

Effects Of Educational Intervention Based On Integrated Social Marketing Approach On Regular Physical Activity of Female Students: A Study Protocol For A Cluster Randomised Trial

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Study protocol

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Abstract

Background: A sedentary lifestyle is recognized as a risk factor for chronic diseases. The aim of this study was to identify the factors related to regular physical activity in adolescents. Also design effective social marketing interventions on these factors in primary schools in Kermanshah (western Iran).

Method: This study will be a parallel randomised controlled trial (RCT) conducted at a secondary school in Kermanshah. This protocol conforms to the Consolidated Standard of Reporting Trials (CONSORT) Statement and is registered at the Iranian Registry of Clinical Trials (IRCT:IRCT20200621047858N1). This research will be conducted in three phases that correspond to the first to seventh stages of the social marketing operational model, i.e. the SMART model. Given that this study is a three-stage study, an interventional study will be conducted to investigate the effect of educational intervention on regular physical activity behavior among female junior high school students. In this study, we will have an intervention group and a control group. In each area (north and south of the city), using the division by the school education department, is divided into three categories (rich, middle-income and low-income) and a simple random method is selected from each category of one school (3 intervention schools and 3 control schools). The sample size required for the intervention and control group is calculated as 108 people. Individuals are evaluated for regular physical activity according to the stages of behavior change before and after the intervention.

Trial registration: IRAN Clinical Trials Register IRCT20200621047858N1 (date of registration: 2020/7/25 randomized controlled trial registered).

Ethics approval: IR.UMSHA.REC.1398.952

Background

The World Health Organization (WHO) recognizes health as the first indicator of a community as well as physical activity and physical mobility in that community(1). A sedentary lifestyle is known to be a risk factor for chronic diseases such as cardiovascular disease, diabetes, cancer and their risk factors such as high blood pressure, high blood sugar and overweight(2, 3). According to the latest data published by the World Health Organization in the Lancet Global Health, non-communicable diseases have caused 40 million premature deaths (70%) worldwide, of which 1.9 million are due to physical inactivity(4). A sedentary lifestyle is inconsistent with a healthy lifestyle and is more frequent in different age groups, especially children and adolescents (5). One in four adults and three in four adolescents (aged 11 to 17) do not follow the WHO recommendations on physical activity to reduce the risk of chronic disease and improve health (6). Physical activity decreases with age in most countries (7–9). The results of a study in Hamedan by Rostami Moez et al. in 2015 showed that about 83% of students do not do moderate to moderate physical activity for 60 minutes a day (10).

Children and adolescents around the world are not immune to the negative effects of sedentary lifestyles, and young people are increasingly sedentary and physically disproportionate, despite popular belief that

young people are more active (11).

Barriers such as time consuming, costly, and exercise-induced fatigue prevent physical activity, whereas factors such as self-efficacy and support from others enhance physical activity in adolescents(12).

Children and adolescents need more physical activity than other age groups to be able to achieve adequate physical growth and mental development (13).

Adolescents' physical health, as the main framework of the young society, is important in playing individual, scientific and social roles, and the absence of physical activity can reduce learning (14), increase the risk of obesity (15), and cause metabolic syndrome (16), whereas studying science was associated to improving health, mental health (17, 18), school performance (19), sleep duration (20) and overall health (21).

According to the above mentioned issues, the importance of regular physical activity in adolescents, especially in student girls who are more prone to diseases such as osteoporosis, as well as providing interventions aimed at improving the physical activity of adolescents and providing healthy lifestyles, can provide appropriate interventions aimed at preventing many diseases during pregnancy and can be considered one of the solutions.

Due to the above effects of sedentary lifestyle and the importance of regular physical activity in adolescents, especially in female students who are more at risk for diseases such as osteoporosis it was found that the amount of regular physical activity in them is less than in male students. Regular physical activity of adolescents for their health is effective and can be the basis for the prevention of many diseases in adulthood. Appropriate intervention programs can be designed in this regard, where the main focus of these interventions is to increase regular physical activity as one of the solutions.

