Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 912 327 5692

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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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Keshavarz Blvd, Poursinia Street ,vice chancellor for research of Tehran University of Medical Sciences

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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

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Position

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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