Original Article

Cardiovascular risk reduction intervention among school-students in Kolkata, West Bengal — The CRRIS study protocol

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ABSTRACT

Background: Increasing burden of cardiovascular risk-factors among adolescent school-children is a major concern in India. Dearth of information regarding the burden of these factors and the efficacy of educational intervention in minimizing them among urban school-students of India called for a school-based, educational intervention involving a representative sample of these students and their caregivers.

Methodology: Using a randomized-controlled design with stratified-random sampling, 1000 students (approximately 50/school) of 9th grade from 20 randomly selected schools (representing all socio-economic classes and school-types) and their caregivers (preferably mothers) will be recruited. Objectives of the study will include: estimation of the baseline burden and post-interventional change in cardiovascular risk-factors, related knowledge, perception and practice among participants in Kolkata.

Data collection: After obtaining appropriate consent (assent for adolescents), collection of the questionnaire-based data (regarding cardiovascular disease/risk-factor related knowledge, perception, practice), anthropometric measurements, stress assessment and cardiological check-up (pulse and blood pressure measurement along with auscultation for any abnormal heart sounds) will be conducted for each participating students twice at an interval of six months. In between 6 educational sessions will be administered in 10 of the 20 schools randomized to the intervention arm. After the follow-up data collection, same sessions will be conducted in the non-interventional schools.

Data analyses and deliverable: Descriptive and inferential analyses (using SAS 9.3) will be conducted to determine the distribution of the risk-factors and efficacy of the intervention

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in minimizing them so that policy-making can be guided appropriately to keep the adolescents healthy in their future life.

1. Introduction

In the era of rapid epidemiological transition,[1,2] alike the global scenario, in India, proportional burden of non-communicable diseases (NCDs) is gradually overtaking the infectious diseases.[1–4] Being one of the principal contributors to these NCDs, cardiovascular diseases are among the leading causes of mortality and morbidities in both urban and rural areas of this country.[5]

Contextual scientific evidences from previous studies identified smoking, obesity, high blood pressure, high cholesterol, diabetes, low consumption of fruits and vegetables, sedentary lifestyles and stress as risk factors for cardiovascular diseases. Although the problems were more severe in urban areas, burden of these risk factors along with the relevant knowledge, perception, awareness and practice were understudied especially among urban adolescents of India.[5]

Recent studies in India revealed an alarming trend of sustained blood pressure elevation among Indian children and adolescents.[6,7] High burden of cardiovascular risk factors and inadequate knowledge regarding them were also evident in this population.[8] During 2006–2008, a multi-centric study also revealed considerably high burdens of obesity (5.3%) and overweight (18.5%) among 8–18 years old school children in India.[9]

Prior research has shown that prevalence of obesity among adolescent urban Indian can be minimized by early initiation of dietary and lifestyle modifications[10] along with measures to prevent other risk factors through development of knowledge and awareness.[8] For most children, atherosclerotic vascular changes are minor and can be minimized or even prevented with adherence to a healthy lifestyle. Thus, intervention must be implemented early enough in life to prevent or delay the onset of atherosclerosis and its clinical manifestations to decrease the risk of coronary artery disease in later life.

But unfortunately unlike developed countries, efforts to educate and motivate the adolescents to acquire healthy habits and avoid harmful exposures are nowadays scanty in India. Hence, armed with the knowledge that cardiovascular risk factors and atherosclerosis are likely to initiate their telling effects during adolescence, a change in the paradigm to initiate early diagnosis, treatment and prevention seemed to be the need of the hour.

2. Rationale

Dearth of information on the burden of socio-demographic and behavioral risk factors of cardiovascular diseases along with awareness regarding them among adolescent school-children was evident in urban India. The extent to which improvement of the relevant knowledge, perception and awareness could be translated into healthy practice was also unclear. Together they called for a baseline estimation of the problems and evaluation of the efficacy of an educational intervention in solving the issues.

To address these, a multi-component, school-based, randomized controlled, educational intervention study with baseline estimation of the burden of cardiovascular risk, related knowledge, perception, awareness and practice among adolescent school-children of Kolkata has been contemplated to minimize the risk factors and improve related knowledge, perception, awareness and practice among them.

Objectives

1. To estimate the burden of demographic, socio-economic, cultural, and behavioral risk factors among adolescent school-goers in urban India.
2. To estimate, the burden of diagnosed cardiovascular diseases among adolescent school-goers in urban India.
3. To assess the knowledge, perception, awareness and practice of adolescent school-goers and their caregivers in urban India regarding cardiovascular risk factors.
4. To measure the efficacy of a school-based multi-component educational interventional program in reducing the burden of these cardiovascular risk factors among urban adolescent school-children in India along with improving their (including parental) knowledge, perception, awareness and practice regarding these risk factors.