This study is based on the aim of identifying the behavior and factors associated with performing regular physical activity in adolescents and in this study, effective social marketing interventions on these factors are conducted in the first secondary school of Kermanshah(west of Iran), and finally evaluated.

Operational patterns for social marketing:

Despite the general knowledge of the principles and concepts of social marketing, its application requires the use of operational frameworks to turn it into a planning model for solving health problems. There are several patterns that suggest details of the planning process based on social marketing. The model presented by Nizer in 1998 is one of the most well-known of these models. The Response Tool (SMART) Social Marketing Assessment and in this model, after performing preliminary planning and determining the behavioral problem, the design and implementation of formative research is considered, which includes audience analysis, market analysis and channel analysis (22).

Conceptual framework:

Social marketing-based strategies for health communication are increasingly being used to facilitate and support the change of health behaviors (23). Behavior change is a complex process; therefore, an approach must be taken that has a positive effect on people's behavior.

One of these approaches is social marketing; a profound approach to behavior change, and seeks to expand and integrate marketing concepts with other approaches to influence behaviors that benefit individuals and communities(24). A review of the research by Fujira et al. using social marketing for physical activity shows that social marketing can be a tool to increase participation in physical activity(25). Stead et al. also showed in their study that one of the behavioral change approaches to increase physical activity that can be used is social marketing(26).

The use of theory in social marketing helps program designers determine whether a particular behavior is primarily related to attitude, norm, self - efficacy, environmental factors, or other social issues or a combination of these factors. (27).

The social marketing approach also relies on the appropriate use of behavioral theory to provide frameworks for developing initiatives by identifying the determinants of health behaviors. By understanding these factors, intervention strategies can be developed, which specifically address important theoretical structures (28).

One of the well-known models that describe the stages of behavior change in an audience group and its principles which are widely used in social marketing is the "model of stages of change in Prochaska". The Transtheoretical model provides a framework for understanding the level of physical activity and behavioral change and provides tangible strategies for how to intervene with specific individuals (29). In this model, it is assumed that individuals can be prepared in different stages of preparation (30). From the point of view of social marketers, this model has three important features: first, separating the target groups based on the stages of behavior change by asking a few relatively simple questions, and second, using an appropriate intervention strategy for the target groups according to the stage of behavior change. They also stressed that the goal of a social marketer for a particular customer should not be to take him one step closer to the approval stage, but to take the consumer to the next step (31). Only through a set of steps will a consumer arrive at the end of social marketing(change behavior permanently)(32).

Table 1
Adaptation of Trans-theoretical model and Social marketing

prochaska and Diclemente's stages of change (behavior change)	The task of Social marketing
Pre contemplation	Creating awareness and interest and changing values
contemplation	Motivate and persuade
Preparation	Create action
Action	Creating action (training and practice and reinforcement, confirmation of changed behavior)
Maintenance	Continuity of change

Aims of the study

The main purpose of this research

The purpose of this study is to evaluate an intervention program consistent with the first and seventh stages of the SMART social marketing operational model designed to enhance the level of physical activity of secondary education girls.

The main question of this research is whether educational intervention is based on the integrated approach of Social marketing to that of the regular physical activity in girl students.

Methods

Design

This study will be a parallel randomised controlled trial (RCT) conducted at a secondary school in Kermanshah. This protocol conforms to the Consolidated Standard of Reporting Trials (CONSORT) Statement and is registered at the Iranian Registry of Clinical Trials (IRCT:IRCT20200621047858N1). Figure 1 shows the study design.

Funding and ethics approval:

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Steps of the study:

This research will be conducted in three phases that correspond to the first to seventh stages of the social marketing operational model, i.e. the SMART model. The first phase will be the qualitative study, the second phase will be the descriptive-analytical study and the third phase will be the intervention.

Steps to Conduct the Study

This research will be carried out in three phases, which correspond to the first and seventh stages of the social marketing operational pattern, namely SMART. The first phase of the qualitative study of the second phase of the study will be descriptive - analytic and the third phase will be of intervention.

