Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Design, implementation and evaluation of the Impact of educational intervention based on the integrated social marketing approach for regular physical activity among female students

Protocol summary

Study aim

1. Determining and comparing the amount of regular physical activity in female high school students before and after the intervention in the intervention and control groups 2. Determining and comparing the rate of change in the structures of the transnational model in female high school students before and after the intervention in the intervention and control groups.

Design

In this study, we will have an intervention group and a control group, the first high school girls will be randomly placed in one of the following two groups: 108 students will receive an educational intervention designed based on a social marketing approach. 108 students in the control group will not receive any intervention from the research team

Settings and conduct

The statistical population of all female students who are studying in the first secondary schools of Kermanshah and in terms of regular physical activity according to the stages of behavior change in the pre-operational group (pre-thinking-thinking-preparation) and operational (practice and maintenance) and They are willing to participate in the study

Participants/Inclusion and exclusion criteria

1) Conscious consent of first grade high school students in Kermanshah to participate and continue their studies 2) Student parental consent for their participation in the study 1) Transfer from the sample school during the study 2) Lack of desire to continue participating in the study 3) Having an incurable disease and physical and mental condition related to physical activity to participate in the study

Intervention groups

Student intervention will focus on regular physical activity (daily walking and aerobic exercise) according to ACSM's (134) ACSM Guidelines for Exercise Testing and Prescription.

Main outcome variables

Changes in the amount of regular physical activity and changes in the structures of the meta-theoretical model

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047858N1**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **prospective**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Azam Geravandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0360

Email address

geravandi_a88@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation and evaluation of the Impact of educational intervention based on the integrated social marketing approach for regular physical activity among female students

Public title

Impact of educational intervention based on the integrated social marketing approach for regular physical activity among female students

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent of high school students in Kermanshah to participate and continue their studies Student parental consent for their participation in the study Kermanshah high school female high school students (seventh, eighth, ninth grade) Students in the age group of 10 to 19 years

Exclusion criteria:

1) Transfer from the sample school during the study Lack of desire to continue participating in the study 3) Having an incurable disease and physical and mental condition related to physical activity to participate in the study

Age

From **10 years** old to **19 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

To select intervention and control groups, first Kermanshah city is divided into north and south, then the covered schools in these areas are divided into control and intervention group in order to prevent the dissemination of information in a simple random way. In each area (north and south of the city) using the division of the school education department into three categories (rich, low-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 after each school. The sample size required for the intervention and control group is calculated as 108 people, which requires 36 students for each school and 12 students from each grade.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamedan, Shahid Fahmideh St., in front of People's Park, Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.UMSHA.REC.1398.952

Health conditions studied

1

Description of health condition studied

Sedentary lifestyle and lack of regular physical activity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of intervention in the stages of behavior change and passing from the pre-operational stage to the operational stage And increase self-efficacy in individuals

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Standard questionnaire: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. The Marcus et al. Scale is used to measure the stages of change. This scale includes a 5-choice question in which a person chooses only one option according to their physical activity conditions. According

to this scale, people in terms of physical activity behavior are in one of the 5 stages of pre-thinking, thinking, preparation, action and maintenance. The criterion for physical activity in this study is activity that is performed at least 3-5 times a week for at least 30 minutes each time; In such a way that it increases the heart rate and respiration and the person sweats, such as brisk walking and cycling. The Norman test will be used to measure change (cognitive-behavioral) processes. Also, Nig et al.'s questionnaire will be used to prepare a questionnaire related to measuring students' self-efficacy, and a questionnaire prepared by Blanchard et al. Will be used to measure decision-making balance.

Secondary outcomes

1

Description
Regular physical activity and changes in body mass index
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Standard questionnaire:The questions related to this section will be related to the International Physical Activity Questionnaire (IPAQ) which examines the status of physical activity in the research sample. This questionnaire is asked in the mode of moderate to severe physical activity and walking during the week. Also, the FITT protocol is used to determine the level of physical activity, which stands for frequency, intensity, time and type. F number of repetitions of physical activity per week, I degree of activity intensity, T is the length of time spent on physical activity, T is the type of physical activity.

Intervention groups

1

Description
Intervention group: Social Marketing Planning + FITT Protocol + ACSM Protocol(Educational interventions are designed based on the results of the first and second phases of the study (qualitative and quantitative study) and the placement of people in different stages of pre-operation (pre-thinking and thinking) and operational (readiness-action and maintenance). The educational package contains theory and Practical educational CD, motion graphics, posters and banners and pedometers. The educational content will be based on the following axes:1. Providing information about diseases caused by inactivity and the role of physical activity in reducing the complications of diseases 2. The benefits of regular physical activity in improving academic and physical performance 3. Appropriate amount and time of regular physical activity 4. Increase students' self-efficacy and emphasize existing benefits and barriers A total of 4 training sessions are planned for those who will be held in the pre-operational phase and two sessions for those who are in the operational phase. Each training session lasts 45 to 60 minutes. Practical training sessions for each class are provided by the physical education instructor in the presence of the researcher in coordination with the school principal in the school gym or prayer hall. According to the ACSM protocol, practical movement training in small groups to learn warm-up exercises, aerobic exercises, Flexibility movements, and muscle strength and cooling will be performed.)
Category
Behavior

2

Description
Control group:They will not receive any intervention from the research team and will be covered by the usual school curriculum.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah girls' secondary schools
Full name of responsible person
Azam Geravandi
Street address
Hamadan, Shahid Fahmideh St., Hamadan University of Medical Sciences
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geravandi_a88@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice -Chancellor for Research, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Azam Geravandi

Position

PhD student in health education and health promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the participants' information, the data file will not be published

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary	Not applicable