

Protocol

School-based physical activity intervention in 11-13-year-olds: study protocol for cluster randomized controlled trial

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ABSTRACT

Background: Targeted strategies to enhance regular physical activity appear to be promising to promote health and well-being of adolescents. This article reports the design of a cluster randomised controlled trial to evaluate the effectiveness of a school-based physical activity programme on the rate and duration of moderate-to-vigorous physical activity, sitting time including screen time, and health-related physical fitness parameters among 11-13 year-old adolescents.

Methods: This is a cluster randomized controlled trial conducted in 360 adolescents from government schools in the Colombo Municipal Council area, Sri Lanka. An individual school was considered as a unit of randomization and the 12 selected schools were randomly assigned to one of two groups: control (six schools) and intervention groups (six schools). The intervention group follows a physical activity programme for 30 minutes on three school days per week, for three consecutive months in addition to the standard practice. The primary outcomes are moderate-to-vigorous physical activity rate and duration and sitting time including screen time. Secondary outcomes are the health-related physical fitness parameters: cardiovascular fitness, muscle fitness and flexibility, and body composition. All the outcomes are measured at baseline and three-months following the intervention.

Discussion: The outcomes of this study will be an evidence-based intervention programme with the potential to be incorporated into the national education system thus promoting health and well-being of adolescents in Sri Lanka.

Trial Registration: Registered at the Sri Lanka Clinical Trials Registry (SLCTR/2018/028).

Keywords: Physical activity, Adolescents, Physical fitness, Moderate-to-vigorous physical activity

INTRODUCTION

Physical activity is essential to maintain overall health and well-being and to reduce obesity and non-communicable diseases (NCDs). Physical activity has declined globally over time due to changing lifestyles, rapid urbanization and economic development. The reduction in physical activity levels in Sri Lanka was

found to be low when compared to the other developed and developing countries.¹ Physical inactivity has been identified as one of the leading causes of death in the world with physical inactivity and obesity identified as risk factors for mortality associated with NCDs in Sri Lanka.²⁻⁶ Physical activity level is low in females and decreases with advancing age.¹⁻³ In Sri Lanka, physical inactivity is higher among women than men.^{1,4} Compared

to adults, children and adolescents engage in higher levels of physical activity, and activity level in adolescents is significantly lower than in young children.⁵ Among adolescents, the frequency and intensity of physical activity in boys is commonly much higher than in girls.³

Targeted strategies to enhance regular physical activity appear to be promising in reducing the risk of cardiometabolic diseases and obesity, thus promoting health and well-being of individuals. The World Health Organization (WHO) declared that by adopting healthy behaviours it is possible to prevent 80% of premature heart disease, 80% of premature stroke, 80% of type 2 diabetes mellitus, and 40% of cancer.⁶ Physical activity has benefits independent of reducing body fat and obesity. These include increasing physical fitness with cardiorespiratory fitness and muscle strength, endurance and flexibility, reducing cardio-metabolic disease risk, increasing bone density and improving psychological health and well-being by lowering anxiety levels and stress.⁷⁻¹⁰ Development and evaluation of interventions to promote physical activity from a younger age is a priority since low levels of physical activity, and physical inactivity during childhood and adolescence often persists into adulthood.^{11,12} Physical inactivity leads to increased body fat which places children and adolescents at greater risk for cardiovascular disease when they become adults.^{13,14}

Behaviour patterns that develop during adolescence track into adulthood.¹⁵ Hence, it is important to focus on improving lifestyle among adolescents. Despite the presence of other risk factors, regular physical activity in childhood and adolescence has the potential to enrich physical, mental and social health leading to better academic achievement.¹⁶ Interventions which promote physical activity are essential in establishing the early development of active lifestyles among children. Specifically, this includes promoting the WHO recommendations of daily physical activity among children and adolescents in the context of play activities, sports, physical education, transport, domestic activities or as planned exercise programmes via individual or population-based approaches. Multi-component approaches comprising physical activity programmes, nutrition education, modified school lunches and community workshops have been identified as the most effective interventions and have been recommended for management and prevention of obesity and to promote healthy lifestyles among adolescents.¹⁷ A Cochrane review emphasized that school-based physical activity interventions have a positive impact on the duration of physical activity, television viewing, maximal oxygen uptake (VO_2 max), and blood cholesterol level among children and adolescents aged 6 to 18 years whereas physical activity rates (i.e. the percentage of the children who are active above the recommended duration of moderate to vigorous physical activity for the respective age category), systolic and diastolic blood pressure, body

