

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of group therapy based on metacognitive model of detached mindfulness on depression, attention performance and executive performances in patients with major depression

Protocol summary

Summary

This study aimed to determine the effect of group therapy based on the metacognitive model of detached mindfulness on depression, attention performance and executive functions in patients with major depressive disorder. The study is a quasi-experimental research which was designed in two groups (intervention and control groups), in three stages of pre-test, post-test, and two months follow-ups. The independent variable of group therapy was based on the metacognitive model of detached mindfulness. It was applied in the interventional group and its effect on the test scores of post-test and follow-up was investigated and compared with the control group. Studied samples were selected among all patients referred to health care centers of Farshchian during 2016. First, the subjects were randomly selected from available samples, then in the patient list, 60 patients were randomly selected as a pilot study and were randomly divided into two intervention and control groups using the Randomizer site. Each of these groups consisted of 30 individuals. Intervention group during eight week sessions (each session lasting one hour) were treated by group therapy based on the metacognitive model of detached mindfulness. In the first session (before treatment) and eighth session (after treatment) the intervention group patients were asked to perform neuropsychological tests (Pre-test and post-test). It should be noted that the time taken to complete the neuropsychological tests for any member of the intervention and control groups was ranged from 45 minutes to one hour. follow-up session was held after two months in the same place.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052828119N1**

Registration date: **2016-12-01, 1395/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-01, 1395/09/11

Registrant information

Name

Marzieh Nazaribadie

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 6085

Email address

marzieh.nazari@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group therapy based on metacognitive

model of detached mindfulness on depression, attention performance and executive performances in patients with major depression	2016-05-15, 1395/02/26 Ethics committee reference number IR.UMSHA.REC.1395.71
Public title The effect of group therapy based on metacognitive model of detached mindfulness on depression, attention performance and executive performances in patients with major depression	Health conditions studied
Purpose Treatment	<u>1</u> Description of health condition studied Mager depression disorder
Inclusion/Exclusion criteria Inclusion criteria: Cases diagnosed with major depressive disorder; with mild depression(score 5-7 in Beck Depression Inventory); and the same medication regimen; Those with age ranges between 18 and 55 years; People with diploma or higher education level; Exclusion criteria Mental (psychosis) and physical disorders are required to receive medication or a special diet, such as diabetes; Absence for more than two sessions.	ICD-10 code f30,f39 ICD-10 code description Mood [affective] disorders
Age From 18 years old to 55 years old	Primary outcomes
Gender Both	<u>1</u> Description Mager depressive disorder and cognitive performances
Phase N/A	Timepoint Pre.post and follow
Groups that have been masked <i>No information</i>	Method of measurement Test
Sample size Target sample size: 60	Secondary outcomes
Randomization (investigator's opinion) Randomized	<u>1</u> Description Depression
Randomization description	Timepoint Pre, post and follow
Blinding (investigator's opinion) Not blinded	Method of measurement Test
Blinding description	
Placebo Not used	
Assignment Parallel	
Other design features	
Secondary Ids empty	Intervention groups
Ethics committees	<u>1</u> Description Intervention in expermental group is group therapy based on metacognitive model of detached mindfulness is treatment that is applied on the experimental group and evaluated impact on depression, executive performances and attention performance.
<u>1</u> Ethics committee Name of ethics committee The Ethics Committee of Hamadan University of Medical Science Street address Hamadan City Hamadan Postal code 65167-4-8741 Approval date	Category Behavior <u>2</u> Description The control group will not receive treatment Category Behavior
	Recruitment centers

1

Recruitment center

Name of recruitment center

Frschian Hospital

Full name of responsible person

Marzieh Nazaribadie

Street address

Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hamadan University of Medical Sciences

Full name of responsible person

Sohila Panahi

Street address

Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Marzieh Nazaribadie

Position

Ph.d

Other areas of specialty/work

Street address

Hamadan

City

Hamadan

Postal code

Phone

+98 81 3821 6085

Fax

Email

Mnazaribadie@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamamadan University of Medical Sciences

Full name of responsible person

Marzieh Nazaribadie

Position

Ph.d

Other areas of specialty/work

Street address

Hamadan

City

Hamadan

Postal code

Phone

+98 81 3821 6085

Fax

Email

Mnazaribadie@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

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Marzieh Nazaribadie

Position

Ph.d

Other areas of specialty/work

Street address

Hamedan

City

Hamedan

Postal code

Phone

+98 81 3821 6085

Fax

Email

Mnazaribadie@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty