-grade5 (3872 steps) **METs** EG-grade1 (6.42 METs, 25 Kcal) *vs* EG-grade3 (6.16 METs, 31 Kcal) *vs* EG-grade5 (6.20 METs, 37 Kcal)
Katz et al., 2010 (35)	Connecticut, USA	Cohort	Active breaks, ("ABC for fitness") 10 min, 3 per day, 6 months	Performance / fitness (Strength Test Battery, Vo2max) BMI	N: 1116 EG: 611 CG: 505 age: grade 2, 3, 4	Pre-post changes, EG *vs* CG **Performance/fitness level** Abdominal strength: EG (+9 curl-ups) *vs* CG (no change in repetitions of curl-ups), $p<0.001$ Trunk extensor strength EG (+1 trunk lifts) *vs* CG (+1 trunk lifts), $p<0.001$ Upper body strength: EG (+2

						push ups) *vs* CG (no change in repetitions of push ups), p<0.001 Aerobic capacity: Vo2max EG *vs* CG, no significant differences **BMI** EG (+0.3) *vs* CG (-0.1) p<0.05

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Table 2 Studies included in the review: Classroom behaviour outcomes.

Study	Country	Study design	Intervention	Outcomes	Sample	Results
Carlson et al., 2015 (27)	Montana, USA	Cohort	Active breaks, 10 min, every day, 24 weeks	Classroom behaviour (teacher-brief survey)	EG: 397 No CG Mean age: 8.8±1.5	Pre-post changes in EG Teacher reported fewer students who lacked effort or gave up easily, p<0.05. Classroom with more MVPA (evaluated on 97 children) reported fewer students who were off task or inattentive p<0.05
Glapa et al., 2018 (21)	Poland	RCT	Active breaks ("Brain Brake" with a video of exercises), 3-5 min, 2 per day, 4 months	Classroom behaviour (APAS questionnaire)	N: 326 EG: 264 CG: 62 mean age: 9.7±1.1	Pre-post changes, EG *vs* CG Significant "Time" interaction effects for the "Training to do personal best" scale of APAS, p<0.05 Significant "Time per Group" interaction effects in "Self-efficacy on learning

						with video exercises" scale of APAS, p<0.001
Goh et al., 2016 (30)	Massachusetts, USA	Cohort with cross-over sample	Active breaks ("Take 10"), 10 min, every day, 12 weeks	Classroom behaviour (TOT: Time on Task)	N: 210 EG: 210 CG: 210 age: grade 3, 4, 5	Pre-post changes, EG *vs* CG EG (TOT: +7.2), p<0.01 CG (TOT: -7.7), p<0.01 EG *vs* CG, p<0.05
Grieco et al., 2009 (32)	Texas, USA	Cohort	Active breaks, 10-15 min, one lesson observation	Classroom behaviour (TOT: Time on Task)	N: 97 EG and CG divided by BMI categories mean age: 8.7±0.4	Three-way analysis: pre-post x groups (EG and CG) x BMI category Pre-post TOT decreased in the inactive condition, p<0.001. Pre-post TOT increased slightly in the active condition, p>0.10 Pre-post TOT changes decreased with each level of BMI (normal weight: -0.39, at risk: -0.68, overweight: -1.28) in inactive condition (p<0.01), while BMI did not interact with TOT in active condition
Grieco et al., 2016 (33)	Texas, USA	Cohort	Active breaks, 10-15 min, one lesson observation	Classroom behaviour (TOT: Time on Task)	N: 316 EG-MVPA: 76 EG-LMPA: 81 CG-game: 87 CG-lesson:	Pre-post changes between groups Pre-post TOT decreased in the CG-lesson (-15,3, p<0.001, effect size: -0.61) Pre-post TOT did not significantly change in the CG-game (+1,5, p: 0.68, effect size: 0.06) Pre-post TOT increased in EG-LMPA (+10.3, p<0.01, effect size: 0.43) and in EG-

					72 age: 7-12	MVPA (+26,5, p<0.001, effect size: 1.22)
Katz et al., 2010 (35)	Connecticut, USA	Cohort	Active breaks ("ABC for fitness"), 10 min, 3 per day, 6 months	Classroom behaviour (ISD work social skills)	N: 1140 EG: 606 CG: 534 age: grade 2, 3, 4	Pre-post changes, EG *vs* CG No significant differences between EG and CG in classroom behaviour
Ma et al., 2014 (36)	Canada	Cohort, with cross-over sample	Activity breaks (“FUNtervals”), 4 min, every day, 3 weeks	Classroom behaviour (TOT: Time on Task)	N: 44 EG: 44 CG: 44 age: grade 2, 4	Pre-post changes, EG *vs* CG The grade 4 improved in both passive (p<0.05) and motor (p<0.01) components of TOT The grade 2 improved in passive (p<0.01, effect size:0.74), verbal (p<0.05, effect size:0.45) and motor (p<0.01, effect size:1.08) components of TOT Students with high rates of off task behavior showed greater improvements
Mahar et al., 2006 (38)	North-Carolina, USA	Cohort with cross-over sample	Active breaks, ("Energizers") 10 min, every day, 12 weeks	Classroom behaviour (TOT: Time on Task)	N: 62 age: 9.1±0.9	Pre-post changes, EG *vs* CG EG (TOT: +8.30), p<0.05 CG (TOT: -0.40) no significant differences
Popeska et al., 2018 (39)	Macedonia	Cohort	Active breaks (“Brain Breaks”), 3-5 min, every day, 3 months	Classroom behaviour (APAS questionnaire)	N: 283 EG: 152 CG: 131 mean age: 9.2±1.0	Pre-post changes, EG *vs* CG Significant “Time” interaction effects for all the components of APAS, p<0.01. Significant “Time per Group” interaction effects

						for the "Promoting holistic health" and "Knowledge and self-awareness for individual application of Brain Break" components of APAS, p<0.01
Watson et al., 2019 (24)	Australia	RCT	Active breaks, 5 min, 3 per day, 6 weeks	Classroom behaviour (TOT: Time on Task)	N: 226 EG: 70 CG: 156 age: 8-10	Pre-post changes, EG *vs* CG At the individual level, pre-post TOT increased in the intervention group with large improvement observed for boys. At the group level, there was no intervention effect on classroom behaviour
Whitt-Glover et al., 2011 (25)	California, USA	RCT	Active breaks, 10 min, every day, 8 weeks	Classroom behaviour (TOT: Time on Task)	N: 4599 EG: 4 schools CG: 3 schools age: grade 3, 4, 5	Pre-post changes, EG *vs* CG EG (TOT: +11%) *vs* CG (no changes), p<0.05

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Table 3 Studies included in the review: Cognitive outcomes.

Study	Country	Study design	Intervention	Outcomes	Sample	Results
Buchele Harris et al., 2018 (26)	Michigan, USA	Cohort	Active breaks (CBPA group active break coordination) , 6 min, every day, 4 weeks	Cognitive function (d2 test of attention)	N: 121 EG-CBPA: 31 EG-Fitbit: 29 CG: 56 age: grade 5	Pre-post changes, EG *vs* CG EG-CBPA showed significant improvement in processing speed (p<0.01), focused attention (p<0.01), concentration performance (p<0.0001) and attention span (p<0.0001) compared with CG. EG-CBPA showed significant improvement in concentration

						performance (p<0.0001) and attention span (p< 0.05) compared with EG-Fitbit (this group was not engaged in AB, but wore a Fitbit as well as the EG-CBPA) No significant changes in all five attention domains of d2 test were found between EG-Fitbit and CG.
Howie et al., 2015 (34)	South Carolina, USA	Cohort	Active breaks ("Brain BITES") 5,10,20 min, 2 per week, 4 weeks	Cognitive function (TMT: Trail Making test, Operational Digit Recall Test)	N: 96 divided in: EG-5min EG-10min EG-20min CG age: 9-12	Pre-post changes, EG *vs* CG The executive function (TMT) and the working memory (digit recall test) did not significantly change in any durations of AB and CG Working memory interacted with BMI (p<0.01): students with lower BMI improved after 20 min intervention, while students with higher BMI decreased performance after 5 min intervention
Ma et al., 2015 (37)	Canada	Cohort whit cross-over sample	Active breaks "FUNtervals", 4 min, every day, 3 weeks	Cognitive function (d2 test of attention)	N: 88 EG: 88 CG: 88 age: 9-11	Pre-post changes, EG *vs* CG All domains of d2 test improved, especially from week 1 and week 2, p<0.05. Analysis by Time off Task (TOT) categories (motor, verbal, passive) revealed that neither motor or passive behaviour predicted changes in selective attention following the intervention. A week relationship was observed in verbal TOT category
Schmidt et al., 2016 (40)	Switzerland	Cohort	Active breaks, 10 min, every day one lesson observation	Cognitive function (d2-R test of attention)	N: 92 EG-AB+cognitive: 25 EG-cognitive: 22 EG-AB:	Pre-post changes, EG *vs* CG Cognitive engagement (EG-AB+cognitive, EG-cognitive) was the crucial factor to increase focused attention and to enhance processing speed

					25 CG: 20 age: 11.8±0.4	
van den Berg et al. 2019 (23)	Netherlands	RCT	Active breaks ("Just Dance"), 10 min, every day, 9 weeks	Cognitive function (d2 test of attention, Fluency Task, Stroop Color-Word Task, Attention Network Task	N: from 448 to 467 in relation to different cognitive tests used age: 9-12	Pre-post changes, EG *vs* CG There were no intervention effects on children's cognitive performance and no significant differences between EG and CG in any of the investigated cognitive outcomes

Masini A, et al. Evaluation of school-based interventions of active breaks in primary schools: A systematic review and meta-analysis. J Sci Med Sport. 2020;23(4):377-384. doi:10.1016/j.jsams.2019.10.008

Table 4 Studies included in the review: Academic achievement outcomes.

Study	Country	Study design	Intervention	Outcomes	Sample	Results
Fedewa et al., 2018 (29)	Kentucky, USA	Cohort	1st group: Only active breaks, 2nd group: Academic based movement breaks, 10 min, every day 9 months	Academic achievement (FastBridge learning Math, Reading standardized assessment)	N: 460 EG-active breaks: 284 EG-academic movement breaks: 176 age: grade 3, 4, 5	Comparison between two interventions at follow up Math achievement: no statistical differences were found between children with only active breaks and those with academic based movement breaks Reading achievement: highest score for EG-active breaks (p<0.01) depending by school grade.
Graham et al., 2014 (31)	Colorado, USA	Cohort	Active breaks during math lesson ("Jump in Math"), 10 min, one lesson observation	Academic achievement (Short quiz on Math material covered during the lesson)	N: 21 EG: 13 CG: 8 age: grade 2	Pre-post changes, EG *vs* CG No difference in performance on the Math quiz or in reported attention or fun during the day lesson. EG was significantly more

						interested (p<0.05) and rated themselves more alert (p<0.005) compared with CG.
Howie et al., 2015 (34)	South Carolina, USA	Cohort	Active breaks ("Brain BITES"), 5, 10, 20 min, 2 per week, 4 weeks	Academic Achievement (Timed Math Test)	N: 96 divided in 4 groups: EG-5min EG-10min EG-20min CG: 96 age: 9-12	Pre-post changes, EG *vs* CG Math scores were higher after the 10-min and 20-min AB, compared with the sedentary condition (effects sizes: 0.24, p<0.05, and effects sizes 0.27, p<0.005, respectively) An interaction was observed with gender (higher score in girls) and aerobic fitness (score increased with fitness).
Watson et al., 2019 (24)	Australia	RCT	Active breaks, 5 min, 3 per day 6 weeks	Academic achievement (Westwood One Minute Test, Wheldall Assessment of Reading Passage Test)	N: 341 EG: 123 CG: 218 age: 8-10	Pre-post changes, EG *vs* CG Linear regression analysis revealed no significant improvement in Math and Reading

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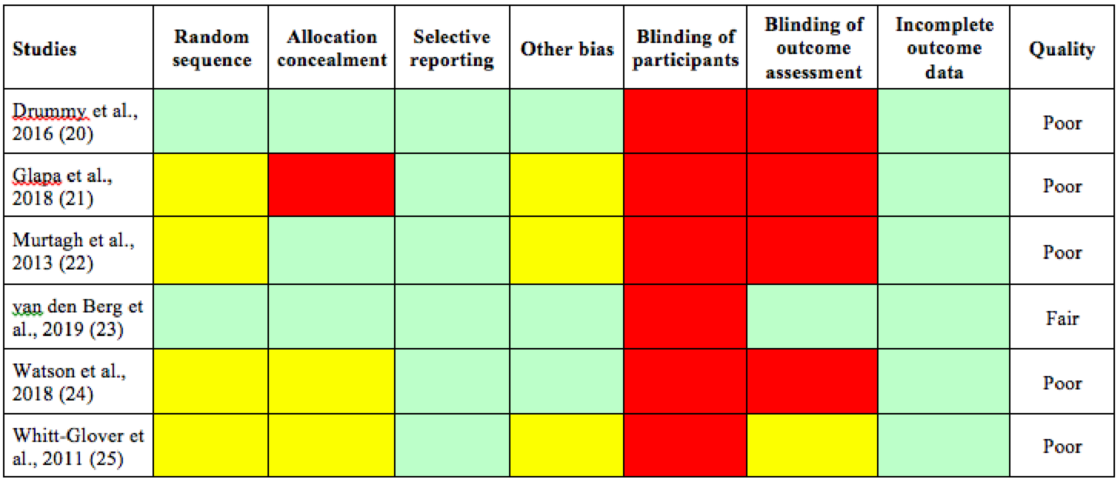
Following the descriptive analyses, we assessed the quality of each study differentiating RCTs from observational studies. In accordance with the Cochrane Tool for Quality Assessment, the six studies classified as RCTs scored a quality level from Poor to Fair (Figure 2): Five studies resulted of Poor Quality and one of Fair Quality (Table 5). Most of the studies do not explain in sufficient detail the randomization or allocation of participants (items #1 e #2) and none of the studies match the blinding of participants criterion (item #5). This is a main factor contributing to the diminishment of study quality. This limitation derives from the nature of the intervention. Since the interventions involve classroom-based ABs, with instruction carried out by the teachers, this results in the inability to blind operators and participants. However, even excluding item #5 in the assessment procedure and calculating an adjusted quality assessment using the six remaining items, the overall

Figure 2 RCTs scored.



Legend green: criterion met, yellow: criterion unclear, red: criterion not met

quality of the studies improves only slightly, one study resulting in a rating of high quality, one with fair quality, and four with poor quality (Figure 2).

In keeping with the STROBE tool, 12 out of 16 observational studies obtained an intermediate rating, three a good rating and one a poor quality score (Table 5). The main weaknesses noted included: lack of description of the study design and the absence of adequate power analyses. Furthermore, some studies did not report exactly the number of participants for each analysed outcome and present various gaps in the data description.

Table 5 Quality assessments of RCTs and observational studies.

Authors	**Study design**	**Tool for assessment**	**Quality**
Drummy et al., 2016 (20)	RCT	Cochrane ROB Tool	Poor
Glapa et al., 2018 (21)	RCT	Cochrane ROB Tool	Poor
Murtagh et al., 2013 (22)	RCT	Cochrane ROB Tool	Poor
Van den Berg et al., 2019 (23)	RCT	Cochrane ROB Tool	Fair
Watson et al., 2019 (24)	RCT	Cochrane ROB Tool	Poor
Whitt-Glover et al., 2018 (25)	RCT	Cochrane ROB Tool	Poor
Buchele Harris et al., 2018 (26)	Cohort	STROBE	Intermediate (23/33)

Carlson et al., 2015 (27)	Cohort	STROBE	Intermediate (22/33)
Erwin et al., 2011 (28)	Cohort	STROBE	Intermediate (22/33)
Fedewa et al., 2018 (29)	Cohort	STROBE	Intermediate (18/33)
Goh et al., 2016 (30)	Cohort	STROBE	Intermediate (22/33)
Graham et al., 2014 (31)	Cohort	STROBE	Low (14/33)
Grieco et al., 2009 (32)	Cohort	STROBE	Intermediate (24/33)
Grieco et al., 2016 (33)	Cohort	STROBE	Intermediate (25/33)
Howie et al., 2015 (34)	Cohort	STROBE	Intermediate (23/33)
Katz et al., 2010 (35)	Cohort	STROBE	Good (26/33)
Ma et al., 2014 (36)	Cohort	STROBE	Intermediate (22/33)
Ma et al., 2015 (37)	Cohort	STROBE	Intermediate (20/33)
Mahar et al., 2006 (38)	Cohort	STROBE	Poor (19/33)
Popeska et al., 2018 (39)	Cohort	STROBE	Intermediate (20/33)
Schmidt et al., 2016 (40)	Cohort	STROBE	Good (26/33)
Stewart et al., 2004 (41)	Cohort	STROBE	Poor (14/33)

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Moreover, the studies were quite heterogeneous in design and differed in outcomes, assessment strategies and statistical analyses. As a result, only 6 out of 22 studies could be included in the meta-analysis, three RCTs [20,22,23] and three observational studies [28,33,38]. Of these, two studies were meta-analysed for “MVPA,” three for “Steps count,” using follow-up results, and two for “Time on Task” using pre-post change as the outcome (Table 2). With respect to the PA outcomes, the meta-analysis findings showed an average, but not statistically significant, increase in terms of total time spent in MVPA in EG compared to CG at follow-up ($p = 0.06$, 95%CI −0.15, 8.74, random model I2 = 38%) (Figure 3A). the same meta-analysis showed a significant improvement in terms of steps count at follow-up for the EG compared with the CG ($p < 0.00001$, 95%CI 0.71, 1.21, random model I2 = 0%) (Figure 3B). With respect to classroom behaviour outcomes, meta-analysis of two studies showed a small but not statistically significant increase in TOT spent by the EG children, compared with the CG, in the pre-post observations ($p = 0.08$, 95%CI −2.76, 55.06, random model I2 = 100%) (Figure 3C). However, the meta-analysis results should be taken with caution due to the small number and poor quality of the studies included.

Table 6 Meta-analytic results with effect estimate of the active breaks intervention on physical and classroom behaviour outcomes

Outcomes	**Studies**	**Participants**	**Statistical Method**	**Effect Estimate**	**p-value**	**I^2**
MVPA: EG *vs* CG	2	419	Mean Difference (IV, Random, 95% CI)	4.29 [-0.15, 8.74]	0.06	38 %
Step count: EG *vs* CG	3	545	Mean Difference (IV, Random, 95% CI)	0.96 [0.71, 1.21]	<0.000 01	0%
Time on Task: EG *vs* CG	2	272	Mean Difference (IV, Random, 95% CI)	26.15 [-2.76, 55.06]	0.08	10 0%

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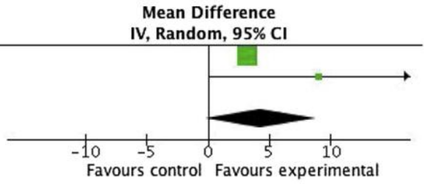
Figure 3 Meta-analysis results related to different outcomes: (A) MVPA, (B) Step count, (C) Time on Task (TOT).