Since this research will be conducted using the principles of social marketing and its integration with the Transtheoretical model all its stages will be done according to the operational model for social marketing based on the first to seventh stages of the SMART model, then a problem will be selected. The next three stages of the SMART model, which include audience analysis, market analysis, and channel analysis, are performed in conjunction with identifying the behavior change stage and other constructs of the Transtheoretical model of a qualitative and quantitative research.

Therefore, all its steps will be carried out according to the operational pattern for the social marketing based on the first and seventh stages of the SMART pattern. In the first stage, the preparatory planning (Preliminary Planning), as a problem, is selected based on the study of scientific resources and documents and the subject of absence or lack of systematic physical activity of teenagers. The next three stages of the SMART model, which include audience analysis, market analysis and channel analysis, respectively, aligns with identifying the behavior and other Transtheoretical model structures in a qualitative and quantitative study.

Phase 1: Qualitative study

Recognition of the vision of the audience is about carrying out regular physical activity and the identification of social marketing strategies including the first and fourth stages of the social marketing operational pattern in this study.

Audience analysis aims to identify students' desires and preferences, market analysis to determine components such as competitors, partners and components of the marketing mix in the field of regular physical activity, and channel analysis to identify appropriate communication and implementation channels of the program.

Phase 2: Descriptive-analytical study:

The status of regular physical activity behavior and the stage of behavior change that the adolescent is in will be examined.

The statistical population of this study will include female high school students and the research site of the girls' high schools in Kermanshah. Using random sampling, three areas (3-2-1) will be done by a multi-stage sampling method.

The information required to implement the third phase of the study (intervention), and part of the second phase (audience analysis), and the third phase (market analysis) and fourth phase (channel analysis) of the SMART model are also done in this phase of the study.

Phase 3: Intervention study including design, implementation and evaluation of the impact of the intervention

After completing the qualitative and descriptive study and based on the obtained results, the fifth stage of the SMART model is performed, which includes the design, production of content and educational materials. In this step, an empirical study of the type of verification will be done to increase the regular physical activity in primary secondary students.

In each area (north and south of the city), using the division by the school education department, is divided into three categories (rich, middle-income and low-income) and a simple random method is selected from each category of one school (3 intervention schools and 3 control schools), and in the next stage, 3 classes from each grade (seventh, eighth, ninth) are selected from each school. The sample size required for the intervention and control group is calculated as 108 people, which are 36 students for each school and 12 students from each grade.

The method of implementation of this study phase will be as follows:

Intervention design:

Given that most studies have used only one model to design interventions and the limitation of intervention studies that have not been done by using social marketing and combining the theoretical model to increase regular physical activity in junior high school students has not been an effective intervention based on the stage findings. The first and second are designed based on the weekly steps of the social marketing approach.

-Production of interventions, materials and pre-tests

Based on the results of the first phase of the study, appropriate strategies and interventions are designed according to the social marketing approach, which includes the following:

- 1- Production of interventions and educational content using the information collected from customer analysis
 - 2- Integrating the social marketing mix into a strategy that can provide a quality product and a desirable exchange (product: regular physical activity - price: time spent doing regular physical activity - promotion: motion graphics, mask with logo and program slogan - analysis Channel: Health Ambassadors Virtual Channel Student - Customer Analysis: Model Structures Demographic Factors).
- Pre-test and review of programs

Considering that the intervention will be done based on the social marketing approach, based on the documents prepared in the previous step and according to the characteristics of the target group (regular physical activity, body mass index status, and stages of changing behavior) according to the program change processes will be designed.

All products, materials, and services used in social marketing programs should be tested with a portion of the target audience to identify their true effects, which can be useful in conducting an initial review to determine the target group. The trainings will be presented to the intervention group using photo clips and motion graphics, printed and electronic training materials, pedometers, masked hats with the program logo and slogan.

