The effect of physical exercise on fundamental movement skills and physical fitness among preschool children: study protocol for a cluster-randomized controlled trial

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Study protocol

Keywords: physical exercise, fundamental movement skill, physical fitness, preschool children, kindergarten, randomized controlled trial, Protocol

Posted Date: January 20th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-149945/v1

Abstract

Background Previous evidence has proven that physical exercise is positively related to preschoolers' fundamental movement skills (FMS) and physical fitness (PF). However, studies to assess the effectiveness of different physical exercise interventions aiming at improving FMS and PF in preschool children are still scarce. To explore and compare the effectiveness of different physical exercise on FMS and PF; ball games (BG), rhythm activities (RA), basic movements (BM) and a combination of all related activities (multiple activities, MA) interventions were conducted among preschoolers.

Methods A single-blind, 5-arm, cluster-randomized trial will be conducted in kindergarten in Shanghai, China. Three hundred healthy preschoolers, aged 4 to 5 years, will be randomized to four intervention groups (BG group, RA group, BM group or MA group) and one control group (unorganized physical activities). Four intervention groups will receive three 30-minute lessons weekly for 16 weeks. At the baseline, the end of 16-week intervention, and 6-month follow-up after the end of intervention, the primary outcomes (FMS and PF) and the secondary outcome (physical activity, PA) will be assessed, as well as sociodemographic and anthropometric data.

Discussion This study will provide vital information regarding the effect of different physical exercise interventions on preschool children's FMS and PF, PA, and the potential interactions between these domains. If the results of this trial are positive, the most effective intervention strategy can be generalized to kindergarten and other preschool educational institutions in practice to promote preschooler's development of FMS and PF.

Trial registration Chictr.org.cn ChiCTR2000029333.

Background

Preschoolers are in a period of rapid physical and cognitive development, and a key time for the development of physical activity (PA) and sedentary behaviors []. Patterns of these behaviors are established early, and are moderately tracked from early childhood to later childhood and adolescence [, , ,]. This period is also a time of acquiring and consolidating fundamental movement skills (FMS) [] and developing physical fitness (PF) [].

Long-term studies have shown that the health benefits, including cardiovascular, musculoskeletal, psychosocial and cognitive advantages, benefited from a physically active lifestyle in childhood are undisputed [,] and the necessity has been proven to cultivate physical exercise habits from an early age for lifespan health []. Furthermore, the behavior patterns established in the first years may persist into childhood and adulthood [,]. Physical exercise is one of the critical ways to achieving, maintaining and improving FMS and PF, and the association between PF and health outcomes, is also being mediated by FMS [,] and PF [].

To become physically active and participating in sports and games, it is essential for children to master FMS and PF. FMS which is defined as basic learned movement patterns that don't happen naturally and are the foundation of more advanced, complex movements required to participate in context-specific physical activities [,], and may benefit children's PF [,]. PF is a multifaceted construct involving physical and physiological components, and another health marker underlying PA performance []. Stodden et al. postulated that PF mediates the relationship between FMS and PA [], although limited evidence supported the mediator role of PF []. And there's evidence supports a positive relationship between physical exercise and FMS, or between physical exercise and PF in preschool children [, , ,].

Two recent systematic and meta-analysis suggested that the results of a physical exercise intervention on PF among preschoolers should be interpreted with care because of the relatively small number of randomized controlled trials (RCTs) pooled in each variable and the quality of RCTs [25,]. The other two reviews on interventions to promote FMS in childcare and kindergarten also showed the worry on the interpretation of the effectiveness of interventions to improve FMS due to the quality of evidence and the lack of long-term follow up [26,]. Furthermore, longitudinal studies that address the interaction between FMS and PF among preschoolers are scarce. Relevant studies are either cross-sectional [] or the subjects of which are older than six years old [,].

