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Effects of a physical activity-enhanced curriculum on increasing physical activity and improving physical fitness in preschoolers: Study protocol for a cluster randomized controlled trial (KID-FIT study)

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A R T I C L E I N F O

Keywords:
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A B S T R A C T

Objective: Physical activity (PA) is critical for healthy development in preschoolers, with long-lasting benefits that can affect later life. The World Health Organization (WHO) recommends that children aged 5–17 years should engage in 60 min of moderate-to-vigorous PA per day. However, physical inactivity in children is on the rise globally, with declines in PA starting at the age of 4 years. Increasing PA during early childhood is important to delay adiposity rebound, promote behavioral changes, improve physical fitness, and facilitate future PA engagement. However, limited evidence has been established on the effects of school-based PA interventions on preschoolers. This study examines the effects and sustainability of a preschool-based PA intervention on increasing PA, improving physical fitness and health in preschoolers, with the exercise dose benchmarked to the WHO PA guidelines.
Methods: This assessor-blinded, two-arm cluster randomized controlled trial will include 3300 preschoolers (aged 5–6 years) from 110 kindergartens in Hong Kong, China. Kindergartens will be randomized into intervention and control groups in a 1:1 ratio. The control kindergartens will continue their usual curriculum of ∼2.5 h PA/week, whereas preschoolers in the intervention kindergartens will engage in an additional 75-min game-based PA class twice per week (extra 2.5 h PA/week) over the preschool year. This multi-component intervention will also target parents, teachers, and the kindergarten environment to further encourage PA in preschoolers and their families. Objectively measured PA, cardiorespiratory fitness and other physical fitness components (muscle strength and power, agility, balance, flexibility, body composition), and psychological health will be examined at the start (0 month) and end (10 months) of the preschool year. Maintenance effects will be assessed after preschoolers' transition into primary school (16 months). Generalized estimating equations or other appropriate statistical models will be used to examine the treatment effects with adjustment for baseline values.
Study impact: This study will investigate the effects of a preschool-based PA intervention with PA dose benchmarked to the WHO recommendations on promoting PA, physical fitness, and health in preschoolers, and its sustainability after preschoolers' transition into primary education. The findings will raise public awareness on the importance of PA in young children, and will inform policy making to facilitate early childhood educational reforms to incorporate adequate PA into preschool curriculums to improve children's health in the long run.
Trial registration: ClinicalTrials.gov (NCT05521490)

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1. Introduction

Sufficient physical activity (PA) is essential for staying healthy at any age. The World Health Organization (WHO) has established PA guidelines for health promotion in people of different ages. It is recommended that children and adolescents aged 5–17 years should engage in at least 60 min of moderate-to-vigorous intensity PA (MVPA) daily,[1] while younger children aged 3–4 years should engage in 180 min of total daily PA that includes at least 60 min of MVPA.[2] Adequate PA during preschool years is critical for children's health and development, with effects that can extend into adulthood. Higher levels of PA in children is commonly associated with better body composition,[3] lower risk of cardiovascular disease,[4] greater physical fitness,[5] and better motor skills development,[6] which are important determinants of overall health and future PA participation. In young children aged 4–6 years, PA is reported to have benefits on cognitive development including on attention, language learning ability, and working memory, which can have positive effects on academic achievement.[7,8]

Despite the numerous benefits of staying physically active, physical inactivity is one of the biggest public health crises of the 21st century.[9] Just as the number of physically inactive adults is on the rise, with over 30 % of adults worldwide having inadequate PA,[10–12] the physical inactivity pandemic is now also affecting younger populations. Indeed, all prevalence studies point to the fact that globally, many children and adolescents do not engage in adequate PA,[13] with the COVID-19 pandemic exacerbating the problem.[14,15] Although evidence on the prevalence of physical inactivity in preschoolers is not well documented,[13,16] recent global studies suggest that while most preschoolers might engage in at least 60 min of MVPA per day,[16,17] almost 30 % of them do not engage in adequate total PA,[17] with over 50 % of them aged 3–4 years not meeting the overall guidelines of 180 min total daily PA that includes 60 min of MVPA.[18] Alarmingly, studies on school-aged children suggest that there is only about one-fifth of preschoolers meeting the overall PA guidelines globally.[19,20] While the majority of prevalence studies were conducted in a Western context, including in North America, Europe, and Australia,[16] a few studies conducted in Hong Kong suggest that physical inactivity is even more prevalent locally. Moreover, China is one of the countries with the highest prevalence of physical inactivity.[21] High physical inactivity in Asian countries (particularly China) is believed to be attributed to a greater focus on academic achievement that leads to schools and parents emphasizing learning over children's participation in PA,[19,22,23] whereas limited PA spaces in preschools can also be a factor.[24,25] Physical inactivity in preschool years is a concern, as a great decline in PA is suggested to start as early as the age of 4–5 years,[26,27] where total PA continually decreases at an average rate of over 4 % per year,[27] with declines even more apparent in girls.[28] Early childhood is a critical timeframe to intervene to promote PA. Given that the trend of PA decrease begins in early preschool years and continues up to the end of adolescence,[16] PA interventions at a younger age can promote long-term behavioral changes and improve physical literacy, which is particularly important to prevent the dramatic decline in PA in later childhood and adulthood.[17,29] For instance, only around 30 % of Hong Kong children aged 6–17 years meet the international referenced standards for cardiorespiratory fitness.[30] Cardiorespiratory fitness is a strong determinant of future health status and mortality risk,[9] hence, increasing PA to strengthen physical fitness in early childhood is also detrimental to children's long-term health.

The growing pediatric obesity epidemic is one of the most apparent consequences of physical inactivity.[31,32] The global prevalence of pediatric obesity was estimated to have increased by over 7-fold between 1975 and 2016.[33] More recently, the WHO reported that the proportion of obese children worldwide has increased by 4 times from 2% to 8% over the past three decades.[34] Similarly, nearly 15 % of Hong Kong school-aged children were found to carry excess weight and ∼50 % of them were obese.[35] Moreover, elevated cholesterol and fasting insulin levels found in >50 % of obese children indicate an increased risk of developing cardiometabolic disease during early adulthood.[36] Childhood obesity is a public health concern, given that the negative impacts on the physical, mental, and social health of children with obesity can be a lifelong problem.[37]

The negative effects of inadequate PA at a young age will continue to affect children's health in later years, with physical inactivity, adiposity, and low cardiorespiratory fitness being the leading risk factors for global

Table 1
Intervention Components involving Multiple Stakeholders.

