

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effectiveness of therapeutic schema and dialectical behavior therapy on cognitive regulation of emotion, cognitive flexibility and maladaptive strategies of worry in patients with depressive disorder.

Protocol summary

Study aim

Compare the effectiveness of schema therapeutic and dialectical behavior therapy on cognitive regulation of emotion, cognitive flexibility, and maladaptive worry strategies in patients with depressive disorder.

Design

Clinical trial with control group with parallel groups consisting of 45 patients with moderate depressive disorder selected by clinical interview based on DSM-V. The presence and severity of depression symptoms were assessed by the Beck depression questionnaire. The study was a blind, randomized study using a table of random numbers (15 people in each group).

Settings and conduct

The research was conducted in the Hami counseling center. Group training sessions were determined and the participants were privately informed to attend the sessions

Participants/Inclusion and exclusion criteria

Inclusion Criteria: receiving a diagnosis of moderate depression, not taking medication Exclusion criteria: Receiving a diagnosis of mild or severe depression, receiving a diagnosis of moderate depression, taking medication at the same time, and having mood problems caused by taking medication.

Intervention groups

1-Dialectical behavior therapy : The protocol of this treatment is implemented in four weeks in a group for 8 sessions of 90 minutes. 2- Schema therapy : The protocol of this therapy is implemented in the experimental group during 8 sessions in the form of 90-minute weekly sessions. 3- Control : This group will not receive treatment during the research, but they will be treated at the end of the research.

Main outcome variables

The main result of the effectiveness of therapeutic schema and dialectical behavior therapy is to reduce the

symptoms of depression and cognitive regulation of excitement, cognitive flexibility and maladaptive strategies of worry.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230517058212N1**

Registration date: **2023-08-06, 1402/05/15**

Registration timing: **retrospective**

Last update: **2023-08-06, 1402/05/15**

Update count: **0**

Registration date

2023-08-06, 1402/05/15

Registrant information

Name

Zohre Jafarzade jahromi

Name of organization / entity

Islamic Azad University, Birjand branch

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 1137

Email address

zjafarzade.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-01, 1401/08/10

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

2022-10-24, 1401/08/02
Actual recruitment end date
2022-12-21, 1401/09/30
Trial completion date
2023-01-24, 1401/11/04

Scientific title
Comparison of the effectiveness of therapeutic schema and dialectical behavior therapy on cognitive regulation of emotion, cognitive flexibility and maladaptive strategies of worry in patients with depressive disorder.

Public title
Comparing the efficacy of schema therapy and dialectical behavior therapy in patients with depressive disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Receive a diagnosis of moderate depression Not taking medicine Non-participation in any type of therapeutic intervention at the same time as participation in the research program Expression of desire to participate in the program in writing

Exclusion criteria:

Receive a diagnosis of personality disorders The presence of mood problems caused by drug use or biological problems

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In this method, 45 people who were selected as samples were numbered from 1 to 45. And these numbers were placed randomly without any particular order in the form of rows and columns in the table. Then one row and one column of the table were randomly selected. The intersection point of the selected row and column was the starting point of sampling. From this point and at the choice of the researcher, a direction (up, down, left or right) was drawn to select the members of the experimental and control groups. The numbers 15-00 obtained from the direction of the researcher's movement were selected as the first test group, and the numbers 16-30 as the second test group, and the numbers 45-31 as the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants generally knew that they

were undergoing psychotherapy. But they did not know that they were undergoing dialectical behavior therapy or schema therapy. Also, the data analyst did not know what treatment each participant was under or in which group they were (but the researcher did).

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

21 Ostad Motahari St

City

Jahrom

Province

Fars

Postal code

74157-13548

Approval date

2022-10-24, 1401/08/02

Ethics committee reference number

IR.BUMS.REC.1401.265

Health conditions studied

1

Description of health condition studied

Patients with depressive disorder

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

Treatment of depressive disorder

Timepoint

Before the study, in the middle of the study (two weeks after the start of the treatment) and after finishing the treatment training sessions

Method of measurement

Beck depression questionnaire

Secondary outcomes

1

Description

Cognitive regulation of emotion

Timepoint

After therapeutic interventions

Method of measurement

Using the cognitive emotion regulation strategies questionnaire of Garnevsy et al. (2002)

2

Description

Cognitive flexibility

Timepoint

After therapeutic interventions

Method of measurement

Using the Cognitive Flexibility Questionnaire of Dennis and Vanderwaal (2010)

3

Description

Maladaptive worry strategies

Timepoint

After therapeutic interventions

Method of measurement

Using the questionnaire of incompatible strategies, Meiryar et al. (1990)

Intervention groups

1

Description

Schema therapy: Schema therapy instructions and techniques were implemented on the experimental group during 8 sessions in the form of weekly 90-minute sessions. The first and second session: these sessions were dedicated to the implementation of the assessment phase and preliminary training of schema therapy. The third and fourth session: introduction, training and application of cognitive techniques was the challenge with the schema. Fifth and sixth sessions: Emotional (experimental) techniques were introduced and taught. 7th and 8th sessions: training and implementation of behavioral pattern breaking techniques, persuading subjects to abandon incompatible coping styles and practice effective coping behaviors.

Category

Treatment - Other

2

Description

Dialectical behavior therapy: The dialectical behavior therapy training protocol was implemented in four weeks as a group for 8 sessions of 90 minutes. In the first session: after getting acquainted with the goals and

rules, the group members were introduced to three mental states, logical, emotional and rational, in the comprehensive awareness skills section. The second session: in this session, in addition to the training of the mental states of the previous session, the training of the skills of what and how skills of comprehensive awareness were taught. The third session: what and how skills were practically taught in the group. Fourth session: In this stage, in addition to reviewing the exercises of the previous session, part of the emotional regulation skill was taught. Fifth session: Another part of emotional regulation skills was taught in this session. Sixth session: In this session, while reviewing the skills of the previous session, the skills of accepting emotions were taught. Seventh session: In this session, a part of the stress tolerance component was taught. In the eighth session, the review of the previous skills was considered as well as teaching how to generalize the skills outside the treatment session.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hami Psychology and Counseling Center

Full name of responsible person

Zohre Jafarzade

Street address

22 Bahman Street, Hakim Medical Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Birjand branch

Full name of responsible person

Dr. Seyyed Abdolmajid Bahrainian

Street address

Ostad Motahari St., Alley 21

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Majid.bahrainian@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University, Birjand branch

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

Islamic Azad University, Birjand branch

Full name of responsible person

Zohre Jafarzade

Position

PhD Student in Clinical Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Parts of the data, such as information about the intervention and its effect on dependent variables, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are

published.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Request for researchers engaged in research in the field of mental illnesses

From where data/document is obtainable

1- The e-mail address of Zohre Jafarzade Jahormi is

zjafarzade.j@gmail.com 2- Zohre Jafarzade's contact number: 09308352827

What processes are involved for a request to access data/document

First, the researcher introduces herself by sending her an email and explaining the reason for the need for data, and in less than a month, she will be answered and the data will be sent.

Comments