

# 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  
**Street address**  
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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hhezomih@yahoo.com

## 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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ampoorasl@tbzmed.ac.ir  
**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**  
Health Promotion  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Haleh Hezomi

**Position**

Phd Candidat

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

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**City**

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**Postal code**

14711-IRAN

**Phone**

+98 41 3334 0309

**Email**

hhezomih@yahoo.com

## 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**