mass index and pulse rate had a lesser improvement.¹⁸ A systematic review by Wareham et al. showed that school-based interventions composed of physical education classes and physical activity related behaviour change to be more effective than family-based interventions.²³ Globally, schools are identified as the ideal setting to implement physical activity programmes since a large group of captive and receptive young adolescents could be easily accessed in one setting.²⁰ Further, school-based physical activity interventions targeting all students in the school would prevent stigmatization of obese and overweight students which may have adverse psychological effects.¹⁸

The WHO's global recommendations on physical activity for health emphasizes moderate-to-vigorous physical activity (MVPA) involving a variety of aerobic activities for a minimum of 60 minutes per day to have a substantial impact on maintaining and promoting healthy cardiorespiratory and metabolic functions among children and adolescents 5-17 years of age.³ MVPAs have been shown to have a positive impact on improving cardio-metabolic function, whereas the effects of low-intensity activities do not appear to be as strong or as consistent.²¹ However, WHO's global recommendations on physical activity for health indicate that vigorous aerobic exercise, resistance exercise focusing on large muscle groups of the trunk and limbs and bone loading activities at least 3 days per week for 20-30 minutes provide health benefits substantiated by a dose-response relationship among this age group.³

Many studies have been conducted in different parts of the world using multi-designed intervention programmes.^{19,21} Nevertheless, the design and implementation of such physical activity programmes are challenging, especially for children and adolescents. Common challenges with interventions are personal factors, and family and community attributes highlighting the importance of rigorous situational analyses of the potential target group.¹⁸ Also, practical limitations regarding implementation of school-based programmes include lack of time, curriculum burden, human and physical resource limitations and may influence participation and continuation. When developing and implementing nationally applicable physical activity programmes for children and adolescents, substantial attention should be paid to knowledge of, and attitudes towards the existing health status and physical activity levels of the target population in the given country, as well as human and physical resources available.

This study primarily aims to evaluate the effectiveness of the school-based physical activity programme on MVPA rate and duration and sitting time including screen time among the adolescents aged 11-13 years. Furthermore, it aims to identify the effectiveness of the school-based physical activity programme on health-related fitness parameters: cardiovascular fitness, muscle fitness and flexibility, and body composition.

METHODS

Study design

The study is designed as a cluster randomized controlled trial to evaluate the effectiveness of the intervention by comparing the MVPA rate and duration, sitting time including screen time, and health-related fitness parameters between baseline and 3-month post-

intervention assessments in selected intervention and control schools. This protocol was designed complying with the Consolidated Standards of Reporting Trials (CONSORT) statement. Figure 1 provides an overview of the study as a CONSORT trial flow chart.²² The study has been approved by the Ethics Review Committee (ERC) of the Faculty of Medicine, University of Colombo, Sri Lanka (EC/16/192) and the trial is registered in the Sri Lanka Clinical Trials Registry (SLCTR/2018/028).