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3. Material and methods

3.1. Study design

A Randomized Controlled Multi-component Educational Intervention Study spanning for one year has been planned to be conducted by Cardiological Society of India, West Bengal Branch and co-ordinated by Mission Arogya Health and Information Technology Research Foundation, Kolkata.

3.2. Study area

Kolkata, West Bengal.

3.3. Study population

As adolescent age is the time when experimentations with unhealthy exposures and lifestyles (smoking, eating junk foods etc) gradually change to long-term habits, to intervene appropriately for the reduction of these risky behaviors, we will target school students of age 14–15 years, studying in the schools of Kolkata.

3.4. Inclusion criteria

1. Students studying in 9th standards in the schools which will be selected randomly from an exhaustive list of Secondary and Higher Secondary level schools in Kolkata
2. Students who themselves with their caregivers will be willing to participate in the study after providing written informed consents (for caregivers) and assent forms (for students).

3.5. Exclusion criteria

1. Any medical or psychiatric illness that may prevent normal communication with the student
2. Participation in any similar ongoing intervention program

3.6. Sample size calculation

Due to the unavailability of the parameters from the study area, for the sample size calculation, we will use evidences from prior research in similar setting elsewhere for the sample size calculation.

Banerjee et al[11] from Pune reported that 61.16% students of 9–10th standard considered reduced physical activity as a risk factor for cardiovascular disease and knowledge regarding other risk factors was less than this proportion. For the estimation of knowledge regarding cardiovascular risk factors among urban adolescent school-goers, we will use parameters this parameter as a proxy for the estimation of the efficacy of the intervention in improving knowledge among study subjects regarding risk factors of cardiovascular diseases. According to the conventional methods, we will consider 10% increase in proportion for knowledge to be an intended outcome in our study as also suggested by a similar intervention study conducted in Tunisia in similar settings.[12] Assuming $\alpha = 0.05$ in a longitudinal intervention study design to detect 10% increase in knowledge with 80% power, using a design of 1:1 distribution of intervention and control arm in the StatCalc module of Epi Info software version 7, the required total sample size need to be 740. Assuming 20% non-response/loss to follow up, 925 students will be necessary to be approached.

For measuring the efficacy in the improvement of awareness, we plan to use parameters reported by Divakaran et al from a study conducted in Kerala in similar settings. Students of 6–10th standard did reveal that 84.8% had poor level of awareness regarding lifestyle risk factors for noncommunicable diseases.[13] Using this parameter in similar methods to minimize this proportion of poor awareness at least by 10% and to detect that change with 80% power

assuming $\alpha = 0.05$ in a longitudinal intervention study design using same software 544 subjects will be required and to allow for non-response/loss to follow up (20%), 680 students will be required to be approached.

For estimation of the efficacy in the reduction of cardiovascular risk among school children, we will use the proportion of students having no physical activity as the proxy for cardiovascular risk factors and the reported parameter (26.4%) from the study Divakaran et al will be used for this purpose. In the aforementioned method 566 will be the required sample size and 708 students will be needed to be invited.

Keeping all these calculations and logistic issues in mind, we will invite 1000 students and their caregivers (preferably mothers) to participate in our study.

3.7. Selection of schools

Initially, an exhaustive list of all schools having 9th standard students in Kolkata city will be prepared and stratified into three socio-economic (higher, middle and low) strata based on average socio-economic condition of the students and three types (co-educational, boys only, girls only). Number of students in 9th standard for each school will also be noted. Now using stratified random sampling (for type of school and socio-economic status) with probability proportional to size, number of schools required to approach 1000 eligible and consenting students of 9th grade will be determined and chosen randomly from the list of schools using random number table so that the representation from each stratum (for socio-economic status and types) into the recruited sample remain as per their distribution in the city. The head of the institution of each of these selected schools will be approached to participate in the study and non-agreeing schools will be individually replaced with randomly chosen alternatives from the respective strata.

3.8. Informed consents and ethical issues

One of the parents (preferably mother as according to the culture in the study area the lifestyle factors are usually more influenced by the mothers at this age) of each individual student of 9th grade will be invited to be present at the school on a particular date for each school along with the students. On that day, each student will be provided with an assent form and the parents will be provided with consent forms. The details of the study, educational intervention and random assignment to either the intervention or the control arm will be explained in details to everyone in languages that they understand properly. Following this, the assent and consent forms will be signed and collected from agreed participants.

The study protocol and related ethical aspects will be reviewed by the Ethics Committee of Barrackpore Population and Health Research Foundation. Subject to their approval, the study will be conducted.

During the study all identified cases of cardiovascular diseases among the participants will be referred to appropriate clinics for treatment and follow up.