A

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Van den Berg 2019	23.8	0.6	168	20.6	0.7	144	81.2%	3.20 [3.05, 3.35]
Drummy 2016	68.2	25.8	54	59.2	21.4	53	18.8%	9.00 [0.03, 17.97]
Total (95% CI)			**222**			**197**	**100.0%**	**4.29 [−0.15, 8.74]**

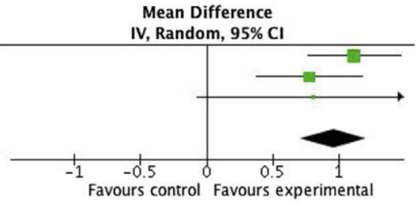
Heterogeneity: Tau² = 6.33; Chi² = 1.60, df = 1 (P = 0.21); I² = 38%
Test for overall effect: Z = 1.89 (P = 0.06)



B

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Erwin 2011 (1)	3.317	1.592	106	2.195	0.919	106	52.1%	1.12 [0.77, 1.47]
Mahar 2006 (2)	5.587	1.633	135	4.805	1.543	108	39.7%	0.78 [0.38, 1.18]
Murtagh 2013 (3)	5.054	2.199	39	4.246	2.008	51	8.2%	0.81 [−0.08, 1.69]
Total (95% CI)			**280**			**265**	**100.0%**	**0.96 [0.71, 1.21]**

Heterogeneity: Tau² = 0.00; Chi² = 1.69, df = 2 (P = 0.43); I² = 0%
Test for overall effect: Z = 7.46 (P < 0.00001)

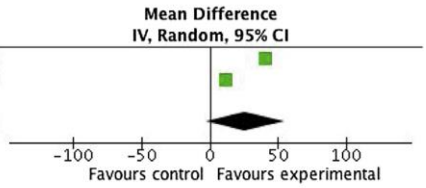


Footnotes
(1) The results were divided by 1000 to simplify the graphic representation
(2) The results were divided by 1000 to simplify the graphic representation
(3) The results were divided by 1000 to simplify the graphic representation

C

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Grieco 2016	26.5	4	76	−14.4	3.2	72	50.0%	40.90 [39.74, 42.06]
Mahar 2006	8.3	3.8	62	−3.1	1.8	62	50.0%	11.40 [10.35, 12.45]
Total (95% CI)			**138**			**134**	**100.0%**	**26.15 [−2.76, 55.06]**

Heterogeneity: Tau² = 434.81; Chi² = 1364.22, df = 1 (P < 0.00001); I² = 100%
Test for overall effect: Z = 1.77 (P = 0.08)



3.4. Discussion

This systematic review expanded upon two recently conducted reviews by addressing more specifically whether ABs carried out only in a classroom setting in primary schools have favourable effects. This approach is quite different from previous studies, which did not restrict their analyses to primary school classroom settings. There is no standard definition for classroom-based PA interventions [9,10]. According to Watson et al. [10] they can take three forms: active breaks, curriculum-focused active breaks, and physically active lessons. The systematic search of the literature found 22 studies assessing the effect of AB interventions on PA levels, children's' classroom behaviour, cognitive functioning and academic achievement. Unlike the review by Watson et al. that examined classroom-based PA interventions, and which found no effect on PA levels [10], most of the studies included in the current review reported significant improvements in terms of MVPA and steps count in children participating in AB interventions. Lasting effects were obtained with the most intense (10 minutes three times/day for 12 weeks) [20] or longer (10–15 minutes once/day for 9 months) interventions [28], showing respectively a significant increase in time spent in MVPA even outside school hours, and in steps count three months post- intervention. These results are in line with the most recent review by Daly-Smith et al., which found that classroom movement breaks and physically active learning increased PA levels [9]. The current meta-analysis indicates a consistent trend, showing an increase in PA, particularly in the number of steps taken. Regarding classroom behaviour outcomes, the majority of studies found an improvement following children's' participation in ABs, and this finding comports with both recent reviews [48,49]. Most studies assessed children's behaviour through the time spent on task (TOT) during lessons and found a positive relation between increasing physical engagement and TOT. These results, confirmed by a very recent study not included in this review [54], can be explained by the capacity of PA to energize children who have difficulty in maintaining concentration during the classroom academic routine. The use of PA interspersed with classroom activity would appear to benefit teaching activity [10,54]. However, the effects of AB on cognitive outcomes are not as conclusive. This finding should be contrasted with a recent review, which found a positive effect of acute PA programs on attention and executive functions [11]. Several possible explanations may account for the different findings including the use of different assessment measures, the duration and also type (with or without cognitive engagement) of AB interventions. Chang et al. conducted a meta-analysis and reported an activity threshold of ≥20 min of MVPA for enhanced cognition. In the current review, almost no AB intervention reached or exceeded 20 minutes [13]. Schmidt et al. suggest that cognitively engaging PA is more beneficial for cognitive functioning than aerobic PA alone [55]. In line with Daly Smith's review, the current review found that ABs have limited or no impact on academic achievement outcomes. This stands in contrast to Watson et al. who found that classroom-based PA interventions led to improvements when a progress monitoring tool was used [10]. Differences in findings may be due to the different classroom-based PA interventions included in systematic reviews. The effect on academic achievement could potentially be more evident in curriculum-focused active breaks and physically active lessons that integrate key learning aspects and reinforce previous lesson content. ABs can be easily introduced in the context of primary school lessons, demonstrating the feasibility and sustainability of a novel tool to increase PA during classroom instruction [31,56]. However, the effect of these programs depends on the teacher's adherence to program content [28]. In this respect, efforts should be made to make teachers more aware of the importance of PA interventions in the school context, considering the advantages not only in terms of movement, but also in terms of classroom learning and students' behaviour. Compared to other types of school-based PA interventions, widely described in the literature and equally effective in improving the motor habits of children [57-59], ABs offer the advantage of being implemented by the class teacher who, in an educational context, is able to calibrate the lesson material according to their teaching requirements as well as the students' needs, choosing when and how to introduce PA breaks.

There are several limitations in the current study worth noting. First, in most of the RCT studies there was limited information regarding the methodology used for randomization schemes and allocation concealment. Consequently, the bias rating was somewhat higher and may have lowered the quality of the analyses. Furthermore, no RCT reported the strategy adopted in order to blind participants. Although using blinding methods in school settings is somewhat complicated, this contributes to performance bias and reduces the quality of the RCTs included in the review. Finally, there was considerable heterogeneity across the different studies included in the review including substantial variation in study design, type of intervention, outcomes assessed and type of analyses used to detect intervention effects. Considering all of these limitations, only a small number of studies were eligible for inclusion in the meta-analyses, suggesting that the final results should be taken with caution. The limitations noted here as well as evidence from other reviews [9,10] suggest it is of paramount importance that future studies adopt more rigorous methodologies and utilize more standardized and validated measures, including comparable outcomes and statistical analyses.

4. Study 2 Active Breaks: A Pilot and Feasibility Study to Evaluate the Effectiveness of Physical Activity Levels in a School-Based Intervention conducted in an Italian Primary School

This Pilot and feasibility study was published in the International Journal of Environmental Research and Public Health:

Masini A, Marini S, Leoni E, et al. Active Breaks: A Pilot and Feasibility Study to Evaluate the Effectiveness of Physical Activity Levels in a School Based Intervention in an Italian Primary School. *Int J Environ Res Public Health*. 2020;17(12):4351. doi:10.3390/ijerph17124351.

Keywords: accelerometers; children; moderate to vigorous physical activity; school-based intervention.

Overview

The results of the systematic review fuelled development of an AB exercise protocol. The author tested the protocol in a pilot study with the aim of analysing its efficacy, feasibility and sustainability when an AB intervention is introduced to primary school children.

4.1 Introduction

An accumulation of scientific evidence continues to support the importance of physical activity (PA) for disease prevention and health promotion in children and youth [1]. Added to this growing body of knowledge, evidence is accumulating showing that sedentary behaviours, defined as any waking behaviours characterized by an energy expenditure of 1.5 metabolic equivalents (METs; 1 MET = rest), both in sitting and lying posture, [2] may have detrimental health consequences from adolescence onward, depending on the type of sedentary behaviour and the age group studied [3]. In their systematic review, Cliff et al. (2016) stated that, while the evidence of a negative association between objectively measured sedentary time and health outcomes is still inconsistent, there is strong evidence that screen time is associated with negative health-related outcomes in children [4]. To reduce the risk of metabolic and cardiovascular diseases and to achieve all the benefits mentioned above, the WHO recommends that children and adolescents ages 5 to 17 years should accumulate at least 60 minutes per day of moderate to vigorous PA (MVPA) [5]. These guidelines are shared by many European countries, except for Germany, and are also followed by Russia [6]. In the US, approximately 24% of children age 6 to 17 participate in 60 minutes of PA. In New South Wales children, this percentage is estimated at 19% [7]. Among European countries, the percentage of children complying with the recommendation is generally low. In fact, in many European Union countries the number of inactive children (not compliant to recommendations) is constantly growing, particularly in Italy, where only 9.5% of boys and 2.6% of girls achieve the daily requirement [8]. School represents an environment where children and adolescents spend most of their time. Because education is offered in almost every country worldwide to children regardless of age, race/ethnicity, gender and socio-economic class, schools are an important if not central place and powerful socializing setting to promote PA and healthy habits for children [9]. The specific role of the school in promoting health behaviour was investigated through various studies, which examined how different school organizational features can affect the adoption of good health practices and avoid risk factors for poor health, also during adulthood [10–12]. In particular, PA promotion in the school setting can be a good strategy aimed at contrasting sedentary behaviours and improving physical skills and fitness.

Although physical education (PE) in the Italian setting is a fundamental part of all grade school curricula, it is often not adequately administered. This is, especially true in primary schools, where the time devoted to PE considerably varies and lessons are performed by generalist teachers lacking proficiency in physical education [13–15]. Consequently, the experience of PA in Italian children is frequently confined to participation in a few training sessions of sport alone, outside the school context, which is not enough to ensure the daily MVPA requirement [16,17]. The European Union guidelines recommend that the full dose of 60 minutes can be accumulated in small doses of at least 10 minutes of PA peppered throughout the day [18]. The Italian Ministry of Health guidelines suggest to use innovative learning theories and a new perception of PE, in which PA is promoted across various school-based activities [19]. In order to meet this goal and help children be active, opportunities are needed outside the traditional occasions of motor activity (recess time and physical education class). Various studies have been conducted in the school setting to evaluate the potential benefits of classroom-based PA interventions [17,20,21]. Incorporating short bouts of activity throughout the school day could be a good strategy for children to accumulate the required amount of PA [22]. Moreover, short duration active breaks (ABs), led by trained teachers inside the classroom, are emerging as a promising way of increasing the PA levels and achieving positive learning outcomes [23].

A recent systematic review coupled with a meta-analysis suggests that ABs have positive effects in term of increasing PA levels and improving classroom behaviour. Lasting effects were obtained with the most intense (10 minutes three/day for 12 weeks) or longer (10-15 minutes once/day for 9 months) interventions. The majority of studies included in the review were performed in the US and Australia, and to a lesser extent, in Europe [24]. Only one study examining ABs was carried out in Italy [25] that involved an AB intervention. The intervention which consisted of two daily PA breaks three times a week in a primary school, showed the feasibility of the program and its potential on the reduction of children's inactivity. However, the study lacked a control group, thus limiting any conclusions that can be drawn.

The limited data available on the efficacy of ABs makes it essential to investigate utilization of PA-related Abs in the Italian setting further. Therefore, in preparation for a future controlled trial, the author conducted a study to pilot-test the effects of ABs on PA levels in children attending a primary school in Northern Italy. Furthermore, the protocol was structured to evaluate children's and teacher's acceptability/satisfaction and, based on their feedback, the feasibility of the intervention.

The hypotheses include that a 14-week classroom AB program would positively affect the level of PA and would be an acceptable and feasible intervention when carried out by teachers.

4.2 Materials and Methods

The author conducted a pre-post quasi-experimental pilot and feasibility study in a primary school of Northern Italy (Istituto Comprensivo "Castelletto," Province of Bologna, Emilia-Romagna Region), from February 2019 to June 2019. The University of Bologna Bioethics Committee approved the study on the 25th January 2019. The study was carried out according to the Declaration of Helsinki and approved by the school board. The study commenced with a preliminary meeting, where the investigator informed the school manager and teachers about the study aims, procedures and intervention duration. The next step involved a general meeting with the children's' parents to explain the intervention content and study requirements.

Students could only participate if they were given parental informed consent, which elaborated use of personal data, risks and benefits, knowledge to be gained, and study requirements.

Based on the teachers' willingness, two out of 10 classes of the primary school participated in the study. One class of third grade students was assigned to the experimental group (AB group) and another fourth-grade class to the control group (CG). The two teachers of the experimental classes participated in a training day to learn about the exercises involved in the AB protocol. Control class teachers did not participate in any training. The children in the control group were only involved in pre- and post-test assessments scheduled during class time. The investigative team provided a detailed manual with all the exercises proposed to the experimental classroom teachers.

The AB protocol was developed on the basis of the literature examined through a systematic review [24]. Several innovations were introduced including use of high-intensity interval training (HIIT), consisting of 40 seconds of vigorous PA alternated with 20 seconds of recovery, performed at least once a day.

Experimental classes performed the AB protocol twice a day, usually the first break in the morning and the second break in the afternoon, for all the weekdays, during an intervention period lasting 14 weeks. Both the experimental and control groups participated in the routine school wide PE classes consisting of 2 hours per week taking place in the gym. Each AB lasted 10 minutes, divided into three different parts (Table 1).

Table 1. Components of the Active Break Protocol

Phase	Aim	Examples of the type of exercises	Duration
Warm-up	Physical activation and mobility	"The traffic light:" all children stand next to the desk and wait for the teacher's commands. When the teacher says "green" the children have to start running quickly on the spot, when the command is "yellow" the children have to slow down and march on the spot; finally, when the teacher says "red" the children have to stop in position.	3 minutes
Tone-up	HIIT; balance; cooperation; coordination exercises	HIIT "jumping jack:" all children perform jumping jack on the spot for 40 seconds, followed by 20 seconds of rest in balance position	5 minutes
Cool-down	Breath control and relaxation exercises to restart the usual academic lesson	"Flower and the candle:" children learn the correct way to breathe by imagining to inhale the scent of a flower and exhale while blowing on a candle	2 minutes

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In order to encourage both teacher and student involvement, teachers were allowed to implement some exercises of the AB programme by using curricular contents (i.e., music, English language, math content). They were asked to provide us comments and suggestions, especially regarding the organization of the classroom environment where the AB protocol was performed.

Baseline data were collected, both in the experimental and control groups, during the three weeks before the intervention. At baseline, weight, height, and waist circumferences of all children were measured (CG and EG), and body mass index (BMI) and waist/ height ratio

(WtHR) were calculated. For students in the EG, the time spent in PA and sedentary behaviour was monitored through Actigraph accelerometers (Actigraph, LLC, Pensacola, FL, USA) (ActiLife6 wGT3X-BT set to 10-s epochs). This instrument is reliable and valid, as supported by various pieces of evidence, especially in children [26–29]. The accelerometer data were analysed through ActiLife 6.13.3 software (ActiGraph, LCC, Pensacola, FL, USA). The activity levels were categorized using Evenson 2008: sedentary cut points (0–100), light (101–2295), moderate (2296–4011), vigorous (> 4012), and MVPA minimum count (2296) [30 –32].

Children in the experimental condition were asked to wear the accelerometers over seven days (five weekdays and two weekend days), only to be removed when bathing, swimming and showering. Accelerometers were attached to an elastic belt around the waist. In keeping with the existing literature [33], children were included in the analysis only if they complied with specific criteria: having worn the accelerometer on at least 3 weekdays and 1 weekend day, and for at least 10 hours every day. After the end of the 14-week intervention, the same measurements and procedures were applied for the follow-up session (for both CG and EG). During both the baseline and follow-up evaluation, the intervention group did not perform the AB protocol. We designed a self-administrated Active Break Questionnaire to investigate several aspects related to the feasibility of the program. Once the intervention finished, both the children and the two teachers from the experimental group completed the AB questionnaire. The children's questionnaire included five items focused on their satisfaction and enjoyment performing ABs, with a three-point categorical response scale (yes, yes/no; no). The questionnaires for teachers assessed their level of satisfaction, intervention feasibility, the perceived efficacy of the Abs, and how well the program was managed.

The teacher assessment also included 18 items exploring potential changes in the Time on Task classroom behaviour, attention and well-being of the children. Response formats ranged from (1) "completely disagree" to (5) "totally agree"

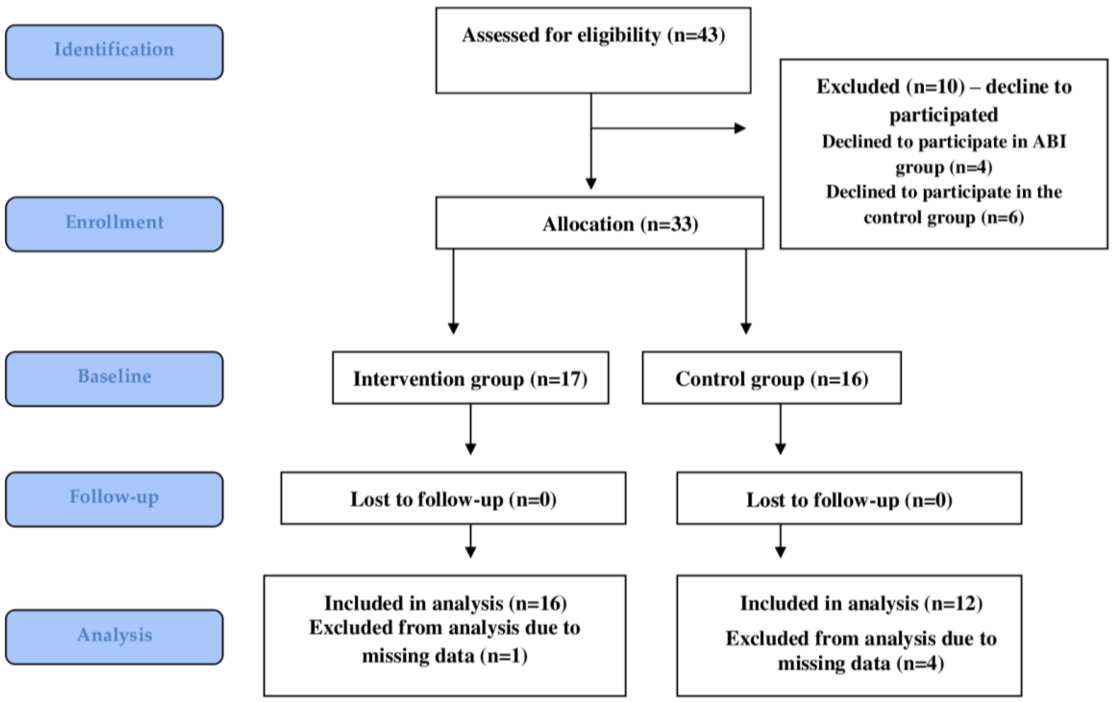
Differences in Actigraph parameters from baseline to posttest were analysed within groups, using the paired-samples t-test. Children were stratified into two categories based on their anthropometric measures, both for WtHR (the value of 0.5 was chosen as cut-off of cardiovascular risk) [34–36] and BMI (overweight/obese and normal-weight children according to the International Obesity Task Force classification) [37]. Data were analysed using ANCOVA adjusting for baseline values, in order to evaluate the time spent in MVPA and for children's WtHR and BMI. Two-tailed significance levels were used, with

$p < 0.05$. All analyses were carried out using IBM SPSS Statistics version 20.0 (IBM, Armonk, NY, USA).

4.3 Results

A total of 43 children were included in the two classes participating in the pilot feasibility study (Figure 1). Ten of the children did not receive parental consent, and were thus not included in the study. Of the remaining 33 participants at baseline (mean age 9.02±0.11; males: 51.5%), 17 were assigned to the experimental group (AB group) and 16 to the control group (CG). The percentage of children with a WtHR ≥ 0.5 was 53.1%, while 55.2% were overweight or obese. The percentage of BMI overweight/obese in the control group was 64.3% vs. AB group 46.7%, the percentage of WtHR at risk (≥0.5) in the control group was 68.8% vs. AB group 37.5%. However, the differences between the groups are not statistically significant. The final analysis was performed on 16 children in the AB group and 12 children in the CG.

Figure 1 Flowchart of participants through each stage of the study.



A total sample of 28 children provided baseline and follow-up measures that showed a normal distribution using the "Explore" function of SPSS (Statistical Package for Social Science). Overall, in the AB intervention group, all Actigraph measures improved at posttest while in the CG, all of the measures showed declines (Table 2).

Table 2 Outcome measures at baseline, follow-up and changes at 14 weeks

	AB Group (n: 16)				**Control Group (n: 12)**				
Variables	**Baseline Mean ± SD**	**Follow up Mean ± SD**	**Change Mean ± SD**	**Within group p value**	**Baseline Mean ± SD**	**Follow up Mean ± SD**	**Change Mean ± SD**	**Within group p-value**	**Between groups p-value[a]**
Sedentary Activity (min/week)	8,124.0 ±485.3	7,955.3 ±435.2	-168.7 ±504.0	0.20	7,753.3 ±432.8	7,880.8 ±548.8	+127.5 ±609.7	0.48	0.79
Weekly MVPA (min)	292.0 ±36.7	356.4 ±171.4	+64.4 ±136.0	0.07	300.5 ±143.6	258.3 ±98.8	-42.2 ±103.5	0.19	0.03
Daily MVPA (min)	36.5 ±18.4	44.6 ±21.4	8.05 ±17.0	0.08	42.2 ±19.7	36.9 ±14.1	-5.3 ±14.4	0.22	0.06
MVPA%	2.9 ±1.5	3.6 ±1.7	0.7 ±1.4	0.07	3.1 ±1.4	2.7 ±1.0	-0.4 ±1.1	0.22	0.03
Step Counts (N/week)	43,921.4 ±13,555.5	57,948.3 ±14,401.8	14,026.9 ±13,746.6	0.01	53,041.3 ±17,089.7	47,602.3 ±16,536.9	-5,5439.0 ±14,076.3	0.21	0.01

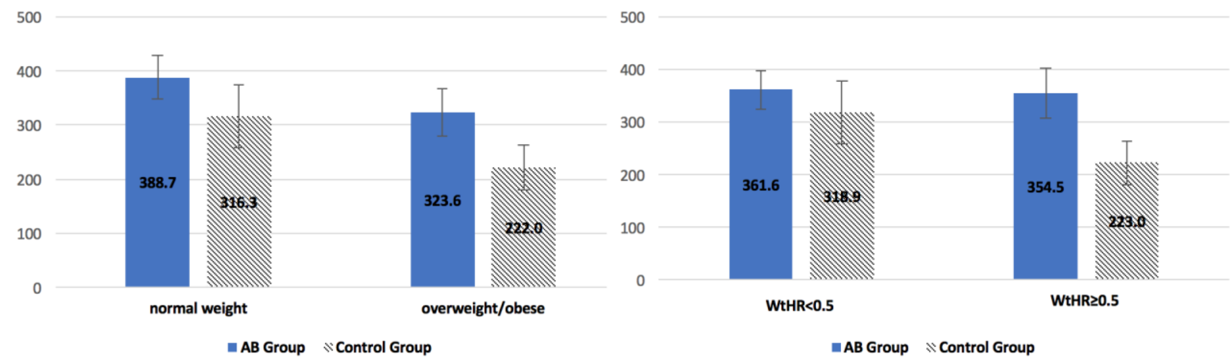
[a]Changes in measures between baseline and follow-up are compared using ANCOVA with correction for baseline scores.
Masini A, et al. Active Breaks: A Pilot and Feasibility Study to Evaluate the Effectiveness of Physical Activity Levels in a School Based Intervention in an Italian Primary School. *Int J Environ Res Public Health*. 2020;17(12):4351. doi:10.3390/ijerph17124351

In the AB group, a reduction in the number of minutes spent in sedentary activity was observed (-168.7 min). Consequently, the weekly and daily minutes spent in MVPA (Weekly MVPA + 64.4 min, Daily MVPA + 8.05 min), and the percentage of time spent in MVPA (+ 0.70%) increased in the AB group. There was also an improvement in the number of weekly step counts (+ 14,026.9), the only variable showing significant pre-post differences in the comparison within the AB group ($p < 0.001$). The CG showed a non-significant decrease in all of the Actigraph measures, from baseline to post-test.

