

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Assessing Effectiveness of Maternal Mental Health Literacy Improvement Program on Mental Health Status of Children

Protocol summary

Study aim

The present study aims to "examine the effectiveness of mental health promotion programs for improving the mental health status of children" in girls' schools in Tabriz.

Design

In the first phase of the study, an initial assessment will be carried out in the studied population and the area where students have high prevalence of mental health problems will be selected as the study population. Then, in the mentioned area, the population selected from homogeneous regions. Then, they will be divided into two groups of intervention and control randomly. Finally, the design, implementation, and evaluation of the intervention program will be carried out.

Settings and conduct

This study will be conducted among high school students of the eighth grade.

Participants/Inclusion and exclusion criteria

Inclusion criteria - Student girls who are studying at the eighth grade. - Mothers of female students attending school at the eighth grade - Girl students studying at the eighth grade who provided written consent from their parents. Exclusion criteria - Girls who are undergoing psychiatric treatment due to severe psychological illnesses, including schizophrenia, delusional disorders, depression and bipolar disorder. - A girl whose mothers are illiterate. - The unwillingness of each student or mother to continue cooperation

Intervention groups

Educating mothers of the eighth grade students and increasing their mental health literacy in them with an emphasis on some aspects of mental health literacy (Intervention group). Mothers of the 8th grade students without training (control group)

Main outcome variables

Mental health, Happiness, Social acceptance, Aggression, Mental health literacy, Loneliness. All variables of the study will be measured through standard self-reporting

questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181004041227N1**

Registration date: **2018-11-05, 1397/08/14**

Registration timing: **prospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Registration date

2018-11-05, 1397/08/14

Registrant information

Name

Haleh Hezomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0309

Email address

hezomih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing Effectiveness of Maternal Mental Health Literacy Improvement Program on Mental Health Status of Children

Public title
Maternal Mental Health Literacy Improvement Program on Mental Health Status of Children

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The total number of students who are studying at the eighth grade. Total student girls who have provided written consent from their parents. The whole mothers of female students are in the eighth grade of education.
Exclusion criteria:
Girls who are psychiatric patients due to severe psychological illnesses, including schizophrenia, delusional disorders, depression and bipolar disorder. Unwillingness of each student or mother to continue cooperation Girls whose mothers are illiterate.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: 128

Randomization (investigator's opinion)
Randomized

Randomization description
In the first phase of the study, an initial assessment will be carried out in the studied population and the area where students have high prevalence in terms of mental health problems will be selected as the study population. Then, in the mentioned area, the population selected from homogeneous regions is then divided into two groups of intervention and control randomly (Simple randomization). Stata software will be used for random assignment. Then, the design, implementation, and evaluation of the intervention program will be carried out.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants in both groups will be blind. So that none of the intervention and control groups will know which one of the groups belongs, and for this purpose the intervention and control group will be selected from separate schools.

Placebo
Not used

Assignment
Parallel

Other design features

The innovation of this study is due to the lack of studies on mental health literacy in the field of schools and students in foreign and domestic research texts, and in view of the fact that in studies conducted on the role and impact of improving the mental health of parents on improving the mental health of students not mentioned.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences Faculty of Health Sciences Department of Health Education and Promotion Attar of Nishapuri St, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5154966151

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.TBZMED.REC.1397.527

Health conditions studied

1

Description of health condition studied

Mental Health Literacy Status

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mental health status of children-Happiness-Social acceptance -Aggression-Loneliness-Mental health literacy

Timepoint

One and twelve weeks after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Mental health-Happiness-Social acceptance-Aggression -

Loneliness
Timepoint
3 months after intervention
Method of measurement
Questionnaire

Intervention groups

- 1**
Description
Intervention group: Mothers whose children are studying at the eighth grade. Training to increase maternal mental health literacy. The training will be for one month and will be two sessions per week, each session lasts for 45 minutes. Training for 128 people will be delivered in the form of lectures.
Category
Diagnosis
- 2**
Description
Control group: 128 mothers whose children are in the 8th grade. They will not be trained.
Category
Diagnosis

Recruitment centers

- 1**
Recruitment center
Name of recruitment center
School
Full name of responsible person
Haleh Hezomi
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Tabriz University of Medical Sciences Faculty of Health Sciences Department of Health Education and Promotion Attar of Nishapuri St, Tabriz, Iran
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Sponsors / Funding sources

- 1**
Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asghar Mohammadpoorasl

- Street address**
Department of Epidemiology and Biostatistics, School of Health, Tabriz University of Medical Sciences, Tabriz, Iran
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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
Tabriz University of Medical Sciences
Proportion provided by this source
50
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
Tabriz University of Medical Sciences
Full name of responsible person
Hamid Allahverdipour
Position
Professor of Health Education and Promotion
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Hamid Allahverdipour

Position

Professor of Health Education and Promotion

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Haleh Hezomi

Position

Phd Candidat

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

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

Title and more details about the data/document

In the form of dissertation and publication of the article.

When the data will become available and for how long

3 months after intervention

To whom data/document is available

Research colleagues

Under which criteria data/document could be used

To improve mental health of students

From where data/document is obtainable

Principal Investigator

What processes are involved for a request to access data/document

University-Department of Education

Comments