In China, the population of young children is 57 million, 81.7% of who enrolled in kindergarten in 2018 [], and children spend approximately 40 hours weekly in kindergarten []. However, there is little empirical evidence showing the effect of physical exercise on preschoolers' FMS and PF in China. Above all, the present trial is designed to respond to the evidence gap. Therefore, the aims of this trial are to 1) develop different types of physical exercises intervention (i.e., BG, RA, BM, and MA) based on previous studies and practical physical education specific for young children; 2) determine the effectiveness of physical exercise interventions in improving preschool children's FMS and PF; 3) identify the comparative effectiveness of these physical exercise interventions in promoting young children's FMS and PF. The research hypothesis is that physical exercise interventions will be better improving children's FMS and PF than unorganized activities, and MA will show better effects than BA, RA, or BM on children's FMS and PF.

Methods

Study design

The study is a single-blind, cluster-RCT study, with the class as a unit for the intervention. This study is a part of Physical Exercise on FMS and PF of preschoolers (PEFP) project, which is ongoing and is during the subject recruitment phase. The PEFP project is a series of studies, including a cross-sectional survey and the RCT aforementioned. The cross-sectional survey will cover six provincial and municipal regions of China, aiming at assessing the epidemiological conditions of FMS and PF among preschoolers, and investigating the associations between FMS, PF and PA. Preschoolers recruited for the RCT will be cluster-randomly allocated to 1 of 5 groups (i.e., four intervention groups and one control group): BG group, consisting of football, basketball games, etc.; RA group, including cheerleading, rhythm exercise, etc.; BM group; MA group combined of all kinds of physical exercise that used in other intervention studies; or unorganized PA group, that is the control group (Control) (See the Additional file 2, Figure 1). The content of the intervention comes from the previous research combined with the consultation and interview of preschool educators [24, 25, 26, 27].

Participants and recruitment

The targeted population is preschool-enrolled children recruited through kindergartens. Eligible participants will be 4 to 5 years old and need to meet all the following criteria: (1) being healthy. (2) getting the permission of their parent or guardian to join in this study, and written informed consent will be obtained. We will exclude individuals who have (1) severe cognitive impairment, (2) major medical or physical conditions affecting their participation in physical exercise, or (3) motor development delay. There will be no restrictions as to sex, ethnicity, or socioeconomic statuses of any of the participants. The study protocol has been approved by the Ethics Committee at the Shanghai University of Sport (102772019RT034) (See the Additional file 3).

Recruitment strategies include promotions at local kindergartens and get agreed on a partnership with Putuo Districst Education Bureau in Shanghai.

Randomization and masking

Recruited kindergartens as a unit will be randomly assigned to receive 1 of 5 interventions via a generated randomization sequence. Because this is a behavioral and skill-specific intervention, eligible children in the same class will get the identical intervention or unorganized game, and study participants and their teachers are not blinded to the intervention group allocation. Primary outcome assessors will be masked to group allocation and remain separate from the intervention teams, and class instructors will be blinded to the study's hypothesis.

Interventions and Procedures

Intervention groups

Development of interventions

The intervention procedures have been developed through 1) formulating framework of exercise programs proposed by American College of Sports Medicine (ACSM) [34]; 2) constructing domain-specific content of physical exercise interventions via reviewing the existing literature for young children [24, 25, 26, 27]; 3) getting open-ended responses concerning how preschool children exercise to improve FMS and PF from preschool education experts and teachers; 4) constructing the intervention procedures; 5) examining the validity of factor structures underlying the intervention procedures by consulting some other preschool education experts and teachers and conducting pilot studies.

Contents of interventions

Each of the four interventions is based on structured lessons, which will involve a 30-minute lesson three times weekly for 16 weeks. In all four groups, each lesson will consist of a 5-minute warm-up, 20 minutes core exercises, and a 5-minute cool-down activity. Warm-up consists of and light-intensity movements (e.g., wrist rotation and leg swing), moderate-intensity activities (e.g., arm rotation and knee-up walk), and higher intensity activities (e.g., arm sprint and on-site running); cool-down will start with moderate-intensity activities, end up with light-intensity movements. The main part of the lesson will include 5 minutes of moderate-to-vigorous intensity according to the respective intervention procedures, at least 2 minutes in vigorous-intensity, every 10 minutes. The four interventions will be carried out in the form of games to increase children's interest, and they only differ in the main part (See the Additional file 4, Table 1). The intervention will be carried out within the PA plan of kindergartens, so as to avoid extra PA for the preschool children in intervention groups.