Stakeholder	Intervention component	Aim and content
Children	Kindergarten-based PA intervention: 75 min game-based PA class x 2 sessions per week (2.5 h additional PA/week)	- Increase children's PA by 2.5 h/week on weekdays in addition to the PA (2.5 h/week) incorporated within the usual kindergarten curriculum to meet the WHO recommendation of 60 min MVPA/day (total of 5 h of in-school PA on weekdays, equating to 60 min MVPA/day). - Different physical fitness skills will be taught and practiced each week to enhance preschoolers' physical fitness and literacy. - The game-based nature of the PA intervention is designed to enhance children's motivation to engage in PA enjoyably, thereby promoting long-term behavioral change toward an active healthy lifestyle.
	Health education leaflets	- Increase children's knowledge and awareness on healthy lifestyle behaviors (e.g., PA, diet, sleep, hygiene). - Children will also bring home the leaflets and share health-related knowledge with their parents, thereby enhancing parents' knowledge on healthy lifestyles.
Teachers	Train-the-trainer (TTT) workshops	- Increase kindergarten teachers' knowledge on young children's health and physical fitness, and improve practical skills on how to enhance the PA environment within the kindergarten and deliver physical education lessons to fulfill preschoolers' developmental needs. - To allow flexibility in attending workshops and avoid interfering with teachers' busy schedule, workshops will be delivered via online monthly videos that can be viewed any time.
Parents	Parent-led weekend PA assignments and games	- Increase PA of all family members during weekends by encouraging parents to lead and complete weekend PA assignments (e.g., climbing 5 flights of stairs, performing 3 sets of star jumps for 10 times each) and to play active games with their children. - Children with high completion rate of family tasks will be rewarded to motivate families to increase PA outside of school time.
	Parent online education workshops	- Increase parents' knowledge on the aspects of health in young children (e.g., PA, diet, sleep, body composition, mental and social health), and provide practical tips to live a more healthy and active lifestyle as a family (e.g., festival healthy eating tips).
	Health education leaflets	- Parents will receive weekly health education leaflets given to their children during PA intervention classes to further increase their knowledge and awareness on healthy lifestyles.
Environment	Purchase of fitness-related equipment with $3000 subsidy	- Enhance the kindergarten environment to increase access of preschoolers to PA-related equipment within school, hoping to encourage PA during structured physical education class and unstructured free-play time, with the aim to increase children's motivation to engage in PA within a PA-friendly built environment.

all-cause mortality,[9,38,39] and for various non-communicable diseases, including cardiovascular diseases (e.g., coronary heart disease, stroke, and hypertension), metabolic diseases (e.g., type 2 diabetes), and cancers.[40–42] The negative impacts of physical inactivity also lead to heavy burdens on health systems and economies, with healthcare costs approaching 54 billion international dollars (INT$) a year.[43] In China, over 15 % of the yearly medical and non-medical costs of non-communicable diseases were attributed to physical inactivity.[44] Therefore, effective interventions promoting PA in preschoolers to prevent pediatric obesity and related negative health impacts are critical for improving public health and reducing the enormous socio-economic burdens.[45]

A study in children with obesity found that over 80 % of them developed obesity during their preschool years (i.e., before 6 years old), suggesting that childhood obesity typically manifests at a young age.[36] Moreover, increasing PA during preschool years is effective in delaying adiposity rebound. Although adiposity rebound is a common phenomenon indicated by a second-time increase in body mass index (BMI) curve around the age of 6 years,[46] a rebound that occurs before 5.5 years was found to be associated with higher risks of gaining fat mass, and developing obesity and metabolic diseases (e.g., type 2 diabetes) in later years compared to those who experienced a rebound after the age of 7 years.[46–49] This highlights the urgency to prevent excess adiposity during preschool years to avoid early adiposity rebound. In addition, targeting younger children is considered to be more effective for behavioral change compared to older children, adolescents, or adults.[50] Preschoolers can generally learn more willingly and readily when given clear guidance. Moreover, their behaviors are also more modifiable at this age as unhealthy lifestyles (e.g., being physically inactive or sedentary, unhealthy eating behaviors) may not yet become lifelong habits.[45,50] Thus, intervening at a younger age may encourage them to be physically active throughout their lives, subsequently improving cardiorespiratory fitness with long-lasting benefits on cardiometabolic health.[51]

