

# BMJ Open Structured, multifactorial randomised controlled intervention to investigate physical activity levels, body composition and diet in obese and overweight adolescents

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## ABSTRACT

**Introduction** There has been a steep increase in the prevalence of adolescent overweight and obesity globally and in India, demonstrating that present prevention strategies are insufficient. Available evidence suggests that multifactorial interventions may improve short-term physical activity (PA), nutrition and psychological behaviour of overweight and obese adolescents but long-term follow-ups and strategies are needed. This study will investigate the effects of a structured multifactorial (school-based and family-based) intervention on adolescent obesity, compared with a single or no intervention.

**Methods and analysis** A pragmatic, clustered randomised controlled trial with 12 weeks of interventions and 3-month, 6-month and 12-month follow-ups will be conducted at multiple participating schools in Karnataka, India. The participants will be overweight and obese male and female adolescents aged 11–16 years and will be randomly assigned by school into three groups: group A (multifactorial intervention, exercise and dietary advice); group B (exercise only); and group C (controls, no interventions). Primary outcome measures are the level of PA and body composition. Secondary outcomes are dietary change, behaviour change, food behaviours, cardiovascular and muscular fitness, quality of life, parental behaviours (physical and mental) and family functioning. Positive intervention results may reduce obesity in adolescents and promote a healthier lifestyle for students and families. A larger, culturally diverse population can benefit from a similar methodology.

**Ethics and dissemination** The study has been approved by the Institutional Research and Ethics Committee (IEC 536-2018), Kasturba Hospital, Manipal, Udupi District, Karnataka, India. A written and verbal informed consent (supplemental material) will be provided to the participants prior to participation. On completion of the trial, the results can be communicated to adolescents and their parents on request, and will be published at national and international conferences and in peer-reviewed journals.

**Trial registration number** CTRI/2019/04/018834.

## BACKGROUND

Improved socioeconomic factors and industrialisation have increased both the availability

## Strengths and limitations of this study

- This protocol tests a multifactorial intervention to facilitate behaviour change in overweight and obese adolescents.
- The experiment is designed addressing the cultural context of the participants in terms of diet.
- This protocol involves all the stakeholders involved in adolescent health, including teachers, parents and adolescents themselves. This is a novel approach in India.
- The protocol involves long-term follow-up of the lifestyle changes among adolescents, providing possibility of longer positive impact.
- The limitation of the study is that, due to financial constraints, objective measures of physical activity are not used.

of processed fast food and the extent of sedentary behaviour across a much broader section of the population in developed and developing countries.<sup>1</sup> These factors have contributed to a considerable increase in overweight and obesity, especially in adolescents, and the risk of lifestyle-related diseases, medical and social issues.<sup>2,3</sup>

The estimated prevalence of Indian adolescent overweight or obesity is between 6% and 24.5% as compared with 11.3% in Europe and 20.5% in the USA.<sup>4–6</sup> India has the second largest population of overweight and obese adolescents globally after China.<sup>5</sup> There has been a steep rise in Indian adolescent obesity from 19.6% to 26.6% varying geographically, with higher percentage in urban Indian adolescents compared with rural counterparts.<sup>7</sup>

Adolescence is a critical determinant of adult health, yet there are limited studies on the effects of interventions encompassing modifiable factors for adolescent obesity.<sup>8</sup> A

meta-analysis of interventions targeting overweight and obese adolescents, including randomised controlled trials (RCTs) with a 1-year follow-up, concluded that there is a substantial research gap considering exercise, familial factors and lifestyle modifications as the foci of treatments.<sup>9</sup> A 2015 Cochrane review reported that family-centred behavioural interventions targeting lifestyle modifications had a profound impact on the reduction of overweight and obesity in adolescents and children,<sup>10</sup> hence the importance of focusing on behaviour changes for both adolescents and parents.<sup>11</sup>

Multiple personal, environmental and biological factors can result in high rates of obesity.<sup>10</sup> High energy intake and low energy expenditure, in the absence of other possible contributing medical conditions, are the leading contributing factors to obesity.<sup>12</sup> Reduction in energy intake and increased physical activity (PA) or physical work, or both, can have a positive impact on weight loss.<sup>13</sup> Previous studies have shown that increasing PA can reduce body mass index (BMI) in adolescent boys and girls, and concluded that significant sedentary time increased body fat in adolescents.<sup>14–16</sup> Therefore, the combination of increasing PA and reducing sedentary time is considered best for targeting adolescent obesity.<sup>17</sup> Moreover, irrespective of body weight, increased PA and decreased sedentary time are associated with more positive health benefits, such as decreased cardiovascular disease-related mortality, cancer-related mortality and all-cause mortality, increased time to onset of chronic diseases and thereby improved quality of life (QoL).<sup>18</sup>

