

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Design, implementation, and evaluation of the impact of mental health promotion program on help-seeking behavior and life satisfaction of female adolescents: application of PRECEDE-PROCEED and Bronfenbrenner's integrated theoretical framework in a mixed study

Protocol summary

Study aim

Effectiveness of the Impact of mental health programs on help-seeking behavior and life satisfaction in adolescents

Design

A clinical trial with parallel groups (intervention and control), 85 students in each group, randomly assigned to each school. Then 2 classes will be selected randomly in each school.

Settings and conduct

The research environment in this study is public high schools for girls in Behbahan city. The research population is the 10th grade female students of these schools in the academic year of 2023-2024 and the research sample is selected from among the 10th grade female students of public schools. After selecting 170 students by random cluster method and assigning them to two experimental groups (85) and control (85), a pre-test using help-seeking intention and help-seeking behavior questionnaires, a life satisfaction questionnaire, and a questionnaire based on the PRECEDE-PROCEED model will be done. After that, educational intervention is implemented the post-test will be done in both experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being a 10th-grade female student, and informed consent of parents and students. Exclusion criteria: reluctance to continue participating in the study, absence of more than one session in training classes, migration from school while studying, history of suicide, history of neurological and mental diseases, separation of parents

Intervention groups

Intervention group: After the pre-test, the intervention will be conducted face-to-face (interactive lecture, conversation, discussion, poster, and pamphlet) for one month. If possible, individual or group learning

assignments are done. Control group: no intervention is done and only pre-test and post-test are taken

Main outcome variables

Help-seeking intention, help-seeking behavior, life satisfaction in students

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230920059474N1**

Registration date: **2023-10-22, 1402/07/30**

Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**

Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Elahe Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1001

Email address

elahezare@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of the impact of mental health promotion program on help-seeking behavior and life satisfaction of female adolescents: application of PRECEDE-PROCEED and Bronfenbrenner's integrated theoretical framework in a mixed study

Public title

The effectiveness of mental health educational intervention on help-seeking and life satisfaction of female adolescents

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent of parents and students Be a 10th grade female student. Education in public schools

Exclusion criteria:

Reluctance to continue participating in the study
Absence of more than one session in training classes
Migration from school while studying history of suicide attempts History of neurological and mental diseases
Separation of parents Having help-seeking behavior in the past years

Age

From **15 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, a multi-stage cluster sampling method will be used. In this way, each of the areas covered by comprehensive health centers in the city of Behbahan is considered a cluster. Considering that Behbahan City has five comprehensive health centers, they will be divided into five clusters, and two clusters will be selected randomly (using a lottery). Then, by identifying and listing the secondary girls' schools of the second period covered by the selected clusters, two schools with the condition of having more than 100 students will be randomly selected from each cluster (using a table of random numbers). Then, two schools will be randomly selected as the intervention group and two as the control group. In this way, 2 tenth grade classes will be randomly selected in each school, that is, 4 classes will enter the intervention group and 4 classes will enter the control group.

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 Shiraz University of Medical Sciences

Street address

Razi Blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1402.081

Health conditions studied**1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Help Seeking for mental health and life satisfaction

Timepoint

The beginning of the study (before the intervention) and 2, 4 months after the educational intervention

Method of measurement

Help-seeking intention questionnaire and life satisfaction questionnaire

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

Predisposing factors

Timepoint

At the beginning of the study (before the intervention), 2, and 4 months after the educational intervention

Method of measurement

A standardized researcher-made questionnaire

2**Description**

Enabling factors

Timepoint

At the beginning of the study (before the intervention), 2, and 4 months after the educational intervention

Method of measurement

A standardized researcher-made questionnaire

3**Description**

Reinforcing factors

Timepoint

At the beginning of the study (before the intervention), 2, and 4 months after the educational intervention

Method of measurement

A standardized researcher-made questionnaire

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

Intervention group: 85 students of tenth-grade public high schools for girls are selected according to the sampling process after conducting a pre-test using a questionnaire of help-seeking intention, help-seeking behavior, and satisfaction with life in students and a questionnaire based on the PRECEDE-PROCEED done. Educational intervention is implemented in the form of at least 6 90-minute training sessions. The general educational strategy includes interactive methods such as interactive lectures, small group techniques, group discussions, questions and answers, and home learning assignments and self-learning materials such as pamphlets and educational booklets, which are implemented by the researcher. In addition, the duration and number of training sessions may be based on desire, conditions of people participating in the class, and other factors to increase. 2 months and 4 months after completing the training, a post-examination will be held.

Category

Behavior

2**Description**

Control group: The control group won't receive any education other than conventional school training.

Category

N/A

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

Second high school female students in Behbahan city

Full name of responsible person

Elahe Zare

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

Vice-Chancellor for Research Shiraz 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?**

Yes

Title of funding source

Vice-Chancellor for Research Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoud Karimi

Position

Associate Professor

Latest degree

Ph.D.

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)

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

Study Protocol

No - There is not 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