Although school-based PA interventions have shown promising effects on increasing PA in children and adolescents aged 6–18 years,[52] conclusive evidence in preschoolers, especially outside the Western context is lacking. Certainty of available evidence is largely limited by the high heterogeneity in study designs, such as differences in intervention target (e.g., targeting parents/caregivers as change agents to increase children PA[53] versus delivering exercise programs directly to preschoolers[54]), as well as variations in intervention modality (e.g., delivery personnel, structural nature of intervention, exercise dosage, duration, frequency) that led to incomparability between study findings. While two reviews suggested greater effectiveness of structured PA interventions[53,55] delivered by professionals,[55] contradictorily another review suggested that unstructured PA interventions might have larger effects on increasing preschoolers' MVPA,[56] supported by two other individual studies that found no effects of structured PA interventions on promoting PA,[57,58] and a study that found significant increase in preschoolers' MVPA after an unstructured teacher-empowered and -led intervention.[59] Thus, given that these highly heterogenous studies are largely incomparable, it might well be too arbitrary to make certain conclusions on the effectiveness of school-based PA interventions on promoting PA in preschoolers.[55] Apart from PA outcomes, inconclusive findings were also found on physical fitness and other health-related parameters (e.g., body composition). While a recent study found no effects of teacher-led PA interventions on improving preschoolers' physical fitness,[60] another study of similar duration found significant improvements in stationary long jump performance and static balance.[61] Whereas for supervised PA interventions, while a meta-analysis of 19 randomized controlled trials (RCT) suggested intervention effectiveness on improving cardiorespiratory fitness, muscular strength and adiposity indicators (e.g., BMI, waist, body fat %) in preschoolers, it is also of note that the small sample size, insufficient documentation of intervention implementation processes, as well as the lack of adjustment for baseline values and confounders in most studies have largely limited the reliability of findings.[62] Indeed, individual studies of different exercise dosages (e.g., frequency, session duration, intervention duration) and modality (e.g., aerobic versus strength-dominated) also led to differential effects on PA, physical fitness and health-related parameters.[57,63–65] A few studies conducted in Glasgow (Scotland), Switzerland, and Spain examined the effect of a one preschool year PA intervention, yet conclusive findings can be hardly reached.[66–68] Some of the reported effects included improvements in motor skills,[66] agility,[67,68] muscle strength,[68] and some adiposity indicators (e.g., body fat percentage and waist circumference),[67] but there were no effects on BMI.[66–68] While Puder et al. (2011) found improvements in cardiorespiratory fitness (measured by 20-m shuttle run),[67] Martínez et al. (2020) suggested significant improvements only in girls.[68] Concerning PA outcomes, no significant increase in objectively measured PA was reported,[66,67] similarly in another European study with a shorter intervention duration of 24 weeks.[69] Lastly, it is also notable that most PA studies among preschoolers were conducted in Western and high-income countries, which limits the generalizability of findings to other places (e.g., Asian countries) with different cultures, schooling and parenting practices.[62] Overall, these together suggested that high quality and conclusive evidence on the effectiveness of preschool-based PA interventions on motivating PA, improving fitness and preventing obesity is lacking, and a well-powered rigorously designed trial with an effective, scalable and well-documented intervention component is needed. So far, no study has also explored the maintenance effects of PA interventions targeting preschoolers after their transition to primary school setting.

Therefore, the aim of this study is to examine the effects of a preschool-based PA intervention with the PA dosage benchmarked to the WHO global PA guidelines to be delivered over a preschool year on increasing PA, improving physical fitness, reducing adiposity, and promoting overall health of preschoolers in their upper-kindergarten year (i.e., the last year of preschool education before transition to primary school). As our targeted preschoolers will be in their last preschool year, nearly all of them should be above the age of 5 years old, thus the WHO PA guideline being referred to is the guideline for 5–17 years old children and adolescents (i.e. 60-min MVPA/day),[1] instead of the guideline for younger children under the age of 5 (i.e. 180-minute total PA/day that includes 60-min MVPA).[2] By incorporating a 6-month follow-up period after the cessation of the intervention, we will also examine whether the intervention effects can be maintained after preschoolers' transition to primary school. This will broaden the study's impact by providing insights on the unexplored facilitators and barriers of PA promotion across the early childhood education continuum to guide further research in primary school settings. Given that children generally spend most of their daytime in school, evidence of an effective PA intervention guided by WHO recommendations would be of particular significance for promoting in-school PA to combat physical inactivity. Standardized interventions with exercise dose benchmarked to the WHO guidelines would also allow potential integration of the PA intervention into preschool curriculums across the globe.

2. Methods

2.1. Subjects and eligibility criteria

This is an assessor-blinded two-arm cluster RCT of a PA intervention named KID-FIT to be carried out in local kindergartens in Hong Kong, China ("kindergarten" is the term commonly used for "preschools" in Hong Kong and will be used interchangeably). A cluster design will avoid intervention contamination by having both control and intervention children in the same kindergarten. Children will be included if they are: 1) aged 5–6 years and beginning upper-kindergarten, 2) able to communicate in basic Cantonese or Mandarin, and 3) able to engage in PA in a standard kindergarten-based setting. Children of both genders will be included to enhance generalizability. A small proportion of upper-kindergarten children who may be aged between 4-5 and 6–7 years for various reasons (e.g., advanced or delayed kindergarten attendance and those repeating a kindergarten year) will also be included to increase generalizability. Children will be excluded if they have 1) an inherent or serious disease that limits their ability to perform PA (e.g., congenital heart disease, pediatric cancer, and Down syndrome), 2) a diagnosis of mental disease that can impair their daily behavior and functioning (e.g., depression, anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, and psychotic disorder), 3) a physical disability (e.g., a disability that requires an assistive walking device), 4) impaired vision or hearing, or 5) an intellectual disability or cognitively deficit requiring special care and educational needs (e.g., handicapped children with learning difficulties).

2.2. Study procedure

Potential kindergartens in Hong Kong will be approached through email and poster distribution. Interested kindergartens will be contacted by project personnel to explain the study. Full-day kindergartens (7–7.5 h in-school time including lunch and afternoon nap) will be preferentially selected for the following reasons: 1) children engage in most of their daily PA in the kindergarten, 2) full-day kindergartens have a more flexible curriculum to implement a PA intervention during school time, and 3) full-day kindergartens are increasingly attended by children of single- or dual-parent working families, and these children are usually disadvantaged by inadequate PA. Agreement forms will be collected from interested kindergartens to confirm participation in the KID-FIT study before randomization. A study invitation with written information will also be provided to parents of children in the included kindergartens to explain the study details. Written informed consent will be obtained from parents with the assents of their children before baseline outcome assessments are conducted. The study has been approved by the Institutional Review Board (IRB) of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster. The study was prospectively registered in ClinicalTrials.gov (NCT05521490) on August 30, 2022 before study commencement on September 1, 2022. The study protocol adheres to the Standard Protocol Items of the Recommendations for Interventional Trials (SPIRIT) guidelines[70] and the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[71,72]

2.3. Randomization

Kindergartens will be randomized into the intervention and usual care control groups in a 1:1 ratio, stratified by the district where the kindergarten is located and by the socioeconomic status of that district where possible (Fig. 1). Hong Kong is geographically divided into 18 administrative districts, and the socioeconomic status of a specific district will be determined based on the annual statistics issued by the local government on the median monthly household income of households located in that district for the purpose of this study.[73] Children will be allocated into intervention or control groups clustered by their kindergartens.