Food behaviour patterns also play a vital role in energy imbalance.<sup>19</sup> Consumption of foods high in fat and sugar, and with decreased fruit and vegetable intake, can be a significant contributor to adolescent obesity<sup>19</sup> and do not meet adolescent dietary guidelines.<sup>20–21</sup> Studies have supported strategies for providing nutritional education and targeting healthy food behaviour to encourage a balanced diet.<sup>22–25</sup> However, interventions that include dietary change and PA seem more effective than those targeting dietary modifications alone.<sup>22</sup>

Genetic factors may play an important role in adolescent obesity.<sup>23</sup> However, parental attitudes and behaviour towards a healthy lifestyle also play a pivotal role, possibly because parents are mainly responsible for food choices in the home environment.<sup>23</sup> There is a high probability that obese parents will have an obese child; therefore, parental involvement in interventions targeting adolescent obesity will be vital.<sup>26</sup> In studies where parents were involved in supporting behavioural changes with their children and were role models in healthy behaviours, there were significantly better outcomes (eg, improved diet, weight loss, family communication) than where parents were not involved.<sup>26–30</sup>

The majority of previous studies in India have evaluated PA and dietary modifications separately.<sup>31–33</sup> Outcome measures included anthropometry, food habits and changes in PA level.<sup>31–33</sup> Separate interventions have been moderately effective in the short term but have not

provided long-term solutions to the obesity problem, as evidenced by the increased rate of obesity.<sup>31–33</sup> There is limited literature on the role played by familial factors such as family functioning, eating patterns and family awareness in the interventions, which contribute significantly to adolescent health.<sup>31–33</sup> A 2010 Indian study conducted among adolescents concluded that parents should be involved in weight-loss interventions through educating their children on healthy eating and PA using validated educational material with long-term follow-up.<sup>32</sup> Recent Indian government recommendations<sup>34</sup> included implementing a systems approach to improving health and weight loss which should involve primary and secondary prevention strategies such as government/health programmes, school-based PA and nutritional education, community education and improvements in urban and rural infrastructure.<sup>34–37</sup> Furthermore, educational material should be culturally conducive with teachers involved in disseminating the benefits of healthy eating and PA.<sup>38</sup>

Since obesity is a result of multiple factors, there is a need to design interventions that target all these factors.<sup>39–40</sup> There is a further need to involve clinicians from different fields with such multisector interventions. Physiotherapists, exercise training professionals, occupational therapists, education professionals, dietitians and medical practitioners may be involved in implementing targeted health interventions to manage overweight populations. Therefore, the results of this study may contribute to primary healthcare strategies to reduce obesity. The purpose of this RCT is to compare the effectiveness of an exercise and dietary intervention that is culturally appropriate and school-based to that of an exercise-only intervention or no intervention for overweight and obese adolescents. We hypothesise that while both interventions may increase PA, the multifactorial intervention will have the most significant improvements in PA, body composition change, diet and behavioural change, and will be more effective long term. This can help prevent and reduce obesity among overweight and obese adolescents.

## METHODS

### Study design

The study is a pragmatic, 12-week cluster RCT with 3, 6 and 12 months of follow-up after baseline. The design incorporates a theoretical framework based on the Theory of Planned Behaviour (TPB).<sup>41</sup> TPB links an individual's beliefs and behaviour and states that the three determinants of attitude, subjective norms and perceived behaviour control can predict or affect one's intent to show specific behaviours.<sup>41</sup> For example, an individual's perception of normative social pressures and the beliefs of peers and family may influence their perception about specific behaviours (eg, adopting an exercise programme or changing their eating patterns). This perception may affect their intention to change behaviours and also to change personal behaviours which require culturally sensitive knowledge translation.<sup>41</sup> In this study, interventions in

schools and family education may contribute to successful adolescent behaviour change towards a healthy lifestyle.<sup>41</sup>

The duration of the interventions was selected based on (1) the minimum time likely to see positive changes in physical fitness and body composition with exercise training, that is, at least 6 weeks as per American College of Sports Medicine (ACSM) guidelines<sup>42</sup>; (2) the availability of the school students to participate in the exercise and education sessions during school hours. The study design incorporates repeated measures data collection and analyses, including the intention-to-treat (ITT) approach, to provide unbiased comparisons among the intervention and control groups. ITT should avoid potential effects of participant dropout or missed data collection (eg, if a student is unwell and unable to attend a test or follow-up session).

### Ethics and dissemination

Our trial results are expected to increase the QoL of adolescent and their parents by increasing awareness about healthy lifestyle. Our results will be communicated to adolescents, their parents, schools and to exercise providers treating adolescents through national and international conferences, and by publications in peer-reviewed journals. The study is conducted as per principles of the Declaration of Helsinki and in accordance with medical research involving the Human Subjects Act (WMO). The research protocol has been approved by the KMC and KH Institutional Ethics Committee (IEC) and has been registered in Clinical Registry Trial, India (CTRI) (CTRI/2019/04/018834) (<http://ctri.nic.in/Clinicaltrials/regtrial.php?trialid=31539&EncHid=65020.40330&modid=1&compid=19>).

