Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Assessment of the effectiveness of group behavioral activation on trajectories of change in depressive symptoms in patients diagnosed with major depressive disorder

Protocol summary

Study aim
Assessment of the effectiveness of group behavioral activation on trajectories of change in depressive symptoms among patients suffering from major depression

Design
Single group, non-blinded, non-randomized trial with a sample size of 60

Settings and conduct
An interventional study in the psychiatry department of Farschian (Sina) Hospital in Hamedan

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 18-65 years; minimum education level of primary school (5 years); definite diagnosis of major depressive disorder; presence of moderate to severe depression; Participant's tendency to participate in group therapy. Non-inclusion criteria: history of major neurological disorders (e.g. Epilepsy, multiple sclerosis); history of substance or alcohol use in the recent 12 months; history of manic or hypomanic episodes; history of psychosis.

Intervention groups
Patients will receive behavioral activation during 10 weeks, the major aim is to recognize patterns of avoidance and replace them with mastery and pleasure behaviors to reduce depressive symptoms.

Main outcome variables
Depression scores based on Beck Depression Inventory (II)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200120046203N1**
Registration date: **2020-03-12, 1398/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-12, 1398/12/22**
Update count: **0**

Registration date
2020-03-12, 1398/12/22

Registrant information

Name
Latif Moradveisi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3827 4185

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effectiveness of group behavioral activation on trajectories of change in depressive symptoms in patients diagnosed with major depressive disorder

Public title

Trajectories of change in depressive symptoms during group behavioral activation

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having the minimum age of 18 and maximum age of 65 Having the diagnosis of major depressive disorder based on clinical interview and Structured Clinical Interview for DSM 5 (SCID) Participants tendency to participate in group versus individual therapy Presence of moderate to severe depression based on Beck Depression Inventory II (BDI-II) Minimum education level of primary school (5 years)

Exclusion criteria:

Presence or history of major neurological disorders (e.g. epilepsy, multiple sclerosis) Presence of prolonged interpersonal issues hindering participation in group Diagnosis of obsessive compulsive disorder Diagnosis of antisocial personality disorder Current or prior substance or alcohol use in the recent 12 months Prior history of hypomanic or manic episode Current or prior history of psychosis History of organic brain damage Simultaneous participation in other psychological therapies

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Hamedan University of Medical Sciences

Street address

Farshchian Hospital, Mirzadeh Eshghi Street

City

Hamedan

Province

Hamadan

Postal code

6516848741

Approval date

2019-09-15, 1398/06/24

Ethics committee reference number

IR.UMSHA.REC.1398.463

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2

Description of health condition studied

Major depressive disorder

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

Primary outcomes

1

Description

depression score in Beck Depression Inventory

Timepoint

Assessment of depression score at baseline, week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 1 month after the last week

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: behavioral activation, in 10 weeks, in 7 to 10 participant groups, the sessions content is as follows: First session learning patterns (groups introduction, introducing the concept of behavioral activation, starting self-monitoring), second session start changing patterns (relating self-monitoring to avoidance, introducing functional analysis of avoidance), third session taking action (changing avoidance into action, setting plans), fourth session understanding challenges (to learn about barriers of change), fifth session rumination (understanding rumination as a barrier to become active, learning the difference between

productive and unproductive thinking, analysis of what makes individual ruminate, identifying behaviors to replace rumination), sixth session mindfulness and being present in the moment (introducing techniques to help individual become engaged in routine activities), seventh session empathizing with self (identifying how individuals speak to themselves that lead to rumination, findings ways to change it to a compassionate voice), eighth session planning ahead (review of previous sessions and individual gains, working on barriers on the way of introduced techniques, plan for the future), ninth session values (aid participants to cope with their life situations through mindful ways of living rather than focusing on the outcome), tenth session resilience (to review future application of learned strategies in times of emotional distress, plan for living a more enjoyable life, giving feedback on participation in group)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry clinic of Farschian (Sina) Hospital

Full name of responsible person

Latif Moradveisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice-chancellor for research and technology, Hamedan University of Medical Sciences, in front of Mardom Park

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Latif Moradveisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Sara Sardashti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not 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
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
No - There is not a plan to make this available

Title and more details about the data/document
All acquired data can be shared after identifying information being omitted and it will be shared with the academic and research centers as well as the Ministry of Health and Education if necessary.

When the data will become available and for how long
Accessible in 6 months after publication of results

To whom data/document is available
Academic staff, health policy makers

Under which criteria data/document could be used
For assessment of usability in similar studies, for planning to improve health outcomes at community level

From where data/document is obtainable
Sara Sardashti, through email contact

What processes are involved for a request to access data/document
Assessment by the person in charge, confirmation by the principal investigator

Comments