After the completion of the study, if intervention is found to be effective, intervention materials will be provided to the control schools also.

3.9.   Baseline data collection

Questionnaire (separate ones for student and parent) for the baseline data collection will be prepared based on our literature review to collect information on socio-demographic characteristics, cardiovascular diseases, related knowledge, perception, awareness and practice of students and one of their parents (preferably mother).

The questionnaire will be pre-tested among 10% of the required sample (here 80) in piloting phase and after checking internal consistency the final questionnaire will be prepared and translated into local languages as per the requirement of the participating schools.

Self-administered surveys involving participating students and their parents will be conducted in the selected schools in a convenient location at a suitable time. Anthropometric and blood pressure measurements will be conducted next. Data on the following aspects will be collected from the students and one of their parents with separate questionnaires.

- Demographic factors
- Socio-economic factors
- Family structure
- Occupation of the parents
- Quality of life (student and parents)
- Education of the parents
- Housing and overcrowding
- Daily activities
- Healthcare utilization
- Stress and strains (student & parents)
- Knowledge, perception, awareness & practices regarding risk factors
- Addiction (student and parents)
- Exercise habits (student & parents)
- History of
  - Having symptoms of specific cardio-vascular ailments (congenital, rheumatic, atherosclerotic and others)
  - Diagnosed cardio-vascular diseases (congenital, rheumatic, atherosclerotic and others)
  - Treatment for cardio-vascular diseases
  - Familial cardio-vascular diseases

3.10.   Intervention

The selected schools will be assigned randomly to either intervention group or control group with blocking for socio-economic status (upper, middle and lower) and types of schools (boys', girls' and co-education). Over 6 months, 6 multi-component classroom based educational interventions (one session per month) will be provided to students of 9th grade by trained persons in the intervention schools and students in control schools will receive usual teaching and health curricula and none of the CRRIS program. In these 6 interactive sessions, students will learn about cardiovascular diseases, different risk factors for cardiovascular diseases and ways of preventing such health hazards, mainly focusing dietary modifications and increasing physical activity divided into following domains:

- Introduction to cardiological diseases with principal focus on coronary artery diseases
- The risk factors of these diseases, their detailed role part 1
- The risk factors of these diseases, their detailed role part 2 and how preventable they are
- Motivational session for the students towards attaining better lifestyle and coping with stress/anxiety
- Prevention of the risk factors for coronary artery diseases
- A motivational sessions for attaining better nutritional practice and dietary modifications to prevent coronary artery diseases

Information will be provided through power point presentations along with age-appropriate videos.

3.11.   Outcome measures

1. Improvement in knowledge, perception, awareness and practices about various cardiovascular diseases, its risk factors and different prevention strategies among participating students and parents
2. Change in BMI or change in body weight of the participating students
3. Change in systolic and diastolic blood pressures of the participating students

3.12.   Variables and definitions

1. **Height:** It will be measured to nearest 0.1 cm using WHO-approved wall-mounted height measuring scale after removing shoes
2. **Weight:** It will be measured to nearest 0.1 kg using standardized mechanical weighing machine after removing shoes.
3. **Body mass index (BMI):** It will be calculated as Body weight (kg)/height (m)^2.
4. **Socio-economic class:** Standard methods like Modified Kuppuswami scale will be used to ascertain the socio-economic status of the families to which the study subjects belonged.[14,15]
5. **Knowledge:** It will be measured in separate domains. Based on standard textbooks and the WHO recommendations an answer to each of the questions will be determined as correct or incorrect. Scores for individual questions (0 for incorrect and 1 for correct answer) will be summed up and rescaled within 10 for each of these domains. The composite score for knowledge will be calculated by adding the scores for all domains and rescaling it within 100. Scores will then recoded into three categories (poor, average, good) using tertiles. The lowest tertiles for composite score and knowledge score for each individual domain will be defined as 'poor', the middle tertiles as 'average', and the uppermost tertiles as 'good'.
6. **Perception:** Perception of the parents and students regarding the current health of the students, their future risk of developing cardiovascular diseases and their risk factors will be measured using Likert scale (1—5 in a 5 point scale from strongly disagree to strongly agree).

7. **Attitude**: Attitude of the students regarding risk factors for developing future cardiovascular diseases will also be measured using Likert scale (1−5 in a 5 point scale from strongly disagree to strongly agree).

8. **Practice**: Practice among the parents and students regarding health-seeking, physical activity, diet and addiction of the students will be evaluated by asking questions about separate domains. Responses will be scored similarly as the knowledge (1 for correct practice and 0 for wrong practice) and the summed up scores for each domain will be rescaled (within 10) and categorized into poor, average and good using tertiles.