To generate the randomized allocation sequence, an online randomization tool Randomization.com will be used.[74] To avoid allocation bias, the centralized independent randomization list will be kept by research staff who will not interact with any children, parents, or kindergarten staff during the recruitment process. To ensure allocation concealment, randomized group allocation of each kindergarten will only be disclosed to research personnel upon contact with the centralized research staff.

2.4. Blinding

All outcome measurements will be carried out by research personnel blinded to the group allocation. Due to the nature of the PA intervention, children and their parents cannot be blinded to their group allocations. Children and parents will be told not to disclose their group allocation during the outcome assessments. Kindergarten staff (e.g., teachers and principals) and coaches delivering the intervention cannot be blinded to the group allocation as well, but they will not be involved in any outcome assessments.

2.5. Intervention

2.5.1. Usual care control group

Kindergartens assigned to the control group will continue with their usual curriculum, which includes approximately 30 min of PA per day. According to the guidelines provided by the Curriculum Development Council for Hong Kong kindergartens, half-day (3–3.5 h in-school time) and full-day kindergartens should respectively allocate 45–60 min and 60–105 min of time for non-academic activities including PA, music, and arts.[75] By assuming equal division of time allocated to the three activities, full-day kindergartens should normally incorporate 20–35 min of PA lessons daily (i.e., total of ~2.5 h of in-school PA per week).

2.5.2. Intervention group

The multi-component PA intervention targeting children, their parents, and teachers will be delivered to the intervention kindergartens. The intervention aims to not only promote PA and improve the health of children and their parents during the intervention period, but also target behavioral changes by motivating children to adopt a physically active lifestyle. The intervention will also target stakeholders (e.g., teachers, parents, and caregivers) who are involved in the children's daily life to augment the effects of the intervention on increasing PA in children.[52,69] The intervention duration is ideally designed to last for the full kindergarten school year (i.e., around September to June of the following year), as a meta-analysis found that an intervention lasting longer than 6 months is generally needed to elicit greater health-related behavioral changes for preventing childhood obesity.[76]

Children in the intervention group will receive a PA-enhanced curriculum over a preschool year consisting of a 75-min gamed-based PA class delivered twice weekly. The duration and frequency of the PA intervention is designed to be added on top of the physical education in kindergarten's usual curriculum to reach a total of 5 h in-school PA/ week (2.5 h/week in the intervention + 2.5 h/week in the usual curriculum), which averages into 60 min PA/day on weekdays. The intervention dose is benchmarked to the WHO guideline of at least 60-min MVPA/day for children aged 5–17 years,[1] as our target population are preschoolers mostly aged 5–6 years in their last year of kindergarten. As decrease in PA was found to begin at the age of 4–5 years,[26,27] with MVPA decreasing more evidently from preschool to school-age years than the transition from childhood to adolescence,[16] interventions that can increase MVPA during the upper kindergarten year are particularly important to prevent a decline in PA that would continue throughout childhood and adolescence.[27]

Game-based PA classes will be delivered by children fitness coaches certified by the Physical Fitness Association of Hong Kong, China (HKPFA). All coaches will complete the training course for Children Fitness Instructors held by the HKPFA, which includes a total of 36 h of lectures on children's growth, motor control, physiological, psychological and social development, as well as on developing child fitness activities and how to plan for and deliver child fitness classes.[77] They will also complete a 2-h written and practical examination and 6 h of practicum before being certified as a children fitness instructor.[77]

The PA games are designed so that children can spend a large proportion of intervention time engaged in MVPA, with the aim to increase in-school PA. As both physical fitness and literacy are important determinants of children's future participation in PA,[17,29] the teaching plan was designed to incorporate different elements to improve cardiorespiratory fitness, muscle strength, fundamental movement skills (including agility, velocity and balance), and to develop physical

