

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of quality of life therapy on hopefulness and health related quality of life in patients with major depressive disorder

Protocol summary

Study aim

Determining The effect of group quality of life therapy on hopefulness and health related quality of life in patients with major depressive disorder

Design

A clinical trial with control group, parallel groups, single-blinded, randomized, on 60 patients. The randomized block method and the online site (mentioned in the previous section) will be used for randomization.

Settings and conduct

The study will be performed at Shahid Rajaei Psychiatric Hospital in Yasuj. Quality of life and hopefulness questionnaires will be filled out by both groups before the intervention. Then, for the intervention group, ten sessions of psychotherapy based on quality of life, will be performed, but for the control group, no intervention will be performed. At the end of the intervention, the research questionnaires will be filled out again by the participants. In this single-blinded study, the evaluator is unaware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Having major depression diagnosed by a psychiatrist, Age over 18 years Exclusion criteria; Unwillingness or withdrawal from the company to continue the study.

Intervention groups

Intervention group: includes 30 patients for whom group psychotherapy based on quality of life will be held for 10 sessions a week for two sessions of one and a half hours. In these sessions, the characteristics of quality of life and its effect on living happily, teaching the CASIO model, respecting one's self, and the five branches of quality of life will be taught. Control group: includes 30 patients who will not receive any intervention during the study.

Main outcome variables

Quality of life - hopefulness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220317054323N1**

Registration date: **2022-06-07, 1401/03/17**

Registration timing: **prospective**

Last update: **2022-06-07, 1401/03/17**

Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

Milad Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3822 6416

Email address

milad.amiri@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-16, 1401/04/25

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of quality of life therapy on hopefulness and health related quality of life in patients with major depressive disorder

Public title

The effect of quality of life therapy on quality of life and hopefulness.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient has major depression diagnosed by a psychiatrist The patient is cognitively able to understand the content and therapeutic training Simultaneously earning a quality of life score below 50 and a hope score below 24 Age over 18 years Willingness and satisfaction to participate in research

Exclusion criteria:

Have severe chronic physical disorders (cancer, multiple sclerosis) Participate in similar therapeutic interventions in the last quarter

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 patients with major depression who meet the inclusion criteria will be selected and randomly assigned to the intervention and control groups through block randomization. For block randomization, according to the total number of 60 patients and the existence of two groups, blocks with sizes of 2, 4, and 6 will be used. For example, if the size of block is 2, we will have two modes AB and BA (A and B are intervention and control groups). In order to create random allocation sequences and concealment, online software with the following address will be used, and a unique randomization code will be generated. Sealed Envelope Ltd. 2021. Create a blocked randomization list. [Online] Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> [Accessed 5 Jun 2022].

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the evaluator or the person who evaluates the questionnaires in the pre-test and post-test stages is not aware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics Committee of Yasuj University of Medical Sciences

Street address

Shahid Motahari Blvd., Yasuj

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591741417

Approval date

2022-05-18, 1401/02/28

Ethics committee reference number

IR.YUMS.REC.1401.013

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

Health related quality of life

Timepoint

Before the intervention - After the intervention

Method of measurement

The World Health Organization Health-related Quality of Life Questionnaire - Brief form. This is a 26-item questionnaire that measures a person's overall quality of life.

2

Description

Schneider hopefulness questionnaire. It has 12 questions and its purpose is to assess people's hopefulness.

Timepoint

Before the start of the study - after the intervention

Method of measurement

Schneider Hopefulness Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes 30 patients for whom group psychotherapy based on quality of life will be held for 10 sessions a week for two sessions of one and a half hours. In these sessions, the characteristics of quality of life and its effect on living happily, teaching the CASIO model, respecting one's self, and the five branches of quality of life will be taught.

Category

Treatment - Other

2

Description

Control group: includes 30 patients who will not receive any intervention during the study. According to ethical considerations, if the results of the interventions are positive in the intervention group, at the end of the research, and if the patients of control group have informed consent, the intervention will be performed on the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofteh Yasuj Clinic

Full name of responsible person

Bahram Mohamadi

Street address

Golestan No. 15

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milad.6916@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Hossein Mari Oryad

Street address

University of Medical Sciences, Motahhari Blvd,
Kohgiluyeh and Boyer-Ahmad Provinces, Yasuj

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oryad.hossein@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Mohamad Malekzadeh

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Yasuj - next to Imam Sajjad Hospital - Campus of
Yasuj University of Medical Sciences

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

Psychology

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Person responsible for updating data

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Email

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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

Not applicable