

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Effectiveness and mechanism of change of mentalization based treatment in mothers with persistent depressive disorder on their children's behavioral problems

#### Protocol summary

##### Study aim

The purpose of this study is to investigate the effectiveness of mentalization based treatment in mothers with persistent depressive disorder on their children's behavioral problems and to evaluate the mechanisms of change of this effectiveness. In addition, the experience of mothers with persistent depressive disorder regarding the intervention program will be investigated

##### Design

Clinical trial with a control treatment as waiting list, without blinding on 34 mothers with persistent depressive disorder

##### Settings and conduct

The location of this research will be psychiatry and psychology treatment centers in Tehran. If the mother's diagnosis of persistent depressive disorder is met and according to the inclusion and exclusion criteria, eligible people will be selected and the research plan will be explained to them. These people after obtaining informed consent, are randomly divided into two intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a diagnosis of persistent depressive disorder based on DSM-5 criteria in mothers, having a child in the age range of 6 to 11 with behavioral problems, The age of the mother between 25 and 50 years, Not participation in other parente training sessions during this clinical trial. Exclusion criteria: Having psychotic symptoms, Having Autism Spectrum, Having Bipolar and Related Disorder, Having Intellectual Disability in mother and child and Having suicidal ideation in mother

##### Intervention groups

The intervention group will receive the mentalization based treatment, which includes 16 group sessions, 1.5 hours per week. The control group, the waiting list, will

not receive treatment until the end of the research project, and at that time will receive the intervention

##### Main outcome variables

Children's Behavioral Problems, Parental Reflective Functioning, Emotion Regulation, Attachment Styles

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230621058549N1**

Registration date: **2024-02-25, 1402/12/06**

Registration timing: **retrospective**

Last update: **2024-02-25, 1402/12/06**

Update count: **0**

##### Registration date

2024-02-25, 1402/12/06

##### Registrant information

##### Name

Zeinab Razmzan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4403 9844

##### Email address

razmzan.z@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-09, 1402/04/18

##### Expected recruitment end date

2023-08-09, 1402/05/18

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness and mechanism of change of mentalization based treatment in mothers with persistent depressive disorder on their children's behavioral problems

**Public title**

Effectiveness of mentalization based treatment in mothers on their children's behavioral problems

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a diagnosis of persistent depressive disorder based on DSM-5 criteria Having a child in the age range of 6 to 11 with behavioral problems The age of the mother is between 25 and 50 years Not participation in other parent training sessions during this clinical trial

**Exclusion criteria:**

The presence of acute symptoms of the disease in the mother so that she cannot answer the questions Having psychotic symptoms Having bipolar disorder and related disorders Having substance related and addictive disorders Intellectual disability in mother Intellectual disability in child Having autism spectrum disorders in mother Having autism spectrum disorders in mother Child's participation in psychotherapy or pharmacological therapy Having suicidal ideation in the mother

**Age**

From **25 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be achieved using the of web-based randomization. Web-based randomization is one of the methods of generating a simple random sequence, which is initially assigned a number to each participant and then using the website, people are randomly assigned to the intervention and control groups. This process will be done using the www.graphpad.com website. Considering that the sample size is 34 participants (17 participants in each group), a number from 1 to 34 will be assigned to each person and It is defined on the website that these numbers will be randomly assigned to one of the two intervention (A) and control (B) groups. In this way, the assigned number in each group indicates the placement of the participant in that group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics committee of Iran University of Medical Sciences

**Street address**

5th Floor of the Central Headquarters, Iran University of Medical Sciences, Next to Milad Tower, Hemat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2023-05-24, 1402/03/03

**Ethics committee reference number**

IR.IUMS.REC.1402.144

**Health conditions studied****1****Description of health condition studied**

Children's Behavioral Problems

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Child Behavioral Problems

**Timepoint**

Before the start of the intervention, immediately after the end of the intervention, 4 months after the end of the intervention

**Method of measurement**

Child Behavior Check List

**Secondary outcomes**

## 1

### **Description**

Parental Reflective Functioning

### **Timepoint**

Before the start of the intervention, after the eighth session of the intervention, immediately after the end of the intervention, 4 months after the end of the intervention

