

# 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**

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##### **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  
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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**  
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  
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Psychology  
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## Person responsible for scientific inquiries

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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**

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**