Table 2

-Theory-based strategies and methods used to modify the structures of the Transtheoretical model

Structure	Modification method	Predicted intervention
Consciousness Raising	Education, feedback, confrontation of expected behavior Media action	In order to increase knowledge in the field of regular physical activity in the lesson plan will be prepared and will be provided to students in the form of predictable media.
Dramatic Relief	Expressing unsuccessful and unpleasant experiences as a result of not having regular physical activity and playing a role	Expressing the experiences of students and peer groups about the effects of inactivity and lack of regular and daily physical activity along with motion graphic display
Environmental Reevaluation	Family intervention	Making the student think about the effects and benefits of regular physical activity and its impact on friends, classmates and family
Self Reevaluation	Mental imagining and clarification of values	Expressing content to create thinking about the effects of regular physical activity and determining self-worth (fitness, more active learning, vitality, physical health)
Self Liberation	Commitment to conduct behavior and have multiple choice	
Counter Conditioning	Replacing active behavior with inactivity	Teaching active behaviors and replacing active behaviors with sedentary activities such as doing appropriate exercises and movements or walking instead of watching TV or web-based and smartphone-based activities
Reinforcement Management	Self-reward, verbal encouragement and giving masked promotional gifts with the slogan and logo of the program	Feedback and expression of the positive effects of regular physical activity on students and encouragement of students by parents, teachers and peer groups (Student Health Ambassador)
Helping Relationships	Changing the Environment	Install a poster at school
Stimulus Control	Supporting family and friends (health ambassadors) to encourage regular physical activity - forming a group to perform daily physical activity (walking) and using the support of school staff and peers (health ambassadors)	Educate health ambassadors to encourage, remind, and discuss regular physical activity - Form a support group with ambassadors to walk on safe paths and educate parents and school staff about regular physical activity and their role in supporting and how to have physical activity.
Social Liberation	Encourage students by successful athletes in the province	Consultation with the Youth Sports Organization - Performing exercises according to the program guidelines at school and at home

Structure	Modification method	Predicted intervention
Self-Efficacy	Practice based on guidelines and increase skills, modeling, verbal persuasion and goal setting in daily activities	To hold practical sessions and how to operate the physical activity is to perform physical activity from less to the right amount and from simple to hard. Practice with a coach and encouragement by the peer group

Implement intervention and evaluation:

The study plan follows the CONSORT instructions (32). Given that this study is a three-stage study, an interventional study will be conducted to investigate the effect of educational intervention on regular physical activity behavior among female junior high school students. In this study, we will have an intervention group and a control group. Female junior high school students will be randomly assigned to one of the following two groups:

Intervention group: Students who receive the educational intervention design based on the social marketing approach and the stage of changing the individual behavior will receive equipment needed for regular physical activity.

Control group: These students will not receive any intervention from the research group and will be covered by routine school exercise programs.

Randomization of the study sample is done in the intervention group and the control group at the school level and is done by a researcher of the study team before evaluating the pre-test data (see Fig. 1). The intervention program lasts for two months, followed by a six-month follow-up period during one academic year.

After designing the intervention, performing the educational intervention (steps 5 and 6 of the SMART model) according to the possible methods mentioned (motion graphic, printed materials, pedometer...) in the intervention group the study will be conducted by a health education specialist and a health promotion expert.

Common recommendations for increasing physical activity among adolescent girls is by using multidisciplinary interventions, especially school-based interventions (33). Another strategy to encourage healthy lifestyles is peer-led education (34).

In order to be used in this study, the peer - led approach will be used in the implementation of interventions by health ambassadors. The program of health ambassadors in four educational courses (first and second elementary, first and second secondary) in urban and rural schools has been developed in cooperation with the Office of Population, Family and School Health and the Office of Education and Health Promotion of the Ministry of Health and Medical Education of the Islamic Republic of Iran. This

program is based on the peer education approach, which is a coherent program to create an effective peer-to-peer network to encourage students to improve their health and provides students with the opportunity to raise awareness of health issues using interactive and participatory values, i.e. group discussions, workshops, panels, role playing, etc.), and transfer it to other peers. Student health ambassadors are the students who volunteer and are interested in group activities in various areas of health.

