STUDY PROTOCOL

Project PaThWay: protocol for a school-based health promotion intervention for prevention of non-communicable diseases (NCDs) behavioral risk factors [version 1; peer review: 1 approved]

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Abstract

Background: Prevention of non-communicable diseases (NCDs) and their behavioral risk factors (tobacco use, unhealthy diet, physical inactivity, harmful use of alcohol) among children and adolescents have garnered paramount importance under the Sustainable Development Goals.

Methods: Project PaThWay is a school-based, two years, multi-component intervention to prevent key behavioral NCD risk factors among school-going children (classes 6-8th; 10-14 years) from private and public schools across two Indian cities (Pune and Bengaluru). We assessed the baseline knowledge, attitude, and behavior related to NCD risk factors (unhealthy diet, physical inactivity, and tobacco use) of the participating students through a survey. The intervention was developed and designed for implementation by the trained teachers and similar-age peers, as facilitators. The teachers and peer leaders were trained through organising school-level orientation workshops for implementation of intervention activities, after baseline assessment. Year 1 of the intervention focuses on the knowledge and learnings and year 2 on enhancing the life-skills (leadership, communication, refusal, health advocacy, etc.). Regular monitoring visits by the project team to ensure intervention activities are being carried out as planned and providing continuous support. The end line evaluation will be done after the completion of two years' intervention to evaluate the effectiveness of the Project PaThWay intervention. Outcome measures will include improved knowledge,

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1

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positive attitude, improve behaviors related to diet, physical activity, and tobacco use, and enhanced skills in handling NCD risk factors. A process evaluation will explore several aspects of Project PaTHWay intervention (fidelity, dosage, reach, adaptations), social validity (acceptability, feasibility, utility).

Conclusion: Project PaTHWay, having a multiple-component intervention, may offer the best chance for success, as it addresses multiple risk factors using multi-pronged strategies. The agents of intervention implementation are trained teachers and similar-age student peer leaders (as facilitators), one of the successful and effective approaches in school-based interventions globally and in India.

Keywords

Non-communicable diseases, behavioral risk factors, schools, children

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Introduction

Non-communicable diseases (NCDs) are the world's leading public health challenge in the twenty-first century, contributing to poor health, economic and life loss, impaired quality of life, and poor social development, equally in high and low-resource countries^{1,2}. The burden of NCDs is also on the rise in India accounting for 65 percent of deaths in 2019 across all age groups³. India is estimated to lose approximately US\$ 3.55 trillion by 2030 if the four major NCDs (diabetes, cardiovascular disease, chronic respiratory disease, and cancer) are not addressed⁴.

Most NCDs are attributable to four common modifiable behavioral risk factors: tobacco use, harmful use of alcohol, unhealthy diet, and physical inactivity⁵. NCDs have been viewed as a problem of adulthood, but children, adolescents, and young people are equally at risk, as these behavioral risk factors are etched during the early years of life i.e. childhood and adolescence. Children and adolescents are aggressively targeted through the marketing of unhealthy products (e.g. tobacco, alcohol, and foods high in fat, sugar, and salt), particularly in low and middle-income countries⁶. Furthermore, many of them grow up in an environment not conducive for the adoption of healthy lifestyles (e.g. participation in physical activities, availability, and accessibility of healthy foods)^{7,8}. Thus, investing in the health and wellbeing of children and adolescents through primary prevention efforts is an imperative step for the success and sustainability of our future generation.

More than half of the NCDs burden may be averted by health promotion and prevention initiatives^{9,10}. Health promotion at school has been considered an effective intervention strategy that can go a long way in preventing and controlling communicable and NCDs by formulating school health policies, healthy physical and social environment, skill-based health education, school health services, and parents and community links¹¹. School is an ideal platform for health promotion interventions, creating a favorable environment for inculcating health promoting behaviors^{12,13} as the information reaches a captive audience, including children, their families, and school staff¹⁴. Schools also provide learning through peers and a social environment that sets norms and can have a substantial influence on health-promoting behaviors and educational outcomes¹⁵. Students can be effective advocates for creating a healthy school and can become “*Agents of Change*” for the community.