There was a significant difference between the AB group and the CG for all measures, except the time spent in sedentary activities and daily MVPA (Table 2).

When children are stratified by BMI categories, the post-intervention time spent in MVPA is longer in normal-weight children compared with overweight/obese children, in both the AB group and CG (Figure 2a). However, theses differences are not significant using ANCOVA and adjusting for baseline values. In addition, when children are stratified by WtHR, the time spent in MVPA is the same in all AB group participants, while the CG children with WtHR ≥0.5 (cardiovascular risk) spent a shorter time in MVPA compared with children with WtHR < 0.5. Therefore, in both the risk and no risk categories of the AB group, a general improvement in the total time spent in MVPA was observed, while in the CG, the subgroup at risk (WtHR ≥0.5) showed poorer outcomes compared with the

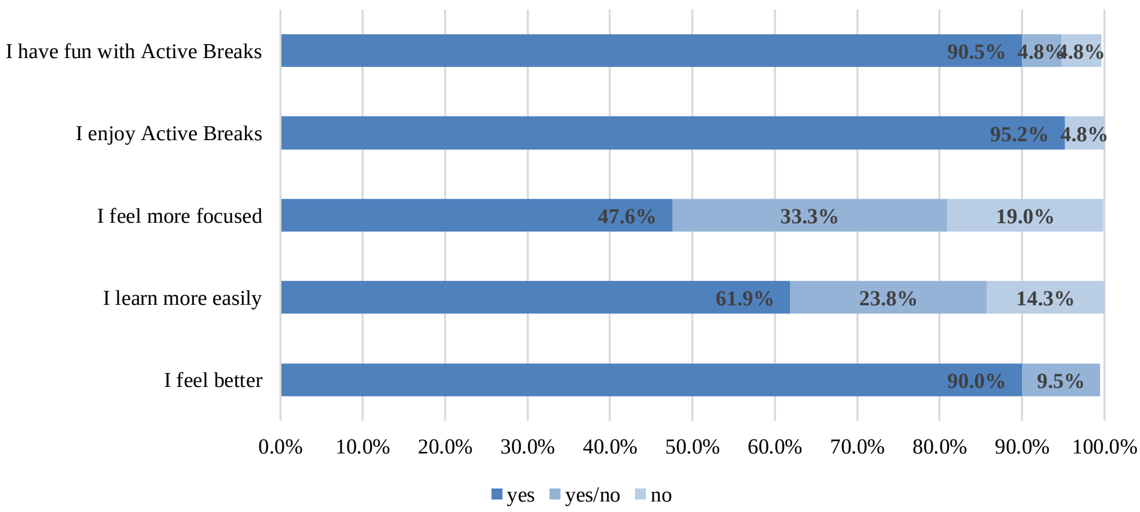
Figure 2. Total time (minutes) spent in weekly MVPA during the follow-up in relation to BMI categories (**a**) and WtHR categories **b**) in AB group and CG, adjusting for baseline values.



not-at-risk subgroup (Figure 2b). Moreover, in this case, there were no significant between-group differences using ANCOVA after adjusting for baseline values.

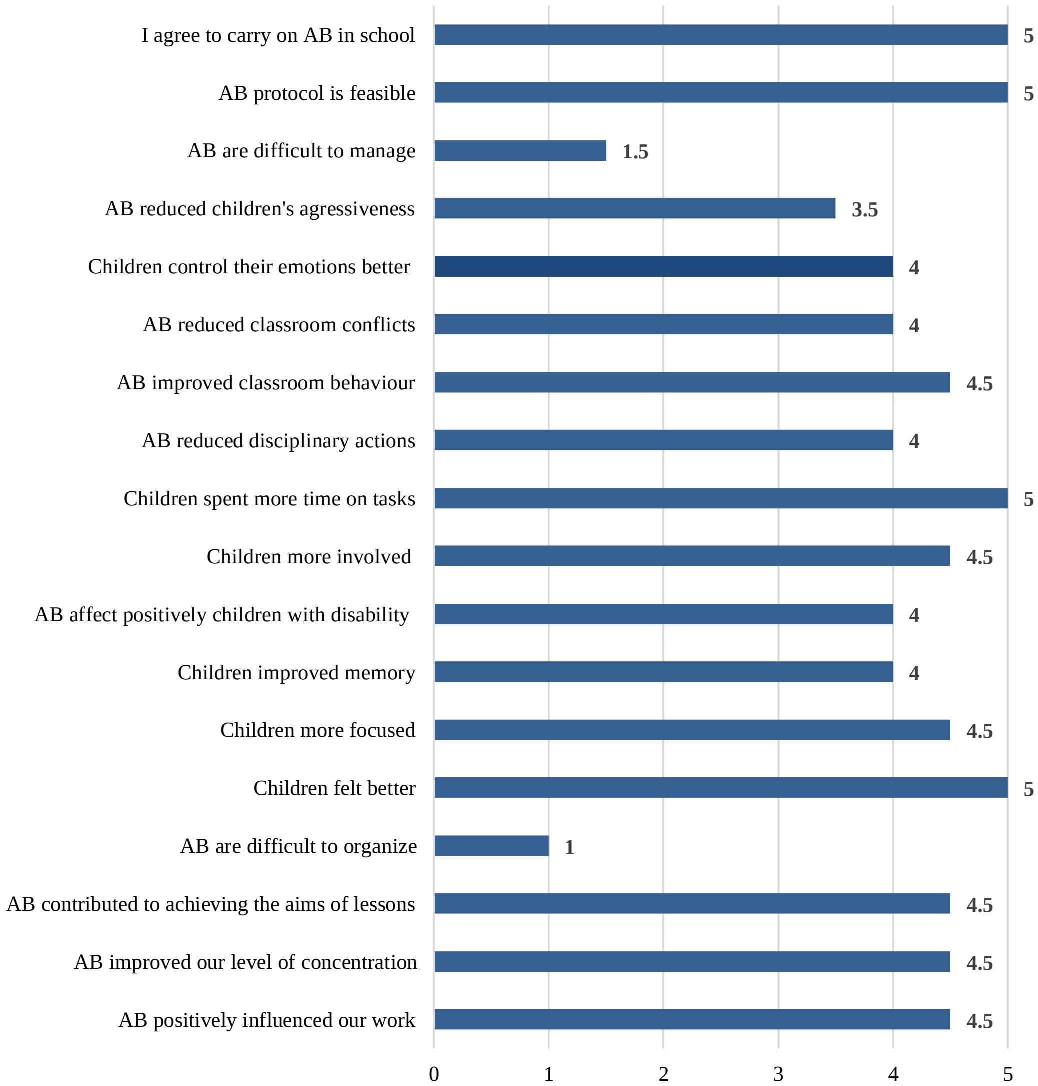
Figure 3 shows the children's feedback after the AB program. Almost the entire sample reported feeling better after the intervention (90.5%), having fun with ABs (90.5%) and enjoying the AB intervention (95.2%). Almost half of the children (47.6%) felt more focused after the AB programme and 61.9% said they learned more easily.

Figure 3 Children's answers to the AB questionnaire.



Teachers stated that children in the AB group improved their time spent on tasks, classroom behaviour and involvement during work activity. Furthermore, teachers reported that the AB intervention reduced conflicts among children. They also reported that exposure to the AB curriculum had a positive influence on the children's work. Teachers assigned positive scores regarding AB feasibility, effectiveness, and management, and they expressed their willingness to repeat the experience (Figure 4). Teachers and children in the control group did not fill out any of the post-implementation feasibility assessments.

Figure 4 Teachers' answers to the AB questionnaire.



4.4 Discussion

This study evaluated the feasibility and efficacy of an AB intervention intended to boost PA levels in young school age children. The AB group showed a pre-post gain in all Actigraph accelerometer measures. Moreover, at the posttest, children in the AB group showed significantly increased levels of MVPA and number of steps compared with the control group. Other studies have shown that classroom-based ABs increase children's physical activity levels [23,38,39]. Daily Smith et al. investigated the effect of ABs with academic content (active learning) on PA level, cognitive and academic outcomes. They found a slight improvement in children's PA level and classroom behaviour, but no effect of ABs on academic achievement and cognitive functioning [40]. However, the absence of effects on cognitive functioning can be attributed to the different domains of cognitive functioning assessed (i.e., mainly memory and long-term memory). Other measures of cognitive functioning, such as attentional processes and speed of processing may be more sensitive to program effects. In addition, it may be important to consider multisensory perception, which is impaired in several developmental disorders, such as dyslexia [41], and autism [42] and may show favourable effects from increased PA.

There is evidence that a single dose of exercise can improve multisensory processing (i.e., the ability to appropriately integrate information from different sensory modalities) particularly with the elderly [43]. However, there is a need to investigate this effect on cognitive ability in children, where this type of perceptual processing is a foundation to learning and cognitive development [44]. In keeping with the WHO recommendations, a school-based intervention with ABs of 10 minutes twice a day including HIIT exercises could facilitate children reaching the daily 60 minutes of MVPA. Moreover, this could represent a viable strategy to promote ABs within classrooms, encouraging healthy lifestyle practices that can be translated into everyday life.

This AB intervention was also demonstrated to be effective in children with WtHR ≥ 0.5, who increased the time spent in MVPA to the same extent as children with WtHR < 0.5. This finding is particularly important, considering that WtHR is an index of cardiovascular risk [34–36] in adulthood and children with high WHTR are those who most need to move actively. In contrast to the AB children, those in the control group showed decrements in their PA habits, and the level of time spent in MVPA at follow-up decreased to a greater extent in at-risk children, compared with those not at risk.

The post-intervention assessment also showed that both children and teachers enjoyed the program and rated it highly. For children, the AB programme was fun, pleasant and gave them a higher tolerance to being in the classroom; teachers found it manageable, useful for controlling children's classroom behaviour and, in general, effective. For teachers, they reported being satisfied with the project, that children were better off after the program, and that it benefited the children's work activity in the classroom. Furthermore, teachers reported they continued to use the Active Breaks instructional materials throughout the following school year, even after the study had terminated. All of this feedback supports the continued use of ABs within the normal school curriculum [25,38]. Other studies showed that classroom-based ABs improved children's time on task behaviour during academic instruction [38,39].

This study has several limitations. First of all, the sample was small and randomization was not used to assign classrooms (or children) to experimental conditions. In many cases, randomization is not possible given the few numbers of teachers within the same that show interest in participation. Other studies focused on classroom AB interventions also have encountered these same issues [39,45,46]. Collaboration by teachers is fundamental to carry out a project of this scope and duration. They contribute to the intervention by arranging classroom time and they develop a favourable mindset to use the teaching methods as part of their regular curricular activities. This then ensures the efforts of researchers will be sustained when the research team no longer supervises the project. Erwin et al. showed that motivated teachers were essential to maintain program adherence irrespective of whether teachers believed in the effect of the intervention [45]. For this reason, in the current study, ABs were conducted only in classes where the teachers showed enthusiasm and interest in the training activity. These and other limitations suggest that the data should be interpreted with caution and furthermore requires replication. Seasonal implementation of the AB program may also factor into the study findings. The baseline assessments were conducted in early January (winter) while the follow-up was conducted in May (spring). Children tend to be more active in the spring and also experience a modicum of weight gain in the winter (some of which is age related). Two additional limitations are also worth considering: active break intensity was not assessed during the intervention and PA was only evaluated with accelerometers. Despite these limitations, the pilot and feasibility study was useful to examine implementation issues and whether an AB intervention can be delivered in a school setting. The results are encouraging and suggest the need to replicate these findings with a larger sample of children and teachers, and investigating the effects of ABs on cognitive functioning and quality of life [47,48].

To our knowledge, only one other study (Calella et al.) has been conducted in Italy to evaluate the feasibility and effectiveness of classroom AB interventions [25]. This study used different assessment tools to measure PA levels and also implemented active breaks using a different method. However, the study did produce similar findings to the current study. Unlike Calella et al. the current quasi-experimental design compared an intervention with a control group, and measured PA levels at posttest after the AB protocol was finished. Therefore, the observed improvements cannot be attributed to the time dedicated to ABs in the classroom, but to the spontaneous PA of the children, which also continued after the intervention.

Other studies are needed to confirm these findings, assessing whether classroom ABs can affect children's motor habits outside the school context. Notwithstanding its limitations, the current study was useful to examine barriers to implementation, program adherence, feasibility and acceptability at both the teacher and child levels.

5. Study 3 A Multiple Targeted Research Protocol for a Quasi-Experimental Trial in Primary School Children Based on an Active Break Intervention: The Imola Active Breaks (I-MOVE) Study

This research protocol was published in the International Journal of Environmental Research and Public Health:

Masini A, Lanari M, Marini S, et al. A Multiple Targeted Research Protocol for a Quasi-Experimental Trial in Primary School Children Based on an Active Break Intervention: The Imola Active Breaks (I-MOVE) Study. Int J Environ Res Public Health. 2020;17(17):6123. doi:10.3390/ijerph17176123

Keywords: cognitive function; fine and gross motor control; moderate to vigorous physical activity; physical fitness; public health; quality of life; school based intervention; sedentary behavior; time-on-task.

Overview

The experience gained during the pilot study led to the planning and design of a quasi-experimental study focused on an Active Breaks intervention with a High Intensity Interval Training component delivered in an Italian primary school: The I-MOVE study.

The I-MOVE study is the core feature of this doctoral project and involved a larger sample of children examining various physical, cognitive, mental and health-related quality-of-life outcomes. All this was a possible thanks to a research team made up of various professionals and researchers that provided support to the project. The publication of this research project provided a foundation to build a mission statement of our research group.

5.1 Introduction

As stated previously, regular PA during childhood is correlated with several health benefits [1,2]. According to the WHO and adolescents, ages 5 to 17, should perform at least 60 minutes of MVPA per day [3] in order to avoid the risk of metabolic and cardiovascular diseases [4]. However, more than half of children and adolescents worldwide do not meet the recommendation of 60 minutes of MVPA per day [5,6] and it is estimated that in Italy only 9.5% of boys and 2.6% of girls achieve the daily amount of PA [7]. Currently, children and adolescents spend most of their time at school [8] providing unfettered access to children regardless of age, race/ethnicity, gender, and socioeconomic class. This makes schools an ideal place to socialize children and for conducting health promotion interventions [9,10,11,12]. Unfortunately, many school settings are not providing children with adequate opportunities to become physically active and may not generate enough PA in children and adolescents. Studies report that children and adolescents in European countries spend 65–70% of school hours in sedentary behaviours [13,14]. It is within this framework that we propose conducting a quasi-experimental study to assess the feasibility and efficacy of a school-based intervention based on active breaks (ABs) to promote PA within the classroom context. ABs are 10–15 minutes bouts of MVPA activity incorporated into the regular school curriculum, performed inside the classroom context and led by teachers during academic lessons. Incorporating active breaks into the school day has been highlighted as a positive strategy for helping children accumulate the required amount of PA [15]. Active Breaks are also emerging as a promising way of increasing PA levels, and achieving positive learning outcomes [16]. Several recent systematic reviews and meta-analyses show that ABs interventions have positive effects in increasing PA levels and improving classroom time-on-task behaviour [17]. In particular, the evidence suggests that with 10 minutes three times/day for 12 weeks of an AB intervention [16] or 10–15 minutes once/day for 9 months [18], it is possible to obtain durable effects. Most studies included in this review were performed in Australia and the US; only one study was performed in Italy [19].

The purpose of the current study is to outline the design, procedures and methods used in the Imola Active Breaks study (I-MOVE study). This study is one of the first to inolve an AB intervention carried out in an Italian school setting. It is also remarkable because the study involves a two-year follow-up and uses a multidisciplinary team that manages the different assessments with multiple outcomes. Furthermore, to our knowledge, the I-MOVE protocol is the first that includes HIIT exercises embedded within the exercise protocol. The I-MOVE study could lead to significant advances in our knowledge base with regard to utilizing PA with children and help develop an "organizational" perspective with respect to program implementation. The specific aims of the I-MOVE Study include:

1. To evaluate the effects of an Active Breaks intervention in increasing total day and school day PA and reducing time spent in sedentary habits in children attending primary school; the study examines the relationship between objective and reported measures of PA and health-related fitness in children.

2. To assess the possible effect of Active Breaks in improving quality of life in children, stratified by anthropometric evaluation, diet habit, socioeconomic status and parent-perceived children's quality of life.

3. To investigate the effects of Active Breaks as a strategy to change the time-on-task behaviour and the cognitive functioning of children (i.e., executive functions and

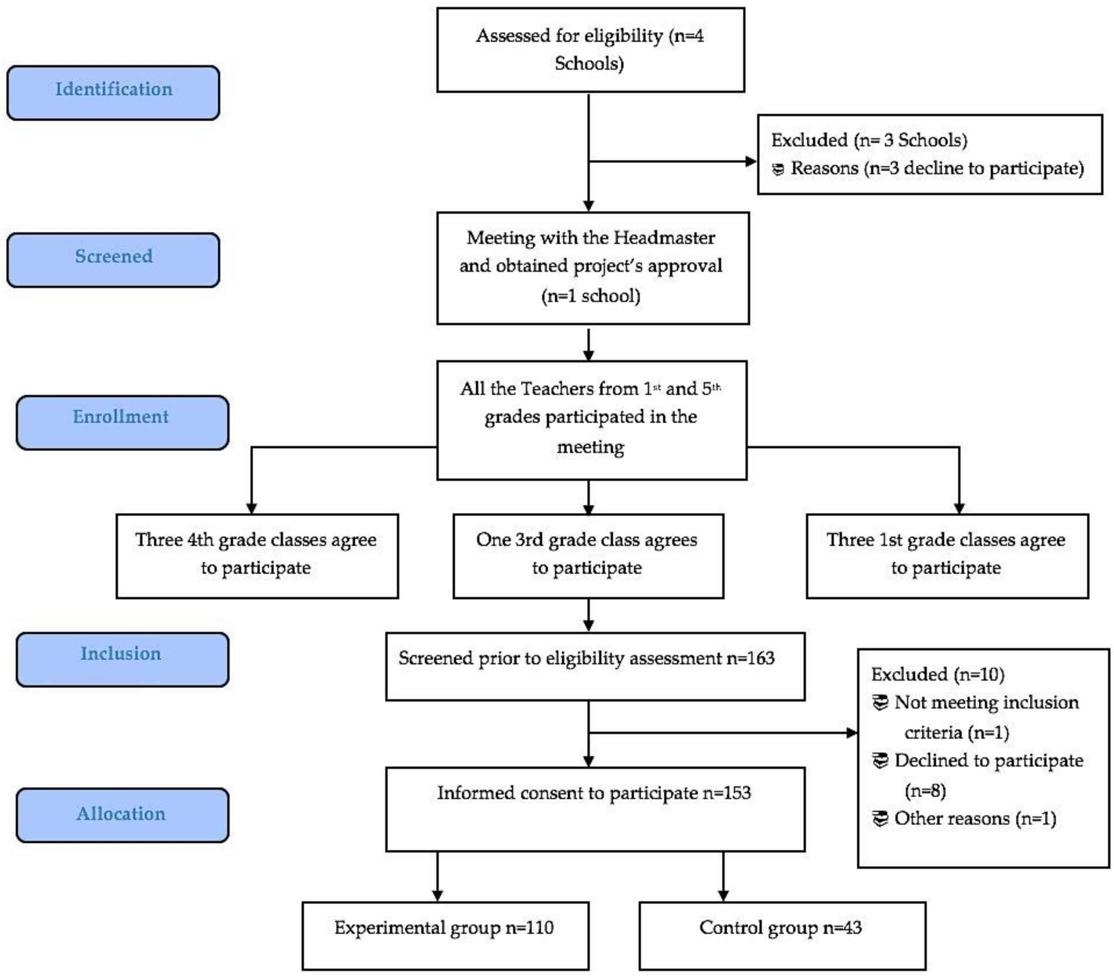
multisensory perception).
4. To investigate the possible effects of Active Breaks in improving the development of fine and gross motor control, quantified using wearable sensors.