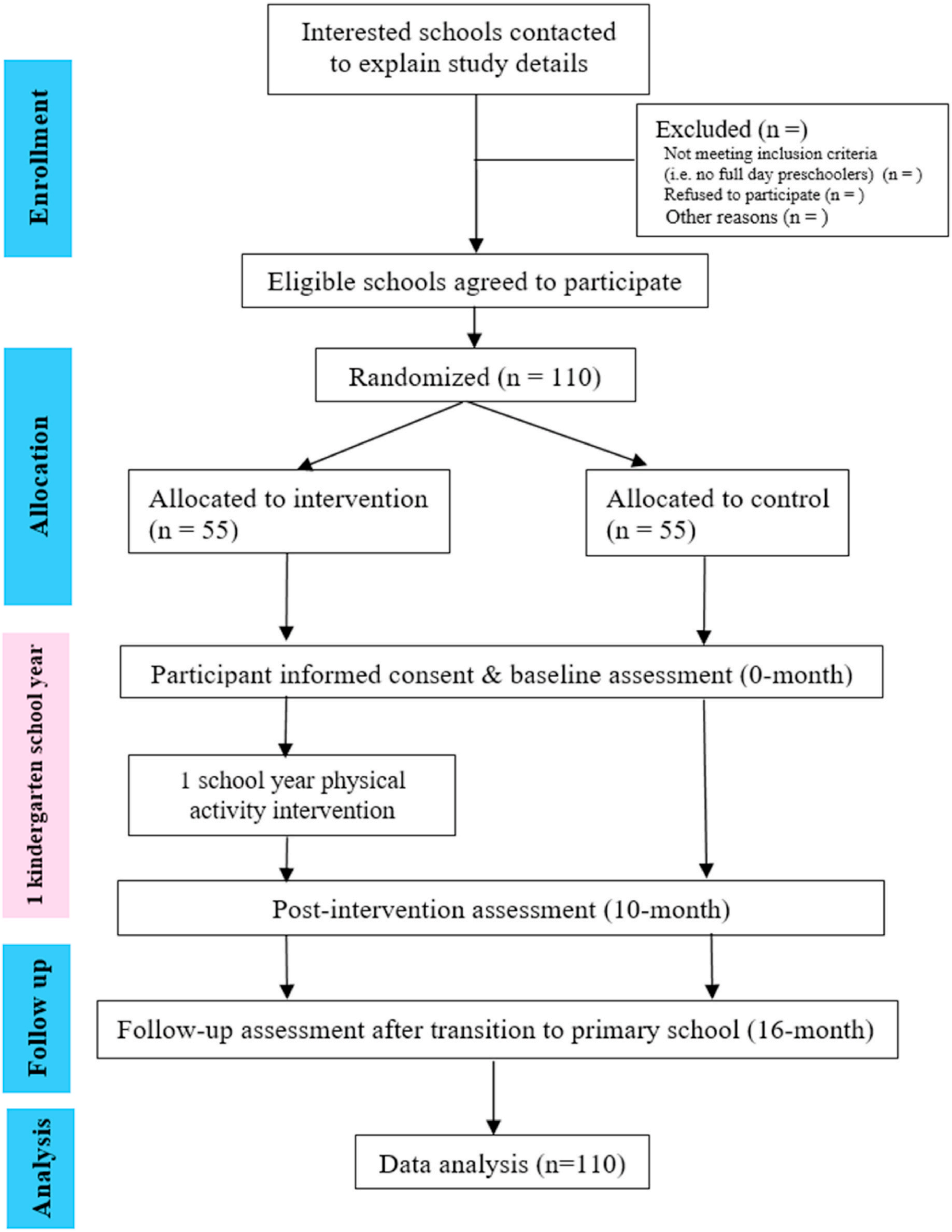

Fig. 1. Flow diagram for cluster enrollment, allocation, participant flow and assessments, and analysis.

literacy through active games. Skills practiced during the intervention will include but are not limited to balance, coordination, jumping (stationary jump, forward/sideways bounce, hop, star jump), ball skills (throwing and catching, rolling, shooting, passing, bouncing, kicking, and dribbling), running skills (speed running, endurance running, galloping, shuttle run, and striding over obstacles), rhythmic movements, and stretching. Teaching materials are designed with reference to teaching plans adopted in a previously completed community service project named "Jockey Club Keep-Fit Formula for Children" (2015–18) with HKPFA, which aimed to improve physical fitness in Hong Kong preschoolers.[78] The current intervention will also promote preschoolers' all-round development including moral, aesthetic, affective, social, cognitive, and language skills, which are all areas suggested in the Kindergarten Education Curriculum Framework.[75] An example of the games in the PA intervention include mimicking the actions of different representative animals from around the world (e.g., pandas from China, kangaroos from Australia, and cheetahs from Africa), which will allow children to learn about different countries while engaging in MVPA (e.g., crawling with limbs like pandas, jumping like kangaroos, and speed running like cheetahs). Another example is team shuttle runs while picking up bean bags (representing rubbish) scattered on the floor, which can teach children the importance of being responsible and clean citizens. The game-based nature of the PA intervention is chosen to create an enjoyable experience for children while being physically active, with the aim to motivate long-term behavioral changes towards increasing habitual PA.

Educational leaflets that contain information on the importance of PA and ways to sustain a healthy lifestyle will be distributed on a weekly basis. The leaflets are designed to provide information on an active healthy lifestyle based on the available information provided by the Hong Kong SAR Government,[79] which covers multidimensional lifestyle components including PA,[80] diet,[81] sleep, and mental and social health. Children fitness coaches will explain the health education leaflets during break periods within the PA intervention classes. Information regarding active lifestyles (e.g., health benefits of regular PA, WHO recommendations for PA and sedentary time, and ways to overcome PA barriers), balanced healthy diets (e.g., food pyramid, macro- and micro-nutrients, healthy cooking methods, food portions, and nutritious food), sleep hygiene, and practical tips for maintaining a healthy lifestyle during festivals (e.g., Christmas and Chinese New Year) will be conveyed to preschoolers and also their families through leaflets that children bring home.

Teachers in the participating kindergartens will receive train-the-trainer (TTT) workshops to learn about knowledge related to children's physical fitness and health (e.g., WHO guidelines on movement behaviors, PA in children with special education needs, and diet), and information to raise their awareness on the importance of PA for healthy all-rounded development in preschool years (e.g., benefits of PA on physical, mental and social health). Although teachers will not be involved in delivering the exercise component of the intervention (i.e. 75-minute game-based PA class × 2 sessions/week), some practical suggestions concerning how to design PA lessons appealing and suitable for young children will also be provided to enhance teachers' ability to structure appropriate daily PA classes in the usual curriculum.[82] The TTT workshops will be packaged as monthly videos that can be flexibly accessed by teachers without interfering with their busy daily schedules.[69] Adherence to TTT workshops will be monitored and indicated by self-ratings on the usefulness of each provided workshop.

Parents will receive online lifestyle education providing basic knowledge on health and fitness (e.g., PA, diet, sleep, festival healthy tips, and hygiene), as well as practical tips on adopting active healthy lifestyles as a family. The online lectures are designed based on the available information provided by the Hong Kong SAR Government,[79] with reference to behavioral change strategies for encouraging intrinsic motivation and adaptive beliefs toward an active healthy lifestyle.[83] Lecture videos will be sent to parents monthly. According to the Hong Kong's 2018 report card on PA for children and youth, the family dimension regarding children's PA engagement had the lowest scoring, which was attributed to the inadequate participation of parents in PA, low involvement in PA with children, and the lack of facilitation for children to participate in sports.[30] To encourage PA among the whole family during weekends, parent-led PA assignments covering fitness exercises (e.g., 15-min brisk walking, three sets of jumping jacks, and walking five flights of stairs or the distance between two bus stops) and family-based game instruction sheets will be distributed to children on a weekly basis. Fitness coaches will demonstrate the fitness exercises and family-based PA games during the intervention classes, so that children can complete the assignments and games together with parents at home during weekends. An award scheme will be established to incentivize children to complete the weekly family PA assignments, with rewards for children that complete the most assignments. It is hoped that each child can play the role of an ambassador to encourage an active lifestyle within the family.