The multi-component, school-based health promotion interventions, developed using evidence-informed theories and models of health promotion, when implemented efficiently, resulted in positive outcomes, e.g., reduction in body weight, body mass index¹⁶, reduced screen time¹⁷, reduction in unhealthy food consumption¹⁸, increased refusal skills and self-efficacy¹⁹. Taking into account the existing evidence, school-based, health promotion intervention under Project PaTHWay has been developed, to comprehensively address key behavioral NCD risk factors (unhealthy diet, physical inactivity, and tobacco use) among school-going children from two Indian cities (Pune and Bengaluru). The Project PaTHWay's intervention is well aligned with the newly launched National School Health

programme under the Ayushman Bharat Scheme of the Ministry of Health and Ministry of Human Resource Development, Government of India. The National School Health programme addresses the need for a comprehensive preventive and promotive health education programme for children of government and government-aided schools^{20,21}. Given the Indian government's current priority on improving students' health through educational environment, Project PaTHWay intervention is a timely initiative considering both public and private school students are equally vulnerable for indulging in an unhealthy lifestyle.

Project PaTHWay described in this paper, may offer the best chance for success, as it addresses multiple risk factors using multi-pronged strategies. Project PaTHWay encompasses the development, implementation, and evaluation of a school-based intervention to prevent behavioral risk factors for NCDs (i.e., unhealthy diet, physical inactivity, and tobacco use) among school-going children (classes 6–8th; 10–14 years). The intervention is designed for implementation by the trained teachers and similar-age peers as facilitators. This approach has been adopted as it has been successful in our previous school-based tobacco control programme²², and nutritional interventions¹³. The specific objectives of Project PaTHWay are to: conduct a baseline evaluation to assess students' knowledge, attitude, and behaviors (KAB) relevant to key behavioral NCD risk factors; develop a school-based, multi-component intervention for improving knowledge and bringing a positive change in attitude and behaviors of students, teachers, parents, and community by promoting healthy behaviors such as healthy diet, physical activity and non-use of tobacco; implement and evaluate the utility, feasibility, and acceptability of the developed intervention for enhancing the KAB of the target population. This protocol paper describes the conceptual model for PaTHWay; its intervention components (e.g., curricula); and implementation and evaluation plan.

Protocol

Study design

Project PaTHWay is quasi-experimental with a pre and post-evaluation.

Site recruitment

Project PaTHWay targeted school-going students (classes 6–8th; 10–14 years) from twenty schools across Pune and Bengaluru, India. Pune is located in Maharashtra and Bengaluru in Karnataka. These cities are highly urbanised and densely populated²³. These states have been selected in Project PathWay as both Maharashtra (71.7%) and Karnataka (72.4%) have the highest NCD burden compared to the national average (64.9%)³. These schools were purposively selected to represent different socio-economic strata (private schools: middle to higher socio-economic status; public schools: lower socio-economic status) within these two cities.

Participant recruitment

Following the selection of the schools, participants (students) were recruited. All students studying in sixth grade (n=1238; Pune: n=806; Bengaluru: n=432) from these twenty schools

were eligible and invited to participate in Project PaTHWay. To invite students to participate in Project PaTHWay, letters were sent out to parents or guardians informing them of the programme and their right to opt-out during the programme. The letter also explained that all students would be involved in the programme if they give their assent. In the first year of the programme (2018-19), students of sixth grades were enrolled from these twenty schools and followed up for two years (through 7th and 8th grades, in 2019-2020 and 2020-21, respectively).