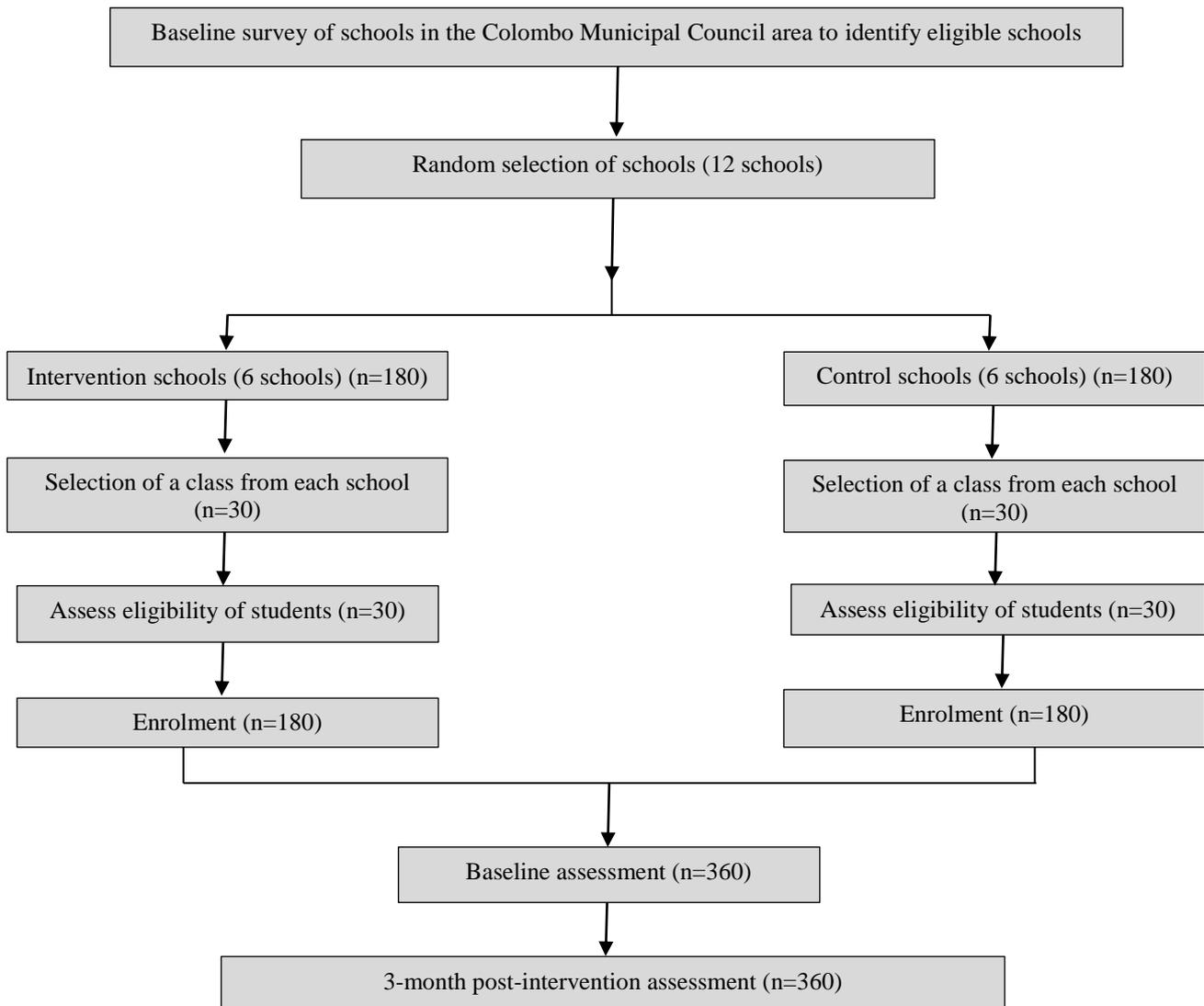


Figure 1: CONSORT trial flow chart of the study.

Sample size

Sample size was calculated to compare the percentage of adolescents who engage in daily physical activity for more than 60 minutes per day between the intervention group receiving a school-based physical activity intervention and a control group engaging in current physical activity in schools. The baseline percentage of adolescents who complete an acceptable volume of MVPA (more than 60 minutes per day) was taken as 19% as reported by the WHO.²³

Based on existing literature, it was considered possible to improve the percentage of adolescents who engage in MVPA of more than 60 minutes per day by 15% following the physical activity intervention.²⁴

