

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Motivational Interviewing on Anxiety and Life Satisfaction of Mothers of Children with Mood Disorders

Protocol summary

Study aim

Determining the effect of motivational interviewing intervention on anxiety and life satisfaction in mothers of children with mood disorders

Design

The clinical trial had a control group with parallel groups, no blinding, randomized on 64 references. The Research Randomizer website (www.randomizer.org) was used for randomization.

Settings and conduct

The research population includes mothers with children aged 10 to 19 years with a diagnosis of mood disorder who referred to Ibn Sina Psychiatric Hospital in Mashhad in 1405. The sample size is estimated to be 64 mothers (32 in the intervention group, 32 in the control group). Sampling is done by convenience method followed by simple random assignment. The intervention group receives 4 sessions of 50-60 minutes of motivational interviewing, and the control group receives usual ward care (including child medication and routine nursing sessions). Data are collected using the Beck Anxiety Inventory (BAI) and the Diener Life Satisfaction Questionnaire (SWLS) in two stages: pre-test and post-test. Data analysis is performed with SPSS version 25.

Participants/Inclusion and exclusion criteria

Mother of a child aged 10-19 with mood disorders Living with a child with mood disorders Anxiety score greater than 8 on the BAI Willingness to participate No history of mental disorder or psychotropic medication No substance or alcohol abuse

Intervention groups

The intervention group will receive 4 sessions of 50-60 minutes of motivational interviewing, and the control group will receive usual ward care (including the child's medication and routine nursing sessions).

Main outcome variables

Anxiety Life satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260728070403N1**

Registration date: **2026-08-27, 1405/06/05**

Registration timing: **prospective**

Last update: **2026-08-27, 1405/06/05**

Update count: **0**

Registration date

2026-08-27, 1405/06/05

Registrant information

Name

Amirmohammad keivanshokooh

Name of organization / entity

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Motivational Interviewing on Anxiety and Life Satisfaction of Mothers of Children with Mood Disorders		Street address	Vakil Abad Blvd
Public title		City	Mashhad
The Effect of Motivational Interviewing on Anxiety and Life Satisfaction of Mothers of Children with Mood Disorders		Province	Razavi Khorasan
Purpose		Postal code	9177943707
Education/Guidance		Approval date	2026-08-10, 1405/05/19
Inclusion/Exclusion criteria		Ethics committee reference number	IR.MUMS.NURSE.REC.1405.054
Inclusion criteria:		Health conditions studied	
Mother of a child aged 10-19 with mood disorders Living with a child with mood disorders Anxiety score greater than 8 on the BAI Willingness to participate No history of mental disorder or psychotropic medication No substance or alcohol abuse		1	
Exclusion criteria:		Description of health condition studied	
Drug and alcohol abuser Having a history of mental disorder and use of psychotropic		Depressive disorder: F32.9 (unspecified major depression)	
Age		ICD-10 code	
No age limit		F32.9	
Gender		ICD-10 code description	
Female		Major depressive disorder, single episode, unspecified	
Phase		2	
N/A		Description of health condition studied	
Groups that have been masked		F33.9 (اختلال افسردگی عودکننده نامشخص)	
No information		ICD-10 code	
Sample size		F33.9	
Target sample size: 64		ICD-10 code description	
Randomization (investigator's opinion)		Major depressive disorder, recurrent, unspecified	
Randomized		3	
Randomization description		Description of health condition studied	
Simple Randomization Individual Using Research Randomizer software (www.randomizer.org) To conceal allocation, opaque, numbered, and sealed envelopes were used. The envelopes were kept in a separate room in numerical order. After each mother completed the pretest questionnaires, the envelope corresponding to the same number was opened and the individual was assigned to the intervention or control group.		Bipolar disorder: F31.9 (unspecified bipolar disorder)	
Blinding (investigator's opinion)		ICD-10 code	
Not blinded		F31.9	
Blinding description		ICD-10 code description	
Placebo		Bipolar disorder, unspecified	
Not used		4	
Assignment		Description of health condition studied	
Parallel		Anxiety	
Other design features		ICD-10 code	
		F06.4	
		ICD-10 code description	
		Anxiety disorder due to known physiological condition	
Secondary Ids		Primary outcomes	
empty		1	
Ethics committees		Description	
1		anxiety	
Ethics committee		Timepoint	
Name of ethics committee		6 weeks	
Ethics committee of Mashhad University of Medical Sciences		Method of measurement	
		Beck Anxiety Inventory	