5.2 Materials and Methods

The I-MOVE study is a school-based intervention using a quasi-experimental design (controlled studies in which exposure was assigned by the investigator without randomization to condition) [20]. The current project was based on a feasibility pilot study [21] and supported by a meta-analysis that examined PA-related school-based interventions [17]. Findings from both the feasibility study and meta-analysis were used to inform the study design and implementation of the I-MOVE study. The intervention trial follows the guidelines of the SPIRITS (Standard Protocol Items for Intervention Trials) Checklist.
The administration of the study was designed to allow effective collaboration and communication among different departments of the University of Bologna. The study was approved by the University of Bologna Bioethics Committee, on the 18th March 2019 (Prot. n. 0054382 of 18/03/2019-[UOR: SI017107-Classif. III/13]). The study was conducted following the Declaration of Helsinki and approved also by the school board.
The study setting was a primary school in the city of Imola (70,075 inhabitants, Bologna, Northern Italy). Invitation letters accompanied by an expression of interest form were sent to the principals of four schools located in Imola. One school expressed interest in participating in the project. After that, a member of our team visited the interested school to provide an overview of the project in front of relevant school staff. Furthermore, a specific meeting with the headmaster was held to obtain the school's agreement. Finally, we organized a presentation day to explain the project to the teachers. Ten teachers from five classes out of 15 agreed to be involved in the project. They attended a training course lasting 8 hours to learn the theoretical basis of the project and understand how to deliver the practical part of the Active Breaks intervention. The parents of the children received a brochure describing the study, and an invitation to attend an information meeting held at their child's school. The purpose of the meeting was to explain the nature of the intervention that would be conducted in the classrooms. At the end of the meeting informed consent was obtained from parents/tutors. The I-MOVE study established the following inclusion criteria: (1) studying in 1st to 5th grade (ages 6–11 years), (2) not

having health problems or physical disability, which might limit the performance of ABs, and (3) having obtained informed consent of parents and permission for personal data collection and processing. Finally, 153 children were enrolled in the study (Figure 1). The mean number of children in the different classes was 22. The study was voluntary and

Figure 1. Flow Chart of the I-MOVE Study.



children were free to withdraw from the study at any point without any consequences or providing an explanation.

An appropriate sample size was estimated considering the actigraph accelerometer measures as the primary outcome measure of the study. Sample size calculations were based on the pilot and feasibility study [21], which detected a mean difference of 98.1 minutes in weekly total MVPA, measured using the accelerometer, between the intervention and control groups. Considering an alpha error rate of 0.05 and power of at least 0.80, the minimum size of the sample was estimated as 48 participants per group, for a total of 96 participants, without considering the nested data structure (i.e., children within classrooms). Power analysis was carried out with Clinicalc.com.

5.3 Intervention

The experimental groups performed the I-MOVE protocol three times/day without a fixed time: usually two breaks in the morning and one in the afternoon every weekday. Active breaks were performed in addition to the normal recess activities. In particular, children got up from their chair, placed it under the desk to ensure their safety and positioned themselves to the side or behind their seat, depending on the type of exercises. Approximately every child needed 1-m diameter of free space around to perform exercises in a safe manner. Each active break consisted of 10 minutes, divided into three different parts (Table 1). The first part, called "warm-up" (2 min.), focused on cardiorespiratory and mobility exercises to prepare children to increase their motor activity intensity.

In the central part, called "tone up" (5 min.), teachers conducted exercises with high-intensity interval training (HIIT), consisting of 40 seconds of vigorous PA alternated with 20 seconds of recovery, with a specific focus on coordination and balance. During the tone-up the children could experiment with and learn basic motor skills such as jumping and throwing. In the last part of the active break, called "cool-down" (3 min.), children performed stretching, relaxation and breath control exercises. Following these exercises the children were recharged to restart their academic lesson.

Table 1 Components of I-MOVE protocol

Phase	Aim	Examples of the Type of Exercises	Duration
Warm-up	Cardiorespiratory and mobility exercises	The chair march: The children all stand up and move their chairs sideways, waiting for the teacher's commands. They begin to march, raising their knees well and resting their toes on the chair, without pushing upwards. Progressively, they also combine the movement of the legs with the alternating movement of the arms.	2 min
Tone-up	High-intensity interval training (HIIT) exercises	HIIT Animal jumps: Children scattered around the classroom have to jump like frogs for 20" then rest for 10" and repeat the exercise 4 times, then they jump like kangaroos for 20" with a 10" break to be performed 4 times.	5 min
Cool-down	Breath and relaxation exercises	The imaginary balloon: Children must inflate an imaginary balloon by inhaling and exhaling, mimicking the progressive expansion of the balloon with the widening of their arms. We ask for a very slow and long exhalation twice as long as the inspiration.	3 min

Teachers in the intervention condition could decide together with the pupils which daily exercises they liked to perform, trying to use the whole range of exercises and varying them as much as possible to maintain the children's enjoyment and motivation. Furthermore, this approach allowed teachers to adapt the active breaks protocol according to their class needs, for example not using contact exercises in particular cases. Clearly, the I-MOVE protocol, performed for 10 minutes three times a day for every day of the week, takes time away from the regular curricular lessons. However, these interventions appear to benefit the classroom behaviour by improving children's attention and making it easier for teachers to instruct students [22,23]. Active breaks are also reported by the teachers themselves as a useful strategy for optimizing the time dedicated to academic lessons in particular because active breaks are able to energize children who have difficulty in maintaining concentration during daily school activities [19,21]

5.4 Data Collection and Outcome Measures

During the I-MOVE study the following outcomes were evaluated: (1) PA and sedentary behaviours; (2) health-related fitness; (3) motor control development during fine and gross (locomotors) tasks; (4) dietary patterns; (5) anthropometric evaluation; (6) socio-demographic and early determinants; (7) cognitive functioning; (8) time-on-task behaviour and (9) quality of life. Table 2 shows all of the measurements that were evaluated at baseline T0 (October 2019), assessed at mid-intervention T1 (October 2020), and at the end of the intervention T2 (June 2021). The process evaluation was performed six months after the end of the intervention T3 (December 2021.) The comparisons between T0, T1 and T2 provided a means to determine the timing of any long-term effect of ABs and whether the effects of ABs are cumulative in time or reach a ceiling after T1 (e.g., if there are cumulative effects, then performance should reveal a pattern $T0 < T1 < T2$; by contrast, if they reach positive effects in a few months and then stabilize, then performances at T1 and T2 should not differ).
Moreover, we planned an assessment at the mid-intervention point to measure an acute effect before the daily active breaks and immediately after the 10-minute bout for cognitive

and time on task outcomes. During this specific mid-intervention we monitored the amount of PA performed during an active break, 10 minutes three times/day, during a school day for a week. This assessment was focused on cognitive functioning and time-on-task behaviours, since these endpoints could be more affected after acute exercises than chronic ones, which has been demonstrated in the literature for some cognitive functioning [24–26].

Table 2 The Imola Active Breaks Study Data Collection and Outcome Measures

Outcome measures	**Baseline October 2019 (T0)**		**Mid-intervention October 2020 (T1)**	**End of intervention June 2021 (T2)**	**6 months after End of intervention December 2021 (T3)**
Personal information (Age, Country)	✓	✓	✓	✓	
PA and sedentary behaviour (accelerometer)	✓	✓	✓	✓	
Total reported physical activity Questionnaire	✓	✓	✓	✓	✓
Health related fitness	✓	✓	✓	✓	✓
Motor control development	✓	✓	✓	✓	✓
Dietary patterns	✓	✓	✓	✓	✓
Anthropometric evaluation	✓	✓	✓	✓	✓
Socio-demographic and early determinants	✓	✓	✓	✓	✓
Cognitive Function	✓	✓	✓	✓	✓
Time-on-task behaviour (Teachers and children self-administrated questionnaire)	✓	✓	✓	✓	✓
Quality of Life	✓	✓	✓	✓	✓
Process evaluation focus group with children	✓	✓	✓	✓	✓
Process evaluation: focus group with teachers	✓	✓	✓	✓	✓

Masini A, et al. A Multiple Targeted Research Protocol for a Quasi-Experimental Trial in Primary School Children Based on an Active Break Intervention: The Imola Active Breaks (I-MOVE) Study. Int J Environ Res Public Health. 2020;17(17):6123. doi:10.3390/ijerph17176123

- PA and Sedentary Behaviour

The time spent on PA and sedentary behaviour was calculated through actigraph accelerometers (ActiLife6 wGT3X-BT). The actigraph accelerometer models GT3X (ActiGraph LCC: Pensacole, FL, USA) monitors objectively the daily PA and sedentary behavior over seven consecutive days. We examined the accelerometer data through ActiLife 6.13.3 software (ActiGraph LCC: Pensacole, FL, USA). The epoch length will be analyzed to 10 seconds to allow a more detailed estimate of PA intensity [27].

The screening and data processing procedures to evaluate time spent in sedentary, total PA and PA at different intensities are consistent with previous studies on children and adolescents [28–30]. The children will wear the accelerometers over a seven-day period (five weekdays and two weekend days), consistent with prior feasibility study. Accelerometers are attached around the waist with an elastic belt, in line with the existing literature [31]. We analysed the accelerometer's data only when children comply with specific inclusion criteria: having worn the accelerometer on at least three weekdays and one weekend day, and for at least 10 hours every day (including sleeping hours). Minutes spent in PA (light, moderate and vigorous) per day are calculated using the Evenson cut points [32]. Physical Activity will also be evaluated with the physical activity questionnaire for children (PAQ-/C).

The PAQ-C is a self-administered, 7-day recall questionnaire, with nine items scored on a five-point scale. This instrument provides a final composite activity score, by taking the mean of the nine items. This questionnaire has been shown to be valid and reliable [33].

- Health-Related Fitness

Health-related fitness was assessed by the following tests: 6-minute running test, 6-minute walking test (used only in 5–6 year-old children, first grade), Harre test, standing long jump test and shuttle run 4 x 10.

The 6-minute running test (6MRT), derived from Cooper's 12-minute test, consists of performing the maximum running distance possible, also walking when tired, for a time of 6 minutes. At the end of the test, the meters covered in the time frame are considered. The test is validated for preschool [34] and school-aged children [35]. The 6-minute walking test (6MWTs) was conducted using ATS guidelines (2002) [36]. All children received the same instructions before undertaking the walking test. The children are asked to walk up and down at their best pace but not to run or race. Teachers explained to the children that it is not a competition. During the performance, no indications such as "Slow down" or "Go faster," will be given, except for encouragement (e.g., "You are doing great" and "Keep going") [37,38]. Only 5–6 year-old children from the whole sample will perform this test, as it is easier and more adaptable to this age group. Both the 6 MRT and the 6 MWT are reliable tests to assess cardiorespiratory fitness in children.

Standing long jump (SLJ) or standing broad jump is a good test to assess lower body strength and can be considered as a general index of upper and lower body muscular fitness in youth [39,40]. The participant stands behind the starting line, with feet together, and pushes off vigorously and jumps forward as far as possible. The distance is measured from the take-off line to the point where the back of the heel nearest to the take-off line lands on the mat or non-slippery floor. The test was repeated twice, and the best score retained (in cm). The Harre circuit (HC), a dexterity's test, is a timed instrument based on simple and dynamic movements repeated in three spatial directions: right, forward and left [41–43]. The subject is required to start standing towards the mat positioned along the circuit, have to perform a forward flip, run towards the cone and head towards obstacle 1, jump over the obstacle and then pass under it. And again cone - obstacle 2 - cone - obstacle 3 - cone - finish line. The shuttle run 4 x 10 test (4x10 SRT) [44] measures agility, speed and coordination while running between two lines drawn on the floor 10m apart and being required to pick up small blocks. The children ran as fast as possible from the starting line to the other line and return to the starting line, crossing each line with both feet every time. This test was performed twice, covering a distance of 40 m (4 m x10 m). Each time the children crosses any of the lines, he/she has to pick up (the first time) or exchange (second and third time) a sponge that is previously placed behind the lines. The stopwatch timing the activity is interrupted when the children cross the end line with one foot.

- Motor Control Development During Fine and Gross (Locomotors) Tasks

Gross- and fine-motor competences were assessed using an instrumented approach based on wearable inertial sensors [45,46]. The selected instrumented approach allows the quantitative analysis of motor competence characteristics (e.g., automaticity, complexity and regularity) and their longitudinal monitoring as related to age and/or motor development. For gross-motor competence 3 inertial sensors (OPAL; APDM: Portland, OR, USA) will be attached, using elastic Velcro bands, to the lower shanks (above lateral malleolus) and lower back (at L5 level) of each child over clothes, and 3D acceleration and angular velocity is acquired from each sensor during natural and tandem gait along a 15 m straight path. Each child walks 3 times back and forth normally (for a total of 45 m) and 1 time in tandem (along the straight line, positioning the heel of the front foot in contact with the toes of the back one), prior to data collection, all participants were allowed to perform a tentative trial (10TW strides) to ensure they understand the tandem gait instructions.

For the assessment of fine-motor competence, the three inertial sensors (OPAL; APDM: Portland, OR, USA) were attached to the wrists (dorsal aspect) and lower back (at L5 level), and 3D accelerations and angular velocity was assessed during the Placing bricks test [47]. Each child, sitting at a desk, attached 18 1×2 Duplo bricks one at a time onto a 6 ×12 Duplo plate using one hand, then the other for the second trial; blocks were positioned on the side of the plate corresponding to the hand to be used, while the opposite hand was kept on the table or used to stabilize the plate according to child's preference. For all trials performance was measured at 128 Hz sampling frequency.

Temporal parameters, variability, regularity, motor complexity, stability and rhythmicity were calculated from acquired motion and represented in a graphical polar plot [46] allowing the investigators to qualitatively characterize different areas of motor control performance.

- Dietary Patterns

The ZOOM-8 study [48] examines in greater depth the dietary habits and PA of Italian primary school children, and the role of the health services in geographic areas with different levels of childhood overweight and obesity, as shown in the Italian surveillance system named "OKkio alla SALUTE."

In the ZOOM-8 study, the anthropometric measures of children are taken and their parents fill in two questionnaires, one general questionnaire including general information along with lifestyle questions (i.e., amount of physical activity, time spent at the screen, sleeping hours, family composition, etc.) and a semi-quantitative food frequency questionnaire (FFQ), built up following the methodology described and validated by Willett [49], consisting of 53 commonly used food items categorized into 11 food groups [50]. The author used the same two questionnaires, asking the children's parent participating in the study to complete these forms and provide specific instructions on completing them at home. Frequency response categories for all food portions ranged from the number of times per day, per week, per month, per year to never. Manufactured products will be reported as number (or fraction) of units consumed.

- Anthropometric Evaluation

Six anthropometric characteristics (height, weight, waist and hip circumferences, triceps and subscapular skinfold thicknesses) were collected according to standardized procedures [51,52]. In particular, height was measured to the nearest 0.1 cm using a portable stadiometer (SECA 217, SECA: Hamburg, Germany). Body weight was measured to the nearest 0.1 kg (light indoor clothing, without shoes) using a calibrated electronic scale (SECA 877: Hamburg, Germany). Waist circumference (WC) and hip circumference (HC) were measured to the nearest 0.1 cm with a non-stretchable tape (GPM measuring tape; DKSH Switzerland Ltd.: Zurich, Switzerland): WC was measured between the lowest rib and the iliac crest and HC at the widest part of the hip. Triceps (TSF) and subscapular (SSF) skinfold thickness was measured to the nearest 0.1 cm on the left side with a Lange caliper (Beta Technology Inc.: Santa Cruz, CA, USA). Triceps skin fold thickness was measured midway between the tip of the acromion and olecranon processes, while SSF raising an oblique skinfold below the inferior angle of the scapula at 45 to the horizontal plane following the natural cleavage lines of the skin. Triceps skin fold thickness and SSF were evaluated according to the Frinsancho cut-off (2008) [53]. Body Mass Index (BMI) was calculated as weight (in kilograms) divided by the square of height (in meters). This index is used to assess the weight status of each participant according to Cole cut-off values by sex and age [54, 55]. Consequently, the author calculated the BMI z-score. Waist/ height ratio (WtHR) was calculated and children were stratified into two categories (≤0.5 and > 0.5); the value of 0.5 is chosen as the cut-off of cardiovascular risk [56 –58]. Body composition parameters (percentage fat (%F), fat mass (FM) and fat free mass (FFM) was calculated using the skinfolds equations of Slaughter et al. (1988) [59] and the cut-off for %F by Laurson (2011) [60] used to identify subjects with lower or higher than recommended values.

- Socio-demographic Determinants.

Parents or guardians filled out a questionnaire (inside the ZOOM8 Questionnaire) [49, 50] containing socio-demographic measures (e.g., sex, age, birth date, place of birth and type of work) as well as their personal habitual PA and sedentary habits.

- Cognitive Function

Two cognitive tasks were administered: one task investigates executive functions (i.e., working memory), which are sensitive to exercise, the other task investigates multisensory perception. Verbal working memory was assessed by means of the backward digit span, a subtest of the Wechsler Intelligence Scale for Children (WISC-IV) [61]. The task involves the verbal presentation of digit series and requires children to repeat the series in reverse order. A performance score was calculated as the highest number of correct digits remembered. Multisensory perception was investigated using the sound-induced flash illusion, SIFI [62,63]. The SIFI consists of the illusory perception of two flashes when one flash is presented simultaneously with two (beep) sounds. Susceptibility to the SIFI is considered an indicator of efficient multisensory processing [64–66]. In this task, 1 or 2 flashes (the number of which has to be reported) is presented together with 1 or 2 task-irrelevant sounds. Different multisensory congruent (1flash/1beep, 2flashes/2beeps) or incongruent (1flash/2beeps) conditions are presented. The stimulus onset asynchrony (SOA) varies amongst trials (with SOAs of 70, 110, 150 and 230 ms) in the 1flash/2beeps and 2flashes/2beeps conditions.

- Time-On-Task Behaviour

The author structured a self-administered Active Breaks questionnaire for teachers to monitor a possible change in children’s behaviour. The teacher’s questionnaire included different domains regarding perceived satisfaction, feasibility, efficacy and organization of the AB intervention. The questionnaire included items investigating potential changes in the time-on-task behaviour, attention and well-being of the children, and their personal attitude in handling, implementing and performing ABs. The author also administered a children's self-administered active breaks questionnaire to explore satisfaction, feelings and pleasure in performing ABs.

- Quality of Life (HRQoL)

The Pediatric Quality of Life Questionnaire 4.0 (PEDsQL) [67] was used to measure the health-related quality of life in the children (HRQoL) and to assess important determinants of health such as daily activities, physical health, social interactions and emotional well-being. A HRQoL total score for children and separately one for parents' perceived children's HRQoL was used in the statistical analyses.

- Process Evaluation of Children and Teachers

At the 6-month follow-up (T3), children and teachers who participated in the study were invited to take part in focus groups. These focus group sessions provided an opportunity for children and teachers to provide feedback regarding the Active Breaks intervention. First, the author conducted focus groups with all the teachers assigned to the experimental group. This session was fundamental to obtain feedback regarding their perception of the program's efficacy, feasibility, and perceived adherence to the protocol. Second, the author invited control group teachers to be part of a focus group. The intention was to better understand their attitude toward possible future involvement in an AB intervention and further explore the reason why they chose not to participate in ABs. This second focus group was essential to outline barriers and facilitators for participation in health promotion interventions. It seems very important to understand, together with the teachers, the feasibility of the project and its integration into daily school activities, without negative effects on children's learning in other subjects (e.g., math, science, and Italian language). In other words, the project is easy to implement without disruption to routine academic activities and will thus not cause problems for teachers in diverse disciplines. It was hoped that the focus group will reveal to control group teachers the positive effects of participation in the program and the involvement of children in PA activities during daily school life. This mixed-methods approach is the best way to measure and understand adoption of health-related programs [68, 69].

5.5 Data Analysis

Data was recorded electronically and stored in a secure system that is safeguarded using two-factor authentication. Each individual received a unique identification code, making the data fully confidential but at the same time providing a secure means to track individuals over time.

The statistical analysis was performed using SPSS (Statistical Package for Social Science) (SPSS Inc. Chicago, IL, USA). Analysis results are reported as the mean and standard deviation for both experimental and control groups and at each assessment wave (T0, T1 and T2). We used the Student's t-test, (for parametric variables) the Mann–Whitney test, (for non-parametric variables) and the Chi-square test (categorical items) to compare general characteristics between groups. Differences between the experimental and control conditions from baseline to post-test and subsequent follow-up were examined using a one-way ANOVA and ANCOVA with covariate adjustment. We set the nominal Type I error rate at $p < .05$ for statistical significance.

- Qualitative Analysis

The research team includes individuals from various professional disciplines including psychologists, medical doctors, statisticians, methodologists, and pedagogists. These individuals conducted qualitative data collection using in-person interviews, in addition to questionnaire data and textual (audio transcribed) material gathered from focus groups. Qualified and competent researchers with backgrounds in qualitative research conducted all of these different arms of the study. The qualitative analyses provided support in evaluating the time on task behaviour outcomes obtained using semi-structured questionnaires. The author used qualitative methods, such as thematic analysis techniques and grounded theory approach [70], to organize and manage the textual data obtained from focus groups. This information, once examined, provided a basis to learn more about implementation of the I-MOVE protocol. Focus groups were audio-recorded and transcribed verbatim. Focus group data is completely anonymous as only first names are used during the course of the focus group. Analysis of the focus group textual data was conducted using the "NVIVO Version 12 Plus" software (Version12; QRS International-Melbourne, Australia).

