

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of a problem-based learning(PBL) health literacy program on improving health promoting behaviors among girl students

Protocol summary

Study aim

The aim of this study is to determine the effect of a problem-based learning(PBL) health literacy program on improving health promoting behaviors among girl students

Design

Educational intervention, Two parallel group Randomised trial design of 360 students(180 in each group) , randomized,no blinded

Settings and conduct

Educational intervention on health literacy program in south Tehran girls high school.. In this study there has been employed Health Literacy Measure for Adolescents (HELMA) and Health Promoting Lifestyle Profile(HPLPII) questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Lack of consent for participating in the study; Female students who are in the age group 15 to 18 years Exclusion criteria: unwillingness to participate in the study; The dissatisfaction of the Parents of student

Intervention groups

This research is a quasi-experimental study with two control and intervention groups.Educational intervention on health promotion behaviors on the dimensions of health literacy is based on problem-based learning method; Then the results are compared with the control group before,one and three months after the intervention.In the control group, the questionnaire will be completed by the person themselves and there will be no training for them

Main outcome variables

Outcome of study is improve health literacy and promote health behaviors in students

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130213012460N16**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **prospective**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Roya Sadedgi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 327 5692

Email address

sadeghir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-11, 1397/07/19

Expected recruitment end date

2019-02-08, 1397/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a problem-based learning(PBL) health literacy program on improving health promoting behaviors among girl students

Public title

The effect of health literacy on health promoting behaviors

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Lack of consent for participating in the study Female students who are in the age group 15 to 18 years

Exclusion criteria:

Unwillingness to participate in the study The dissatisfaction of the Parents of student

Age

From **15 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **360**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method will be done by simple random method. In this way, after the list of schools in south Tehran, randomly selected eight schools, then the four schools will be placed in the intervention group and four schools will be placed in the comparison group. Finally, by referring to each school and coordinating with the responsible, the samples will be selected by simple random sampling with a coupled number to reach the desired sample size. These samples come together on special days at the school, and they are invited to participate in the study by familiarizing them with the subjects and expressing the research goals.

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, School of Public Health, Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Poursina St., School of Public Health, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14155-6446

Approval date

2018-06-12, 1397/03/22

Ethics committee reference number

IR.TUMS.SPH.REC.1397.052

Health conditions studied**1****Description of health condition studied**

Health literacy

ICD-10 code

Z41

ICD-10 code description

Encounter for procedures for purposes other than remedying health state

2**Description of health condition studied**

Health promoting behaviors

ICD-10 code

Z71.0

ICD-10 code description

Person encountering health services to consult on behalf of another person

Primary outcomes**1****Description**

Health promoting behaviors

Timepoint

Before, one and three months after intervention

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

health literacy

Timepoint

Before, one and three months after intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

In the intervention group, the following measures will be done: Holding educational interventions in order to

improve health literacy and health promoting behaviors. Intervention will take place over a month of training sessions (4-5 sessions) in form of problem-based learning (PBL). Every session will take 60 to 90 minutes. In these sessions, the attempt is sharing necessary information and instructions on the health promoting including behaviors and health literacy.

Category

Prevention

2**Description**

Control group: In the control group, questionnaire will be asked to complete. There was no intervention for control group.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Girls' High Schools covered by South Tehran Health Center

Full name of responsible person

Mrs.Akram-o-Sadat Mohseni Tekye

Street address

Keshavarz Blvd, Vesal Shirazi St, Shafiee Alley, South Tehran Health Center

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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