Project PaTHWay intervention

Project PaTHWay is a school-based, skill-oriented intervention, developed for teachers and student peer leaders, to deliver theme-based activities for preventing behavioral risk factors (unhealthy diet, physical inactivity, and tobacco use) of NCDs. The intervention package (curricula) was developed based on a review of evidence-based interventions^{13,24,25}, the social-ecological model²⁶, findings from the students' baseline KAB assessment²⁷, and formative research conducted with various stakeholders, including, teachers (n= 28), students (n=62), officials from state health and education department (n=15) and civil society representatives (n=4). The development of the intervention package was also guided by the members of the Technical Advisory Committee, formulated for this study, consisting of national and international members with domain expertise. The experts having background in epidemiology, public health, and designing and evaluating behavioral change interventions for youth.

The curricula comprise of twenty activities on four themes (health, diet, physical activity, and tobacco) with an average delivery time of 35–40 minutes for each session, over a two-year implementation period (Table 1). Year 1 of the intervention focuses on the knowledge and learnings and year 2 on enhancing life-skills (leadership, communication, refusal, health advocacy, etc.). A vital component of the intervention is to provide a supportive environment at school (increase availability of healthy food options in and around schools, healthy canteen menus, supportive physical activity environment, a tobacco-free environment within and around schools) and at home (increased availability of healthy food options at home, promoting healthy breakfast, promoting physically active environment at home, nurture smoke/smokeless tobacco-free norms at home) to sustain healthy behavior change (Figure 1: Project PaTHWay's Intervention Model).

The intervention activities comprise of teacher-led discussions at the beginning and end of each session, and peer-led small group activities (e.g., ice-breakers, card games, comic book, role plays, worksheets, case studies, preparing healthy birthday menu, letter writing for a newspaper, etc.) as the main focus of each activity. The intervention was designed considering the active engagement of students and peer leaders. As an extension of the classroom activities, a series of school-level activities (mock parliament on health, health-related art competitions, activities advocating for tobacco-free school), and competitions (poster-making, slogan writing, health quiz, etc.) were incorporated as part of the intervention. Theme-based posters, audio-video films were also developed as part of the intervention material to complement the classroom activities

and reinforce the message. Postcards and health calendars were also incorporated into the curricula, for sending home through the children to sensitise their parents, to disseminate information and messages on healthy lifestyle practices among families. All the programme resources (manuals, posters, audio-video films) were translated into the regional languages i.e. Marathi (Pune) and Kannada (Bengaluru), to facilitate understanding and uptake of the learning resources.

The trained teachers and similar-age student peer leaders, as facilitators, are the agents of Project PaTHWay intervention implementation. The teachers and peer leaders were trained by the research team having expertise in designing, implementing, and evaluating behavioral change interventions. These teachers and peer leaders were trained through separately organised school-level orientation workshops at the start of the programme. These workshops primarily involved an introduction to the curriculum, programme learning resources, briefing of each session, and its delivery. The teachers and peer leaders were given comprehensive training manuals that provided the background to each session, steps for implementation of intervention activities, all necessary teaching material and resources (card games, comic books, and worksheets). In total, 65 teachers and 74 peer leaders were trained in 20 school-level workshops.

The intervention sessions are scheduled fortnightly to avoid disruption of their academic calendar. Each participating school shared the roster for the implementation of activities with the study team in advance. Year 1 intervention activities (2019–2020) were implemented physically by the trained teachers, facilitated by student peer leaders, in schools in the presence of the project PaTHWay team. Multiple monitoring visits were made by the project team to ensure intervention activities were being carried out as planned and to provide continuous support. After completion of each intervention activity, project team members recorded the attendance for each activity, the number of peer leaders who facilitated the activity with teachers, and the duration to complete the activity. During our second year of intervention implementation, COVID-19 hit India. Hence, the implementation of the year two intervention was modified to conduct virtually (Zoom/Google Meet/Teams), due to the closure of schools, following the Government of India's lockdown protocols to prevent the COVID-19 transmission. The implementation of year 2 intervention through virtual sessions is only happening in private schools, as reaching out to the public schools is challenging due to the digital divide (weak mobile networks, lack of access to mobile phones, and low digital comfort). No intervention sessions were held virtually in public schools considering this challenge.