The data collected and related documents will be submitted periodically to IEC and it will be monitored by the IEC and CTRI.

### Patient and public involvement

The protocol was developed based on extensive literature search. We identified best possible interventions available in financially constrained trial, culturally feasible mode, contextual barriers and facilitators for intervention delivery. We piloted the protocol with 60 obese adolescents for establishing the adolescent's perspective of the intervention and feasibility of its delivery. Based on the participant's response and feedback, the intervention was modified.

### Setting of the study

The study will be conducted in government and private primary and secondary English-medium schools in Udupi Taluk, Karnataka, India. Participant screening and data collection will be completed at each school.

### Selection

Prior to the 12-week intervention, parents of possible participants will be contacted through the school in person to explain the informed consent and the importance of a healthy diet and exercise. If parents are

unavailable for a face-to-face school discussion, they will be contacted by telephone. Following the intervention, follow-up meetings or telephone contact will be done at 3, 6 and 12 months. Data will be collected from all the adolescents in the school environment to avoid social stigma, with data analysis carried out by the research team at the Department of Physiotherapy, Manipal Academy.

### Recruitment

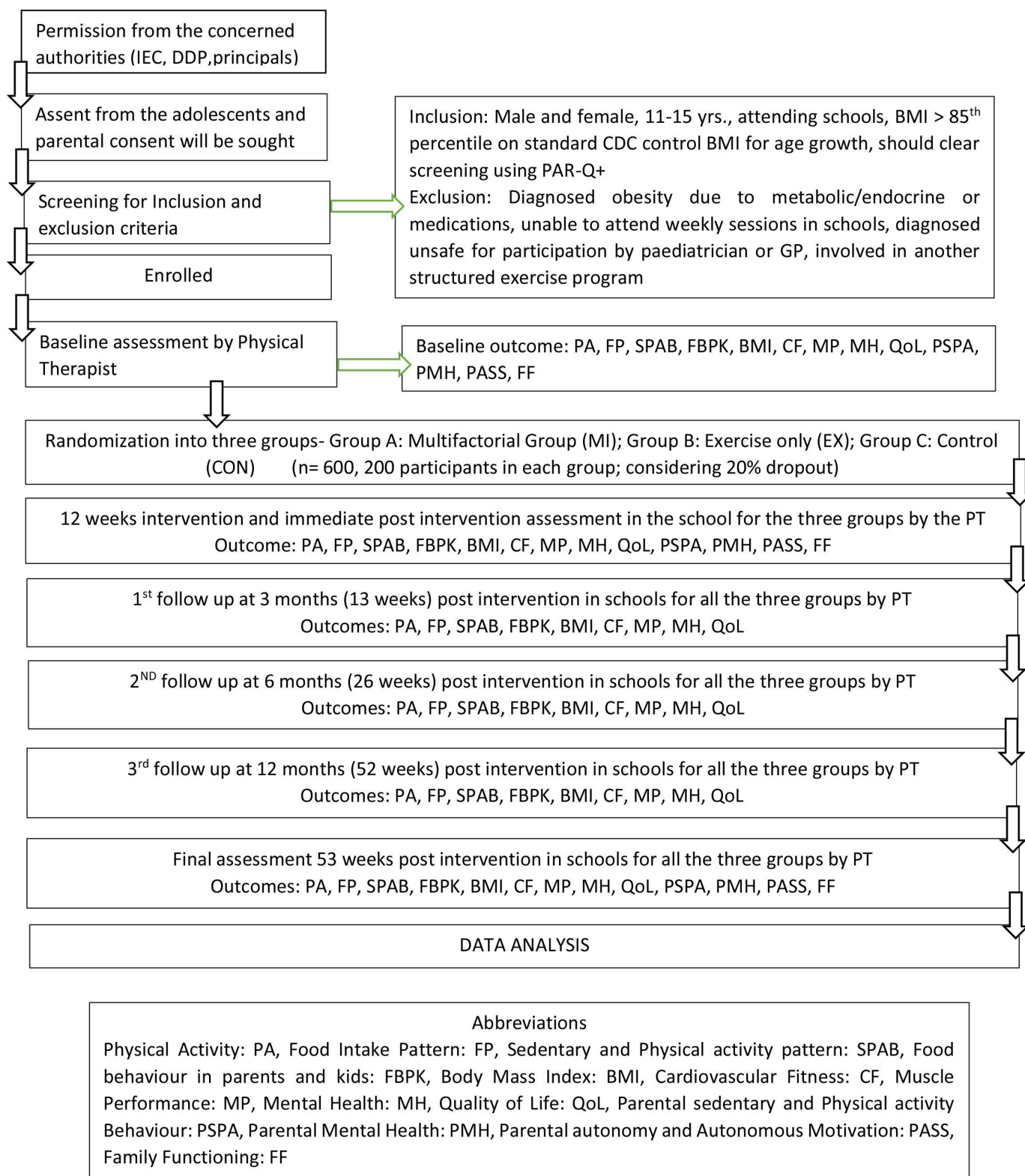
Permission to conduct the study from the Office of the Deputy Director for Public Instruction, Udupi District, Karnataka, India, followed by permission from the school principals, will be gained prior to student recruitment in each school. A list of the government and private primary and secondary English-medium schools in Udupi Taluk, Karnataka, will be obtained from the District School Registration Office and invited to participate in the project. Schools will be divided into five zones depending on geographical locations (approximately 5 km minimum distance between each school) in Udupi Taluk and schools from each zone will be selected. [Figure 1](#) shows the flow chart of the study. Recruitment of students and families will occur before the allocation of schools to either of two intervention groups or the non-intervention group. The additional opportunities for exercise, advice and education for students and parents will be promoted to assist in recruitment. Informed consent from the parents and assent from each adolescent before recruitment will be obtained. Adolescents volunteering to participate will be screened for inclusion and exclusion criteria. All the participant data will be kept confidential, and the research team will conduct the data analysis. The study recruitment will commence in approximately January 2021 and will end in February 2022.