- Harmonization and Standardization

A protocol operation manual was prepared in advance and used by all of the participants involved in the program evaluation. This manual details the data collection methodology and provides a codebook description for all of the instruments used (i.e., their source including authorship, reliability information, items used, and response formats). The author provided a detailed instructional manual, which explains the exercises to all teachers involved in the Active Break study experimental condition. Each teacher had the opportunity to adapt the exercises to his/her class and to add elements if necessary. The protocol foresaw three daily breaks lasting 10 minutes. Every two months, teachers will be asked to report whether they will be able to comply with the frequency and intensity established by the protocol or if changes will be made in the program delivery.

5.6 Discussion

The Italian guidelines on PA reinforce the importance of maintaining healthy levels of active movement in children and adolescents [71]. Thus, results from the proposed study can provide much needed evidence to support these recommendations and facilitate knowledge transfer. Furthermore, the findings can support ABs as a new public health strategy for schools and a model of educational practice oriented to the well being of children and teachers that supports quality of school life. Recent studies have stated that a poor amount of PA in children and adolescents is considered a crucial risk factor for chronic diseases in adulthood [4]. Moreover, the 2016 data from the Italian surveillance system “OKkio alla SALUTE” [72] reported that 21.3% of children are overweight, 9.3% are obese, and an additional 2.1% are severely obese. These alarming statistics can be coupled with the negative impact that PI has on the healthcare system including costs for treatment and remediation. Therefore, it is becoming increasingly important to propose sustainable and feasible interventions to promote PA. Many studies have been conducted in schools to evaluate the potential effects of classroom-based PA interventions [73–75]. Incorporating active breaks throughout the school day has been reported as a promising way for children to reach the recommended levels of PA [15]. Furthermore, active breaks conducted by trained teachers inside the classroom are quickly being recognized as a viable and cost-effective strategy for increasing PA levels and achieving positive learning outcomes [16]. However, consistent with a review by Wassenaar et al. [76], the literature focused on school-based interventions needs to be more methodologically rigorous and attend to several important issues. Foremost among these are the need for long-term follow-up assessments, continued exploration of the effect of different PA characteristics (intensity and duration), additional monitoring of the PA dosage that participants receive, and analysis of potential confounds (e.g., sex, ethnicity and socioeconomic status). To our knowledge, this is the first study conducted in Italy to investigate the efficacy of an active breaks intervention with long-term follow-up and including a varied set of outcomes. Our hypothesis is that the results of the I-MOVE study can provide much-needed evidence that supports health promotion in a school setting. Moreover, the intervention can help children to reduce their sedentary behaviour [16] and improve their quality of their life. From an educational point of view, it would seem that the program Active Breaks can represent an effective means to improve classroom behaviour, as well as benefiting children's attention and cognitive functioning [19,21]. Finally, findings from the I-MOVE study may provide evidence from a scientific point of view to show how this type of intervention can be an effective primary preventive strategy to be implemented in the school context.

6. Study 4 The Determinants of Health-Related Quality of Life in a Sample of Primary School Children: A Cross-Sectional Analysis

This cross sectional study was published in the International Journal of Environmental Research and Public health:

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Keywords: Actigraph; BMI; PedsQl questionnaire; body image; children; health-related quality of life; parent's proxy report; physical sctivity

Overview

During the initial stages of the I-MOVE project it was possible to examine various health outcomes and their determinants. In particular, within our sample of school children, I tried to identify the determinants of the health-related quality of life (HRQoL), assessed with a self-reported validated questionnaire. There is a growing literature examining (HRQoL), especially focused on health outcomes among children and adolescents including, but not limited to physical and social functioning, mental health, and well-being [1]. The WHO defines quality of life as ''the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." [2].

6.1 Introduction

Measures of HRQoL assess important aspects of health that are not detected by traditional physiological and clinical measures. Health-related quality of life is a multidimensional construct with many sub-dimensions capturing subjective experience, including PA, psychological well-being, social interaction, and school performance. In summary, HRQoL reflects a personal self-evaluation and perception of well-being, enjoyment, and satisfaction with life, general health and functioning [3,4]. Many factors are associated with HRQoL in children, including demographic (i.e., age and gender) and socio-economic characteristics of the family environment (i.e., parental education level, parents' employment situation, family wealth and resources, housing status, and rate of urbanization). Williams et al. [5] reported that children of mothers with a low educational level had lower HRQoL scores and also were more likely to be in higher weight categories than children with mothers of a higher education. Costa et al. [6] also reported that lower father's and mother's educational level and being unemployed is associated with lower mean scores for all dimensions of HRQoL. With regard to age and gender, Keating et al. [7] reported that adolescents have a lower HRQoL than children, and girls have a lower HRQoL than boys.

Wu et al. suggested that elevated levels of PA are associated with higher HRQoL, whereas a low level of PA and higher time spent in sedentary behaviour are inversely related to health-related quality of life among children and adolescents [8]. Given that HRQoL is multidimensional, it is feasible that some dimensions may be more affected by the weight condition or PA level than others. Many well-established studies have reported the benefits of PA including preventing obesity, improved skeletal health, and better mental, and emotional and psychological health in children [9–15]. The WHO recommends children and adolescents ages 5–17 perform at least 60 minutes of moderate-to-vigorous PA (MVPA) per day [16]. However, this PA recommendation has not been achieved by the majority of young people worldwide [17–24]. Children and adolescents spend more time engaging in sedentary activities than a decade ago because of the increasing use of screen-based electronic devices (e.g., smartphones, tablets, and laptops) and widespread access to the Internet [25]; this type of sedentary behaviour may have a significant impact on health, as it is independently associated with weight status and obesity [26]. Nowadays, obesity is a public health problem in many countries, not only among adults, but also in children. In Italy, the most recent data from the national surveillance system reported 21.3% of children as overweight and 9.3% of children as obese, including 2.1% of children being severely obese [24,27]. The prevalence of overweight and obesity among children, although there has been a decrease from 2008 to 2016, still remains one of the highest in Europe. In 2015, the United Nations established "The Sustainable Development Goals," in order to identify the prevention and control of NCDs as an important global health priority. Among several NCD risk factors, obesity is particularly concerning and has the potential to negatively interfere with many of the health benefits that have contributed to increased life expectancy [28]. Currently, it is widely known that being overweight and obese entail health consequences, not only limited to physical health, but to other problems including body dissatisfaction, negative body image, low self-esteem, depression, stigmatization, and social marginalization, which can influence psychological and social health [29]. Body image is a multidimensional construction reflecting a mental representation of one's own body appearance, not linked to the actual physical appearance, that is likely to affect other domains of psychological health [30,31]. Furthermore, body image distortion prevents individuals from objectively perceiving their body size [32]. This occurs when the perception of a body or parts of a body do not satisfy the culturally or socially determined body image [33].

Obesity-related complications and comorbidity represent a major public health concern. This occurs even in children, and can have nonmedical short-term consequences including adverse effects on psychosocial well being and quality of life [34,35]. A recent review suggests that a higher weight status has a moderate to strong negative influence on overall HRQoL in pediatric populations [36]. For instance, in their review of several studies Tsiros et al. found an inverse relationship between HRQoL and BMI. Other potential determinants of children's HRQoL could be the parents' perspective about their child's health. The parent–child agreement regarding HRQoL in general is low to moderate and appears to change as the child ages. Clearly, there is an increasing need to take into account parents' evaluation about their children's quality of life in order to be able to intervene and possibly remediate signs of decreased HRQoL in children at an early stage [37].

To the best of our knowledge, very few studies have evaluated parents' and children's perspective on Quality of Life [5] and none have been performed using Italian community samples of primary school children. Considering the importance of investigating HRQoL in these types of populations, we conducted a cross-sectional study. The study is part of a quasi-experimental trial in primary school children using the Imola Active Breaks (I-MOVE) Study [38].

The present cross-sectional study aims to explore anthropometric measures, parent's education, PA level, parent-reported/self-reported HRQoL, and body image as potential predictors of children's HRQoL, using a school-based convenience sample. We hypothesized that children's HRQoL is primarily influenced by objectively measured PA and BMI. In particular, we expected that, in our sample, children spending more time engaging in PA and/or with a lower BMI would report better HRQoL.

The study extends prior work in this area in several ways. First, the study assesses parents' HRQoL and the parents' perspective of their child's QoL. Second, the study also measures body image as a potential determinant of childrens' HRQoL. Third, the study examines PA levels using objective measures obtained from accelerometers, which provides a means to analyse not only the amount of 60-minutes recommended per day, but also different intensities as well as other metrics (moderate, vigorous, light intensity of PA, MVPA, sedentary time, and steps count). These innovations provide important added value as most of the literature examining PA in children has only assessed PA levels using self-reported methods [8].

6.2 Materials and Methods

Study Design and Participant

The present study uses baseline data collected from the I-MOVE study [38] conducted between October 2019 and December 2019. The study took place in a primary school of the Emilia Romagna region, Imola (Italy). The University of Bologna Bioethics Committee, on 18 March 2019, approved the study (Prot. n. 0054382 of 18/03/2019—(UOR: SI017107-Classif. III/13)).

We enrolled 151 children ages 6 to 10. A total of 110 children had complete data on the study measures. If children were absent or unavailable during the study period, they were classified as "missing" [38].

Study Variables and Instruments

Data were collected using different assessment strategies including self-report questionnaires, anthropometric, and physical activity assessments. All of the children and parents who agreed to participate in the study participated in the evaluation. Both parents could fill questionnaires.

Health-Related Quality of Life

Health-related quality of life was assessed using the Italian version 4.0 of the Pediatric Quality of Life Inventory (PedsQL) [39]. Children self-completed the PedsQL questionnaire in classroom following instructions provided by the research team.

We used self-reported children's HRQoL, self-reported adult HRQoL total score and the parents perceived child's HRQoL total score diversified according to the children's age (8–12- and 5–7-year-old children) [40–42]. Khairy et al. recommended the use of PedsQL questionnaire as a simple, easy and reliable measurement model for assessing HRQoL [43].

The PedsQL questionnaire has 23-items (Total PedsQL) divided into four domains that were used to assess the children's level of difficulty in Physical Functioning (PF-8 items) and psychosocial health divided into Emotional Functioning (EF-5 items), Social Functioning (SF-5 items), and School Functioning (SchF-5 items). Consistent with Varni et al. every item was reversely scored and linearly transformed to a 0–100 scale, so that higher scores indicate better HRQoL [39]. To reverse score items, we transformed the 0–scale items to 0–100 as follows: 0 = 100, 1= 75, 2 = 50, 3 = 25, and 4 = 0.

Demographic Variables

Parents or guardians also responded to socio-demographic and anthropometric questions (i.e., gender, education level, weight, and height) using the ZOOM8 validated Questionnaire [44,45].

Body Image Perception

To evaluate the parent's body image perception about their children, each family was invited to choose among a set of silhouettes the one that best identified the body image of their children [46]. Parents selected two different silhouettes: the first regarded the image that they believed was the most similar to their children ('actual figure') and the second was the image that parents desired for their children ('ideal figure'). A Mother's Feel Ideal Difference (FID) index was calculated by subtracting the ideal figure score from the actual figure score. A positive FID score indicates the actual figure was bigger than the ideal figure and a negative score indicates the actual figure was thinner than the ideal figure. A FID score of 0 indicates no discrepancy between actual and ideal figures.

Improper perception of weight status of their children was evaluated by means of Mother's FAI (Feel weight status minus Actual weight status Inconsistency). We calculated an inconsistency FAI score by subtracting the conventional code assigned to the actual weight status of the participant (1 = underweight; 2 = normal weight; 3 = overweight; 4 = obese) from the code that the child's mother perceived. A FAI score of zero indicates no inconsistency in weight status perception; a positive score indicates that weight status is overestimated whereas, a negative score indicates that weight status is underestimated.

Anthropometric Variables

Six anthropometric characteristics (height, weight, waist and hip circumferences, triceps and subscapular skinfold thicknesses) were collected according to standardized procedures [47,48]. In particular, height was measured to the nearest 0.1 cm using a portable stadiometer (SECA 217, SECA: Hamburg, Germany). Body weight was measured to the nearest 0.1 kg (light indoor clothing, without shoes) using a calibrated electronic scale (SECA 877: Hamburg, Germany).

Waist circumference (WC) was measured to the nearest 0.1 cm with a non-stretchable tape (GPM measuring tape; DKSH Switzerland Ltd.: Zurich, Switzerland): WC was measured between the lowest rib and the iliac crest. Waist and height were used to calculate the Waist/height ratio (WtHR) to stratify children in two categories (0.5 and >0.5); the value of 0.5 is chosen as the cut-off of cardiovascular risk [49–51]. Body Mass Index was calculated as weight (in kilograms) divided by the square of height (in meters). The BMI was used to assess the weight status of each participant according to Cole cut-off values by sex and age [52,53].

Triceps (TSF) and subscapular (SSF) skinfold thickness was measured to the nearest 0.1 cm on the left side with a Lange caliper (Beta Technology Inc.: Santa Cruz, CA, USA). TSF was measured midway between the tip of the acromion and olecranon processes, while SSF raising an oblique skinfold below the inferior angle of the scapula at 45° to the horizontal plane following the natural cleavage lines of the skin. TSF and SSF were evaluated according to the Frinsancho cut off (2008) [54]. Body composition parameters (percentage fat (%F), fat mass (FM) and fat free mass (FFM)) were calculated using the skinfolds equations of Slaughter et al. (1988) [55].

Physical Activity Variables

The time spent in PA and sedentary behaviour was monitored through Actigraph accelerometers (Actigraph, LLC, Pensacola, FL, USA) (ActiLife6 wGT3X-BT set to 10-s epochs). The accelerometer data were analysed through ActiLife 6.13.3 software (ActiGraph, LCC, Pensacola, FL, USA), with an epoch length set to 10 s to allow a more detailed estimate of PA intensity [56].

The data processing procedures to evaluate total time spent in sedentary behaviour and PA at different intensities are consistent with previous studies on children and adolescents [17,57-58]. The children wore the accelerometers, around the waist in the right side, with an elastic belt [59], over a seven-day period (five weekdays and two weekend days), and removed them only when bathing, swimming and showering. We computed the accelerometer’s data only when children were complying with some specific inclusion criteria such as: having worn the accelerometer for at least 10 h every day (sleeping hours included) during 3 weekdays and 1 weekend day). The Evenson cut points were used to calculate the minutes spent in physical activity (light, moderate and vigorous) per day [60].

Statistical Analysis

All analyses were carried out using SPSS, version 22 (Statistical Package for Social Science) (SPSS Inc. Chicago, IL, USA) and STATA, version 13 (StataCorp 2013. Stata Statistical Software Release 13. College Station, TX: StataCorp LP). Categorical variables are presented as frequency (percentage) and continuous variables are presented as means and standard deviation (SD).

We applied multiple linear regression to determine factors associated with HRQoL. Using backwards stepwise analysis all variables were tested for inclusion in the final regression model. The nominal alpha significance level was set to $p \leq 0.05$.

6.3 Results

Study Participants

Table 1 shows the main participants' characteristics.

Table 1. Baseline characteristics of the participants

Characteristics	**Total Sample (*n* = 151) N (%) or Mean ± DS**
General Information	
Age	7.77 ± 1.42
Gender (male)	*n* = 83 (54.2%)
Mother's education	
Low	*n* = 21 (16.2%)
Medium	*n* = 60 (46.2%)
High	*n* = 49 (37.7%)
Father's education	
Low	*n* = 26 (20.3%)
Medium	*n* = 71 (55.5%)
High	*n* = 31 (24.2%)
Mother's BMI	22.68 ± 3.15
Father's BMI	26.52 ± 3.59
Anthropometric measures	
BMI	17.74 ± 2.72
Normal-weight	*n* = 102 (67.5%)
Over-weight	*n*= 33 (21.9%)
Obese	*n* = 16(10.6%)
%F	16.83 ± 4.98
WtHR	0.46 ± 0.04
Non at risk	*n* = 125 (83.9%)
At risk	*n* = 24 (16.9%)
Body Image	
Under	*n* = 44 (34.4%)
Correct	*n* = 74 (57.8)
Overestimation	*n* = 8 (7.8%)
Physical Activity Outcome	
Daily MVPA	
Meet the recommended level	*n* = 57 (38.3%)
Not meet the recommended level	*n* = 92 (61.7%)
Weekly MVPA	328.14 ± 127.22
Weekly Light PA	1661.54 ± 388.77
Weekly Moderate PA	214.31 ± 78.00
Weekly Vigorous PA	113.82 ± 58.33
Weekly Sedentary time	6655.44 ± 489.08
Weekly Total Steps	54,557.73 ± 16,681.01
HRQoL Children	
PedsQl Children Total score	72.02 ± 13.28
PedsQl Physical Health	74.25 ± 13.83
PedsQl Psychosocial Health	70.79 ± 15.87
PedsQl Emotional Functioning	67.26 ± 21.19
PedsQl Social Functioning	74.97 ± 18.71
PedsQl School Functioning	70.18 ± 19.09
HRQoL Parent proxy-reports	
PedsQl Total score	79.19 ± 10.86
PedsQl Physical Health	82.73 ± 13.29
PedsQl Psychosocial Health	77.25 ± 11.87
PedsQl Emotional Functioning	72.96 ± 13.47
PedsQl Social Functioning	81.42 ± 15.15
PedsQl School Functioning	77.29 ± 16.26
HRQoL Adult self-reports	

PedsQl Total score	77.92 ± 9.88
PedsQl Physical Health	77.77 ± 12.55
PedsQl Psychosocial Health	77.97 ± 10.68
PedsQl Emotional Functioning	66.86 ± 15.57
PedsQl Social Functioning	85.71 ± 12.30
PedsQl Work Functioning	81.33 ± 11.45

BMI—body mass index; %F—percentage fat mass; WtHR—waist to height ratio; PA—physical activity counts per minute; PedsQl—Pediatric Quality of Life Inventory.

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Mean age of the full sample was 7.77 (SD = 1.42) and 54.2% were male. The prevalence of normal-weight and overweight/obese were 67.5% and 32.5% respectively. A smaller percentage (46.2%) of mothers reported a medium education (high school diploma) (fathers 55.5%).

The PedsQL Total Score for the sample was 72.02 (SD = 13.284). The average scores for the different domains were: Physical Health ($\bar{X}$ =74.25, SD = 13.83), Psychosocial Health ($\bar{X} =$70.79, SD = 15.87), Emotional Functioning ($\bar{X}$ = 67.26, SD = 21.19), Social Functioning ($\bar{X}$ =74.97, SD = 18.71), and School Functioning ($\bar{X} =$70.18, SD = 19.09). Using the recommended Cole cut-off, the sample was stratified in three categories [52,53]. A majority of the sample (67.5%) was categorized as normal weight, 21.9% overweight and 10.6% as obese. Stratifying children with WtHR, 83.9% were categorized as not at risk and 16.9% were considered at cardiovascular risk. Considering Actigraph parameters, the mean daily MVPA was $\bar{X} =$54.67, SD = 21.24, in fact exclusively 38.8% of children met the recommended level of 60 minutes of PA per day.

In terms of body image, 57.8% of parents reported that their child had an "adequate" body image, 34.4% underestimated their child's body image while an additional 7.8% overestimated their child's body image.

Linear Regression Analysis

A stepwise regression analysis was performed in order to investigate which variables would be used in the final regression model (represented in the adjusted conditions in Tables 2 and 3A,B). As is customary, the variables of age, BMI, and gender were used in all of the regression analyses (and entered first). With regard to the total PedsQL score, a stepwise analysis revealed that mother's BMI, parent's proxy-reports PedsQL total score, levels of PA, and body image should be included in the model. Indeed, a fully adjusted regression model showed that moderate PA was significantly and positively associated with the total PedsQL score (p < 0.05). Moreover, the regression analysis indicated a positive and significant association (p < 0.05) between sedentary time and total PedsQL score (Table 2). The full model accounted for 14.21% of the variance in PedsQL.

Table 2. Factors from the total domain associated with health-related quality of life in children

	HRQoL Total Score (*n* = 109) **Reg. Coeff. (95% CI)**	***p*-Value***
Gender	−3.26 (−8.46; 1.94)	0.22
Age	0.38(−1.47; 2.4)	0.68
BMI	0.35 (−0.58; 1.28)	0.46
Mother's BMI	−0.54 (−1.24; 0.15)	0.12
Sedentary [a]	0.03 (0.00; 0.57)	**0.04***
Light PA [a]	0.03 (0.00; 0.05)	0.09
Moderate PA [a]	0.075 (−0.01; 0.14)	**0.03***
Total Parent proxy-reports	0.17 (−0.03; 0.38)	0.10
Body image	3.51 (−0.44; 7.46)	0.08

* Significant *p*-value < 0.05; [a] accelerometer measured count per minutes calculated as weekly total minutes spent in sedentary, light, and moderate activity.
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In predicting physical health (Table 3A), the regression analysis was adjusted for mother's BMI, and adult self-reported physical health after performing a backward elimination model. Mother's BMI was the only statistically significant measure and negatively associated with physical health of the children ($p = 0.02$, $R^2 = 0.1945$).