Outcome evaluation

All baseline measures were completed before the implementation of the intervention, and follow-up will occur after the completion of intervention implementation. All the measures at baseline were assessed through a questionnaire. This questionnaire was developed based on the socio-ecological model²⁸, adapting measures from reliable instruments that have been validated with adolescents in India^{29–32} and questionnaires used by the authors

Table 1. Outline of Project PaTHWay curricula.

Curricula Theme	Number of activities under themes	Activities	Level of Change ³⁵	Participatory action approach	Learning Outcomes
Health	5	1. Ice-breakers 2. Healthy and Unhealthy actions 3. My Health Cards 4. My Health Corner 5. My Adolescent Friendly Health Clinic	Intrapersonal	Ice-breaking session, card game, worksheet	<ul style="list-style-type: none"> Enhance knowledge about the importance of healthy lifestyle and its effect on health. Explain the importance of developing healthy behaviors early in life towards contributing lifelong health benefits. Provide students with the knowledge to differentiate between healthy and unhealthy behaviors. Awareness regarding Adolescent Friendly Health Services (AFHS).
Physical Activity	4	1. My Fitness Goal 2. Circuit game 3. Day of a squirrel 4. Watch before you leap	Intrapersonal	Interactive games, fitness goal sheet, role play	<ul style="list-style-type: none"> Getting to know about being physically active and its benefits for good health. Self-tracking of physical activity pattern and moving towards the recommended goals.
Diet and Nutrition	6	1. Case study 2. My birthday plate 3. Plan my daily 3 breakfast 4. Choose my sugar cards 5. The sweet battle 6. Mock Parliament	Intrapersonal and Interpersonal	Case studies, preparing healthy birthday menu, cards game, story, mock parliament	<ul style="list-style-type: none"> Improve knowledge about the importance of a good diet. Empower students to identify healthy and unhealthy foods. Understand the importance of daily breakfast. Understand why sugar intake should be controlled and minimized.
Tobacco	7	1. Map your community 2. Comic book 3. Towards a tobacco-free community: 4. Community walk 5. Say No to Tobacco- Help others and yourself 6. Make your school Tobacco-free 7. Creating a tobacco-free home	Organisational, Community, home, Environment	Comic book, walk to a community, letter writing for a newspaper, role play, advocacy for tobacco-free school, worksheet	<ul style="list-style-type: none"> Explain adverse consequences (health, economic, social) of tobacco use. Identify and explain the factors that make adolescents vulnerable to tobacco use. Sensitise students how Adolescent Friendly Health Clinics (AFHCs) can help to quit if someone is using tobacco. Introduce students to the concept of tobacco-free schools and homes.

of this paper in previously conducted studies in India^{22,33,34}. The questionnaire was pre-tested to assess its validity (face and content) and reliability (internal reliability of attitude construct) before the commencement of data collection. An English version of the questionnaire was administered in private schools, and Kannada and Marathi versions were administered in public schools in Bengaluru and Pune, respectively.

The key baseline findings suggest that the knowledge about tobacco use being harmful was higher than the knowledge about a healthy diet and the importance of physical activity. Differences in these behaviors by gender, school type showed that both boys and girls of private and public schools are vulnerable for indulging in an unhealthy lifestyle practices²⁷. The same

survey will be administered at the end line (after completing the intervention) to evaluate the effectiveness of intervention. Due to the COVID-19 pandemic, the end line survey is planned virtually. The survey will be implemented only with the students who will receive the complete two-year intervention (physically and virtually). A positive increase in the KAB of students relevant to the behavioral risk factors targeted by this programme is expected at the end of two years. We anticipate that there will be changes in:

Knowledge and skills among students

- Increase percentage with correct knowledge about healthy lifestyles (healthy eating, physical activity, no tobacco use)

Figure 1. Project PaTHWay's Intervention Model.