The environment of the kindergartens will be equipped to further motivate in-school PA. All intervention kindergartens will be provided with HKD $3000 subsidy for purchasing fitness-related equipment (e.g., balance beam, bean bags for throwing practice, jumping cords, fitness balls, and rubber bands) as needed, aiming to provide a more PA-encouraging environment to preschoolers. Enhancing the built environment can facilitate children in performing structured PA during PA lessons and promote unstructured PA during play time.

For detailed descriptions of each intervention component, please refer to Table 1.

2.5.3. Intervention fidelity

The main component of the intervention is the game-based PA class, which will be delivered by certified children fitness coaches. To avoid bias in the intervention delivery due to individual teaching styles of fitness coaches, we will recruit a large pool of coaches to minimize individual variations and all of them will be briefed prior to the start of intervention delivery. They will be provided with standardized teaching plans and will be closely supervised during regular kindergarten visits by research personnel (on a monthly basis during the first half of the preschool year and bi-monthly during the second half) to ensure the intervention delivery quality meets the study design and aims. Research personnel will also maintain close contact with coaches outside of class time to monitor any problems or areas needing improvement, and to ensure high quality and fidelity of the intervention delivery. The PA level of children will be objectively monitored using ActiGraph accelerometers during the intervention class.

2.6. Outcome measures

Outcomes will be assessed at three time points: 1) at the start of the preschool year (Pre; 0 month); 2) at the end of the preschool year (Post; 10 months), and 3) at 6 months after intervention cessation when children have already entered Primary 1 (Follow-up; 16 months) (Fig. 1).

2.6.1. Primary outcomes

2.6.1.1. Physical activity (PA). An ActiGraph device (GT9X Link, Actigraph, USA) with a three-axis accelerometer will be used to objectively measure daily PA. The use of an ActiGraph accelerometer for measuring PA has been previously validated in preschoolers (3–5 years old).[84] Children will wear the ActiGraph on their wrist for 24 h over 7 consecutive days. Data will be considered valid if PA is measured for a minimum of 4 days with ≥8 waking hours of registration per day,[85–88] with or without the inclusion of a weekend day.[89] Non-wear time will be excluded from the analysis, which is defined as a minimum of 60 consecutive minutes of zero counts,[87,90,91] with an allowance of 2-min interruptions (non-zero counts) accompanied by two 30-min windows of zero counts before and after that allowance.[92] As younger age groups are more prone to spontaneous and fragmented movements, which can easily break up the sedentary bouts,[86] a 60-min zero count period was chosen as the non-wear period instead of longer timeframes. Concerning the choice of epoch length, while there is presently insufficient evidence of high certainty to suggest an optimal epoch length for measuring PA in preschoolers,[93–95] previous studies and reviews supported that a 60-s epoch length is sufficient to accurately measure their PA.[93,96,97] Nonetheless, as emerging evidence also suggested that shorter epoch lengths might be preferable to capture PA in young children due to their sporadic movement patterns,[98–100] data recorded in both 10-s and 60-s epoch lengths will be analyzed. Sleep time will be excluded from the PA analysis. The software ActiLifeV6.11.7 will be used to clean and process the ActiGraph data to examine daily time spent on PA of different intensities. Average time spent on light PA, MVPA, and total PA per day will be extracted from accelerometer data using validated cut-points for preschoolers (Evenson 2008,[101] Pate 2006,[84] Butte 2014,[102] Johansson 2015[103]). Given the lack of consensus on the optimal cut-points for classifying PA intensities in young children,[17,104,105] total activity counts per day (TAC/d) will also be derived as an alternative measure of daily total PA volume, which was found to be more closely correlated to PA energy expenditure measured using doubly labeled water compared to MVPA classified by cutpoints.[106] TAC/d will be calculated by dividing the total vector magnitude counts by the number of calendar days with wear time.[107]

2.6.1.2. Cardiorespiratory fitness. Cardiorespiratory fitness (also known as maximal aerobic power or maximal oxygen consumption) will be assessed by a 20-m shuttle run test, which is a valid and reliable test for determining the maximal aerobic capacity in children.[108] We will adopt the Leger protocol,[109] which involves a shuttle run of 20 m at an initial speed of 8.5 km/h, progressively increasing by 0.5 km/h every minute (stage). The Leger protocol has been found to be reliable in estimating cardiorespiratory fitness in children,[109,110] and has been adopted in other preschool trials.[67,68] Children will be instructed to run back and forth on a 20-m course following a signal emitted from a pre-recorded tape. The frequency of the "beep" increases as the speed of each stage increases. The last stage number will be recorded, corresponding to the final stage that the child can complete at the pace of the emitted signals (i.e., they stop when they cannot reach the other side of the 20-m course before the next "beep"). Cardiorespiratory fitness will be expressed as the maximum number of stages that can be completed in the 20-m shuttle run test.

2.6.2. Secondary outcomes

2.6.2.1. Muscular strength and power. Upper body muscle strength will be assessed using a spring-type handgrip dynamometer designed for children (Takei Kiki Kygyo Grip Dynamometer, Takei Scientific Instruments Co. Ltd., Niigata, Japan). Handgrip strength test has been found to be a valid measure of muscle strength in child populations.[111] The dynamometer will be held and squeezed with the dominant hand using maximum effort while standing with a straight arm. Children will be allowed three attempts. The first attempt will be a trial run to familiarize with the handgrip test. The best result from the second and third attempts will be taken.

Lower-body muscle power will be assessed by stationary long jump and vertical jump. Both jump tests measure lower-body explosive muscular strength, which are commonly used to examine musculoskeletal fitness in children.[108,111,112] For stationary long jump, children will stand behind the take-off line and then jump forward with both feet landing together. The distance reached by the back of the heel will be recorded. For vertical jump, children will jump upwards while trying to touch the highest point using their dominant hand. The vertical jump height is calculated as the highest position touched minus the standing height with the dominant hand raised. Children will be given with three attempts, and the best result from the second and third attempts will be taken.