Each school was taken as a cluster and the cluster size was considered as 30 adolescents; the intraclass correlation coefficient (ICC) was assumed to be 0.1, $\alpha=0.05$ and the power of the study as 80%.^{25,26} The following equation was used to calculate the minimum sample size,

$$N = \frac{(z_{\alpha/2} + z_{\beta})^2 [P_1(1-P_1) + P_2(1-P_2)] [1 + (m-1)\rho]}{(P_1 + P_2)^2}$$

A minimum of 120 adolescents are required for each arm of the study. With 30 adolescents per cluster, the minimum number of clusters per group is 4. In order to obtain an equal number of adolescents from each of grades 6, 7 and 8 in each of the intervention and control groups, an additional 2 clusters (schools) were selected for each of the intervention and control arms making a total of 6 clusters comprising 180 children in each arm of the study. Each arm of the study has 2 clusters of children each from grades 6, 7 and 8, respectively.

Population

Adolescent girls and boys aged 11 to 13 years from the selected government schools in the Colombo Municipal Council area, Sri Lanka.

Inclusion criteria

- Adolescent girls and boys between 11-13 years of age.
- Parents' informed written consent and the child's assent.

Exclusion criteria

- Presented with chronic illness or on long-term medication.
- Presented with any recent fractures, dislocations, muscle or ligament injury which may affect participation in physical activity.
- Failed any physical examinations done prior to any sporting activity.
- On medical advice not to participate in competitive sports.
- Parents give written indication of any contraindication to participate as provided on the consent form.

Selection of schools and children

The list of schools in the Colombo municipal council area was obtained from the Ministry of Education and was screened for the selection criteria mentioned below. The co-education schools were excluded from the school list.

Selection criteria for schools from the school list

- Availability of physical education and health sciences subjects in the school curriculum as an Ordinary Level Examination subject with 2 periods per week (45 minutes × 2) as recommended by the Ministry of Education.
- Availability of basic resources (physical education teachers, play grounds or space for outdoor sports

activities) to engage in physical activities during, after or before school.

- Have at least one qualified physical education teacher or instructor within the school.
- Have at least 30 or more students in each class of grades 6, 7 and 8.
- Having at least 02 or more classes in each of grades 6, 7 and 8.

A baseline survey was carried out in all the listed government schools situated within the Colombo Municipal Council area to assess whether the selection criteria given above were satisfied. Thereafter, the eligible girls and boys schools were listed separately in alphabetical order. From each list, every fifth school was selected and included in the final list of 12 schools (6 boys' schools and 6 girls' schools). The selected 12 schools were randomly allocated to either intervention or control arms such that the intervention arm comprised 6 schools and the control arm comprised 6 schools. From each school, one class was selected either from grades 6 or 7 or 8 randomly and all the adolescents of the selected classes who fulfilled the inclusion criteria were recruited in to the study.

Designing the intervention programme

The intervention programme was designed using data from a comprehensive situational analysis. Data for the situational analysis were obtained through in-depth interviews and focus group discussions (FGDs). FGDs were conducted with all stakeholders; adolescent girls and boys, school teachers and parents in the Colombo district. Each focus group consisted of 8-10 individuals of the respective category. The venue, time and date were planned to suit the participants of FGDs and the duration of the discussions were set up a priori. FGDs were carried out until saturation point was reached, adequate to develop the physical activity intervention. Each session was recorded and a record keeper was assigned to take all the notes of sessions. Meetings of experts were conducted with the directors, project officers of the Family Health Bureau and the Nutrition Unit of the Ministry of Health, the sports and physical education unit of the Ministry of Education and Health and Physical Education Unit subject teachers to obtain necessary information to design the physical activity intervention programme. Existing physical activity programmes were also considered when designing the new physical activity programme. The activities for the new programme were designed and selected considering the following factors:

- Likes and dislikes of students (which were evident from the FGDs)
- Resources (space, equipment, trainers)
- Time constraints
- Ability to perform in the school uniform
- Simple and fun activities, which could be performed by all students including the less active

The potential physical activity intervention was further developed and altered in consultation with experts in the field consistent with national and international policies.