- Improved critical thinking skills, refusal skills, decision-making skills
- Increase percentage of those who know about the consequences of tobacco use and the benefits of quitting
- Improved skills to: (a) resist social influences to use tobacco (i.e., develop resistance skills); and (b) promote tobacco-free environments in their homes, and communities (i.e., develop advocacy skills)
- Increased knowledge about government efforts such as Adolescent Friendly Health Clinics for seeking clinical and counseling services

Behaviors of students

- Increase percentage of students with daily breakfast consumption
- Increase in the frequency of fruits and vegetables consumption per day
- Increase in the frequency of whole-grain consumption per day
- Increase in the frequency of milk and milk products consumed per day
- Decrease frequency of intake of sugar-sweetened beverages (SSBs)

- Decrease consumption of outside unhealthy food
- Increase in frequency of reading nutritional labels
- Increase percentage participating in at least 60 minutes of moderate-to-vigorous physical activity per day
- Decreased percentage engaged in sedentary activities (> 2 hours per day)
- Reduce experimentation and decrease susceptibility to tobacco use (cigarette, bidis smokeless tobacco, and e-cigarette)

Process evaluation

The in-depth evaluation of project PaThWay's reach, feasibility, acceptability, dose, and fidelity will be measured through process evaluation, as described in Table 2³⁶. The process evaluation data will be collected using: (1) forms to document attendance at the orientation workshops (teachers and peer leaders) and intervention sessions (students participation), (2) post-training satisfaction survey (teachers and peer leaders), (3) feedback forms for each intervention activity (teachers and peer leaders), (4) focus group discussions after completion of the intervention to capture the acceptability of programme components, implementation challenges and facilitators, programme improvement suggestions and any unintended consequences of the programme (students, their parents, and teachers), (5) observations of implementation of intervention activities (study team members), and (6) data collection through the end

line survey to measure the participation of students in intervention activities.

Data management

All quantitative and qualitative data will be stored in the lock and key computers at the Public Health Foundation of India. The Data Manager, along with the Research Assistant, will be responsible for cleaning and coding the quantitative data and transcribing qualitative data.

Analysis plan

The analysis will specify random effects at the school (cluster) and class levels. The primary analysis will only use the intervention (dummy coded on class level) and stratification variables (on school level) as independent variables. Sensitivity analyses will be conducted for adding pretests and imputation of missing data. If subgroup analyses (gender and city) are to be conducted these will be defined in the statistical analysis plan as well. The process data will be analysed using a framework³⁶ to measure the extent to which Project PaThWay intervention was delivered or received as planned, participant interactions and responses to intervention, effectiveness, its suitability and sustainability for translation into routine practice.

Ethical consideration

Permissions for implementation of the study were obtained from the Maharashtra State Board of Secondary and Higher Education and the Karnataka Secondary Education Examination Board. Approval from authorities at schools, written active informed

Table 2. Process Evaluation method.

Process Instrument	Data collected (when?)	Filled by (whom?)	Indicator variable
Teacher's training attendance sheet	At training (workshop with teachers)	Study team member	Proportion of teachers trained
Peer Leader's training attendance sheet	At training (workshop with student peer leaders)	Study team member	Proportion of student peer leaders trained
Teacher Training Satisfaction survey	After training workshop with teachers	By each teacher who attended the orientation workshop	Level of satisfaction of teachers with the content, relevance, duration, structure, strategies and methodology adopted
Peer Leader Training Satisfaction survey	After training workshop with peer leaders	By each peer leader who attended the orientation workshop	Level of satisfaction of peer leaders with the content, relevance, duration, structure, strategies and methodology adopted
Attendance sheet for each activity	After administration of each intervention activity	Each teacher who will implement the activity	Proportion of students who participated in each activity
Activity feedback form	After administration of each intervention activity	Each teacher who will implement the activity	Relevance of activity to students, enthusiasm in participation, usefulness of resources provided
Activity feedback form	After facilitating each intervention activity	Each peer leader who will facilitate the activity	Relevance of activity to students, enthusiasm in participation, usefulness of resources provided
Focus Group Discussions	After completion of intervention	Students, their parents and teachers	Capture the acceptability of programme components, implementation challenges and facilitators, programme improvement suggestions and any unintended consequences of the programme

