

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effects of affective expectations on affective experience and anhedonia among anhedonic patients suffering from major depression disorder

Protocol summary

Study aim

The effects of affective expectations on affective experience and anhedonia among anhedonic patients suffering from major depression disorder

Design

Clinical trial with control group, with parallel groups, single-blind, randomized. For randomization, people are placed in the control or intervention group through lottery.

Settings and conduct

The research will be conducted in Hafez and Ebne Sina hospitals in Shiraz. The participants will be randomly divided into two groups of inducing positive and neutral expectations. Participants in the positive expectancy induction group are given very positive explanations about the movie that will be played for them. While the subjects of the neutral emotion induction group will be given explanations about the movie that only explain the events that happened in the movie without using any special emotional charge. The participants are aware of the study as a whole, but they are unaware of which group they belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: initial diagnosis of major depressive disorder with anhedonia, Age range from 18 to 65 years. Exclusion criteria: The presence of comorbid disorders, including substance abuse, psychotic disorders, bipolar disorder, anxiety disorders, and psychotic symptoms, active suicidal ideation, History of head injury or neurological diseases.

Intervention groups

Intervention group: induction of positive expectations. Participants in the positive expectancy induction group are given very positive explanations about the movie that will be played for them. Control group: induction of neutral expectations. Explanations about the film will be provided, which only explain the events and happenings

in the film without using any special emotional load.

Main outcome variables

Affective Experience Anhedonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230513058161N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Somayeh Daneshvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 8351

Email address

somayedaneshvar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of affective expectations on affective experience and anhedonia among anhedonic patients suffering from major depression disorder

Public title

The effects of affective expectations on anhedonia among patients suffering from major depression disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Initial diagnosis of major depressive disorder with anhedonia Age range from 18 to 65 years

Exclusion criteria:

The presence of comorbid disorders, including substance abuse, psychotic disorders, bipolar disorder, anxiety disorders, and psychotic symptoms. Active suicidal ideation History of head injury or neurological diseases

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets and write "intervention" on one and "control" on the other. Then, upon each patient's visit, he/she is asked to pick one of the sheets randomly, and based on this, the patient is assigned to the intervention or control group. It is continued in the same way for other patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

The general design of the experiment is explained to the participants, but the subject does not know which group will be placed in. In this way, the general objectives of the research are explained to the subjects before the implementation of the research: In this research, we intend to investigate the symptom of anhedonia in major depressive disorder using psychological interventions. However, subjects are not told which of the experimental or control groups they have been placed in.

Placebo

Used

Assignment

Parallel

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

5th floor, Shiraz University Central Building, Islamic Republic Blvd,

City

Shiraz

Province

Fars

Postal code

7194684471

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

IR.SUMS.REC.1401.573

Health conditions studied**1****Description of health condition studied**

Major Depression Disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes**1****Description**

Anhedonia

Timepoint

Before and after the intervention

Method of measurement

Positive Valence Systems Scale-21 questionnaire

2**Description**

Affective Experience

Timepoint

Before and after the intervention

Method of measurement

Affective Experience questionnaire

Secondary outcomes**1****Description**

Probabilistic reward Learning

Timepoint

Before and after the intervention

Method of measurement

Probabilistic reward task

Intervention groups

1

Description

Intervention group: induction of positive expectations. Individuals in this group will be given a very positive description of the movie they are about to see, on the basis that the movie will be very enjoyable, such as: "This movie you are about to see is one of the best movies I've ever seen." It is a popular comedy that is very enjoyable. The aim of this statement is to induce excitement and positive emotion towards watching the clip in order to increase the interest of the person in watching the clip.

Category

Treatment - Other

2

Description

Control group: The people of this group will be given an explanation about the movie, which only explains the events and happenings in the movie without using any special emotional load.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Babak Hosseini

Street address

Hafez Hospital, Chamran Blvd

City

Shiraz

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Postal code

7194634786

Phone

+98 71 3647 9080

Email

Hafez@sums.ac.ir

2

Recruitment center

Name of recruitment center

Ebne Sina Hospital

Full name of responsible person

Ebrahim Moghimi Sarani

Street address

Hafez Ave, 8th Ave

City

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Postal code

7146676541

Phone

+98 71 3228 9601

Email

sinahosp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

Street address

7th floor, central building of Shiraz University of Medical Sciences, Zand Ave

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Email

vrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Somayeh Daneshvar

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**

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Full name of responsible person

Somayeh Daneshvar

Position

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Latest degree

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Person responsible for updating data

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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

All potential data can be shared in SPSS file format after de-identifying people.

When the data will become available and for how long

Access start 6 months after the results publication

To whom data/document is available

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

Under which criteria data/document could be used

The necessary conditions for sending a request to access data or documents are email to the corresponding author. Only statistical analyzes similar to those performed in the present study are allowed, including independent t-student tests and multivariate analysis of variance tests.

From where data/document is obtainable

Email to the corresponding author

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

Applicants can send their request via e-mail to the responsible author, then within a maximum period of one month, the corresponding author will send them the required documents or files.

Comments