The physical activity intervention comprises 3 programmes that are being conducted simultaneously each week with different activities in each programme to avoid monotony. All 3 programmes are similarly structured with different activities and for a period of 30 minutes. This was done since it was evident from the FGDs with both girls and boys that doing the same activities daily or continuously contributed to boredom and reduced motivation to continue the activities. Since the intervention was designed to be conducted 3 days per week for 3 months, the students were requested to do the 3 programmes variably which is likely to increase adherence to the programme. Due to time constraints, the intervention was designed for a period of 30 minutes.

Intervention programme

Each programme will consist of the following:

- Warm up: 5 minutes (aerobics and dynamic stretching for major muscle groups of the body).
- Flexibility and endurance training activities: 8 minutes (focusing on major muscle groups of upper limbs, lower limbs and trunk).
- Strength training activities: 6 minutes (focusing on major muscle groups of upper limbs, lower limbs and trunk).
- Cool down: 3 minutes (slow rhythmic aerobic activities).
- Fun games: 8 minutes.

Delivery of the intervention

The physical activity programme is delivered to the students of the selected intervention schools via qualified physical education teachers. The experts first introduced the programme to the teachers and trained them on how to implement it to the students. Thereafter, the trained teachers introduced the programme to the students.

Frequency and duration of the intervention

The physical activity programme is designed for 30 minutes. It is conducted within school hours, on 3 weekdays (Monday, Wednesday and Friday) for 3 consecutive months.

Study groups

- Control group: All the participants in the control group were requested to continue their normal routine activities during the regular physical education periods (2 x 45 minutes per week) conducted by the school.

- Intervention group: All the participants in the intervention group are following the physical activity intervention programme in addition to the standard physical activity practices conducted by the school.

Study period

The study is being conducted over a period of 3 months. All outcomes are measured at baseline and at the conclusion of the intervention (3 months from the commencement of the intervention). The principal investigator visits the intervention schools to assess the continuation and progress of the intervention.

Outcomes

The following outcomes are measured at baseline and at the conclusion of the intervention (3 months from the commencement of the intervention).

- Assessment of MVPA rate, duration of MVPA and sitting time including screen time using the validated interviewer administered Physical Activity Recall Questionnaire (PARQ).
- Health related physical fitness parameters such as cardiovascular fitness; muscle strength, endurance and flexibility; and body composition will be measured at baseline and 3-months from the commencement of the intervention.

Procedures

Recruitment

Following the baseline survey and random selection of 12 schools (6 girls' schools and 6 boys' schools), permission was obtained from the principals of the respective schools. The schools were assigned into the control and intervention arms. Only one class (either from grade 6, 7 or 8) was randomly selected from one school. Initially, class teachers were informed about the study and all students of the selected class were contacted and informed via the class teachers. Participants were selected according to the inclusion and exclusion criteria. Parents' informed written consent and the child's assent was mandatory to participation in the study. Baseline measurements were done among both the groups using the validated PARQ, general questionnaire, anthropometric measurements and physical fitness tests as mentioned below in September 2018.

Measurement tools

Anthropometric measurements

Height is measured to the nearest 0.1cm using a stadiometer (Seca 225 by SECA GmbH & Co. Kg., Hamburg, Germany) in standing position. The scale is placed on a flat surface and the participant is requested to

stand barefoot, heels together with arms hanging by the side. Both heels, buttocks, back of shoulder are placed in vertical plane and head in horizontal Frankfurt plane. Then height is measured and the mean of duplicate measurements obtained. If the difference between the two values is greater than 5 mm a third will be taken.

Weight is measured to the nearest 0.1 kg using a calibrated electronic scale (Seca 803 by SECA GmbH & Co. Kg., Hamburg, Germany) placed on a flat surface prior to the measurement and with the participants in lightweight clothing and barefoot. Standard weights are used for standardization on each measurement day. Waist circumference (WC) is measured to the nearest 0.1 cm with a one meter long, flexible and non-stretchable measuring tape (Seca 200 by SECA GmbH & Co. Kg., Hamburg, Germany) with calibrations in centimeters and millimeters. Measurement are taken while the participants are in standing position and at the end of normal expiration at the midpoint between the lower border of the lowest palpable rib and iliac crest in the mid-axillary line as the reference point, with the tape all around the body in a horizontal position. All measurements are taken according to the international standard methodology - International Society for Advancement of Kinanthropometry protocol.²⁷

Measuring MVPA rate and duration and screen time

MVPA rate and duration, and sitting time including screen time are collected using the validated interviewer administered PARQ from adolescents of both control and intervention groups at baseline (0 weeks) and at 3-months (12 weeks) post-intervention.