Control group

To avoid the impact of sports or activities experience on the FMS and PF of preschool children in the control group, preschool children in the control group will do "unorganized PA", while the intervention groups were carrying out the designed lessons. The unorganized PA in this protocol is defined as: (1) children do PA without the instructions of teachers, who are only responsible for the safety of children; (2) the types and intensity of activities are not affected by the teachers; (3) competitions organized by young children spontaneously, such as racket, dribbling and balance beam competitions are also unorganized PA. The PA content of the control group will be reported by their teacher

once a week, to ensure that the PA content of preschool children in the control group meets the requirements of the intervention program.

Delivery and fidelity checks of interventions

Before the beginning of the main intervention study, a workshop for interventionists (PEFP members) and a pilot study will be carried out to examine 1) the feasibility of the teacher training program and 2) the feasibility of the intervention program.

In the training-the-trainer workshop, a teacher of each participating kindergarten will be trained individually by one researcher at kindergarten or university location. The training will be carried out with a prepared intervention portfolio, presentations, and visual materials. Following the train, a guided interview will be conducted by a second researcher to obtain information regarding a) teaching and mediation competence of the teacher using methods and materials, with consideration of the preschoolers' characteristics; b) whether the teacher will implement the interventions as planned; c) the comments on improvements in the training and general remarks.

In the pilot study, each interventionist will carry out physical exercise intervention lessons according to the randomized group, and provide feedback on the feasibility of the lessons according to different criteria (time, content, goals, etc.) using a checklist provided by researchers.

In addition, the PEFP members will also keep in close touch with preschool teachers via instant networking software. So that we can proceed to experiment forward, share information, and solve potential problems timely. Firstly, files and videos of intervention procedures will be distributed to class instructors (teachers) ahead of time and remind them of the contents that are going to be implemented. Secondly, the teamwork group will solve the problems encountered by the instructors online.

There are no special requirements and controls for children's life, learning and other activities in the intervention process.

Conditions for termination of intervention

During the intervention period, the child who is injured affecting the normal progress of the intervention, attend less than 2/3 of the whole intervention curriculum, or is absent from the intervention curriculum for two consecutive weeks, will be excluded from the primary data analysis. FMS and PF of all subjects will be assessed before and after the intervention, and the end of the 6-month follow-up, the results will be used for auxiliary analysis if necessary. This study is totally voluntary participation, so participants actively apply for withdrawal for personal reasons will not be arrested.

Measurement slots

Participants will take the assessment for three times, baseline, the end of the intervention, and the end of 6-month follow-up. At each measurement time point, we will assess participants' FMS, PF, PA and descriptive data (such as age, sex, weight, height) within one week. The executive plan of FMS and PF is outlined in Figure 2 (See the Additional file 2).

Measurements

There will be primary and secondary outcome measures, and descriptive measures.

Primary outcome measures

The primary outcomes in this study are FMS and PF.

FMS

Children's FMS will be assessed by a battery of tests. Domain-specific content of FMS assessment was constructed in three phases. Phase 1 focused on the existing mature instrument for measuring FMS [35]. Three major sub-domain tests were expected to represent FMS competence: (a) locomotor skills, (b) object control skills, and (c) stability skills. Underlying these subtests, six-factors were postulated to be related to FMS comprising the two types of locomotor skills (running and jumping) aforementioned, two types of object control skills (gross and fine motor object control ability) and two types of stability skills (static and dynamic balance). Phase 2 involved a review of the existing FMS literature to identify each of the three subtest constructs [36]. Phase 3 involved the use of a panel of experts to evaluate the FMS measurements and consisted of a series of rounds before a final consensus was reached by the panel. After two rounds of the 3-phase, a total of three general categories representing FMS were identified. The final pool of FMS assessment items was incorporated into three subtests, two items each, that is the measurements of running and hopping for locomotor skills, bouncing a ball, jamming coins and kicking for object control skills, and balance beam (for dynamic balance) and one-leg stand (for static balance) for stability skills [35, 36, 37,38] (Table 2, in the Additional file 4).