Measuring the effectiveness of the intervention, the students of the intervention and control groups completed the questionnaire by self-declaration in two shifts, once before the intervention (T1) and once 6 months after the educational intervention (T2) in terms of the status of the improved Transtheoretical model structures. Students will also be asked about regular physical activity and, if possible, parental involvement.

The economic situation and environmental factors are measured only at the beginning of the study. Moreover, the process evaluation is carried out to monitor as much as the intervention program runs during the original study. The body mass index will also be measured in two stages before intervention and six months after intervention.

In this phase, the body mass index status of both groups (intervention and control) will be evaluated. The assessment will include measurements of height and weight so that these measurements will not cause any discomfort to the participants in the study and will last only a few minutes. All assessments will be performed in a quiet environment with standard tools.

The educational intervention will focus on regular exercise of physical activity (daily walks and aerobic exercise) according to protocols⁽³⁵⁾(ACSM's Guidelines for Exercise testing and Prescription). The FITT protocol is also used to determine the level of physical activity, which stands for frequency, intensity, time and type; F the frequency of repetition of physical activity per week, I the degree of activity intensity, T during the time spent on physical activity, and T type of exercise (36).

Considering that intervention is based on the social marketing approach, it will be designed based on the documentation prepared in the preceding phase according to the characteristics of the target group (the level of the regular physical activity, the physical mass index condition, and the steps of change of each person) according to the processes of change in the program.

The method of data collection will be in the form of a questionnaire and through self-report. Due to the fact that this study uses a Transtheoretical model the data collection tool follows this model. To measure the stages of change from the scale of Marcus et al (37), the measurement of change processes (cognitive - behavioral) and Norman's self - efficacy the questionnaire and colleagues ' self - efficacy questionnaire were used (38) A questionnaire developed by Blanchard et al. will be used to assess decision balance (39).

Sample calculation method and its number:

The study sample includes adolescent girls aged 12–16 years old in the first secondary schools under the auspices of Kermanshah University of Medical Sciences, which will be done by random sampling from three areas (3–2–1) using a multi-stage sampling method.

First, simple random sampling from each of the mentioned regions is a number of schools (girls), from selected schools (with respect to sample volume), from each grade level, and from selected classes, where samples are characterized by simple random sampling.

In the intervention section, taking into account the two test groups the controlling sample volume will be using the following equation:

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

in terms of test confidence level 95 % () and test power of 80 % (40) with respect to similar studies (40) by considering the standard deviation of physical activity in the first week and at least a significant difference between 0.7 and 10 % of the probable loss of samples was estimated at least for 108 persons per group.

Table 3
Eligibility criteria:

Criteria / study phase	quality	Descriptive	Intervention
Inclusion criteria	<p>First secondary school students who do not have physical activity</p> <p>Lack of land illness</p> <p>Completion of the interview consent form by the participants</p>	<p>Female students of the first year of high school in Kermanshah (seventh, eighth, ninth grade)</p> <p>Conscious consent to participate in the study</p>	<p>1st level of secondary school in kermanshah province for study and continued study</p> <p>The parents 'parents' consent to their participation in the study</p>
Exclusion criteria	<p>Students do not cooperate in the interview</p> <p>Not co - operate with students in an interview.</p>	<p>Having a debilitating illness and physical and mental condition in connection with physical activity to participate in the study</p> <p>Lack of cooperation in completing the questionnaire</p>	<p>Transfer from the sample school during the study</p> <p>Reluctance to continue participating in the study</p> <p>Having a debilitating illness and physical and mental condition in connection with physical activity to participate in the study</p>

Data analysis:

After data collection, the analysis was done using SPSS and AMOS software and the significance level of the tests was 5 percent. In data analysis, in addition to providing descriptive statistics, factor analysis, multiple linear regression and two-group independent T-path analysis will be used to analyze the data. In the intervention stage, inferential statistics including analysis of covariance, analysis of variance and paired T-test, McNemar and if necessary, repeated measures analysis will be used to evaluate the effect of the intervention in the groups.