Table 3B shows results of the model predicting psychosocial health adjusted for body image, parent proxy-reports of psychosocial health, and PA levels. There was a positive and significant ($p < 0.01$) relation between parent's proxy-report and the children's psychosocial health ($R^2 = 0.1421$).

Interestingly, the child's gender, BMI, and age were not significantly associated with any of the HRQoL domains.

Table 3 (A) Factors associated with health-related quality of life in children for the physical health domain. **(B)** The associated factors of the health-related quality of life in children for the psychosocial health domain

(**A**)

	Physical Health (*n* = 114) **Reg. Coeff. (95% CI)**	***p*-Value***
Gender	−1.90 (−6.70; 2.89)	0.43
Age	−1.62 (−3.46; 0.22)	0.08
BMI	0.43 (−0.54; 1.39)	0.38
Mother's BMI	−0.91 (−1.68; −0.15)	**0.02***
Physical health from the adult self-reports	−0.16 (−0.36; 0.03)	0.1

(**B**)

	Psychosocial Health (*n* = 115) **Reg. Coeff. (95% CI)**	***p*-Value***
Gender	−0.24 (−6.20; 5.72)	0.9
Age	1.87 (−0.27; 4.01)	0.09
BMI	−0.84 (−2.33; 0.66)	0.27
Sedentary [a]	0.03 (−0.01; 0.06)	0.10
Moderate PA [a]	0.06 (−0.02; 0.13)	0.14
Light PA [a]	0.02 (−0.01; 0.06)	0.17
Psychosocial health parent proxy-reports	0.40 (0.18; 0.61)	**0.00***
Body image perception	3.60 (−0.89; 8.18)	0.12

* Significant *p*-value < 0.05; [a] accelerometer measured count per minutes, calculated as weekly total minutes spent engaging in sedentary, light, and moderate activity.
Masini A, et al. The Determinants of Health-Related Quality of Life in a Sample of Primary School Children: A Cross-Sectional

Analysis. Int J Environ Res Public Health. 2021;18(6):3251. doi:10.3390/ijerph18063251

6.4 Discussion

This study investigated relations between anthropometric measures, parent's education, PA level, parent-reported/self-reported HRQoL, and perceived body image of the child as potential predictors of children's HRQoL using a sample of primary school children. The main finding of this study was that more time spent in moderate intensity PA was positively associated with higher reported HRQoL in children, the latter assessed using a total PedsQL score. These results are in line with previous studies [8,19,61]. Indeed, a systematic review and meta-analysis confirmed that children with higher levels of PA reported better HRQoL [19]. Furthermore, the association between PA and HRQoL's was consistent, regardless of weight status, age, socio-economic characteristics, and sex [8]. Within our sample, weekly moderate PA levels, measured using objective instruments, were significant predictors of HRQoL.

In addition, Wafa et al. found a positive relationship between HRQoL and MVPA, indicating that children who were physically active reported a better quality of life [19]. However, in their regression models, this relationship was no longer significant following covariate adjustment. Conversely, in our study, the relationship between the total PedsQL score and higher levels of moderate intensity PA remained significant even with covariate adjustment.

Contrary to most of the studies focused on QoL, we found that gender and age were not significant factors associated with HRQoL. These findings comport with Khairy et al. [43], who found that gender differences in HRQoL were probably not very important in childhood, but took shape during adolescence, disproportionately affecting girls. In addition, the same authors found that certain factors affecting QoL become more active during adolescence and may have been less critical during primary school. Tsiros et al. [36] suggest that it is essential to take into account the parent's perceived HRQoL for their child. Indeed, in our sample, we observed that the parent's proxy-report of their child's psychosocial health was positively and significantly associated with the child's self-reported psychosocial health. Williams et al. however, found less agreement between parent proxy and child-reported HRQoL in 12-year-olds compared with younger children [5]. Therefore, HRQoL the match between perceptions by children and their parents likely begin to differ with increasing age. This may occur because the child develops a more complex and independent understanding of the world, rather than accepting their parental opinions [36]. We also found a statistically significant and negative association between mother's BMI and child's physical health. To the best of our knowledge, there are no studies that consider parent's anthropometric measures as predictive factors of QoL in the physical health domain. The literature confirms an association between parent's BMI, child's BMI [62], and health behaviour [63]. Therefore, if one considers that the family and related environmental contexts affect children's lifestyle, it makes sense that the mother's BMI might be associated with the child's HRQoL.

A majority of studies in this field have shown that a higher weight status has a moderate to strong negative influence on overall HRQoL in pediatric populations [3,19,36]. Nevertheless, the children's sample in our study did not report a significant difference in QoL related to different BMIs. Similarly, some smaller US studies did not find a significant relationship between BMI and HRQoL [64-66]. Differences in findings between studies can arise for several reasons including the smaller sample size in our study, which may introduce bias toward normal-weight participants. Indeed, only a small part of the sample was categorized as "obese," and this can influence the study findings. Furthermore, unlike others we also found a positive association between time spent engaging in sedentary behaviour and the total PedsQl score. It is possible, because we did not use the child's daily sleep hours as a factor in computing sedentary activities, that we did not obtain the expected inverse association between time spent in sedentary behaviour and children's HRQoL. Nevertheless, the use of accelerometers is the most widely accepted method of objectively measuring time spent engaging in PA in youth [67].

7. Study 5 The Impact of COVID-19 on Physical Activity Behaviour in Italian Primary School Children: A Comparison Before and During the COVID Pandemic with a Focus on Gender Differences

This study was published in the BMC Public Health:

Dallolio L, Marini S, Masini A, et al. The impact of COVID-19 on physical activity behaviour in Italian primary school children: a comparison before and during pandemic considering gender differences. BMC Public Health. 2022;22(1):52. doi:10.1186/s12889-021-12483-0

Keywords: Accelerometer; COVID-19; Children; Physical inactivity; Sedentary behaviour.

Overview

Covid-19 has inevitably changed the general lifestyle of the world's population, and this has been even more troublesome for children and adolescents. With this study I investigated the effects of the pandemic, one year after the first lock down, on PA levels in the sample of primary school children involving in the I-MOVE study.

7.1 Background

The benefits of physical activity (PA) for children's health and well-being are well-known [1,2]. A growing body of evidence shows that greater amount and higher intensity of PA during childhood is associated with multiple beneficial outcomes such as cardiorespiratory and muscular fitness, cardio metabolic and bone health, academic performance, cognitive function, and mental health [3].

As many of these benefits are observed with an average of 60 minutes of moderate-to-vigorous daily PA, the updated "World Health Organization guidelines on physical activity and sedentary behaviour," published in November 2020, confirmed that this is the minimum dose of PA that children should accumulate every day of the week [4]. Despite this evidence, prevalence estimates from intercontinental PA surveillance data are consistent in finding an insufficient level of PA in children across the world particularly evident among girls in comparison with boys of the same age [5,6]. A study conducted in Europe [Steene-Johannessen J. at al.,] using accelerometers as PA objective measures, found that only up to 29% of children are categorized as sufficiently physically active, performing an average of at least 60 minutes of PA per day, with substantial region-specific differences. In particular, the prevalence of adequately active children was higher in Northern (31%), intermediate in Central (26%), and significantly lower in Southern Europe (23%) [6]. With regard to gender differences, and using objective measures with Actigraph, boys were more active (13 minutes MVPA/day) and spent less time in sedentary behaviour compared to girls (8 min./day) [6].

The lack of adherence to PA guidelines, referred to as Physical Inactivity (PI) [7], is an established risk factor that has been identified as an important leading cause of death worldwide. Moreover, PI has already been identified as a pandemic issue [8]. Katzmarzyk et al. recently provided the most complete description of the global health burden associated with PI, suggesting that it is responsible for a total of 7.2% of all-cause deaths and for a substantial proportion of NCD, ranging from 1.6% for hypertension to 8.1% for dementia [9]. There is also evidence accumulating that as a consequence of the policies aimed at controlling the spread of the coronavirus disease (COVID-19), there has been a substantial increase in global PI levels in all age groups [10-13]. Thus, it has been hypothesized that the COVID-19 pandemic can exacerbate the pandemic of PI [14,15].

In their scoping review examining effects of COVID-19 on children's PA habits, Yomoda et al. found a significant decline in PA [12]. In particular, the authors reported that the decrease was more prevalent among boys and older children and in those who live in apartments or houses with limited spaces and urban areas. This may be related to the fact that boys are used to practice organized team sports, activities that were curtailed during the pandemic [16].

The 21 studies included in the Yomada et al. review presented data related to the first half of 2020, when schools closure and lockdown measures were adopted almost worldwide. One of the highest school closure rates was reached at the end of March 2020 when schools were closed in 167 countries, affecting 82.8% of the world's learners (more than 1.4 billion children and adolescents) https://en.unesco.org/covid19/educationresponse#schoolclosures.

As schools provide children with several opportunities for being physically active, such as PE class and school playtime, [17,18] a reduction in PA during the first wave of COVID-19 could be expected. Healthy behaviours such as active commuting to schools (i.e., walking or cycling), which represent a strategy to raise PA levels, have been restricted during COVID-19 and it was difficult to think these healthy habits could be compensated at home [19]. Furthermore, during this period, other restrictions such as the closure of playgrounds, parks, recreational and sport facilities reduced the possibilities to be engaged in both structured and unstructured PA [20]. Finally, adolescents with lower physical fitness were observed to have further reduced PA levels during the pandemic [19].

Lopez et al. examined cardio fitness status during the COVID-19 confinement and found an overall small decrease in VO2 max that was statistically significant only for adolescent girls [21]. Although short-term changes in children's PA levels due to COVID-19 were observed, to our knowledge, little is known about changes over a longer period and after the first peak of COVID-19 pandemic. Thus, it is reasonable to consider that PA levels will continue to decline, paving the way toward even worse conditions than before the pandemic [12]. This alarming scenario suggests that it is fundamental to investigate the long-term effects of the COVID-19 on children's PA [12]. Moreover, another important gap in the literature is that most of the studies examining PA in children during the COVID-19 pandemic did not include objective measurements [12]. Therefore, the present study aims to examine the impact of COVID-19 on the PA of an Italian sample of primary school children by comparing PA levels before and after the re-opening of schools during COVID-19 pandemic and determining whether there are meaningful gender differences.

7.2 Materials and Methods

Study Design and Participants

The present study involved a pre-post analysis, using a randomized sample from the I-MOVE study that took place in a primary school of a northern Italian city (Imola, Emilia Romagna Region). The I-MOVE study received approval from the University of Bologna Bioethics Committee, on 18 March 2019 (Prot. n. 0054382 of 18 March 2019 (UOR: SI017107-Classif. III/13)). The study was conducted following the Declaration of Helsinki. Informed consent was obtained from all parents and/or legal guardian(s) of the participants.

Data collection and outcomes

A baseline assessment was completed in October 2019 and a second intermediate follow-up assessment was conducted in January 2021 after one year of the COVID-19 pandemic.

Socio-demographic information for each participant was obtained during the baseline assessment. Parents' education level was stratified into three categories: low (completed primary and middle school), medium (high school diploma) and high (university degree).

In October 2019, anthropometric characteristics of the children were collected following standard procedures [22,23] by the study research staff. In particular, height was measured to the nearest 0.1 cm using a portable stadiometer (SECA 217; Hamburg, Germany), body weight was measured to the nearest 0.1 kg (light indoor clothing, without shoes) using a calibrated electronic scale (SECA 877; Hamburg, Germany).

Given the health-related restrictions that took place during the pandemic and the importance of maintaining physical distancing, the research team could not carry out anthropometric measurements during the second intermediate assessment. Hence, the parents of children participating in the I-MOVE study remotely reported anthropometric characteristics of their child, i.e., height and weight, using an online questionnaire in January 2021.

Body-Mass Index (BMI) was calculated as weight (in kilograms) divided by the square of height (in meters). This index was used to assess children's weight status according to the recommended Cole cut-off values by sex and age [24,25].

PA outcomes were monitored through self-report and objective measures both in October 2019 before the COVID-19 and in January 2021 during the COVID-19 pandemic when schools were re-opened. Self-reported PA questionnaires for children (PAQ-C) were used to investigate PA during school time, leisure time and PA during organized sports. The PAQ-C is a self-administered, 7-day recall questionnaire, with nine items scored on a five-point scale. This instrument yields a final composite activity score by calculating the mean of the nine items. The questionnaire has been shown to be valid and reliable [26].

Objective PA and time spent in sedentary behaviours (SB) data were assessed using an accelerometer actigraph (Actigraph, LLC, Pensacola, FL, USA) (ActiLife6 wGT3X-BT set to 10-s epochs). The actigraph assessment was carried out following a careful sanitization of the instrument before and after each use.

The children were instructed to wear the actigraph on their right hip using a specific waistband [27] over a seven-day period (five weekdays and two weekend days), with the exclusion of water activities (e.g., showering, bathing or swimming). Actigraph data were examined through ActiLife 6.13.3 software (ActiGraph, LCC, Pensacola, FL, USA), with an epoch length of 10 s to allow a more detailed estimate of PA intensity [28]. Valid wear time was defined based on a specific inclusion criterion: having worn the accelerometer for at least 10 h every day (sleeping hours included) during at least 3 weekdays and 1 weekend day. The cut-points suggested by Evenson were used to calculate the minutes spent per type of physical activity (light, moderate and vigorous) per day [29].

Statistical Analysis

Data analysis was carried out using SPSS, version 22 (Statistical Package for Social Science) (SPSS Inc. Chicago, IL, USA). Continuous variables are presented as means and standard deviation (SD), and categorical variables are presented as frequency (percentage). Considering the normal distribution of our sample, verified by the Esplora SPSS function, we analysed differences in PA outcomes, both objective and self-reported, before and during COVID-19 within groups, using the paired-samples t-test for continuous variables and the Chi-square test for categorical measures. Gender subgroup analysis was performed using one-way ANOVA. Significance level was set to $p < 0.05$.

7.3 Results

Sample description

A total of N=77 children were randomized within the I-MOVE study and enrolled in the present study. Table 1 shows the general demographic characteristics of the sample, collected in October 2019, before the COVID-19 pandemic. Children's ages ranged from 7 to 10 years, with an average age of 7.84 (SD 1.41) and BMI of 17.80 (SD 2.82). A majority of the sample was male (60.80%). The most prevalent parents' education level reported was medium.

Table 1 Sample characteristics

Variables	N (N=77)	Mean ± SD or %
Age (n, years)	77	7.83 ± 1.42
Male (n, %)	48	62.3%
Female (n, %)	29	37.7%
BMI Total (n, score)	78	17.81 ± 2.85
Mother Education		
Low (n, %)	12	18.2%
Medium (n, %)	31	47.0%
High (n, %)	23	34.8%
Father Education		
Low (n, %)	17	25.8%
Medium (n, %)	36	54.5%
High (n, %)	13	19.7%

BMI= body max index

Dallolio L, et al. The impact of COVID-19 on physical activity behaviour in Italian primary school children: a comparison before and during pandemic considering gender differences. BMC Public Health. 2022;22(1):52. doi:10.1186/s12889-021-12483-0

Physical activity levels

Table 2 describes changes between before and during COVID-19. From 2019 to 2021 the sample participant's age and BMI, as expected, increased significantly. Participants' BMI scores increased on average within the normal range, while the children's distribution in the different weight categories, based on the International Obesity Task Force (IOTF) cut-offs, varied with a significant reduction of children with normal-weight (71.1% versus 68.4%) and increase of children with over-weight (21.1% versus 26.3%). All actigraph parameters showed significant declines over time: weekly and daily minutes spent in PA significantly decreased by 30.59 and 15.32 minutes, respectively, from before to during COVID-19 (p value ≤0.01).

A similar decrease was observed in the duration of the time spent in PA of different intensity: light (-16.16 ± 267.67), moderate (-15.80 ± 65.86) and vigorous (-15.19 ± 46.06), with a significant decrease for both moderate and vigorous PA but a non-significant decrease in light PA. The same reduction was also observed for the weekly step counts. Overall, in October 2019, 57.1% of the sample did not reach the recommended level of PA, and this percentage increased significantly in January 2021, with a total of 88.3% of children not meeting the recommended levels of PA. In contrast, the author observed a significant increase of minutes (+1196.01 ± 381.49) spent in sedentary activities.

The self-reported PA measurement, assessed with the PAQ-c questionnaire and completed by N=52 children, followed the same trend of the objective actigraph measurement. The PAQ-c total score significantly decreased from October 2019 to January 2021 (-0.87 ± 0.72).

Table 2 Changes between before and during the COVID-19 pandemic

Variables	Before COVID-19 Mean ± SD or %	During COVID-19 Mean ± SD or %	Changes Mean ± SD	P Value*
Age (years)	7.84 ± 1.41	9.19 ± 1.41	+1.35 ± 0.03	<0.0001*
BMI (score)	17.49 ± 2.76	17.91 ± 3.00	+0.10 ± 0.21	0.05*
BMI Cole cut-off				<0.001*
Normal weight (n, %)	54 (71.1%)	52 (68.4%)		
Overweight (n, %)	16 (21.1%)	20 (26.3%)		
Obese (n, %)	6 (7.9%)	4 (5.3%)		
Weekly MVPA (min)	332.94 ± 118.42	301.95 ± 109.81	-30.59 ± 120.87	0.01*
Daily MVPA (min)	55.44 ± 19.1	40.13 ± 14.18	-15.32 ± 16.21	<0.001*
Adhering to MVPA guideline of 60 min/d; (n, %)	33 (42.9%)	9 (11.7%)		<0.001*
Not adhering guideline	44 (57.1%)	68 (88.3%)	N= -24	<0.001*
Sedentary Activity (min/week)	6605.88 ± 417.30	7801.89 ± 409.92	+1196.01 ± 381.49	<0.001*
Step Counts (*n*/week)	54687.39 ± 13015.37	51534.86 ± 11615.04	-3152.53 ± 11433.77	0.02*

Light (min/week)	1711.06 ± 308.33	1694.92 ± 297.54	-16.16 ± 267.67	0.60
Moderate (min/week)	219.79 ± 72.26	203.99 ± 68.00	-15.80 ± 65.86	0.04*
Vigorous (min/week)	113.15 ± 53.40	97.95 ± 47.36	-15.19 ± 46.06	0.005*
Physical Activity Levels (PAQ-C score) N=52	3.06 ± 0.75	2.19 ± 0.57	-0.87 ± 0.72	<0.001*

Changes in continuous measures between before and during pandemic were compared using Students' t-test for paired samples and Chi-Square test for categorical variables. LABELS: MVPA: moderate to vigorous physical activity; BMI: body-mass index; PAQ-c: physical activity questionnaire for children. * Significant p-value < 0.05.
Dallolio L, et al. The impact of COVID-19 on physical activity behaviour in Italian primary school children: a comparison before and during pandemic considering gender differences. BMC Public Health. 2022;22(1):52. doi:10.1186/s12889-021-12483-0

Gender differences

Significant gender differences were observed for both objective and self-reported measures of PA during the COVID-19 pandemic as compared to the same period one year and a half before (Table 3).

Table 3 Gender differences between before and during COVID-19 pandemic (N=77).

Variables	Before COVID-19		During COVID-19		Before and During COVID-19 Changes Mean ± SD		P value*
	Boys (N=48)	Girls (N=29)	Boys (N=48)	Girls (N=29)	Boys (N=48)	Girls (N=29)	
Weekly MVPA (min)	368.69±116.58	273.76± 97.11	316.60± 114.87	277.70± 98.00	-52.09±110.46	+3.94±85.89	0.02*
Daily MVPA (min)	61.38± 19.58	45.63± 16.18	41.83± 14.70	37.30± 13.01	-19.54±16.55	-8.32±13.13	0.003*
Not meeting the recommended levels (<60minper day MVPA)	21 (43.75%)	23 (79.31%)	41 (85.42%)	27 (93.10%)	N=+20	N=+4	0.02* (girls) ns (boys)
Weekly sedentary activities (min)	6532,40± 392.26	6727.52± 435.67	7794.82± 359.03	7813.60± 489.38	+1262.42± 386.60	+1086.08±350.39	0.05*
PAQ-c total score	3.34 ± 0.72	2.69± 0.78	2.25± 0.60	2.08± 0.64	-1.10±0.80	-0.60±0.52	0.01*

*Changes between before and during pandemic were compared using Oneway-Anova stratifying results by gender for continuous measures and Chi-square test for categorical measures. LABELS: MVPA: moderate to vigorous physical activity; PAQ-c: physical activity questionnaire for children.
Dallolio L et al. The impact of COVID-19 on physical activity behaviour in Italian primary school children: a comparison before and during pandemic considering gender differences. BMC Public Health. 2022;22(1):52. doi:10.1186/s12889-021-12483-0

Weekly time spent in PA significantly decreased significantly in boys (Δ = -52.09 ± 110.46) while girls did not undergo a substantial decrease over the total PA. However, there was a slight increase in the weekly PA from before to during the COVID-19 pandemic. Both groups reduced their daily PA, especially boys (Δ = -19.54 ± 16.55), and the number of children who did not reach the PA guidelines of ≥60 min/d of PA increased in our sample and this change was significant for girls. Before the pandemic, girls in our sample had very low daily levels of MVPA (45.63 ± 16.18) and the 79.31% did not meet the recommended levels of PA. The COVID-19 pandemic has further exacerbated this condition with 93.10% of girls in January 2021 who reported levels of MVPA lower than 60 minute per day. Considering the sedentary behaviour before COVID-19, girls were more sedentary than boys (girls: 6727.52 ± 435.67 vs boys: 6532,40 ± 392.26) and during the pandemic increases in sedentary behaviour was greater in girls (girls: 7813.60 ± 489.38 vs boys: 7794.82 ± 359.03)

Generally speaking, both boys and girls increased their time spent in sedentary activity of +1262.42±386.60 and +1086.08±350 minutes per week, respectively, with a greater increase for boys. Finally, also the PAQ-c total score calculated from before to during COVID-19 was significantly lower in boys than girls.

