

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

Fars

Postal code

71946-34786

Phone

+98 71 3647 9531

Fax

+98 71 3647 9592

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

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3212 2884

Fax

+98 71 3235 6996

Email

ghasemiy@sums.ac.ir

Web page address

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

City

Shiraz

Province

Fars

Postal code

71946-34786

Phone

+98 71 3647 9531

Fax

+98 71 3647 9592

Email

samira_ranaie@yahoo.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Dastgheib

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

Street address

Psychiatric Ward, Hafez Hospital, Chamran Blvd

City

Shiraz

Province

Fars

Postal code

71946-34786

Phone

+98 71 3647 9531

Fax

+98 71 3647 9592

Email

adastgheib@sums.ac.ir

Web page address

<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

Psychiatrics

Street address

Psychiatric Ward, Hafez Hospital, Chamran Blvd

City

Shiraz

Province

Fars

Postal code

71946-34786

Phone

+98 71 3647 9531

Fax

+98 71 3647 9592

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