Results

The primary outcome: Change in Trans-theoretical Model Constructs

Individuals are assessed in order to conduct regular physical activity according to the steps of change behavior in the pre-operational stage (pre-contemplation, contemplation, preparation) group, as well as from the of the trans-theoretical model structures at first and at the end of the follow - up of intervention.

The Secondary outcome: change in the rate of regular physical activity in female high school students

The number is evaluated according to changes in the amount of regular physical activity which are assessed in terms of frequency, intensity, time and type according to the FITT protocol, and changes in the volume of physical activity in terms of being active and inactive and walking using steps.

Discussion

Physical inactivity is the fourth cause of premature death (40). Only a small group of teenagers perform at least 60 minutes of middle - to - day physical activity per day according to the WHO guidelines (41).

The purpose of this study was to investigate the effect of educational intervention based on marketing-social approach and combining the trans-theoretical model on regular physical activity of female students, both in school and out of school. Social marketing in promoting regular physical activity is potentially a key step in support of increased participation in lifestyle change.

Adolescents are considered in terms of regular physical activity according to the stages of behavior change in the pre-operational stage (pre-contemplation, contemplation, preparation) and operational (action and maintenance) groups. Therefore, theory-based intervention programs are needed to enhance regular physical activity.

The program is also based on the peer education approach, which is a coherent program aimed at creating an effective peer-to-peer network to encourage students to improve their health and provides students with the opportunity to raise awareness of health issues through interactive values and gain participation (group discussions, workshops, panels, role playing, etc.) and transfer it to other peers.

The effect of peers, social support and girls' self-efficacy on the mediation of the effect of the intervention program on their regular physical activity will be examined. In addition, the potential moderating role of socioeconomic status, environmental factors, and BMI is tested.

In addition to examining these explicit hypotheses, the findings of this project can be used in a more general sense and the importance of promoting regular physical activity in and out of school through the physical activity in the curriculum can be established. The educational concepts and teaching methods of PE can be improved according to the purpose of active healthy living. Applied teaching modules can also be developed based on study findings.

Social marketing has been identified as a potentially effective strategy to increase healthy behavior choices (42, 43), and capitalizing on the value of health communication increases the likelihood that young school peers will make healthy behavioral choices (44, 45).

Strengths and limitations of this study

This study has several strengths; use of the social marketing framework and the integration of all structures of the meta-theoretical model in the field of increasing regular physical activity. From a moral point of view, no student will be blamed for being overweight or obese because all participants participate

in the intervention regardless of the body mass index status. Another positive aspect of the study is the large number of participants, which makes it possible to analyze a relatively large number of variables in multivariate analysis without extracting the data set. Follow-up is done over a long period (six months), and allows for the study of the long period of behavior change that occurred.

Trial Status

Enrolment into the study started on 25 July 2020. Recruitment is expected to be completed by 1 September 2020 and follow-up assessment in a further 6 months.

Abbreviations

BMI: Body mass index; CONSORT:Consolidated Standards of Reporting Trials; WHO:World Health Organization; RCT:Randomised Controlled Trial; ACSM's:American College of Sports Medicine; FITT:Frequency, Intensity, Time, Type of Exercise; SMART:Social Marketing Assessment of Response and Tools

Declarations

Competing interests:

The authors declare that they have no competing interests

Ethics and dissemination

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Ethics Committee of Hamadan University of Medical Sciences with proprietary ID, IR.UMSHA.REC.1398.952.The results of this experiment will be sent for publication in journals and distributed to school officials and parents of teenagers

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Consent for publication:

Not applicable

Author contributions:

BM: design, analysis and manuscript writing. FR: design and analysis, manuscript writing. RH: design, data analysis and **critical** revision, intervention development. LT: design, analysis, manuscript writing. AG:

design, analysis, intervention development, manuscript writing and critical revision. All authors read and approved the final manuscript.