### Sample size

The sample size was calculated considering one of the primary outcome measures (BMI Z-score), based on an unpublished pilot study conducted for the primary research project. The significance level was considered at 0.05/3 to be 2.59, adjusted for the three comparisons. With the power of the study at 80%, the anticipated population SD of the outcome variable would be 2.13, and the minimum clinical difference is assumed to be 1.5. The average cluster size was considered to be 10, and 0.3 was determined as the intraclass correlation coefficient (ICC). Based on these values, the sample size required for the study will be 750 overweight and obese adolescents, assuming a 37% attrition rate.<sup>43</sup> There will be 250 participants in each group (groups A, B and C).

### Randomisation and allocation

As the total sample size of the study is 600 participants, we anticipate being able to recruit 20 overweight or obese adolescents in each school; therefore, a total of 30 schools will be invited to participate in the study. Block randomisation of the schools will be performed with five blocks, representing different geographical regions, with six



**Figure 1** (Consolidated Standards of Reporting Trials) flow of the study.

participating schools in each block. The block randomisation sequence will be created by a computer-generated programme created by a biostatistician. To ensure allocation concealment from the leading investigator, the random sequencing of schools for each block will be placed in opaque envelopes, handed to a staff member

from the Department of Physiotherapy Faculty, who is not participating in the study. The block randomisation will be used to avoid selection bias and ensure that participants are assigned to groups with equal probability, therefore increasing the power to detect statistical differences between groups.



After baseline assessment of outcome measures, participating schools will be randomised into three groups equally, as described by Doi and Simpson.<sup>44</sup> The allocation of each school to a specific group will also be done using sealed envelopes. The group allocation for each school will be revealed to the lead investigator by the same faculty staff member (as described above) after opening the sealed envelopes. The schools will be randomised into group A multifactorial intervention (MI) or group B exercise only (EX) or group C control group (CON). Each school will be allocated to one of the three groups, that is, participating students within each school will do the same group intervention (such as MI, EX only or no activity/CON).

Each school's intervention will be organised by the lead investigator. The intervention plan and structure will be provided to each school principal and relevant school staff by the lead investigator. After the school allocation and intervention, due to the nature of the interventions, it will not be possible to blind the school staff, clinician and the researchers who actually deliver the interventions and complete the assessments of students.

### Participant characteristics

The inclusion criteria for the study are (1) males and females aged 11–16 years, who are attending schools in Karnataka; (2) a BMI higher than the 85th percentile on the standard Centres for Disease Control BMI-for-age growth charts. Overweight is defined as a BMI at or above the 85th percentile and below the 95th percentile. Obesity is defined as a BMI at or above the 95th percentile<sup>45</sup>; (3) should satisfactorily pass health screening for safely participating in PA using the Physical Activity Readiness for Everyone (PAR-Q+).<sup>46</sup>

The exclusion criteria are (1) a general practitioner's medical diagnosis of obesity due to metabolic and endocrine disease, or to medications (eg, psychotropic pharmacology); (2) current treatment for psychiatric disorders; (3) unable to attend twice-weekly sessions at the designated intervention locations; (4) a report by potential participants that they have been assessed as unsafe or unfit to participate by a general practitioner or paediatrician; (5) potential subjects, participating in another structured exercise programme. We recommend that if students report mental health issues such as anxiety or depression, related to their participation in study, that they be offered counselling either through the school, their general practitioner, social support services or the local hospital.