Measuring health related physical fitness parameters

The following tests are used to measure the health-related physical fitness parameters of adolescents in both groups at baseline (0 weeks) and at 3-months (12 weeks) post-intervention.

Cardiovascular fitness

Cardiovascular fitness is measured by the 20-meter shuttle run which is used to estimate the aerobic capacity (VO_2 max).²⁸ The adolescents are asked to run back and forth across a 20-meter marked pathway in time to background music played. A beep sound on the audio recording indicates the time when he/she should reach the end of the tract controlling the speed of the run. The test begins with a lower speed and gradually the speed increases with each beep. Ten students will perform the test at a time. Participants will be asked to continue running until their speed cannot be maintained according to the signal provided by the audio track. The number of laps completed during the test is recorded. The prediction equation of Mahar et al. is used to estimate the cardiovascular endurance.²⁹

Muscular endurance and strength

Curl up test

The Curl up test is performed according to the instructions provided in the FITNESSGRAM[®] test administration manual.³⁰ The test will be performed on a flat surface. Participants lie flat on their backs, arms straight and by the side of the body with palms down and fingers straight. Knees are bent to approximately 140 degrees with feet flat on the floor. When the participant is positioned correctly, a 4.5 inches wide strip of velcro tape is affixed on the testing surface in a way that the longest fingertip of each hand touches the end of the near edge of the strip. Then to perform the test, the participants are asked to flex the spine while sliding the fingers across the floor until the fingertips of each hand reach the far edge of the strip. This is done by moving the arms and the shoulders up and down according to the specified pre-recorded cadence (20 curl ups/minute). After each curl up the participant returns to the starting position and then repeats the same. Shoulders must remain relaxed throughout the curl-up and feet and buttocks must stay on the floor. The number of curl ups performed in the correct way until a maximum of 75 curl-ups are recorded.

90° Push-ups

This test is performed according to the instructions provided in the FITNESSGRAM[®] test administration manual.³⁰ The participant first lies on prone position and the hands and feet with legs kept straight and slightly apart on a flat surface will support the body. The hands are placed slightly wider than the shoulders with fingers stretched. When performing the test, the body should be lifted up from the floor until the elbows are straight while keeping the back and legs straight. Then the body is lowered until the elbows are flexed up to 90° angles and upper arms are parallel to the floor. This movement is repeated according to the specified pre-recorded cadence (20 push-ups/minute). The continuous number of push-ups performed in the correct way is recorded.

Flexibility

The back-saver sit and reach test is performed according to the instructions provided in the FITNESSGRAM[®] test administration manual.³⁰ A box is prepared similar to that of the flexometer to measure the flexibility.³⁰ It is made using two pieces of wood of 30 cm/12 inches high attached at right angles to each other. A measuring tape is placed on the top of the box with the '0' end towards the participants side. The participants have to remove shoes and sit facing the device with one knee fully extended and feet flat against the face of the box. The other knee is flexed with feet flat on the floor. Participants are asked stretch out arms forward while placing the hand on top of each other along the scale for four times and at the fourth time the hands should be kept in place for at least 2 seconds to get the measurement. Then the participant

switch the position of legs and repeat the test. Measurements are recorded to the nearest 0.5 inches.

Body composition

Body composition is measured using Bioelectrical Impedance Analyzer (BIA) (US 229-DF50, ImpediMed Limited, Australia). The participants are asked to lie down on a non-conductive surface and electrodes are attached to hand and foot in accordance with the manufacturer's instructions. Then the electrodes are connected to the BIA machine via crocodile clips. Total body water (TBW), impedance and resistance are recorded and the BIA equation validated to Sri Lankan children is used to assess body composition.³¹

The outcomes measurement time points are described in Table 1.