2.6.2.2. Flexibility. Flexibility will be assessed by the standard sit-and-reach test.[113] Children will sit on the ground with their back straight against the wall and both legs fully extended against the sit-and-reach box. They will be instructed to put one hand on top of another and slowly reach forward as far as they can. The maximum distance reached by the hand on the box will be recorded. Children will be given three attempts, and the best result from the second and third attempts will be taken.

2.6.2.3. Movement speed and agility. Agility will be assessed by a 4 × 10-m shuttle run test. The 4 × 10-m shuttle run test has been widely applied to assess motor fitness[108,111] and can infer movement speed and agility.[114] Children will be timed running back and forth between the 10-m course over four laps. Two cones will be placed at a 10-m distance opposite from the starting point. Children will be instructed to run at their maximum speed and pick up the cones one at a time and return to the starting point. A shorter completion time indicates better performance. Children will be given two attempts, and the best result (shorter finishing time) will be taken.

2.6.2.4. Balance. Balance ability will be assessed by balance beam test, which has been found to be a valid and reliable measure of dynamic balance in preschoolers.[115] Children will walk barefoot on the balance beam (3-m long and 3-cm wide) with the heel of one foot touching the toes of the other foot. The number of successful steps performed on the beam will be recorded. Children will be given three attempts, and the best result from the second and third attempts will be taken.

2.6.2.5. Anthropometry and body composition. Height will be measured using a 150 cm metal ruler with an accuracy of ±0.1 cm. Body weight, and body composition will be assessed using a calibrated electronic digital weighing scale with a capacity of 200 kg and accuracy of ±0.05 kg (MC780, Tanita, Japan). The weighing scale is a bioelectrical impedance-based multi-frequency segmental body composition analyzer approved by the U.S. Food and Drug Administration. Children will be weighed barefoot and in light clothes. BMI will be calculated and compared to the gender- and age-specific BMI. Waist circumference will be measured using an inelastic measuring tape to the nearest 0.1 cm. Waist measurements will be taken midway between the lowest rib and the superior border of the iliac crest on bare skin. The average of the two measurements will be taken.

2.6.2.6. Sedentary behavior and screen time. Sedentary behavior will be objectively assessed using a wrist-worn Actigraph for 7 consecutive days. Objectively measured sedentary time will be extracted using a validated sedentary cut-point for wrist-worn accelerometer data,[116] with ≤3958 counts per minute considered sedentary behavior. This cut-point has demonstrated high classification accuracy (ROC-AUC = 0.85–0.86) in children aged 5–8 years.[117] An activity logbook will also be used to record children's time spent on sedentary activities, screen time (e.g., television viewing, computer gaming and smartphone/tablet usage) and bed time, which will be filled in by their parents for 7 consecutive days.

2.6.2.7. Psychological measures & health-related quality of life. The Treatment Self-Regulation Questionnaire (TSRQ) and Theory of Planned Behavior Scale (TPBS) will be used to assess children's autonomous motivation and social cognitive beliefs on healthy active lifestyles, respectively. The TSRQ is a psychometrically validated scale widely applied to assess motivation for healthy behaviors (e.g., PA, diet).[118] Only six items from TSRQ examining autonomous motivation for exercise will be adopted in this study. The TPBS consists of 16 items examining intention, subjective norm, perceived behavioral control and attitudes on healthy lifestyle, which reflects individuals' social cognitive beliefs for PA participation.[119] The Chinese version of both scales have demonstrated consistent and satisfactory reliability (Cronbach's alpha of 0.68–0.86).[120–122] All questions will be graded on a simplified 3-point Likert scale (disagree/neutral/agree). Children will answer both questionnaires with the assistance of their parents.

The Kiddy-KINDL instrument will be used to assess health-related quality of life in children. The Kiddy-KINDL is a version of the KINDL instrument designed for children aged 4–6 years. It consists of 12 items covering six major areas: 1) physical well-being, 2) psychological well-being, 3) self-esteem, 4) family, 5) friends, and 6) everyday functioning. The items are scored on a 3-point Likert scale (never/sometimes/very often) and a general score is calculated from all the items, with higher scores representing a better health-related quality of life. The Kiddy-

KINDL instrument has demonstrated high internal consistency (Cronbach's alpha of 0.75) with satisfactory psychometric properties in preschoolers aged 3–5 years.[123] The Chinese version of the KINDL instrument has also been validated and been reliably used to examine health-related quality of life in the young Chinese population (Cronbach's alpha of 0.81 and test-retest reliability of 0.77).[124]

2.6.2.8. General well-being. The Early Development Instrument (EDI) will be used to assess the general well-being of children. The EDI evaluates children's readiness for school based on five developmental domains: 1) physical health and well-being, 2) social competence, 3) emotional maturity, 4) language and cognitive development, and 5) communication skills and general knowledge. It has been validated psychometrically in preschoolers.[125] The Chinese version of the EDI has demonstrated high internal consistency and reliability in Hong Kong preschoolers (Cronbach's alpha of 0.70–0.95 and test-retest reliability of 0.89).[126] The EDI will be filled in by the teachers of the participating children.

2.6.2.9. Program adherence. Children's attendance at intervention classes and dropout rate will be recorded to indicate adherence to the intervention. Parents' adherence will be evaluated by the completion rate of the voluntary-based weekend parent-led PA assignments. The reasons for dropout will be ascertained and reported.

2.6.2.10. Major life event. Information on any major life events will be collected by research personnel during the monthly contact with parents. Children or parents who experienced a major life event (e.g., death of close relatives, parent divorce, diagnosis of serious illness, etc.) that can significantly affect their psychological well-being and motivation for PA will be advised to terminate the study and will be included in intention-to-treat (ITT) analyses.