### Outcome measures

All the primary and secondary outcome measures will be assessed at baseline and at the timelines and follow-up assessment points during the study, as shown in [table 1](#). [Figure 2](#) shows the trial's organisational structure with the intervention components or inputs linked to specific physical, dietary, and behavioural assessments and desired outcomes (final outputs). Trained physiotherapists,

research team members and school physical education staff will assess all the outcome measures.

### Primary outcome measures

The specific primary outcomes are (1) levels of PA in school-attending adolescents as measured with the Physical Activity Questionnaire-Adolescent (PAQ-A)<sup>47</sup>; and (2) BMI and mid-arm circumference using tape by standard procedures to the nearest millimetres.<sup>48</sup>

### Secondary outcome measures

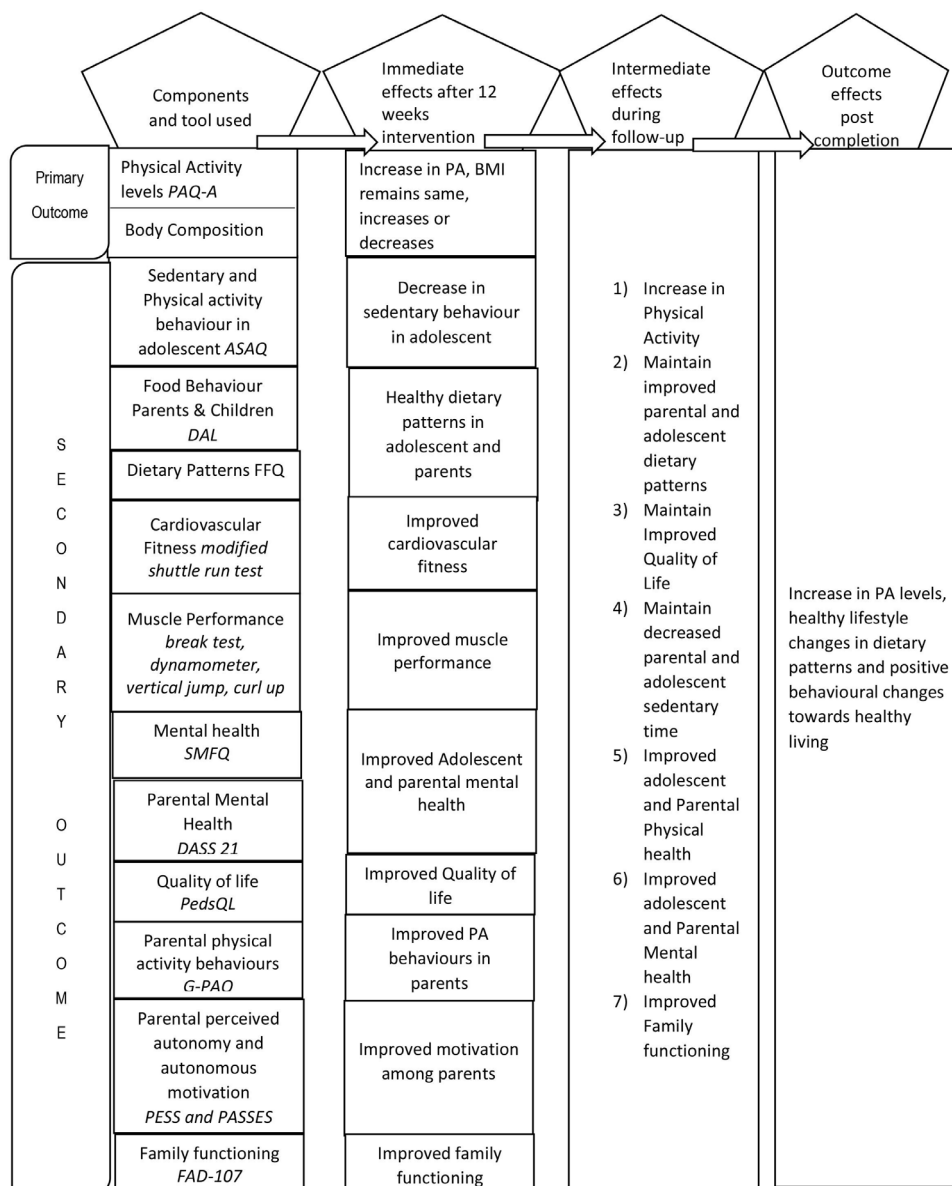
Permission from the authors has been sought to use and cross-culturally validate all the questionnaires except G-PAQ and Dietary and Lifestyle Questionnaire (DAL), as these are already cross-culturally validated. Sedentary and PA behaviour among children will be assessed using: (1) The Adolescent Sedentary Activity Questionnaire (ASAQ) (ICC=0.57)<sup>49</sup>; (2) food behaviour in parents and adolescents will be assessed using the Dietary and Lifestyle (DAL) questionnaire (ICC=0.56)<sup>50</sup>; (3) food patterns and behaviours in this cohort will be assessed with the pre-developed Food Frequency Questionnaire (FFQ), based on dietary guidelines prescribed in the *Dietary Guidelines for Indians* (2018), a manual developed by the National Institute of Nutrition (NIN) and Indian Council of Medical Research (ICMR). The analysis of FFQ will be carried out using 'Dietsoft' software<sup>51</sup>; (4) cardiovascular fitness will be measured using Modified Incremental Shuttle Run test<sup>52</sup>; (5) muscle performance will be measured with the Manual Muscle Test (break test) for quadriceps, biceps and middle deltoid. Handgrip strength using a handheld dynamometer (Chatillon MSE 100),<sup>53</sup> vertical jump test for lower limb muscle power using the Sargent Jump Test protocol, and the Canadian Standardised Test of Fitness Curl Up Test for abdominal muscle endurance.<sup>54</sup> All break tests and handgrip muscle testing will be performed on the non-dominant limb, and each test will be performed three times, with the average score used for analysis.<sup>53</sup> For the vertical jump test, three measures will be taken, and the highest value will be recorded. The Curl Up Test will record the number of curl-ups performed correctly in 60s.<sup>54</sup> (6) The mental health of the adolescents will be assessed using the Short Moods and Feeling Questionnaire (SMFQ) (ICC=0.757, ICC=0.853),<sup>55</sup> and parental mental health using Depression Anxiety Stress Scales (DASS-21) (sensitivity of 79.1% and specificity of 77.0%)<sup>56</sup>; QoL will be assessed using the Paediatrics Quality of Life Teen Report (PedsQL) (ICC= (alpha=0.88 child, 0.90 parent report))<sup>57</sup>; (7) parental sedentary and PA behaviours will be measured using G-PAQ questionnaire<sup>58</sup>; parental perceived autonomy and autonomous motivation will be assessed using a modified version of the Perceived Autonomy Support Scale for Exercise questionnaire (PESS and PASSES) (ICC=0.755)<sup>59</sup> and family functioning using the McMaster Family Assessment Device (FAD-107) (internal consistency 0.72 to 0.92).<sup>60</sup> The questionnaires will be validated by the process described by Huang and Wong.<sup>61</sup> Briefly, the questionnaires will be

