Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

" Comparing the effectiveness of self-compassion therapy and psychoeducation using the Barcelona method on the level of perceived stress in caregivers of bipolar patients"

Protocol summary

Study aim

A Comparative Study of the Effectiveness of Self-Compassion Therapy and Barcelona Psychoeducational Training on Perceived Stress Among Caregivers of Patients with Bipolar Disorder

Design

The sample size was determined based on power analysis using G*Power software (effect size = 0.36, significance level = 0.05, and power = 95%), resulting in a total of 72 participants (36 participants per group). Randomization was performed using a block randomization method with a 1:1 allocation ratio. The random sequence was generated using Random Allocation Software.

Settings and conduct

blinding is typically required in a clinical trial. However, due to the nature of the interventions, blinding of participants and personnel is not feasible in this study. Nevertheless, the data analyst will remain blinded to the type of intervention during the statistical analysis phase to reduce potential bias.

Participants/Inclusion and exclusion criteria

Age between 18 and 55 years Ability to read and write No history of major psychiatric disorders or use of psychotropic medications, assessed using the BSI-53 questionnaire Caregivers whose patients have experienced at least two mood episodes during the course of the illness or have been hospitalized more than once Individuals who are the primary and consistent caregivers of the patient and are willing to participate in the sessions

Intervention groups

Interventions are defined as the procedures implemented within the study to evaluate their effectiveness or potential effects on outcomes of interest.

Main outcome variables

Change in caregivers' perceived stress score measured by the Perceived Stress Scale (PSS) at three time points (baseline, post-intervention, and one-month follow-up); Change in caregivers' self-compassion score measured by the Self-Compassion Scale (SCS) at three time points (baseline, post-intervention, and one-month follow-up).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260619069869N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

Name

Mahfam Mojazi-Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3222 3596

Email address

mmojazy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

" Comparing the effectiveness of self-compassion therapy and psychoeducation using the Barcelona method on the level of perceived stress in caregivers of bipolar patients"

Public title

Two Approaches to Reducing Stress in Caregivers of Patients with Bipolar Disorder: Self-Compassion Therapy and Barcelona Psychoeducation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 55 years Ability to read and write. No history of major psychiatric disorders or current use of psychotropic medications, as assessed by the Brief Symptom Inventory-53 (BSI-53). Primary caregivers of patients with bipolar disorder who have experienced at least two mood episodes during the course of their illness or have been hospitalized more than once. Individuals who have been the patient's primary caregiver on a regular basis and are willing to participate in the educational sessions.

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is considered essential to maintain internal validity throughout a randomized controlled trial. However, given the nature of the intervention in this study, participant and interventionist blinding will not be feasible. Nevertheless, to minimize assessment and analysis bias, the statistician responsible for data analysis will be blinded to group allocation and type of intervention. Following randomization, self-compassion and perceived stress among caregivers will be assessed using the Neff Self-Compassion Scale (SCS) and the Brief Symptom Inventory-53 (BSI-53). These questionnaires will be completed by caregivers at three time points: baseline (pre-intervention), immediately after the completion of the intervention (post-test), and one month following the intervention (follow-up), for both study groups. Data collection will be performed using paper-based questionnaires when necessary and will be supervised by the principal investigator to ensure completeness and accuracy of responses. The intervention will consist of eight 45-minute sessions delivered over four weeks (two sessions per week) for participants in both groups. Training sessions will be conducted in a group format with approximately 10 participants per group. Sessions will be held at Yahya Nejad Hospital in a designated conference and training room. The intervention will be delivered by the responsible neurosurgery resident involved in the study implementation. The content of the educational program is based on the book “The Mindful Path to Self-Compassion” by Christopher Germer. The primary outcome of this study is the reduction in perceived stress among caregivers of patients with bipolar disorder, measured using the Perceived Stress Scale (PSS) immediately after the intervention and at one-month follow-up.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Yahyanejad Hospital, Mostafa Khomeini Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4713655647

Approval date

2026-06-16, 1405/03/26

Ethics committee reference number

IR.MUBABOL.HRI.REC.1405.10

Health conditions studied

1

Description of health condition studied
Bipolar Disorder (Bipolar I and Bipolar II disorder) and its associated caregiver burden, specifically perceived stress among family caregivers of patients with bipolar disorder.

ICD-10 code
F31.0

ICD-10 code description
F31 – اختلال دوقطبی (Bipolar affective disorder)این کد شامل طیف اختلالات خلقی دوقطبی است که با دوره‌های مانیا، هیپومانیا، افسردگی و یا حالت‌های مختلط مشخص می‌شوند.

Primary outcomes

1

Description
Change in caregivers' total perceived stress score, measured by the Perceived Stress Scale (PSS-14) at three time points: baseline, immediately after the intervention, and one-month follow-up.Change in caregivers' total self-compassion score, measured by the Self-Compassion Scale (SCS) at three time points: baseline, immediately after the intervention, and one-month follow-up.

Timepoint
Baseline (Pre-intervention): Prior to the initiation of the intervention program.Post-intervention: Immediately after completion of the 8-session intervention program (end of week 4).Follow-up: One month after completion of the intervention sessions.