2.6.2.11. Adverse event. Adverse events will be closely monitored and recorded by teachers, coaches, and research personnel, or voluntarily reported by children and parents. Research personnel will communicate with parents regularly to ascertain and record any adverse events such as fatigue, dizziness, headaches, knee strain injury, and joint/muscle pain, etc., which may be related or unrelated to the intervention. Any adverse event will be immediately followed up to see whether it can be addressed. All necessary information about the adverse event will be collected and documented. Participants who experienced sustained serious adverse events that can affect their daily function will be terminated from the study and will be included in the ITT analyses. In accordance with the principles of Good Clinical Practice and CONSORT reporting of harms,[71,127] the principal coordinator will ascertain the reason, nature, and severity of the adverse event, as well as the potential association with the intervention, which will then be ratified by the co-principal investigators. The adverse event procedures will be applied to all children in the intervention and control groups.

2.7. Sample size

The sample size estimation was based on the primary comparison of cardiorespiratory fitness outcomes between groups. Sample size calculation was performed using the Optimal Design Software.[128] A 90 % power and 0.05 maximum chance of committing false positive error was adopted. Based on previous findings from a study using 20-m shuttle run test in young children with a mean age of 5.1 years {effect estimate 0.32 [95 % confidence interval (CI) 0.07–0.57] reported by Puder et al.}[67] and another study on children aged 4–7 years [effect estimate of girls 1.19 (95 % CI 0.31–2.08) reported by Martinez-Vizcaino et al.],[68] an effect size of 0.20 was conservatively taken. This effect size is consistent with a small reported effect size of 0.22 (95 % CI 0.14–0.30) in a meta-analysis on school-based PA interventions for improving cardiorespiratory fitness in children aged 3–12 years[129] and another reported effect size of 0.25 (95 % CI 0.08–0.42) for exercise interventions on improving cardiorespiratory fitness in preschoolers.[62] A cluster size of 30 children in a kindergarten with an intra-cluster correlation coefficient of 0.05 was taken. To allow for a 20 % dropout rate, 3300 children (from 110 kindergartens; 30 children per kindergarten) will be needed.

Cardiorespiratory fitness, instead of PA, was used to estimate the sample size due to the following reasons: 1) significant intervention effects on improving accelerometer-assessed PA are lacking from rigorously designed studies in the preschool population,[61,66,67] and highly heterogenous study designs limited the certainty and implication of effect sizes pooled in reviews,[55,56,130] and 2) despite limited comparability to our intervention design, a review that conducted a subgroup analysis with interventions incorporating structured PA lessons to increase preschoolers' PA suggested an effect size of 0.53 [95 % CI 0.12–0.94], which is larger than the effect size suggested for cardiorespiratory fitness (0.20), thus the outcome with smaller expected effect size (cardiorespiratory fitness) served as the outcome for sample size calculation. Given that cardiorespiratory fitness is a significant mediator on the health benefits of PA, using it to estimate sample size is considered appropriate.

2.8. Statistical analysis

Data will be presented as mean ± standard deviation. The ITT principle will be adopted to handle missing data. To assess the treatment effects, generalized estimating equations (GEE) or other appropriate statistical models will be used with adjustment for baseline values. The dependent variable of the main model will include measurements at post-intervention, while the independent variables will include group and baseline measurements. Adjustments will also be made for potential confounders that might affect treatment effects (e.g., age, gender, socioeconomic status of district, etc.). Sensitivity analysis will be performed using the per protocol principle by including participants with satisfactory attendance rate (e.g., 80 %) to intervention classes. SAS software will be used to perform statistical analyses. $P < 0.05$ will be set as the level of significance, with estimates to be accompanied by 95 % CI.

Data will be collected and reported following the CONSORT guideline,[71,72,131] and the template for intervention description and replication (TIDier).[132]

3. Discussion

This study protocol describes the rationale and design of a cluster RCT conducted in Hong Kong kindergartens to investigate the effects of a preschool-based PA intervention with PA dosage benchmarked to the WHO PA global recommendations. The intervention aims to increase PA and improve the cardiorespiratory fitness and health of preschoolers, and assess the sustainability of the intervention after preschoolers moved on from their preschool studies to primary education.

Our PA intervention will target multiple stakeholders involved in the daily life of children. The importance of involving preschool teachers, parents, and caregivers to augment the effects of school-based interventions for increasing PA and improving fitness of preschoolers has been highlighted in a previous study.[69] Therefore, in addition to a children-focused intervention, increasing teachers' and caregivers' health-related knowledge, encouraging parents to co-participate in PA with children, and creating a PA-motivating school environment will further enhance the effectiveness of the preschool-based PA intervention. The holistic approach of targeting essential components of health (PA, diet, sleep, mental and social well-being) is believed to be important for cultivating behavioral changes towards a healthy lifestyle among children and their families. Moreover, another strength of the intervention is that the exercise dosage aligns with the WHO recommendations of 60-min MVPA per day, so that children can already engage in sufficient PA within school time. The intervention will also extend beyond school days, by encouraging family-based PA during the weekends through parent-led assignments and games, thereby motivating families to incorporate regular PA into their daily lives.

To our knowledge, this is the first rigorous and well-powered cluster RCT with a follow-up period conducted in a Chinese context aimed at examining the effects of a preschool-based, WHO recommendation-guided PA intervention on increasing PA and improving physical fitness and health of preschoolers in their last preschool year. In addition, the follow-up period will allow us to explore whether the intervention effects can be sustained as preschoolers transit into primary school. This might be able to provide insights on the possible facilitators and barriers to successful PA promotion on a continuum from preschool to primary school. It is expected that this study will establish valuable evidence on an effective and scalable intervention that can be applied in local and global preschool settings to reduce physical inactivity in young children and to combat the obesity epidemic. The findings will also raise public awareness on the importance of active lifestyles in young children, and guide early childhood educational reforms to incorporate more PA in the curriculum of preschoolers to improve health of children in the long run.[37,38]

Competing interests

The authors declare no conflicts of interest relevant to this article.

Ethics approval and consent to participate

This study has been approved by the IRB of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (reference number: UW 19–498). Audition of trial by the IRB will be conducted by the submission of the annual progress reports. Informed consent will be collected from parents with the assents of their children (participants) prior to the enrollment into the study.

Trial status

This study was registered prospectively in ClinicalTrials.gov (NCT05521490) on August 30, 2022 before trial commencement. First children consent was collected on September 1, 2022, and the study is expected to be completed by December 31, 2026.

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