**Table 1** Outcome measures and timeline of measurements in the study

Timepoint	Study period							
	Enrolment	Allocation	Post-allocation				Trial end point	
			Baseline	12 weeks	Follow-up (weeks post intervention)			
				13	26	52	53 weeks post intervention	
Enrolment								
Eligibility screen	X							
Informed consent	X							
Randomisation		X						
Intervention								
Group A (multifactorial)			██████████					
Group B (exercise only)			██████████					
Group C (control)			██████████					
Assessment/tool								
Primary outcomes								
Physical activity (Physical Activity Questionnaire-Adolescent (PAQ-A))			X	X	X	X	X	
Body mass index (BMI) (standard procedures)			X	X	X	X	X	
Secondary outcomes								
Sedentary and physical activity behaviour (The Adolescent Sedentary Activity Questionnaire (ASAQ))			X	X	X	X	X	
Food behaviour of parents and adolescents (Dietary and Lifestyle (DAL) questionnaire)			X	X	X	X	X	
Food intake pattern (Food Frequency Questionnaire)			X	X	X	X	X	
Cardiovascular fitness (Modified Incremental Shuttle Run test)			X	X	X	X	X	
Muscle Performance (Manual Muscle Test (break test), handheld dynamometer, Sargent Jump Test, Curl Up Test)			X	X	X	X	X	
Mental health (the short Moods and Feeling Questionnaire (SMFQ), Depression Anxiety Stress Scales (DASS-21))			X	X	X	X	X	
Quality of life (Paediatrics Quality of Life Teen Report (PedsQL))			X	X	X	X	X	
Parental sedentary and physical activity behaviours (G-PAQ questionnaire)			X	X	X	X	X	
Parental perceived autonomy and autonomous motivation (PESS and PASSES questionnaire)			X	X	X	X	X	
Family functioning (McMaster Family Assessment Device (FAD-107))			X	X	X	X	X	

validated in five steps.<sup>62</sup> In step one, the questionnaires will be forward translated into local languages by qualified bilingual translators and several translations will be

produced.<sup>61</sup> In the second step, questionnaires will be back-translated into English language by another bilingual translator. In the third step, a review committee



**Figure 2** Organisational structure of the trial with interventional components.

comprising of five multidisciplinary experts in local culture and language will be formed.<sup>61</sup> They will review and compare the source and the translated versions of the questionnaire.<sup>61</sup> Discrepancies in translations will be resolved using a five-point Likert scale.<sup>61</sup> Based on the expert's comment, the items will be deleted or modified and new items will be generated until the translation is fully comprehensible.<sup>61</sup> Finally, the experts will verify the cross-cultural equivalence of the source and the final version.<sup>61</sup> Pretesting of these versions will be done in step four.<sup>61</sup> In this step, the source and final versions will be submitted to a group of bilingual people, who will rate the equivalence of each item between the source and the final versions.<sup>61</sup> Any low equivalence item will be revised using step two again.<sup>61</sup> In the final step, the score weighing will be done to adapt the weights of each score in cultural context.<sup>61</sup> This is will be done using factor analysis by a biostatistician in the research team.<sup>61</sup>

