

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Diagnosis and Treatment of Bipolar Disorder Based on Symptoms Network Data Analysis

#### Protocol summary

##### Study aim

1. Mapping relationship and determination of more prominent symptoms in GAD and Bipolar disorder network
2. Finding appropriate psychological treatment

##### Design

Replicated single-case experimental design with convenience sampling

##### Settings and conduct

Using data from the American Comorbidity Survey, the polychoric correlation matrix of the symptoms was extracted and their relationship map was plotted based on four indices: closeness, betweenness, strength, and expected effect. After identifying the most important symptoms, treatment protocol will be designed with a cognitive-behavioral approach and third-wave treatments. In the intervention phase, after the selection of patients with bipolar disorder (n=6) and baseline evaluation in 3 sessions, psychotherapy interventions will be conducted in the psychiatric ward of Hafez Hospital according to designed protocol. This study is a replicated single-case experimental design in which each patient acts as their control group. Patients will be evaluated for depression, anxiety and mania variables and the results are compared with pre-treatment conditions. To investigate the reliability of therapeutic effects, patients will be re-evaluated for aforementioned variables 1 month after the end of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion: 1) Bipolar disorder 2) Stable condition and adequate pharmacological treatment in previous 3 months 3) Ages 15-54 years 4) No psychological treatment at the time or before entering the study 5) Signing a written consent  
Exclusion: 1) Acute phase of bipolar disorder 2) Active drug abusers 3) Borderline personality disorder 4) Severe physical disabilities 5) Mental retardation

##### Intervention groups

Designed protocol using a cognitive behavioral and third-wave therapies to target more important symptoms

##### Main outcome variables

Assessment of Depression; Assessment of Anxiety; Assessment of Mania

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141221020378N3**

Registration date: **2020-03-18, 1398/12/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-18, 1398/12/28**

Update count: **0**

##### Registration date

2020-03-18, 1398/12/28

##### Registrant information

##### Name

seyed ali dastgheib

##### Name of organization / entity

shiraz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 9319

##### Email address

adastgheib@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Diagnosis and Treatment of Bipolar Disorder Based on Symptoms Network Data Analysis

**Public title**

Determination of the most important symptoms of bipolar disorder and treatment of the disease based on them

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Bipolar disorder Stable condition and adequate pharmacological treatment in the previous 3 months  
Ages 15-54 years No psychological treatment at the time or before entering the study Signing a written consent

**Exclusion criteria:**

Individuals in the acute phase of bipolar disorder Active drug abusers Borderline personality disorder Severe physical disabilities Mental retardation

**Age**

From **15 years** old to **54 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **6**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

**Street address**

Hafez Hospital, Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

71946-34786

**Approval date**

2020-01-15, 1398/10/25

**Ethics committee reference number**

IR.SUMS.REC.1398.1188

**Health conditions studied****1****Description of health condition studied**

Bipolar Disorder

**ICD-10 code**

F31

**ICD-10 code description**

Bipolar disorder

**Primary outcomes****1****Description**

Assessment of Depression

**Timepoint**

Immediately after each session of treatment and 1 months after end of treatment

**Method of measurement**

Beck Depression Inventory; Hamilton Rating Scale for Depression

**2****Description**

Assessment of Anxiety

**Timepoint**

Immediately after each session of treatment and 1 months after end of treatment

**Method of measurement**

Beck Anxiety Inventory

**3****Description**

Assessment of Mania

**Timepoint**

Immediately after each session of treatment and 1 months after end of treatment

**Method of measurement**

Young Mania Rating Scale

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

In the new network theory of mental disorders, the causal relationship between symptoms and the importance of more central symptoms in treatment has been emphasized. Using data of the American Comorbidity Survey, the polychoric correlation matrix of the symptoms was extracted with the help of the psych software and the correlation map of the symptoms was plotted based on four indices: closeness, betweenness, strength, and expected effect. Using the unit scale, the algebraic sum of the indices was calculated and the most important indicators were identified. Then, the protocol was designed using a cognitive behavioral therapy and third-wave therapies to target more important symptoms. In the intervention phase, six patients with bipolar disorder were selected by convenience sampling method. The statistical method of this study will be replicated single-case experimental design that ethical in psychotherapy interventions in which each patient acts as their control group. The study will be conducted in the psychiatry ward of Hafez Hospital. After selecting patients and evaluating baseline in 3 sessions, psychotherapy interventions will be conducted in accordance with designed protocol in 12 sessions. Following psychotherapy interventions, patients will be evaluated for depression, anxiety and mania variables and the results are compared with pre-treatment conditions. To investigate the reliability of therapeutic effects, patients will be re-evaluated for aforementioned variables 1 month after the end of treatment.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Psychiatric centers affiliated to Shiraz University of Medical Sciences

##### Full name of responsible person

Seyed Ali Dastgheib

##### Street address

Hafez Hospital, Chamran Blvd

##### City

Shiraz

##### Province

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##### Postal code

71946-34786

##### Phone

+98 71 3647 9531

##### Fax

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##### Email

hafez@sums.ac.ir

##### Web page address

<https://hafez.sums.ac.ir/page-hafezHP/fa/58/form/pld6977>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

Central building of Shiraz University of Medical Sciences, Zand St.

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Fax

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##### Email

ghasemiy@sums.ac.ir

##### Web page address

[http://research.sums.ac.ir/fa/vice\\_chancellor\\_introduction/vice-chancellor.html](http://research.sums.ac.ir/fa/vice_chancellor_introduction/vice-chancellor.html)

#### Grant name

Vice Chancellor of Research, Shiraz University of Medical Sciences

#### Grant code / Reference number

20185

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

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Samira Ranaie

##### Position

Ph.D. Student

##### Latest degree

Master

##### Other areas of specialty/work

Psychiatrics

**Street address**

Psychiatric Ward, Hafez Hospital, Chamran Blvd

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr. Seyed Ali Dastgheib

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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<https://hafez.sums.ac.ir/page-hafezHP/fa/58/form/pld6977>

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Samira Ranaie

**Position**

Ph.D. Student

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

samira\_ranaie@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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