Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of The Effect of Integrated Treatment of Family Focused Therapy (FFT) and Social Cognition and Interaction Training (SCIT) on the Signs and Symptoms, Interpersonal Relationships, Relapse and Quality of Life among Patients with Bipolar Type 1 and study of the effective elements of these two therapeutic approaches.

Protocol summary

Study aim

Determining the effectiveness of combined family focused treatment(FFT) and social cognition and interaction training(SCIT) in reducing signs and symptoms, improving interpersonal relationships, preventing recurrence and improving the quality of life of bipolar patients type1; Determining the main components of effective of combined family focused treatment(FFT) and social cognition and interaction training(SCIT)

Design

Randomized clinical trial with control group, with parallel groups, randomized, phase 2 on 75 bipolar patients 1, Excel software rand function will be used for randomization. From April 2021 to April 2022 with 3-months follow-up

Settings and conduct

Ward 2 of Baharan Psychiatric Hospital in Zahedan, will not be blinded in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of bipolar disorder type 1 with the diagnosis of a psychiatrist; Age between 18 to 45 years; Willingness and obtaining the consent of the patient's main caregiver Exclusion criteria: History of alcohol and substance abuse; History of Brain damage; Had a mental disorder other than the main diagnosis; Severe personality disorder

Intervention groups

Intervention group 1: In addition to drug treatment, this group will be received family-focused treatment with their primary caregiver, and after two-week wash out period will received social cognition therapy and interaction training. Intervention group 2: In addition to drug treatment, this group first will be received social cognition therapy and interaction training. After two-week wash out period will received family-focused treatment with their primary caregiver. Control group: This group will only be treated with medication and will not receive any intervention.

Main outcome variables

signs; Symptoms; Interpersonal relationships; Relapse and quality of life in bipolar patients type 1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049755N1**
Registration date: **2021-04-11, 1400/01/22**
Registration timing: **prospective**

Last update: **2021-04-11, 1400/01/22**
Update count: **0**

Registration date

2021-04-11, 1400/01/22

Registrant information

Name

Maryam Yosefi tabas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0045

Email address

ma.yosefi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-04-14, 1400/01/25
Expected recruitment end date
2022-04-14, 1401/01/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of The Effect of Integrated Treatment of Family Focused Therapy (FFT) and Social Cognition and Interaction Training (SCIT) on the Signs and Symptoms, Interpersonal Relationships, Relapse and Quality of Life among Patients with Bipolar Type 1 and study of the effective elements of these two therapeutic approaches.

Public title
Effectiveness of Integrated Treatment of Family Focused Therapy (FFT) and Social Cognition and Interaction Training (SCIT) In Patients with Bipolar Type 1
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Bipolar disorder type 1 has been diagnosed by a psychiatrist Having a score between 14 -18 in the Cognitive complaints in bipolar disorder rating assessment (COBRA) Don't having more than 3 recurrences At least had a high school education Having a score below 9 had in the Young Mania Scale Consent must be Obtained from patient's primary caregiver for participating in the study
Exclusion criteria:
Had a history of alcohol and substance abuse. Had a history of brain injury. Had a mental disorder other than the main diagnosis. Had a severe personality disorder (diagnosed by a psychiatrist) Had simultaneous visits to psychological clinics for psychological treatment.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
More than 1 sample in each individual
Number of samples in each individual: **1**
In family-focused therapy, in addition to the patient, his or her primary caregiver will also be present at the sessions.
Randomization (investigator's opinion)
Randomized
Randomization description
The method of random allocation will be drawing a number as a lottery container containing 25 balls for the experimental group 1, 25 balls for the experimental group 2 and 25 balls for the control group. Then the balls will be randomly taken out without replacement from the container and the sequence will be written on a piece of paper. The first number will be assigned to experimental group 1, the second one to experimental group 2 and the third one to control group, and this process will be continued until the last number.Allocation concealment will be also done only in data analysis.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features
This study included a review of the combined effectiveness of the two treatments. In family-centered therapy, the presence of the patient's primary caregiver is essential for education. But the treatment of social cognition and interaction training will be only on patients. to evaluate the effective elements of the two therapies will be used of researcher-made checklists that will be completed by a researcher colleague of the patient's family members. Based on this, we will develop an integrated protocol according to the effective components of the two treatments in accordance with Iranian culture.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Social Welfare and Rehabilitation Science
Street address
Kodakyar Ave, Daneshjo Blvd, Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.USWR.REC.1398.195

Health conditions studied

1

Description of health condition studied
Bipolar disorder type 1

ICD-10 code
F31.77
ICD-10 code description
Bipolar disorder, in partial remission, most recent episode mixed

Primary outcomes

1

Description
Score of depression in Beck Depression Inventory
Timepoint
Before the intervention, after the completion of the first intervention, after the completion of the second intervention, follow-up
Method of measurement
Beck Depression Inventory

2

Description
Score of quality of life of patients in Quality of Life Questionnaire
Timepoint
Before intervention, after completion of the first intervention, after completion of the second intervention, follow-up
Method of measurement
Quality of Life Questionnaire (WHO-QOL-BREF)

3

Description
Score of mania in Young Mania Questionnaire
Timepoint
Before the intervention, after the completion of the first intervention, after the completion of the second intervention, follow-up
Method of measurement
Young Mania Questionnaire

4

Description
score of Interpersonal relations in social performance questionnaire
Timepoint
Before the intervention, after the completion of the first intervention, after the completion of the second intervention, follow-up
Method of measurement
social performance questionnaire

Secondary outcomes

1

Description
Relapse
Timepoint
Before intervention, after completion of the first intervention, after completion of the second intervention, follow-up
Method of measurement
scores above 20 in the Beck Depression and Young Mania Inventory

2

Description
Social performance
Timepoint
Before intervention, after completion of the first intervention, after completion of the second intervention, follow-up
Method of measurement
Social Performance Questionnaire

Intervention groups

1

Description
Intervention group 1: This group ,in addition to receiving medication, will be received 15 sessions of family-focused treatment with their primary caregivers twice a week. After the Completion of the intervention and a 2 week wash out period, patients will be received social cognition and interaction training twice a week.
Category
Prevention

2

Description
Intervention group 2: This group ,in addition to medication, will be received 15 sessions of social cognition and interaction training twice a week. After Completion of the intervention and 2-week wash out period, patients will be received family-focused treatment twice a week with their primary caregiver.
Category
Rehabilitation

3

Description
Control group: This group will be received medication.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan Baharan Psychiatric Hospital
Full name of responsible person
Maryam Yosefi Tabas
Street address
In front of the Ghalla Department; Imam Khomeini street; Zahedan

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noor Mohammad Bakhshani
Street address
Second Floor; Headquarters building; University Campus; Dr. Hesabi square, Khalij-e- Fars boulevard
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Province
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9816743463
Phone
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Email
nmbs14@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Maryam Yosefi Tabas
Position
PhD student in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
Psychology
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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
Undecided - It is not yet known if there will be 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
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
Information of primary and secondary consequences will be shared.

When the data will become available and for how long
3 months after the results are published.

To whom data/document is available
Academic institutions

Under which criteria data/document could be used
people intend to repeat the protocol in psychiatric hospitals.

From where data/document is obtainable
By email address: ma.yosefi@uswr.ac.ir

What processes are involved for a request to access data/document
2 to 3 months

Comments