7.4 Discussion

The present study evaluated the impact of COVID-19 restrictions on PA levels in an Italian sample of primary school children comparing data from October 2019 to January 2021.

After China, Italy was the second country in the world that experienced the impact of COVID-19 with high COVID-19-related mortality, particularly in the early months of the pandemic [30]. For this reason, Italy was the first European country to enact measures for school closure and to implement a national lockdown to contain the spread of COVID-19 [31]. In particular, schools were closed on 5th March 2020 and re-opened on 14th September 2020. During this period, education was not interrupted but continued online. After this period, primary schools remained open, except between 8th March 2021 and 7th April 2021 (1 month of distance learning).

In this study, all children obtained a general reduction in all actigraph measures. A greater decline was observed among boys, who reduced their PA levels significantly more than girls. However, it should be noted that girls had generally lower levels of MVPA before COVID-19 and a lower percentage met the WHO recommendations about the amount of PA every day; in January 2021 there was a further deterioration of this inequality.

Our results are in line with recent literature regarding the impact of the pandemic restriction on children's PA levels. [12,13,32,33]. In particular, Yomoda et al.'s scoping review summarized data related to the first half of 2020, when lockdown measures were in place in many countries. These authors found that the COVID-19 pandemic caused a decline in PA among children, especially in boys and in older children/adolescent [12]. A cohort study conducted in Dutch primary school children found that, even after the lockdown measures and the re-opening of the schools (June 2020), PA still decreased, while screen and sedentary time increased [34].

Pietrobelli et al. conducted a study on children and adolescents with obesity, comparing data from May-July 2019 to March-April 2020, and found 2.30 h/week lower exercise's time [32]. This reduction is in line with another Italian study that evaluated, the effects of the COVID-19 quarantine in youth 15 days after the first lockdown (10th March 2020). As expected, staying at home without the possibility to go outside changed many routines, and during the quarantine, only 15.5% of youth practiced at least 60 minutes of PA [35]. Our results confirm this negative trend and seem to suggest that COVID-19 can negatively affect the children's PA levels even after one year since the beginning of the pandemic.

Another alarming factor, in line with other studies [20,32,34], was the increasing amount of time spent in sedentary activities. ten-Velde et al. studied Dutch primary school children and found that, despite the re-opening of schools, they did not observe a reduction in SA.

The reduction in PA and the increase in SB is particularly alarming because, as previous research suggests, even brief periods of sustained physical inactivity can have detrimental effects on muscle mass, glucose homeostasis, cardiovascular function and structure, and increase cardiovascular risk factors [10,36].

To our knowledge, this is the first Italian study to provide objective and self-reported PA data aiming at assessing the long-term effects of COVID-19 on children's PA behaviours. Moreover, in line with our findings, a recent systematic review with meta-analysis [Runacres et al.] found a moderate impact of the COVID-19 pandemic on children' sedentary time. However, all the studies included in the review only used self-reported measurements to assess sedentary time and, furthermore, they were not focused on a longer impact of COVID-19 but on the effects of lockdown or similar restrictions (such as school closures or homestay requirements) [37]. Considering that PA habits in childhood are of great importance as children who are active in their youth are more likely to continue of being active into adulthood [38] and that the effects of COVID-19 could be prolonged, public health stakeholders should consider these findings to prevent the negative effects of PI among children by promoting strategies to restore PA to sufficient levels.

Parents, schools, health policymakers, and governments need to be aware of this situation and consider these findings in order to promote proactive strategies and interventions to improve PA levels and prevent the negative effects of PI [12,33]. As structured settings, schools, afterschool programs, summer and sport camps all have readily shown they can provide substantial amounts of PA during attendance and can make an important contribution to health-enhancing PA [18]. In general, these types of settings can be favourable environments for pursuing the health and well being of children. Furthermore, school time and physical education lessons can make a difference and provide both adequate environments and support to encourage children to be physically active [17].

The findings suggest that classroom PA programs should be included in school health guidelines as an integrative approach in cooperation with educative stakeholders to re-establish the recommended level of PA and reduce the increase in sedentary behaviour [39].

Our study has several limitations. First, the sample was small and came from an ongoing study, which could introduce a modicum of sample bias. Although this population might not be representative of the Italian primary school population but only of a region with a good culture supporting active lifestyles, our findings provide an accurate estimation of the PA patterns among primary school children. Moreover, few studies used both objective and self-reported measures to assess PA levels [34]. Although the PAQ-c questionnaire has been proved to be an acceptable and reliable instrument [26], some concerns remain about the variability of self-assessments conducted by the participants [40]. Furthermore, previous research [34] showed that seasonal weather variations could affect PA results. Nevertheless, we performed the assessments both in autumn and winter in order to make pre- and post-assessments comparable in terms of seasonal period. Pandemic restrictions prevented us from performing certain assessments and we had to rely on the parents to provide data. We did not analyze age and BMI sub-categories given the sample size, which needs to be further explored to detect gender and developmental differences. However, during the baseline assessment, no statistically significant differences were found stratifying by BMI and age.

8. Study 6 The effect of an Active Breaka Intervention on Physical and Cognitive Performance: Results from the I-MOVE study

Manuscript in preparation

Overview

The present study is the final part of the longitudinal I-MOVE study. The I-MOVE study is one of the first studies, settled in Italy and conducted with a long-term follow-up.

In the present study I underline the effect of an Active Breaks intervention on physical health and cognitive functioning among primary school children.

8.1 Introduction

The PA levels are influenced by the opportunities to be active including limited play spaces, unsafe environments, and increased screen time habits. The most frequented environment for children is the school where they spend most of their daily time. The school gives access to all children regardless of age, gender, ethnicity, and socioeconomic class. [1] Precisely for this reason, recently the scientific literature was mainly focused on the importance of promoting PA before/during school and in the extra school to provide additional opportunities for children to be physically active. [2-6] However, sedentary activities are still the most common within the school setting [7].

Moreover, integrating PA into the school day might have not only physical health benefits. New evidence suggests that school-based PA interventions could be beneficial for cognitive performance, working memory, attention, processing speed in children that are able to affect learning and academic achievement at school, as well as classroom behaviour [8-11].

In particular, the interest in the use of PA within curricular lessons is growing during the last few years especially regarding Active Breaks (ABs) intervention [4,5,12,13]. ABs involve short bouts of moderate to vigorous physical activity (MVPA) conducted by the appropriately trained teachers and delivered during or between curricular lessons.

A recent systematic review suggests that multi-component interventions that incorporate PA throughout the school day (e.g. physically active lessons, physical active breaks) may have the strongest impact on time spent in MVPA [14].

To date, the ABs interventions have shown, albeit with great heterogeneity, an effect on different health outcomes including PA, cognitive health and classroom behaviour however results require further confirmation. [4,12,13]

Most of the active break studies included in recent reviews had a common limitation, consisting in short duration of the intervention from few weeks [15,16] to a maximum of one school year [17].

In light of these findings and a growing body of evidence, we started a multiple targeted quasi-experimental study in 2019: the Imola Active Breaks (I-MOVE) Study [18].

To authors knowledge, the I-MOVE study is one of the first studies, conducted in Italy, with a long-term follow-up and with innovative ABs intervention including high intensity interval training exercises (HIIT).

The goal of the study was to evaluate the effect of an AB intervention on physical health and cognitive functioning. We hypothesize that ABs lead to improved weekly MVPA levels, improved cognitive performance and better outcomes in terms of childrens' classroom behaviour.

8.2 Materials and Methods

Study design and participants

The I-MOVE study was a quasi-experimental study [19] conducted with primary school children living in the city of Imola, Emilia-Romagna, Italy.

The Bioethics Committee of the University of Bologna approved the I-MOVE study, on the 18th March 2019 (Prot. n. 0054382 of 18/03/2019-[UOR: SI017107-Classif. III/13]) and the study was endorsed by the University of Bologna (Italy). The study was conducted following the Declaration of Helsinki and approved by the school board.

School and participants recruitment were conducted in 2019 and described in detail in the research protocol [18].

Intervention

The AB protocol was based on the previous pilot study 1. Teachers in the experimental group (ABsG) participated in a specific training conducted by kinesiologists, Following the training, each teacher was given a detailed manual of the proposed exercises. Control group's (CG) teachers did not participate in any special training and their class were only involved in pre-post evaluation.

The ABsG performed the I-MOVE protocol three times a day, when the teachers thought it would be appropriate. I described the ABs protocol previously in the research protocol

[18]. Each AB starts with a warm-up part of 2 minutes focused on cardiorespiratory and mobility exercises, the central 5 minute tone up part contains exercises with high-intensity interval training (HIIT), consisting of 40s of MVPA alternated with 20s of recovery, with a specific focus on coordination, balance and cognitive task. During the last 3 cool-down minutes, children perform stretching, relaxation and breathing control exercises. After this final part, all classes re-engage the academic lesson. The ABsG started the Active Breaks intervention in October 2019.

Data collection and Outcome measures during Covid-19 Pandemic

The Covid-19 pandemic and the subsequent containment restrictions inevitably led to certain design changes in the study. First of all, during the lockdown (March 2020-June 2020), the ABs protocol was conducted through distance learning. When the school academic lessons resumed in person (from September 2020), it was recommended that teachers conducted AB in the classroom using the mask and observing physical distancing. Where possible teachers could perform ABs outdoors in the courtyards or gardens to achieve higher intensities.

A baseline assessment was conducted in October 2019 and follow-up assessment was conducted in May 2021. Socio-demographic information was obtained during the baseline assessment. Parents' education level was stratified into three categories: low (completed primary and middle school), medium (high school diploma) and high (university degree).

At baseline, anthropometric characteristics were collected by staff researchers using standard procedures [20,21]. Height was measured to the nearest 0.1 cm using a portable stadiometer (SECA 217; Hamburg, Germany), body weight was measured to the nearest 0.1 kg (light indoor clothing, without shoes) using a calibrated electronic scale (SECA 877; Hamburg, Germany). Body-Mass Index was calculated using weight (in kilograms) divided by the square of height (in meters). The BMI was used to assess children's weight status according to the recommended Cole cut-off values by sex and age [22,23]. Considering the strict school rules imposed during the pandemic and the importance of maintaining physical distancing, the research team could not carry out anthropometric measurements during the final assessment. Hence, the parents of children participating in the I-MOVE study self-reported anthropometric characteristics of their child, i.e. height and weight, using an online questionnaire in May 2021

The PA levels and sedentary behaviour was calculated through Actigraph accelerometers (ActiLife6 wGT3X-BT). The Actigraph accelerometer models were GT3X (ActiGraph LCC: Pensacole, FL, USA). The Actigraph assessment was carried out following a careful sanitization of the instrument before and after use. We examined the accelerometer data through ActiLife 6.13.3 software (ActiGraph LCC: Pensacole, FL, USA). The epoch length was settled to 10 s to allow a more detailed estimate of PA intensity [24].

Children were instructed to wear the Actigraph, over a seven days period (five weekdays and two weekend days), on their right hip using a waistband [25] removing the accelerometer during water activities (e.g., showering, swimming). The data was analysed using cut-points recommended by Evenson to calculate the minutes spent per type of physical activity (light, moderate and vigorous) per day [26]. We used specific inclusion criteria for wear time validation: 10 h every day wearing Actigraph (sleeping hours included) during at least 3 weekdays and 1 weekend day.

Physical activity levels were also calculated using the valid and reliable self-reported Physical Activity for Children Questionnaire (PAQ-C). The questionnaire is a self-administered, 7-day recall questionnaire and used to examine the reported PA during school time, leisure time and PA during sport activities [27].

We designed an ad hoc self-administrated Active Break Questionnaire to investigate several aspects related to classroom behaviour, as well as satisfaction and motivation to comply with the instructional programme. Both the children and the teachers of the ABsG completed the questionnaire. Children's questionnaire included items investigating satisfaction, feelings and pleasure in performing ABs as well as changes in their classroom behaviour, attention, and well being. The answers were divided into three qualitatively distinct response formats (yes, yes/no; no). The teacher questionnaire included various domains regarding the level of satisfaction, feasibility, effectiveness and management of the ABs. The questionnaire included 18 items exploring potential changes in the classroom behaviour time, children's well-being, learning and attention capacity and also their personal attitude in managing, implementing and organizing ABs to facilitate the teaching activity. Teachers were asked to provide a score from 1 to 5 for each question. During baseline, the questionnaire was filled in paper format while during the follow-up we used remote administration via Google Form.

The working memory cognitive test was also administered with respect to physical distancing regulations and school policy. Verbal working memory was assessed by means of the backward digit span, a subtest of the Wechsler Intelligence Scale for Children (WISC-IV) [28]. The researchers verbally presented a digit series of numbers and required children to repeat the series in reverse order. The score was calculated as the highest number of correct digits remembered.

The health related physical fitness (PF) test was also performed in a manner compliant with pandemic regulations.

The health-related PF test included: 6-min running test [29,30] 6-min walking test (used only in younger children) [31], and standing long jump test [32,33]. All children received the same instructions before undertaking the each test [34,35].

The Pediatric Quality of Life Questionnaire 4.0 (PedsQL) [36] was used to monitor the health-related quality of life in the children (HRQoL) and to assess important determinants of health such as daily activities, physical health, social interactions and emotional well-being. The PedsQL presents 23-items (Total-PedsQL) divided in two domains that were used to assess the children's level of Physical (PF-8 items) and Psychosocial health (PF-15 items).

Statistical analysis

Statistical analysis was performed using SPSS (Statistical Package for Social Science) (SPSS Inc. Chicago, IL, USA). Summary descriptive statistics for continuous measures were reported as means and standard deviations and descriptive information for categorical variables was presented as frequency (percentages) for both ABs-G and CG at baseline and follow-up. Differences in continuous variables from baseline to follow-up were analysed within groups, using the paired-samples t-test for continuous variables and Chi-square test for categorical measures. Between groups differences over time were analysed using ANCOVA adjusted for baseline measures. A p-value lower than 0.05 was considered statistically significant.

8.3 Results

Figure 1 shows the flow chart for participating children across the intervention study.

In October 2019, 153 participants were enrolled but only 133 completed the study in 2021. Parents of 16 children withdrew consent to participate in the assessment due to Covid-19 and 4 children changed schools.

Figure 1 I-MOVE Flow-chart

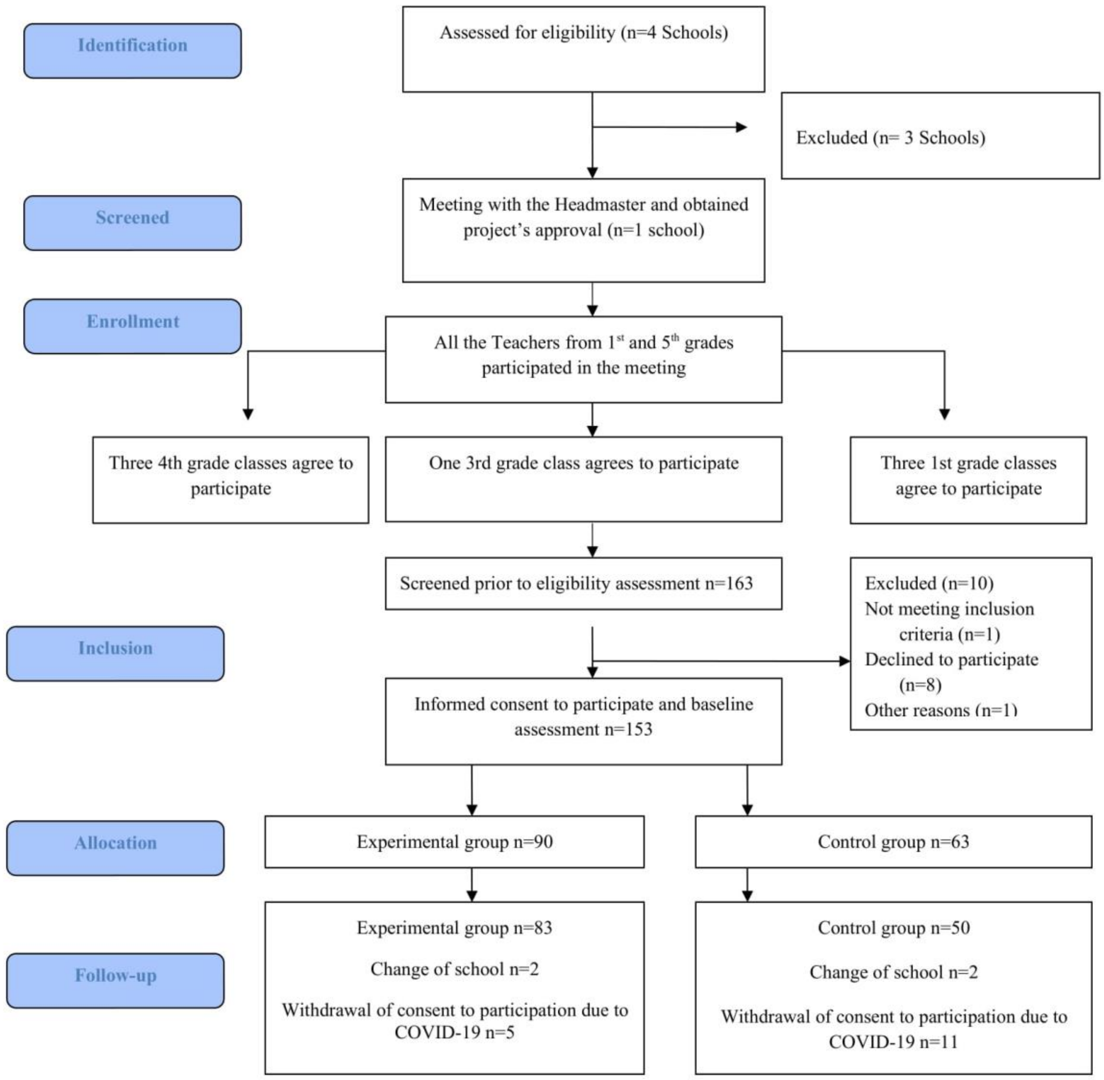


Table 1 reports the participant's characteristics at baseline in 2019 differenced by ABs group and control group. The mean age in Abs-G was 7.66±1.50 with 49.4% of female while in the CG the mean age was 7.92±1.26 with 44.0% of female. No significant differences between groups were found regarding age, sex, anthropometric conditions and educational level of the parents/tutors.

Table 1 Baseline samples' characteristics

Variables	**ABsG (n=83)** **Mean ± SD or %**	**CG (n=50)** **Mean ± SD or %**
Age (n, years)	n=83 7.66±1.50	n=50 7.92±1.26
Male (n, %)	42 (50.6%)	28(56.0%)
Female (n, %)	41 (49.4%)	22(44.0%)
BMI Total (score)	17.45±2.78	18.01±2.66
BMI IOTF category		

Normal-weight (n,%)	58 (71.6%)	22 (56.4%)
Over-weight/obese (n.%)	23 (28.4%)	22 (43.6%)
Mother Education		
Low (n, %)	9 (12.5)	8 (19.5%)
Medium (n, %)	31 (43.1%)	21 (51.2%)
High (n, %)	32 (43.4%)	12 (29.3%)
Father Education		
Low (n, %)	15 (21.1%)	9 (22.5%)
Medium (n, %)	39 (54.9%)	21 (52.5%)
High (n, %)	18 (23.9%)	10 (25.0%)

BMI: Body Max Index

Anthropometric and physical fitness results

Change in anthropometric measures between ABs-G and CG before and after the intervention is represented in Table 2. The percentage of children in the normal weight category in the ABs-G increased (from 71.6% to 74.1%), whereas the percentage of children with normal weight in the CG decreased from (56.4% to 53.8%). Likewise, the percentage of children in the overweight/obesity category increased in CG and decreased in ABs-G (CG pre: 43.6% Post: 46.2% vs ABs-G pre: 28.4% post: 25.9%, p=0.02). Baseline values of the 6 minutes Cooper test for the CG were significantly lower than during the follow-up (change: -156.42±187.53, p=0.005). In contrast, the ABS-G performance saw a slight improvement from baseline to follow-up (change: 1.77±136.03, p=0.94). There were significant between-group differences even with adjustment for baseline values. For the standing long jump both children in the ABs-G and CG significantly improved their performance (ABS-G pre: 113.58±23.62 post: 127.36±29.78; CG pre: 110.77±18.96 post: 128.06±19.31 respectively); however no statistically significant differences were found between the two groups.