PF

We will use PF test kits, which consist of the measurements of the balance beam walk to assess balance ability, handgrip and standing long jump for upper and lower limbs strength respectively, sit-and-reach for flexibility, 10-meter shuttle run for agility, hopping for coordination, and 20-meter shuttle-run for cardiorespiratory fitness [39, 40, 41, 42, 43, 44] (Table 3, in the Additional file 4).

Secondary outcome measures

Secondary outcome measures in this study will be PA.

PA

PA will be assessed in both subjective and objective way, in which GT3X+ accelerometers (Pensacola, Fla., USA) and Preschool-age Children's Physical Activity Questionnaire (Pre-PAQ) will be used, respectively [45, 46].

In an objective way, preschool children participating in this study will be instructed to wear the accelerometers over their waist for consecutive seven days, and will stop wearing them while they go to bed, during bathing and water activities. Teachers, parents, and preschool children will be instructed to take care of the devices and log the time when the devices took off. Before handed out to the children, the accelerometers will be set to record activity counts in 3s epochs [47].

In a subjective way, we will use Pre-PAQ, which is a 37-item, 3-day parent-reported questionnaire, measuring regular PA and sedentary behaviors of the parent and the preschool-aged child in the home environment. The Pre-PAQ has been shown to have acceptable validity and reliability in a sample of parents of preschool-aged children. PA intensity and sedentary activity minutes will be analyzed separately according to weekday or weekend [48].

Descriptive measures

Descriptive measures in this study will be (1) sociodemographic characteristics; (2) anthropometric data, including height, weight, and body mass index (BMI).

Sociodemographic characteristics

Parents will be instructed to complete a questionnaire about child's information including the date of birth and sex, household factors, family's socioeconomic characteristics (family income, parental and primary guardian education, and parental employment status), the child's health status (reporting medical conditions and medications, if any) and child's sleep time.

Anthropometric data

Standing height barefoot will be measured using a stable stadiometer (GMCS-SGZG3, Jian-Min, Beijing) to the nearest 0.001 m. Bodyweight with light clothes will be measured using a portable scale (GMCS-YERCS3, Jian-Min, Beijing) to the nearest 0.1 kilograms (kg). BMI was calculated by height and body weight:

$$\text{BMI}\ \ (\text{kg}/m^2) = \frac{\text{Weight}\ \ (\text{kg})}{(\text{Height})^2\ \ (m^2)}$$

Statistical analysis

Sample size

The primary outcome variables in this study are FMS and PF. Before recruitment, a priori power analysis was performed in G*Power 3.1 to calculate the sample size necessary to detect meaningful changes in the total raw scores of six FMS (i.e., running, hopping, one-handed in-situ bouncing a ball, hand jamming coins, beam walking and one-leg stand) and seven PF (i.e., beam walking, standing long jump, sit-and-reach, 10-meter shuttle running, 20-meter shuttle running, handgrip strength, and hopping). Using an alpha of 0.05 and a power of 80%, the calculations were based on the effect sizes reported in a recent systematic review [49]. The expected effect size of intervention on object control skills, locomotor skills, and PF was at 1.03, 0.42, and 0.36 (standardized mean difference, SMD), respectively. With reference to these results, a prudent estimation of effect size (SMD=0.42) was used for calculation. The required sample per group was calculated to be 51. Based on previous studies, we presumed a drop-out rate of 15%, implying a minimal sample size of 51/ (0.85) =60 children in each group. The total size is 300.

Data collection

To ensure the validity of data, we will recruit testers having no conflicting interests with this study. Sessions of the training-the-testers workshop will be provided for testers participating in this study. The workshop will (1) cover the development characteristics, special needs in young children, 2) deliver the basic concepts, testing skills, and emergency plans for children. However, the aim, hypothesis, intervention procedures, and subjects' information in this study will be blinded to testers.