Secondary outcomes

1

Description

Satisfaction with life

Timepoint

6 weeks

Method of measurement

Satisfaction with life scale

Intervention groups

1

Description

Intervention group: Motivational Interviewing (MI) is a participatory, goal-oriented, and empathetic counseling approach designed by Miller and Rollnick (2013) that emphasizes strengthening the individual's intrinsic motivation to change harmful behaviors. This method is implemented in a non-judgmental and supportive environment and in the present study, it is held individually and face-to-face with each mother to help her discover and strengthen her intrinsic motivations to manage anxiety and improve her quality of life. Sessions are held in a private and quiet room in the child psychiatry ward of Ibn Sina Hospital in Mashhad, which is equipped with two comfortable chairs, a small table, and adequate lighting. Required forms, including BAI and Diner questionnaires, and a demographic information form, are provided during the sessions. The intervention consists of 4 40-minute sessions, held once a week for 4 consecutive weeks. The first session, titled Building a Therapeutic Relationship, is dedicated to establishing a trusting relationship, explaining the structure of the sessions, exploring the mother's concerns and challenges, expressing empathy, and identifying strengths and past successes. The second session aims to identify and strengthen internal motivations, explore the mother's values and aspirations, use the importance scale, stimulate a conversation about change with the DARN-C technique (desire, ability, reasons, need, commitment), and strengthen self-efficacy. The third session, focusing on examining barriers to change and resolving oscillations, identifies barriers and ambivalence, uses the two-way review technique, and returns to strong motivations for change. Finally, the fourth session, titled Step-by-Step Planning for Stress Management and Improving Quality of Life, includes brainstorming to find practical solutions, developing a SMART (specific, measurable, attainable, realistic, timed) action plan, and strengthening commitment and final summation. The main techniques used in these sessions include open-ended questions, affirmations and praise, simple and complex reflections of feelings and content, summarization, numerical scales of importance and confidence, and mutual consideration of the pros and cons of change. Between sessions, mothers are asked to do simple home exercises such as a daily record of positive and negative feelings, daily diaphragmatic breathing practice for 5 minutes, and a diary of

situations in which they successfully managed their emotions, each taking about 5 to 10 minutes a day.

Category

Behavior

2

Description

Control group: The control group will receive standard hospital care during the study period (4 weeks), including routine nursing sessions to follow up on the child's medication status and general education for the mother, monthly general consultation with the ward's psychiatric nurse, access to the treatment team to answer questions, and continuation of the child's medication treatment as recommended by the treating psychiatrist, and will not receive any structured motivational interviewing intervention. In order to observe fairness and ethics in the study, after completing the follow-up phase and collecting all data, a summary of the motivational interviewing training will be provided to the control group in the form of a 60-minute individual or group session (depending on the mothers' preference) so that this group can also benefit from this method.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان ابن سینا مشهد

Full name of responsible person

سید محمد حسین بحرینی طوسی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Tayebe pourghaznein

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some data, such as information on the main outcome,

can be shared.

When the data will become available and for how long

Access begins 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Allowed

From where data/document is obtainable

Amir Mohammad Keyvan Shokooh Mobile: 09155615792

Zip Code: 9177943707 Email:

a.keivanshokooh@gmail.com Mashhad Medical Sciences Campus

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

Send email. Accept and send after a week.

Comments