9. **Stress:** The stress level of the students will be measured using standardized stress scale of Cohen et al titled Perceived Stress Scale − 10 (PSS-10) following the algorithm mentioned in the scale itself.[16−19]

10. **Overweight & obesity:** Children with a body mass index (BMI) >85th percentile of reference data will be considered overweight and those with a BMI >95th percentile will be considered obese. The reference data will be used to identify the cut-off points from the CDC dataset for BMI.[20−24]

11. **Blood pressure:** It will be measured twice on right arm using a standardized sphygmomanometer in sitting position and mean of two will be reported. Blood pressure (BP) percentiles would be determined adjusting for age, sex, and height percentile, using the guidelines of American Academy of Paediatrics, The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents and National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents classified according to the following ranges: normal (<90th percentile), pre hypertension (90th−94th percentile), hypertension (HTN) stage 1 (95th−99th percentile), and hypertension stage 2 (>99th percentile).[2,25,26]

12. **Addiction:** Use of addictive substances (tobacco etc.) in last six months.

3.13. Post-intervention data collection

Post-test data and anthropometric measurements along with blood pressure will be collected after 4 weeks of completion of last module of intervention in similar manner by administering the same baseline questionnaire in similar settings to participants and their parents. In control schools, same questionnaire will be administered once more over the same time period as in intervention schools and likewise anthropometric measurements and blood pressure will be recorded.

4. Data entry and management

Collected data will be entered into the computer on daily basis on two separate computers by trained data entry operators. Accuracy of the data will be ensured by multiple logic checks and cross-tabulation. Internal consistency and quality will be checked by comparing the data in two computers by the research team. For ensuring data safety and confidentiality, both computers will be password protected and all questionnaires will be kept under lock and key.

Data will be cleaned after completion of data entry. An exhaustive codebook will be prepared from the questionnaire and will be updated with newly formed recoded variables with its value label. All statistical analysis will be done using SAS 9.3.

5. Statistical analysis plan

5.1. Descriptive analyses

Frequency distributions of socio-demographic characteristics of students like gender, parental education, family type, family history, living status of parents etc will be obtained in intervention and control schools and their differences will be assessed by chi-square test. Frequency distributions of outcomes across strata of socio-demographic variables will be examined. Absolute change and percent change between baseline and post test values will be measured.

5.2. Inferential analyses

5.2.1. Intervention effect
Paired t tests will be performed to evaluate whether there is a significant overall impact of this 9 week educational intervention across all outcome variables by comparing baseline and post test values in intervention school. Student's t test will be conducted to examine the impact of CRRIS program by comparing baseline and post test values, which will be obtained from intervention and control schools.

Modifying effects of covariates (independent variables) on the impact of CRRIS on outcomes will be analyzed by using one way analysis of variance (ANOVA) and Multivariate ANOVA (MANOVA).

5.3. Associational analyses

5.3.1. Individual level
Simple, multiple and multinomial regression analyses will be performed to estimate the associations between socio-demographic variables with change in 1) knowledge/awareness/perception score 2) practice score 3) BMI 4) Systolic and diastolic pressures. Further, regression analyses will be conducted to estimate the associations between knowledge score and self-reported practices (moderate to vigorous physical activity and dietary modifications).

5.3.2. School level
Using schools as the unit for analyses, appropriate multilevel regression analyses will be performed to take of stratified cluster randomization, sample weights and correlation of individuals from same school.

6. Deliverables

- Results and their interpretation will be communicated scientifically to the concerned authorities for policy implications and intervention program designing

- Scientific communication for the advancement of knowledge and research development will be made appropriately

7. Research communication and engagement

- The research team will have a clear strategy regarding the communication of the results and finding of the research to the stakeholders and engagement of the concerned community in the field of research during the project.
- Initially parents, school authorities and concerned personnel will be engaged in the development of the study plan, identification of the study site, development of the research infrastructure and awareness of the participants regarding the project itself. With the help of appropriate personnel the actual mobilization of the school authorities will be done.
- During the study all the interim reports and interpretation of the results along with the progress report of the execution phase will be communicated to the Cardiological Society of India, West Bengal Branch for appropriate communication to the stakeholders. Feedback and necessary help from them will also be sought for smooth functioning and dynamic incorporation of the study experience into the operationalization of the study during its intervention phase.
- At the end of the research, results of all analyses will be interpreted to prepare appropriate reports in a manner so that it will be understandable for the stakeholders. The study findings will be communicated properly to the researchers, stakeholders and policy makers so that they can appropriately design customized health programs and targeted intervention for the reduction of the cardiovascular risk factors efficiently among the school-children of India.

Conflicts of interest

All authors have none to declare.

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