Data management

All research data entry by two people respectively, then summary and double-check. Consent forms will be stored separately from participant data, and a unique identifier code will be assigned to each participant. Data will be deleted immediately from voice recorders after the transcription, with pseudonyms used in all reports in place of participant's names. Data will only be accessible to primary researchers and statisticians after applying to the research group. Data will be stored for a maximum of 5 years before being securely destroyed.

All phases of this study will be monitored by a data safety officer, who has worked for monitoring data collection and data analysis. The data safety officer is responsible for data management and distribution of applied data, and will not get the details of the research. Management of trial data will be in accordance with the data management plan, which has been developed and approved by the project group.

Data analysis plan

Baseline characteristics and unadjusted study outcome measures will be summarized by intervention groups using descriptive statistics such as mean (± SD) or percentage (%) and used to assess between-group equivalence at baseline. Prespecified baseline covariates in both primary and secondary outcome analyses will include age, sex, FMS capacity, PF level, PA level.

Baseline demographic descriptors and primary and secondary outcome measures will be compared across groups by using analysis of variance for continuous variables and the χ^2 test for categorical variables. The planned descriptive data on measured-point FMS and PF are tabulated across the intervention groups and control group. In our primary analysis of the FMS and PF outcome, we will use repeated-measures Analysis of Variance (ANOVA) to estimate the differences with their corresponding 95% CIs comparing BA group, RA group, BM group and MA group with control group.

Multilevel linear regression models will be constructed to assess the effectiveness of the physical exercises on FMS and PF performance. The baseline data of the outcome variables, assessment points, intervention groups, and any imbalanced covariance will be added to the model along with kindergartens and PA as random effects. The interaction between physical exercise and FMS, PF will be tested.

Secondary analyses will investigate the effect of the intervention on other domains using different types of regression analyses, depending on the outcomes. Logistic regressive analyses will be constructed to assess the interference factors. The models will be used to assess the effect of forms of physical exercise, as well as to explore associations between secondary outcome measures, and will adjust for various confounding factors (e.g. sex, PA).

Ethics and dissemination

All participants will provide electronic or written consents. Children's informed consent will be filled in by their primary guardian, and the administrator of the participating kindergartens will be instructed to sign the corresponding consent. Ethics has been obtained from the ethics review committee of Shanghai University of Sport before participants were recruited.

One of the primary purposes of this study is to explore the development mode and content of kindergarten physical education curriculum. The funding organization will not intervene in the design and implementation of the study. However, the research results will be reported and approved by the project committee (composed of relevant experts organized by the sponsor), and can be used as a reference for China's preschool education policymakers and

related departments. The promotion of the research results provides data and theoretical support for the development of Chinese kindergarten physical education curriculum, and provides more "Chinese evidence" for the intervention of FMS and PF for international children.

To prevent the leakage of sensitive information, only the research primary investigator and main collaborators can access the database. In addition to the completion report of the research project, the results of the study will be published in a peer-reviewed journal. Each participating kindergarten will receive a study report and suggestions based on this study. Findings of the study will also be shared with the Shanghai Education Commission, which helps to recruit preschoolers and preschool educators in Shanghai.

Discussion

A panel of researchers has recommended that policies be implemented to increase PA, improve FMS proficiency, and PF level in preschoolers through school-based initiatives in China [50, 51, 52]. However, scarcity of relative physical education lessons specific for preschoolers' limit opportunities for students exposed to the acquisition of FMS capacity and meet PF standards. The interventions in this study have several strong points. It uses existing school sports facilities (e.g., football, basketball) or even no sport devices (in rhythm activities) to arouse children's interests to learn and practice motor skills and improve PF level, with not overburdening parents and teachers. Neither does it require any changes to the curriculum. Overall, the PEFP program represents an attracting strategy for improving FMS and PF levels among preschool children, providing motor skills related activities through structured in-school time.