Method of measurement
The level of self-compassion among caregivers will be measured using the Neff Self-Compassion Scale, and perceived stress will be assessed using the Brief Symptom Inventory 53-item questionnaire (BSI-53).Both instruments are self-report questionnaires completed by the caregivers of patients.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive a structured self-compassion training program based on the Mindful Self-Compassion approach by Christopher Germer and Kristin Neff. The intervention will consist of eight sessions, each lasting 45 minutes, delivered over four weeks (two sessions per week). Sessions will be conducted in a group format with approximately 10 participants per group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yahyanejad Hospital

Full name of responsible person
Mahfam Mojazi-Amiri

Street address
yahyanejad hospital- mostafa khomeini street- babol-mazandaran-Iran

City
Babol

Province
Mazandaran

Postal code
4713655647

Phone
+98 11 3222 3505

Email
yahyanejad.hos@Mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
mahfam mojazy-amiri

Street address
بابل ، خیابان مدرس ، خیابان شهید مصطفی خمینی ، بیمارستان شهید یحیی نژاد

City
babol

Province
Mazandaran

Postal code
4713655647

Phone
+98 11 3222 3505

Email
yahyanejad.hos@mubabol.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Mahfam Mojazi-Amiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Babol, Modares Street, Shahid Mostafa Khomeini Street, Shahid Yahyanejad Hospital
City
Babol
Province
Mazandaran
Postal code
4713655647
Phone
+98 11 3222 3505
Email
mmojazy@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mahfam Mojazi-Amiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Babol, Modares Street, Shahid Mostafa Khomeini Street, Shahid Yahyanejad Hospital
City
Babol
Province
Mazandaran
Postal code
4713655647
Phone
+98 11 3222 3505
Email
mmojazy@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mahfam Mojazi-Amiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Babol, Modares Street, Shahid Mostafa Khomeini Street, Shahid Yahyanejad Hospital
City
Babol
Province
Mazandaran
Postal code
4713655647
Phone
+98 11 3222 3505
Email
mmojazy@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data of participants (such as age, gender, and caregiving status), after removal of any direct or indirect personal identifiers. Primary outcome data, including scores from the Neff Self-Compassion Scale and the Brief Symptom Inventory 53-item questionnaire, measured at three time points (baseline, post-intervention, and one-month follow-up). Anonymized participant codes to enable longitudinal tracking of data without the possibility of identifying individuals.
When the data will become available and for how long
Access to the anonymized study datasets and supporting documentation will begin 6 months after publication of the main study results in a peer-reviewed journal. The data will remain available for a period of 5 years from the start of the data sharing period, allowing qualified researchers to request access for secondary analyses during this timeframe.
To whom data/document is available
Academic researchers and faculty members affiliated with universities and recognized research institutions Independent researchers with a clearly defined academic affiliation Industry-based researchers, provided they

have a clearly stated research purpose, approval from an appropriate ethics committee (if applicable), and a recognized institutional affiliation

Under which criteria data/document could be used

Approved research purpose only: Data must be used exclusively for the objectives described in the approved research proposal. Any deviation requires prior written approval from the study team. Permitted types of analysis: Only statistical and epidemiological analyses consistent with the original informed consent and ethical approval are allowed. This includes descriptive analyses, inferential statistics, regression modeling, and secondary hypothesis testing related to psychological and behavioral outcomes. Machine learning or advanced data mining approaches are permitted only if explicitly stated in the approved proposal. No re-identification attempts: Any attempt to re-identify participants or link the dataset with external data sources is strictly prohibited.

From where data/document is obtainable

Formal correspondence with the Principal Investigator (PI) Requests must be submitted in writing directly to the Principal Investigator. This is the primary and fastest route for review and processing of data access applications. Research Office or Ethics Committee Secretariat If access cannot be arranged through the Principal Investigator, or if legal/ethical review is required, requests should be submitted through the institutional Research Ethics Committee for further processing

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

1. Submission of Formal Request The applicant must submit a written request to the Principal Investigator including: Exact title of the proposed research Objectives of data use Planned statistical or analytical methods Ethics approval documentation (if available) Estimated duration: 3–7 working days for initial registration and screening of the request 2. Initial Review by the Principal Investigator (PI) The PI evaluates the alignment of the request with the original study objectives, protocol, and ethical constraints. Clarifications or revisions may be requested from the applicant if necessary If approved, the request is forwarded to the next stage Estimated duration: 1–2 weeks 3. Research Ethics Committee Review (if required) If the data are sensitive or secondary use of data is involved, the request is reviewed by the institutional ethics committee. Assessment of confidentiality safeguards and informed consent compliance Evaluation of proposed analyses Estimated duration: 2–4 weeks (depending on committee meeting schedules) 4. Data Use Agreement (DUA) Execution After scientific and ethical approval, a formal Data Use Agreement is signed between the parties, specifying: Restrictions on data use Prohibition of participant re-identification Publication and dissemination conditions Estimated duration: 3–7 working days 5. Data Preparation and Release The dataset is de-identified and prepared in a standardized format before being shared with the applicant. Estimated duration: 1–2 weeks

Comments