## Intervention

Baseline evaluations need to be done with all participants irrespective of which group to which they are allocated. All the interventions will be school-based. The baseline assessment will be conducted by the physiotherapist. The multifactorial (MI) group A will include PA, diet education for the adolescent and parent education about healthy eating and PA/exercise. A qualified dietitian and physiotherapists will develop a manual educating student and their parents about healthy diet and optimum PA for the adolescent age group. This manual will be validated as part of the study.<sup>62</sup> Briefly, the validation process involves the distribution of the educational material to parents and adolescents in the MI groups, which will account for approximately 30% of the total study cohort. MI participants will be from different regional areas and socioeconomic levels, providing a realistic sample of the Karnataka population. The manual text is printed in both

English and Hindi with illustrations and diagrams of PA modalities, PA recommendations, food groups, dietary guidelines, portion sizes and so on. The validation process will involve the evaluation of the initial draft material by three experts (a clinical dietitian and two clinical exercise physiologists) followed by a revision process prior to pilot distribution. A pilot sample of students and families (n=50) who are not involved in the main study will be asked to evaluate each component of the manual using a seven-point Likert scale and to provide written feedback with suggestions and comments. The feedback responses (scores) will be entered into spreadsheets; analysis of question components and factor analysis will be done using principal component analysis (PCA). Internal consistency of scores will be analysed using Cronbach's alpha with a score of at least 0.6–0.7 or above indicating reliable consistency. Further edits may then be made to form the final pilot draft of the manual which will be distributed to all MI participants. The information manual will provide pictorial education about the food-based guidelines for the adolescents considering the cultural variations and dietary needs. The dietary education will be provided to the parents by the physical therapist at the beginning of the sessions, and to reinforce the dietary habits, an educational manual will be distributed. Any dietary concerns of the parents during the study will be addressed by the physical therapist and the dietitian.

The adolescents in the MI group will be given exercise, according to ACSM guidelines, for 60 min for 2 days a week during the physical therapy (PT) classes under the supervision of a physiotherapist and physical education teacher. These sessions will consist of moderate to high-intensity exercises based on the Pictorial Children's Effort Rating Table (PCERT), which will significantly increase their heart rate and breathing.<sup>63</sup> The PA sessions will include both aerobic and strength training exercises. Aerobic exercises will comprise activities such as running, jogging, brisk walking and jumping. Strength training exercises will involve playing activities, body weight exercises and strengthening with TheraBands.<sup>64</sup> Participants will also be educated about the importance of regular PA and healthy eating pattern verbally in the

educational session at the beginning of the intervention of the programme. Post-intervention follow-up will be conducted at the school. Participants missing sessions for 2 weeks continuously will be considered for dropout. Educational awareness programmes will be conducted for the parents, and after the programme, the validated informative booklet will be circulated among the parents. The exercise prescription has been described in [table 2](#).

Group B (EX) participants will be given exercise only for 45 min during PT classes under the supervision of a physiotherapist and physical education teacher. The same procedures as for group A will be followed but with no dietary education or behaviour change advice. Post-intervention follow-up will be carried out as per group A. The group C control (CON) participants will be encouraged to continue their regular daily activities and dietary pattern. They will also be reassessed post-study and at follow-up points. No nutritional education will be provided to the parents in group C. [Figure 3](#) provides the Template for intervention description and replication (TIDieR) checklist explaining the details of the intervention.

### Statistical analysis

Statistical analysis will be done using IBM SPSS Statistics for Windows (2015), V.15. Descriptive statistics will be used for demographic data. Shapiro-Wilk test will be used to analyse normal data distribution. Data will be log-transformed if the data are not normally distributed. Repeated measures analysis of variance will be used to compare means between the three groups and across four time periods (group and time effects) with a Bonferroni post hoc test for multiple comparisons. The value for statistical significance will be  $\leq 0.05$ . Cohen's effect size will be used to determine the magnitude of any changes, with the effects being described as small (0.2), medium (0.5), large (0.8) or very large (1.2). The standard ITT approach will be used if there is missing data due to a missed exercise or testing session, that is, all participants that are randomised must be included in the final analysis and analysed according to the intervention group

**Table 2** Exercise prescription for adolescent

Frequency	Intensity	Time	Type
▶ 2 days/ week	▶ Upper limb: 4–5 muscle groups/8–12 reps/1–3 sets ▶ Lower limb: 4–6 muscle groups/9–15 reps/1–3 sets	▶ Start with no weight ▶ Gradually add 0.5–1 kg weight after every three sessions ▶ Each session: 20–30 min	▶ Strength training ▶ TheraBands ▶ Body weight exercises
	▶ Based on Perceived Rate of Exertion for Children (PCERT scale), where HR increases	▶ Start with 30 min session ▶ Later increase to cumulative 60 min/ day	▶ Cardiovascular/Flexibility exercises ▶ Jumping, running

HR, heart rate.



