Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 71 3725 1001

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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 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
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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