parental consent and student assent were also sought. Information sheets were sent home from the schools to parents of all eligible students, wherein the Project PaTHWay details were mentioned. The consent stated the permission for data collection, scientific publications, dissemination in conferences by maintaining the confidentiality of the study participants and anonymity of the collected data. The study protocol was reviewed and approved by the Institutional Ethics Committees at Public Health Foundation of India (*TRC-IEC-373/18*) and NIMHANS (NIMHANS/EC-[BEH.SC.DIV]15th MEETING/2018).

Monitoring of adverse events

Adverse events, defined as a negative, emotional and behavioral occurrence, or sustained deterioration in a research participant, will be captured as part of the study. Any adverse event reported in the study will be informed to the Institutional Ethics Committee of PHFI by the Principal Investigator (MA) and of NIMHANS by the regional Investigator (AK).

Dissemination plan

Several activities will be undertaken to support the dissemination of study findings:

- 1) by publishing research articles in peer-reviewed journals for public health researchers and academia to fill the existing research gap,
- 2) disseminating the findings in national and international conferences, webinars, seminars, and all NCD and educational policy forums (at central and state level).

The participants will be anonymised in all dissemination activities.

Study status

Ongoing. The year 2 of intervention implementation is ongoing and endline data is yet to be collected.

Discussion

This paper described the protocol of a quasi-experimental, school-based, multi-component, health promotion intervention designed for school students in India. There is a need to amplify health promotion education activities and context-specific health intervention materials for students by engaging parents and communities. The COVID-19 pandemic is the most

crucial global health calamity of this century as well as the most formidable challenge humanity has faced since World War II³⁷. Children and adolescents are highly vulnerable to the impacts of the pandemic, but these ramifications are manifold and require immediate attention³⁸. The children and adolescents are at more risk due to reduced physical inactivity and unhealthy eating, due to confinement at home. Thus, Project PathWay is a timely initiative for preventing NCD behavioral risk factors by engaging teachers, peer leaders and students. To the best of our knowledge, this is the first of its kind intervention developed for school children that comprehensively capture all the behavioural NCD risk factors. The Project PaThWay intervention developed is suitable to the context as it considers the perception of various stakeholders (findings from formative research), existing knowledge, attitude, and behaviors of the target group (findings from baseline assessment), and review of evidence-based interventions. We envisage that intervention may improve knowledge and bring a positive change in attitude and behaviors of students, teachers, parents, and other adults (at the community level), by promoting healthy behaviors (healthy diet, physical activity, and non-use of tobacco) and reducing the risk of NCDs. Earlier, strategies addressing NCD risk factors emphasised secondary prevention and treatment, but now the shift in approach is primary prevention of NCDs that would slow the exponential growth of NCD burden by impeding the development of risk factors³⁹. The management of NCDs and their risk factors have also gained a prominent position under the Sustainable Development Goals and its targets⁴⁰. Relying entirely on the treatment option in developing countries like India is not an effective strategy, rather focusing on strengthening protective factors at a young age provides an adequate opportunity for reducing the NCD burden⁴¹.

There are few limitations as the study design is quasi-experimental so the statistical association emerging at the end of the study may not imply causality. The schools were not randomly selected from the population but were representative of the mix of types of schools (Public and Private) in these two cities and hence limits the generalisability of the study findings.

Data availability

No data are associated with this article.

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A good study, indeed it's the need of the hour to focus intervention strategies on children for a healthy future generation. Schools are an apt place to imbibe discipline related to healthy living and eating among children.

A little more explanation may be provided by the authors regarding tools/ techniques that will be used to impart knowledge on reading food labels and advertising among the study participants.

Authors can explain with already existing data on-screen time in support of this sentence "There is an increased dependency on digital media which has increased the screen time among children".

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Nutrition, Liver disease, Non communicable disease, clinical nutrition

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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