Table 1: Outcome measurement time points for the intervention and control groups.

Outcome	Baseline (0 weeks)	3 months follow-up (12 weeks)
Sociodemographic data	X	
Anthropometric measurements	X	X
Rate and duration of MVPA measured by PARQ	X	X
Cardiovascular endurance	X	X
Muscular strength and endurance	X	X
Muscular flexibility	X	X
Body composition	X	X

Pilot study

The intervention was pretested on adolescent girls and boys aged 11-13 years from 2 different schools in Colombo Municipal Council area. The physical education teachers of the two schools were trained to deliver the designed physical activity programme. The teachers were instructed to conduct the programme for 30 minutes on 3 school days for 4 consecutive weeks.

Data collection and handling

Data collection is performed by trained professionals and data are entered into a password protected computer database by the principal investigator. The hard copies of questionnaires are stored in a cupboard under a lock and key. The data collection sheets do not include the personal identification data of the adolescents.

Statistical analysis

Data are entered in to a SPSS (Statistical Package for Social Sciences version 20.0) database. Descriptive statistics will be generated for demographic data and all measurements in both the intervention and control groups.

The MVPA rate and duration, and sitting time including screen time and health-related fitness parameters: cardiovascular fitness, muscular strength and endurance, flexibility and body composition (anthropometry, fat mass and fat free mass) will be considered as the major outcome variables. Effectiveness of the intervention will be assessed by comparing differences in baseline and post-intervention measurements between intervention and control groups using repeated measures analysis of variance (ANOVA). A p value <0.05 will be considered as statistically significant.

DISCUSSION

This article presents the design of a cluster randomized controlled trial primarily aimed at designing, implementing and evaluating a school-based physical activity intervention programme for adolescents 11-13 years of age in selected government schools in the Colombo Municipal Council area of Sri Lanka. Adolescence ranges between 10 and 19 years.²³ In this study, only adolescents aged 11-13 years were selected as the schools did not permit us to enrol older students, since the Ordinary level examination, which is compulsory for eligibility to proceed to the Advanced level course is conducted for the 14-16 year age group. The physical activity intervention was designed to be carried out for 30 minutes duration on three days per week. The importance of conducting physical activity interventions on a daily basis has been emphasized in many studies.³²⁻³⁶ Unlike in many Western countries, Sri Lankan school hours are comparatively less (6 hours), from 7.30 am to 1.30 pm. Therefore, it is challenging to allocate a longer time duration for a physical activity programme. Further, during the FGDs with the teachers, it was revealed that the curriculum burden is high and that teachers find it challenging to cover all mandatory content during school hours, sometimes necessitating the conduct of extra classes before or after school. Considering this, and with the permission of the Ministry of Education, the current physical activity intervention was designed for 30 minutes duration on three days per week. Further, the intervention was planned to be carried out for three consecutive months, since one school term consists of a 3 month period followed by nearly 3-4 weeks of school vacation. The physical activity intervention consists of aerobic activities, stretching and strengthening activities targeting the major muscle groups of the body. The intervention requires a minimum of physical and human resources to ensure that any school can easily implement it and also to encourage inactive students to be engaged in physical activity thereby

placing importance on creating a physical activity culture for the future.

When measuring the MVPA rate and duration, sitting time including screen time, a validated PARQ is used since it gives the opportunity to measure physical activity in a large group of students within a short period of time.³⁷ Also, the health-related fitness parameters are measured using simple field tests rather than using sophisticated laboratory procedures since it is intended to introduce the tests to the school teachers and for students to assist in the assessment of their physical fitness status. If successful, it is intended that the outcome of this evidence-based intervention programme will be incorporated into the national education system as to date there are no published randomized control trials in this regard in Sri Lanka.

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Conflict of interest: None declared

Ethical approval: The study has been approved by the Ethics Review Committee (ERC) of the Faculty of Medicine, University of Colombo (EC/16/192)

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