Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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

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Person responsible for updating data

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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