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Figures

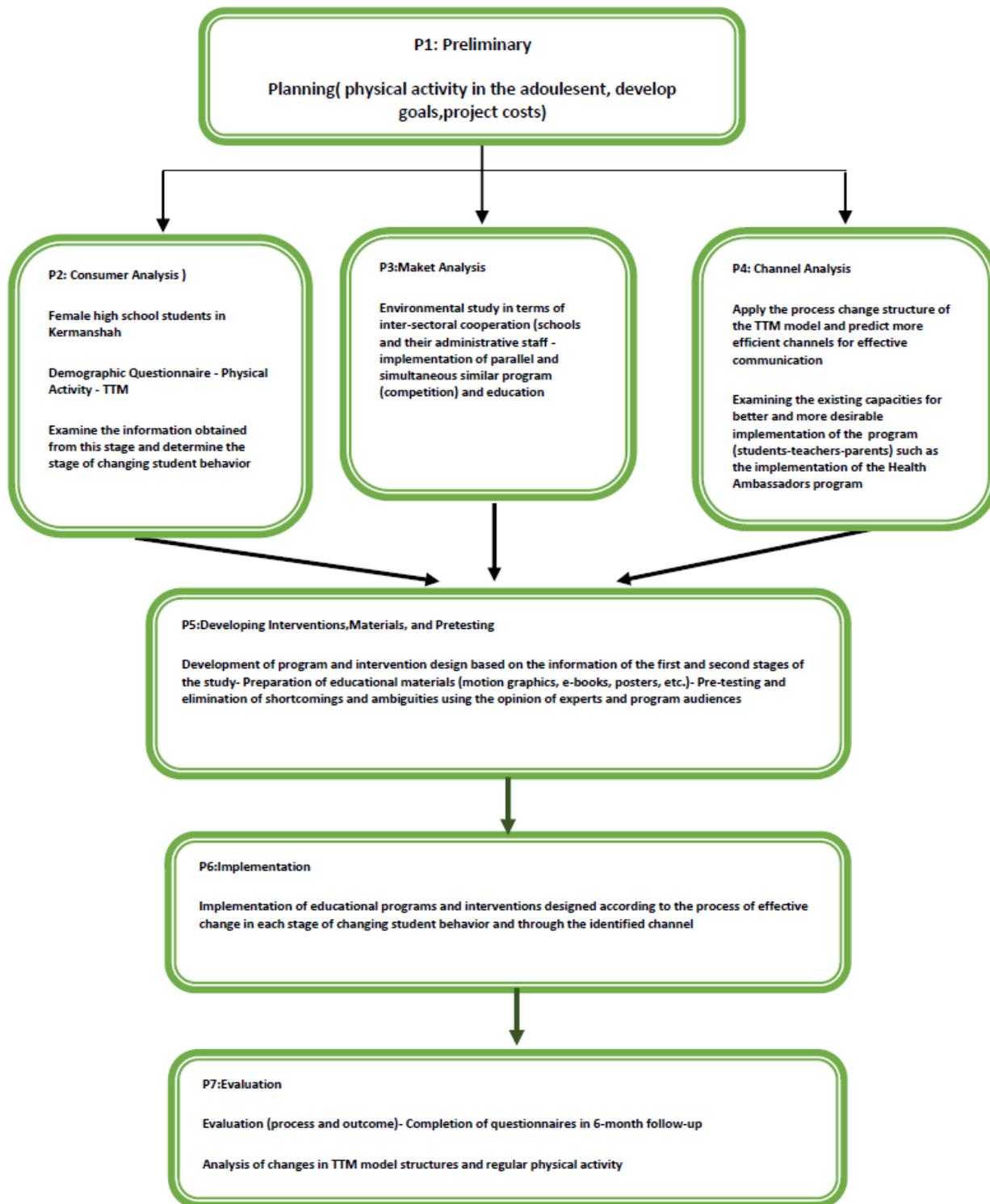


Figure 1

Conceptual framework of Social Marketing