**TIDiER CHECKLIST FOR INTERVENTION**

Sr no	Item	Description
1)	Intervention name	Exercise and behaviour modification
2)	Why	The multi-factorial intervention will have significant improvements in PA, body composition change, diet, and behavioural change, and will be more effective long-term. This can help prevent and reduce obesity among overweight and obese adolescents.
3)	What	The physiotherapist will provide the educational intervention to the parents and the adolescents at the beginning of the intervention. This education will consist of education on healthy diet and physical activity. Parents will be educated about optimal diets and nutrition. The physical activity intervention will be provided to the adolescents under the supervision of physical therapist and physical educator in the participating schools. The physical activity intervention has been developed using American College of Sports Medicine guidelines [42].
4)	How	Face to Face
5)	Where	In school
6)	When and How much	Physical activity programs will be conducted in school as follows: 2 days/week, Upper Limb: 4-5 muscle groups/8-12 reps/1-3 sets, Lower Limb: 4-6 muscle groups/9-15 reps/1-3 sets, Start with no weight, Gradually add 0.5-1 kg weight after every three sessions, Each session :20-30 mins, Strength training with Therabands and Body weight exercises. 2 days/week, Based on PCERT scale, where HR increases, Start with 30 mins session, Later increase to cumulative 60 mins/day, Cardiovascular/ Flexibility exercises such as jumping, brisk walking and running.
7)	Tailoring	Strength exercises include body weight exercise and cardiovascular exercises, which will be given according to the PCERT scale, so that the exercises will be tailored to each adolescent's capacity.
8)	Modifications	Not relevant as the intervention has not started
9)	How well planned (for adherence)	To improve adherence, long term follow up in the school has been planned post intervention and before final assessment. The first follow up is at 3 months (13 weeks), the second follow up is at 6 months (26 weeks) and the third follow up is at 12 months (52 weeks). Parental involvement in the intervention is considered and encouraged. The intervention includes exercises which will be enjoyed by the adolescent and the exercises are tailored to individuals within a group setting at each school to encourage compliance. The nature of the intervention is face to face, so the adolescents get the opportunity to speak to the therapist about their intervention, health and weight.

**Figure 3** TIDiER checklist for intervention reporting.

to which they were originally assigned, regardless of the intervention received, withdrawals or loss to follow-up.

The responses from the questionnaires will be collated, tabulated and analysed using SPSS. The questionnaire responses will be scored and assessed using numerical scores, and food frequency questionnaire (FFQ) will be analysed using 'Dietsoft' software. As stated previously, the educational booklets will be validated using PCA and Cronbach's alpha (SPSS).

## DISCUSSION

Adolescent overweight and obesity are an alarming major health issue because of the expected health and economic burden both in India and globally.<sup>65</sup> Obesity and the probable sequelae of chronic diseases such as metabolic, cardiac and cancer conditions are a multifaceted problem that requires multifactorial interventions.<sup>66</sup> The current evidence suggests that altering PA, food patterns and behaviour are individually useful only in the short term, but combined interventions with long-term follow-up can be more effective.<sup>67</sup> This RCT will assess the

effects of a school-based programme that includes family and parental participation, a novel approach in India. The intervention comprises best practice components in a combined intervention that may have a more significant long-term impact on younger people's health.

This study's primary outcome measures are PA levels and anthropometry. The secondary outcome measures in the study include dietary habits, adolescent and physical fitness measures, sedentary time (adolescents and parents), adolescent and parental mental health, QoL and family functioning. These are essential factors to be considered for adolescent health needs, regardless of the issue of being overweight or obese. As the most evidence to date emphasises that a multifactorial approach is the most successful concerning weight management and behaviour change, this study aims to gain vital information about current PA and dietary habits and significantly alter the PA and food habits of overweight/obese adolescents, and improve awareness of the same in the parents, thus having substantial short-term and long-term impacts on health.



We expect the intervention participants to be more involved in healthy eating and optimal PA levels for long-term follow-up. To promote intervention adherence, we will include educational material to students and parents, keeping cultural variation and awareness in mind. The long-term follow-up is a vital component that is relatively novel in India. It is one of the first studies to use this multifactorial approach intervention for Indian adolescents and parents.

If the study findings are positive, they may help reduce unhealthy eating patterns and increase PA levels among obese adolescents. The findings can be implemented on a larger scale and with culturally diverse communities, as part of a cohesive national strategy involving all stakeholders.

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