### **Method of measurement**

Parental Reflective Functioning Questionnaire

## 2

### **Description**

Attachment Styles

### **Timepoint**

Before the start of the intervention, after the eighth session of the intervention, immediately after the end of the intervention, 4 months after the end of the intervention

### **Method of measurement**

Adult Attachment Style

## 3

### **Description**

Emotion Regulation

### **Timepoint**

Before the start of the intervention, after the eighth session of the intervention, immediately after the end of the intervention, 4 months after the end of the intervention

### **Method of measurement**

Difficulties in Emotion Regulation Scale

## **Intervention groups**

## 1

### **Description**

Control group: There will be a waiting list in such a way that individuals will not receive treatment until the end of the research project, and at that time they will receive the present intervention.

### **Category**

Other

## 2

### **Description**

Intervention group: The mentalization based treatment that will be implemented in the present study is a program developed by Burn et al. (2019) under the title of Lighthouse Parenting Program. This program, which consists of 16 sessions of 1.5 hours and is held once a week in groups, is specifically designed for at-risk parents with a special focus on child development. The purpose of the program is to improve the mentalizing capacity, that is, parents' active curiosity about the child's inner world and efficient and productive reflection and reflection of their thoughts, feelings and reactions. This program helps parents approach their children with

an inquisitive mindset, identify where and how their parenting mindset can fail, and try to fix their mindset when they fail. This process represents the central metaphor of the program; The lighthouse metaphor presents parents as beacons who should provide gentle light for their child's journey and be a guiding light that can guide the child to the shore when support, help or comfort is needed.

### **Category**

Behavior

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Clinic of Faculty of Behavioral Sciences and Mental Health

#### **Full name of responsible person**

MohammadBagher Saberi Zafarghandi

#### **Street address**

No. 1, Shahid Mansouri St., Niayesh St., Sattar Khan St

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۴۲۵۶۱۳۱۱۱

#### **Phone**

+98 21 6655 1655

#### **Email**

zeinabrazmzan@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Dr Reza Falak

#### **Street address**

5th Floor of the Central Headquarters, Iran University of Medical Sciences, Next to Milad Tower, Hemat Highway, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۴۳۹۶۱۴۵۳۵

#### **Phone**

+98 21 8670 2504

#### **Email**

falak.r@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes  
**Title of funding source**  
Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Zeinab Razmzan  
**Position**  
PhD Candidate of Clinical Psychology  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 1, Shahid Mansouri St., Niayesh St., Sattar Khan St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۵۶۱۳۱۱۱  
**Phone**  
+98 21 6655 1668  
**Email**  
zeinabrazmzan@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Zeinab Razmzan  
**Position**  
PhD Candidate of Clinical Psychology  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 1, Shahid Mansouri St., Niayesh St., Sattar Khan St  
**City**  
Tehran  
**Province**

Tehran  
**Postal code**  
1445613111  
**Phone**  
+98 21 6655 1668  
**Email**  
zeinabrazmzan@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Zeinab Razmzan  
**Position**  
PhD Candidate of Clinical Psychology  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 1, Shahid Mansouri St., Niayesh St., Sattar Khan St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۵۶۱۳۱۱۱  
**Phone**  
+98 21 6655 1668  
**Email**  
zeinabrazmzan@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

It is possible to misuse individual raw data

### 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

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Results from statistical analysis and reports of clinical outcomes will be available. Also, the informed consent form will be available for the Research Ethics Committee of Iran University of Medical Science

### When the data will become available and for how long

The beginning of the period of access to the findings is

one month after the publication of the data in the form of thesis and article

**To whom data/document is available**

All researchers and health policy makers can access clinical findings and statistical analysis results. The informed consent form will only be available to the Research Ethics Committee of Iran University of Medical Science

**Under which criteria data/document could be used**

The data will be available for stablishing meta-analysis, as well as for developing new protocols and presenting of

reports at health-related conferences

**From where data/document is obtainable**

Applicants can contact the following email addresses.

Respondent's name: Zeinab Razmzan

zeinabrazmzan@yahoo.com

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

Answering the requests and sending the desired data will be done by email and will take about a month

**Comments**