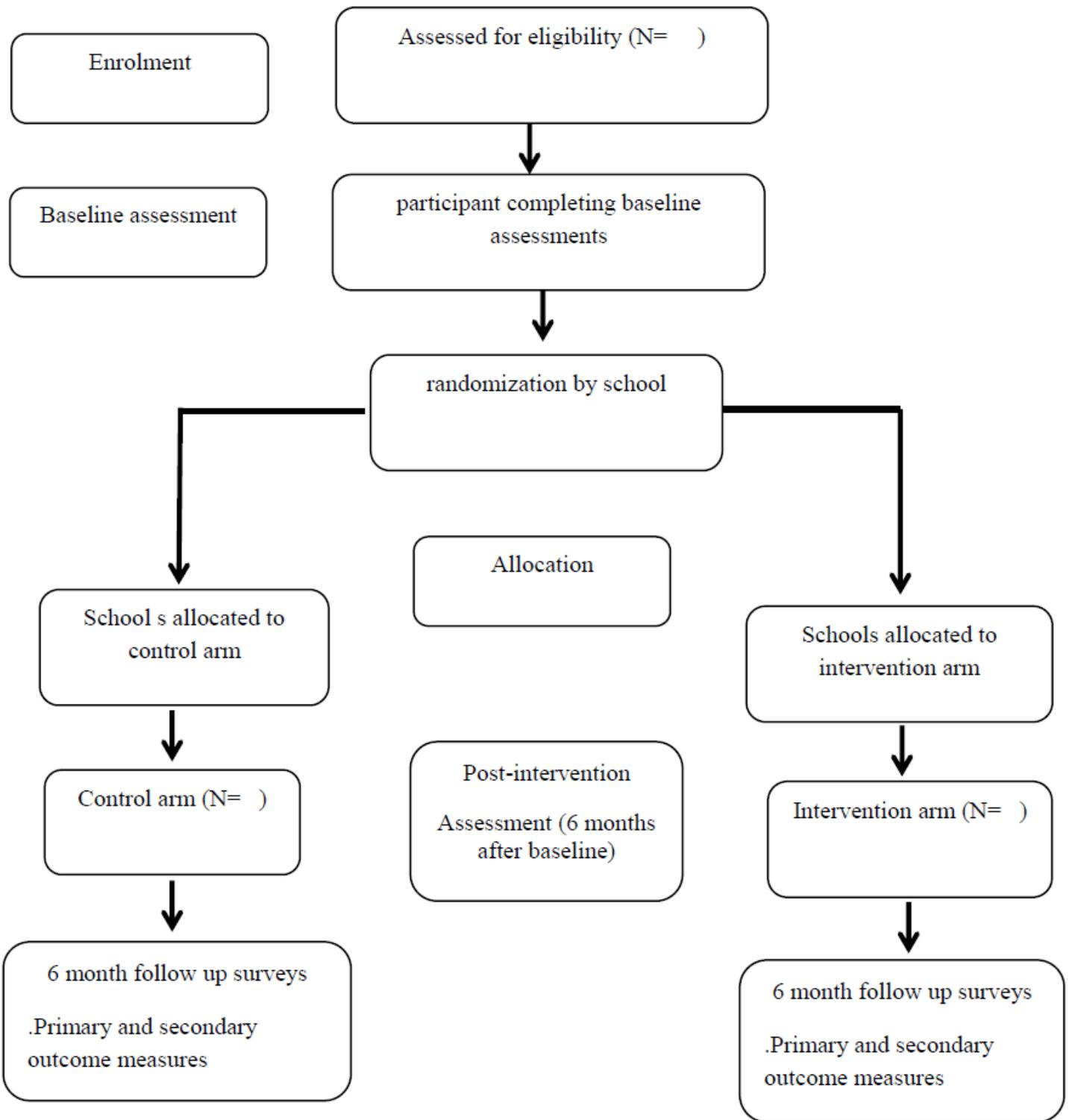


Figure 2

CONSORT flow diagram

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