Cognitive functioning results

Working memory performance significantly increased from baseline to follow-up in both ABsG and CG (pre-post change: ABs-G +1.30±1.17 vs CG 0.96±1.20). However, the change was larger for the ABsG (p=0.05). (Table 2)

Table 2 Changes from baseline to follow-up after the intervention in both groups

Variables	**ABsG**				**CG**				
	Baseline Mean ± SD	**Follow-up Mean ± SD**	**Change Mean ± SD**	**Within p-value**	**Baseline Mean ± SD**	**Follow-up Mean ± SD**	**Change Mean ± SD**	**Within p-value**	**Between p-value**
Anthropometric									0.02*

condition									
Normal weight	58 (71.6%)	60 (74.1%)			22 (56.4%)	21 (53.8%)			
Overweight/obese	23 (28.4%)	21 (25.9%)			17 (43.6%)	18 (46.2%)			
Cardio fitness test									
6 minute Cooper (meter)	902.76 ±130.30	904.53 ± 178.28	1.77 ±136.03	0.94 ns	958.77 ± 155.00	802.35 ±127.97	-156.42 ±187.53	0.005*	0.01*
Standing long jump	113.58 ±23.62	127.36 ±29.78	13.78 ±21.80	0.01*	110.77 ±18.96	128.06 ±19.31	17.29 ±12.87	0.01*	0.37 ns
Cognitive function									
Working memory (point)	3.06 ±1.11	4.36 ±11.22	1.30 ±1.17	0.001*	2.98 ±0.92	3.94 ±1.03	+0.96 ±1.20	0.001*	0.05*
Objective PA									
Weekly MVPA (min)	348.88 ±128.27	371.05 ±149.14	23.16 ±129.82	0.12 ns	295.60 ±100.98	346.80 ±136.05	51.20 ±115.71	0.004*	0.61 ns
Vigorous PA (min)	120.94 ±62.64	126.72 ±70.70	5.78 ±65.84	0.44 ns	104.16 ±49.81	115.71 ±61.22	11.55 ±52.58	0.14 ns	0.95 ns
Moderate PA (min)	227.95 ±72.96	245.33 ±87.57	17.39 ±74.91	0.04*	191.44 ±59.36	231.09 ±87.66	39.65 ±81.95	0.001*	0.46
Light PA	1739.37 ±317.62	1852.27 ±519.15	112.91 ±361.64	0.007*	1625.90 ±327.73	1723.31± 396.35	97.41 ±430.69	0.12 ns	0.36
Sedentary behaviour	6551.74± 405.41	7760.03± 462.52	+1208.29 ±416.00	0.001*	6734.00± 428.44	7812±828.62	+1077.97 ±645.21	0.001*	0.59
Self-reported PA									
PAQ-c score	3.03±0.74	2.75±0.71	-0.28 ±0.70	0.05*	3.32 ±0.43	2.93 ±0.46	-0.38 ±0.56	0.05*	0.60 ns
Health related quality of life									
Peds-Ql total score	72.14±13.13	79.74±11.00	+7.60±14.28	0.000*	69.71±12.92	77.90±10.49	+8.19±17.43	0.022*	0.56
Physical health score	72.28±15.21	82.06±12.66	9.78±16.27	0.000*	74.21±12.70	83.45±9.84	9.24±16.40	0.007*	0.71
Psychosocial Health	72.06±15.04	78.50±11.88	+6.44±17.41	0.012*	67.35±15.87	74.94±12.43	7.59±20.28	0.06	0.28

[a] Within group changes are compared using paired-t-test; [b] Between group comparisons conducted using ANCOVA adjusted for baseline values; *Significant p-value < 0.05

Objective and Self-reported PA

Table 2 shows the mean activity counts registered by accelerometer for the ABsG and CG. Actigraph results show that the weekly time spent in MVPA increased in both groups from baseline to follow-up with no statistically significant difference between groups. In the CG the weekly MVPA at the baseline was 295.60±100.98 and during follow-up was

346.80±136.05 underlying an increase of 51.20±115.71 minutes in a week with a p-value=0.004. For the ABsG the weekly MVPA at the baseline was 348.88±128.27 and during follow-up 371.05±149.14 with a change from pre- to post-intervention of 23.16±129.82 minutes. Examination of the difference in PA intensities from baseline to follow-up shows that both the ABsG and CG children increased their minutes spent in vigorous PA, albeit these gains were not significantly difference both within and between groups (ABs-G pre: 120.94±62.64 post: 126.72±70.70 vs CG pre: 104.16±49.81 post: 115.71±61.22).

Time spent in moderate PA significantly increased within both group (AbsG pre: 227.95±72.96, post: 245.33±87.57 p=0.04; CG pre: 191.44±59.36, post: 231.09±87.66 p=0.001) but the between-group differences were not significant. Minutes spent in light PA significantly increased only in the ABsG (+112.91±361.64, p=0.007) compared to CG (+97.41±430.69 p-value=0.36). The time spent in sedentary behaviour significantly increased both in AbsG and CG, +1208.29±1077.07, p=0.001 respectively, but no significant differences were observed from baseline to follow-up when comparing the groups. Both groups significantly decreased in their self-reported PA levels using the PAQ-c questionnaire from baseline to follow-up (total score change in ABsG= -0.28±0.70 vs. change in CG=0.38±0.56, p=0.05). None of the between-group differences were significant.

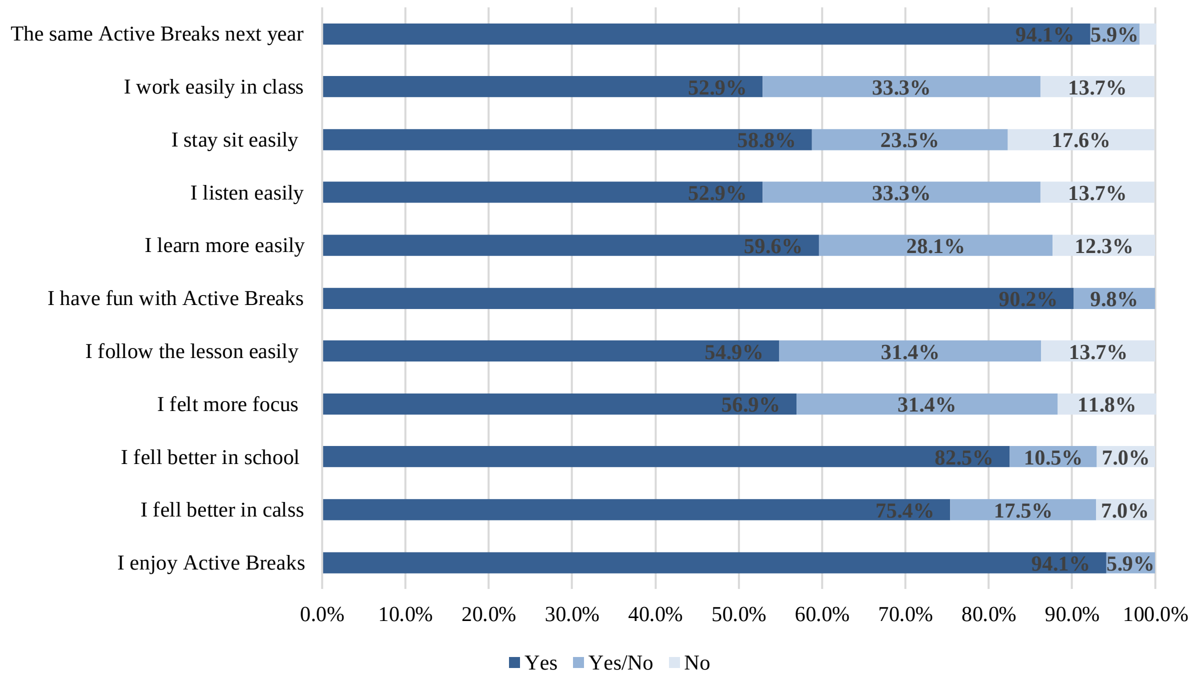
Health related quality of life

There were no significant differences between groups for the HRQoL (Ped-QL); however, within each group there were statistically significant improvements for the total score (ABsG pre:72.14±13.13 post:79.74±11.00, p=0.000 vs. CG pre: 69.71±12.92 post:77.90±10.49; p=0.002) and for physical health (ABsG pre: 72.28±15.21 post: 82.06±12.66, p=0000 vs. CG pre: 74.21±12.70 post: 83.45±9.84, p=0.007). Psychosocial health significantly improved only in the ABsG (ABsG pre: 72.06±15.04 post: 78.50±11.88 p=0.012 vs. CG pre: 67.35±15.87 post: 74.94±12.43 p=0.06), (Table 2).

Classroom behaviour

Figure 2 shows the results of the classroom behaviour and satisfaction questionnaire data after 1 year and a half of the Active Breaks intervention.

Figure 2 Percentage of positive response to the classroom behaviour and satisfaction questionnaire



Almost the entire sample of children wanted to continue with the intervention in the next year, they enjoyed and had fun with the intervention. Only a very small percentage (2%) of children stated they would not continue with the intervention in the future. Children also reported improvements in their quality of school life including feeling better in class (75.40%) and in school (82.50%) when using active breaks. There were also improvements in their time on task behaviours: 52.90% reported they work easily in class, 58.80% reported they can stay seated easily, 52.90% said they could listen more clearly, and 59.60% said they learned better and were more focused after ABs.

Teacher's perception

Table 3 shows teachers' responses after 1.5 years of the AB intervention. The classroom behaviour total score significantly improved from baseline to follow-up (change: +6.14±3.85, p=0.01). Analysis of the subdomains of classroom behaviour also showed a significant improvement in the children's well-being and learning skills (+2.57±1.90; +2.43±2.44) respectively. The last domain regarding teaching activity increased from baseline to follow-up, but did not achieve statistical significance.

Table 3 Teacher perception of classroom behaviour questionnaire in ABsG

Variables (N=7)	Baseline Mean ± SD	Follow up Mean ± SD	Change Mean ± SD	P-values
Classroom behaviour (total score)	50.57±9.90	56.71±11.50	+6.14±3.85	0.01*
Children's well-being	17.00±3.87	19.57±4.31	+2.57±1.90	0.01*
Children's learning	16.14±2.61	18.57±4.20	+2.43±2.44	0.04*
Teaching activity	17.43±3.95	18.57±3.16	+1.14±1.45	0.07

Within group changes are compared using paired-T-Test; *Significant p-value < 0.05

8.4 Discussion

The I-MOVE study investigated the effect of an Active Break intervention on physical and cognitive health over the course of 1.5 years. The I-MOVE intervention includes 10 minutes of ABs delivered three times every day and can be intermingled with regular academic activities. The program demonstrated a positive effect on the childrens' cognitive and cardio-fitness performance, anthropometric measures and classroom behaviour.

With regard to cognitive functioning, the intervention findings show that both ABsG and CG improved working memory performance. Much of this may be age-related as children in this age group undergo rapid cognitive development [37]. However children in the ABsG obtained a statistically significant improvement post-intervention suggesting a beneficial effect of active breaks in increasing working memory performance. PA can improve students' cognitive function, and metacognitive skills, the latter including working memory, attention and processing speed [38,39]. These findings are in line with other previous studies and a recent systematic review that confirmed the use of classroom-based PA as part of standard lessons can achieve positive effects on cognitive functioning [12,40-42].

The results of the intervention also showed promising findings with regard to physical health. In particular PF test showed that the AB intervention with HIIT exercises can facilitate maintaining cardio-fitness performance. The original study hypothesis suggested that high intensity exercises provide a protective effect supporting fitness performance, which dramatically dropped over time in the control group. Very few studies have emphasized the effect of ABs in physical fitness status [43] Kats et al 2020]. However this is a fundamental marker of health in childhood. Future interventions should continue to monitor physical fitness status using motor tests [44]. The HIIT exercises included in the middle part of ABs contained not only cardiorespiratory fitness exercises but also speed and agility games, that are fundamental in the development of physical fitness status [44].

Both objective and reported physical activity measures did not significantly change between the two experimental conditions after the intervention although there was a trend toward improvement in both groups with increasingly higher levels of all actigraph values in the experimental group. Previous studies, even those with short duration, found a favorable effect of active breaks on students' physical activity levels [5,15,16,45,46]. There were no ABs effects found for time spent in sedentary behaviour. Neil-Sztramko et al.'s Cochrane systematic review found that school-based interventions promoting PA and PF in children had little to no impact on overall time spent in MVPA and may have little to no impact on time spent sedentary. However, the authors highlight that within school-based interventions, the most effective for increasing MVPA are active breaks [14]. The I-MOVE study lasted 1.5 years during which time the pandemic forced some changes regarding the ABs protocol. Most important was the health regulations regarding the lockdown, during which time childrens' physical activities were strictly regulated and they engaged in distance learning. As a result, COVID-19 significantly altered habits and lifestyles, especially in children and adolescents and especially relevant to physical activity levels and sports [47]. To date, children in our sample improved their levels of physical activity after experiencing substantial changes during COVID-19 [47]. Even then, the scores on the PAQ-c questionnaire pertaining to sport and physical activity out of school remained very low. Likewise, the minutes of sedentary lifestyle increased compared to 2019 and this could be a long-term effect of COVID-19 [48-50]. In light of this, it is still unclear regarding the potential effect of active breaks in increasing PA levels and reducing sedentary behaviour during the COVID-19 pandemic.

In respect to childrens' health related quality of life, no effect was found in the physical or the psychological domain. Notwithstanding, there is still a growing interest in the effects of ABs in the area of health related quality of life. Kvalø et al found positive effects on children's self-reported psychological well-being, social support and peers, and school environment in a RCT implementing physically active lessons, with active breaks and homework [51].

Overall, children expressed positive evaluations toward the AB intervention. In fact, they felt better at school, were more focused, and they experienced enjoyment and a desire to continue the intervention in the future. The experimental teachers highlighted a general improvement in classroom behaviour focused mainly on the childrens' well-being and learning skills. These positive results comport with other similar studies that analysed ABs effect in improving classroom behaviour [6,45,52-56]. Teachers reported a positive but non-significant trend in improving their work using active breaks, however this outcome requires more investigation due to the small sample of teachers involved in the study.

Positive satisfaction, reported by both children and teachers, represents an important aspect of the feasibility of ABs intervention in a primary school context.

The I-MOVE study contains some limitations worth noting. First, during the COVID-19 pandemic, the Italian schools changed the structure of students’ lessons, favouring either distance learning or if possible outdoor activities. These changes could explain the increase in physical activity levels in the control group, which then diminishes any experimental effects. Furthermore, teachers did not adhere totally to the protocol during distance learning and this deviation may diminish the potential long-term benefits of active breaks. Furthermore, given COVID restrictions, at one point in time we had to rely on parents to provide metrics including BMI data for their children. This change in assessment strategy erases any standardization of methods.

A further limitation of the study concerned the analysis of sedentary lifestyle through accelerometers. Although objectively monitoring the minutes spent in sedentary activity is very important, the accelerometer often does not take into account the different types of sedentary lifestyle such as screen based sedentary behaviour.

9. Conclusion and Implications for Future Studies

The purpose of this Ph.D. dissertation was to evaluate an intervention focusing on promoting physical activity in children using a "community-wide" approach. Tied to this effort, was establishing whether a school-based intervention to promote physical activity is feasible, efficacious and sustainable over time. The first aim of this study was to investigate the current fund of knowledge with regard to school-based interventions targeting health promotion using "Active Breaks." This was done by conducting a systematic review with meta-analysis (Study 1). Previous reviews examined the effects of classroom-based physical activity interventions on classroom behaviour, physical activity levels, cognitive and academic performance of children. The goal of the first study addressed more specifically the effect of ABs carried out in classroom settings, exclusively in primary school-aged children. Study 1 findings show that ABs facilitated children's PA levels in a favourable manner, allowing them to reach the WHO recommended 60 minutes per day of MVPA. Additionally, ABs are more likely to enhance time on task behaviour of children during the school day.

Based on these findings we can conclude that there is a positive trend highlighting the beneficial effects of an AB intervention on time spent in MVPA and in classroom behaviour, while there are limited or no benefits for cognition and academic performance. The results of this systematic review provided a basis to plan and conduct a pilot feasibility study (Study 2). The pilot study demosntrated positive results from a brief AB intervention. The ABs protocol provided evidence of being effective and feasible, thanks to its ease of administration and sustainability. This was also confirmed by the positive feedback received from both children and teachers. Conceivably, Active Breaks can be used to reduce inactivity, paving the way for children to reach the recommended goal of 60 minutes daily of MVPA. The pilot and feasibility study showed the feasibility and efficacy of the AB protocol in primary school children and represented the basis for Study 3, a quasi-experimental trial: the Imola Active Breaks (I-MOVE) study.

The I-MOVE study, started in 2019, provided a means to investigate the effects of the ABs protocol on a larger sample of primary school children including monitoring health outcomes, cognitive functioning, classroom behaviour and health-related quality of life (Study 3).

Using cross-sectional data obtained from the baseline assessment of the I-MOVE study, I was able to investigate health determinants associated with health-related quality of life (Study 4). The findings suggest that moderate physical activity is positively associated with general health-related quality of life. These results underline that implementation of PA interventions, including active breaks or active school recess, during class time and even outside of class time, and supplementing these activities with health-related homework programs on PA, may provide benefits in terms of children's quality of life.

It is worth noting that during the course of executing the I-MOVE study, the COVID-19 pandemic started. This major public health event forced design changes that required modifications in the study protocol and program implementation. Despite these dramatic changes, Active Breaks once again demonstrated that it is feasible to implement in school settings and quite sustainable even in a complex public health emergency such as COVID-19. Study 5 provided a means to further examine the effects of COVID-19 on physical activity levels and considers gender differences. During the COVID-19 pandemic, even after the re-opening of schools, all children reduced their PA levels and increased sedentary behaviours. This was documented by both objective and self-report measures. The decrease in activity was especially remarkable in boys suggesting that they have been disproportionally affected by lockdown restrictions. The current findings highlight the need for strategies to promote PA and reduce sedentary behaviours in children to prevent deleterious long-term effects from COVID-19 restrictions. Reflecting on the compilation of findings, there is increasing evidence that communities need to create educational networks (family, school, sport and recreational environments) connected to each other to address the growing problem of child sedentarism.

The longitudinal component of the I-MOVE study (Study 6: commencing in 2019 and ending in 2021) showed that the intervention was effective in improving both cognitive functioning and physical health. Among those children exposed to the intervention, the Active Breaks intervention fostered improvement in children's working memory, compared to children not exposed during the same time frame. This suggests that a classroom-based PA can have a positive effect on childrens' cognitive functioning.

Despite various difficulties associated with the pandemic, ABs proved to be sustainable and play a protective role with regard to physical fitness and weight status. The ABs intervention, and in particular the high intensity interval training exercises, contributed to improved physical fitness status in the experimental group. Likewise, ABs contributed to weight control in experimental children; however, additional studies are needed with larger sample sizes and with more objective measures to demonstrate a lasting anthropometric effect from ABs.

The evidence shows that ABs could be a valid strategy for increasing physical activity levels in children while they attend school and limiting their sedentary behaviour. However, additional randomized control studies, especially with long-term follow-up, are needed to clarify the durability of this effect.

Children exposed to the AB intervention reported they felt better at school and were more focused. Moreover, the experimental teachers highlighted a general improvement in classroom behaviour in particular they reported an improvement in childrens' well-being and their learning capabilities. Furthermore, results of the AB intervention highlight the intervention's feasibility, suggesting based on teacher feedback that the protocol was easily managed in the classrooms and that both teachers and children wish to continue the intervention in the future. The fact that the AB intervention was adapted some what during Covid-19, using distance learning, represents an important public health finding reinforcing that the program can be altered from its original design and still net positive gains. The accumulation of evidence from the work conducted for this thesis reinforces that Active Breaks represents a cost-effective strategy that can be easily implemented in school settings regardless of age and gender differences and can contribute to making the school a more dynamic environment for both physical and cognitive health.

Implications for Future Studies

Active breaks conducted in school settings represent effective ways to achieve positive outcomes in multiple domains including health, well being and cognitive functioning. In this respect, this easily implemented and cost-effective program can be considered an innovative public health intervention. Children and teachers are satisfied to use this intervention in their lessons. For this reason, the next step will be to disseminate an evidence-based practice to as many schools as possible with the goal of achieving integration into school curriculums nationwide. With this in mind, it will be essential to demonstrate the effectiveness of this school-based physical activity intervention on a larger scale with different populations in unique settings and through multicentre studies.

Moreover, the majority of the studies included in the literatures analyzed the use of classroom-based physical activity interventions in primary school children highlighting feasibility and applicability in the primary school context, whereas secondary school and high school setting were less investigated. For this reason, future studies will have to test the effectiveness of these interventions in a different setting of middle and high school.

In parallel, recent literature underlines how important it is to take more account of the whole school environment to promote health. In this frame school-based interventions with extracurricular activities and homework components could maximize family engagement and potentially improve the success of this type of intervention. In particular the concept of extracurricular activities and homework promoting health would be considered. For this reason, I am involved in a European Erasmus Sport Plus project "EUMOVE Let's Move Europa: school-based promotion of healthy lifestyles to prevent obesity" aimed at implementing a comprehensive set of strategies and resources to enable the educational community to promote healthy lifestyles.

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