Although there is relevant effectiveness of programs to improve FMS and PF in health preschoolers, they need to be interpreted prudently as they are based on low-quality evidence, intervention strategy combined with other factors (e.g., nutrition, environment) and immediate post-intervention effects without long-term follow-up [24, 25, 26, 27]. Moreover, in China, except for a policy-driven study for early childhood PF promotion [28], there is a lack of empirical studies concentrating on improving FMS and PF with school-based physical exercise program intervention. It seems imperative that a school-based intervention to promote FMS and PF will be useful for preschool children, who are in the period of a vital window in time for FMS acquisition and PF development. In addition, a potential cohort, which will be initiated based on this program, will open up possibilities for future research into the influence of early childhood factors on future habitual PA, motor proficiency, health, etc.

Trial status

Recruitment of kindergartens for the RCT is complete by the September 7, 2020, primary outcome of participants have been collected by the September 21, 2020. The intervention is being delivered and data collection for secondary measures is underway. Recruitment of participants for the cross-sectional survey is underway.

Challenges and limitations

The current protocol has some challenges. First, the participants in this study are 4-5-year-old preschool children who are featured in incapable of built-in self-control on attention and behavior, therefore, it will be difficult to keep them to follow the designed physical exercise program. In order to reduce the influence of this situation, the research group will equip each intervention group with two researchers to ensure preschool children's safety and the intervention quality. Second, the intervention will last 16 weeks, which will cause a great human resource pressure on PEFP group. We plan to stagger the intervention time of two close kindergartens, but the intervention is carried

out between 8:30 and 11:30 in the morning. In this way, the researchers assigned by the PEFP group could assist more intervention groups within the time allowed.

There are some limitations to this protocol. First, young children are in a rapid period of growth and development, it is difficult to identify whether the natural growth or exercises intervention contributes to the improvement of children's FMS and PF. Like other studies, this protocol will set up a control group in the same school with each intervention group to reduce the confounding impact of natural growth as far as possible. Second, the intervention of this study will last only 16 weeks, which seems insufficient. However, the duration of FMS or PF intervention in previous studies varies from eight weeks to one academic year or longer [53, 54, 55, 56].

Abbreviations

FMS
Fundamental movement skills
MD
Mean difference
PEFP
Physical Exercise on Fundamental movement skills and Physical Fitness of preschoolers
PF
Physical fitness
Pre-PAQ
Preschool-age physical activity questionnaire
RCTs
Randomized controlled trials
SD
Standard deviation
SMD
Standardized mean difference

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee at the Shanghai University of Sport (102772019RT034), with informed consent (See the Additional file 5).

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors of this manuscript declare no conflict of interest.

Funding

This study is funded by the National Philosophy and Social Science Foundation of China (19BTY077) and Shanghai Key Lab of Human Performance in Shanghai University of Sport (11DZ2261100) will fund the publication of this manuscript (See the Additional file 1). The fund management organs have the responsibilities of managing the Funds, and supervise the implementation of this project. However, the funding agencies have no role in the development of the study design, collection, analysis, interpretation of data, manuscript development, or the decision to submit the manuscript for publication.

Authors' contributions

GXW and YHZ conceived the protocol and wrote the main manuscript. YL conceived the study, promoted the progress and put forward suggestions for revision of the manuscript. BL provided the test content of FMS, designed the test process of primary outcomes of FMS and PF, and revised the FMS test content. SS, LS, FW and CER designed the BA, RA, BA and MA intervention plan, and wrote the corresponding part in the manuscript. All authors have read and approved the final version of the manuscript.

Acknowledgements

We would like to thank Si-Tong Chen and Yahan Liang for their answers to the consultation on mathematical statistics and their contributions to the formulation of the intervention contents for preschool children. We would like to thank Ms. Yinglei Teng of Shanghai Putuo District Education Bureau for introducing kindergarten to the research group as well. We would like to thank preschool educators for participating in the consultation meeting on the implementation of the intervention and put forward valuable opinions and suggestions on the implementation process of the intervention. We would also like to thank kindergartens, teachers and parents who have agreed to participate in the program.

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