Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

The Comparison of positive psychotherapy via face to face vs. virtual reality on emotional experiences, life satisfaction and suicidal ideation of patients suffering from major depressive disorder, admited to hospital

Protocol summary

Study aim

the aim of this study is determining the effect of positive psychotherapy using virtual reality on emotional experiences, life satisfaction and suicidal thoughts of patients with major depression hospitalized in hospitals of Shiraz University of Medical Sciences.

Design

A clinical trial with two-way blind parallel groups, in which 78 patients will be placed in two intervention and control groups by cluster randomization method.

Settings and conduct

At first, patients with major depression hospitalized in neuropsychiatric hospitals affiliated to Shiraz Medical Sciences, based on the information in the ir file, on the first day of transfer to the department (from psychiatric emergency room), in terms of entry and exit criteria, and eligible patients with Using randomization software, they will be completely randomly placed in two intervention and control groups. After completing the informed consent form, the participants of both groups are asked to complete the questionnaires. The people in the intervention group will receive the treatment in virtual reality and the people in the control group will receive the treatment in person, and after the end of the study, the questionnaires will be completed again by the people of both groups.

Participants/Inclusion and exclusion criteria

.Age above 18 years .Having a diagnosis of major depression based on the psychiatrist's opinion (based on the information in the patient's file) .having suicidal thoughts

Intervention groups

All patients with the entry criteria allocated to the intervention group will receive 3 sessions of positive psychotherapy through virtual reality, and the control group will receive face-to-face positive psychotherapy.

Main outcome variables

Depression, positive psychotherapy, virtual reality, emotional experiences, life satisfaction, suicidal thoughts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048893N7**
Registration date: **2022-11-16, 1401/08/25**
Registration timing: **prospective**

Last update: **2022-11-16, 1401/08/25**
Update count: **0**

Registration date

2022-11-16, 1401/08/25

Registrant information

Name

Maryam Shaygan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 7345

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of positive psychotherapy via face to face vs. virtual reality on emotional experiences, life satisfaction and suicidal ideation of patients suffering from major depressive disorder, admited to hospital

Public title

The Comparison of positive psychotherapy via face to face vs. virtual reality on emotional experiences, life satisfaction and suicidal ideation of patients suffering from major depressive disorder, admited to hospital

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Willingness to participate in the study Ability to read and write at the fifth and sixth grade level Having a diagnosis of major depression based on the psychiatrist's opinion (based on the information in the patient's file) Having suicidal thoughts based on the information in the patient file and diagnostic interview screening questions (CIDI) by the senior psychiatric nursing student Absence of psychotic symptoms in the patient Not suffering from other mental disorders, including personality disorders, bipolar disorder or mental retardation, alcohol and substance abuse disorder, and dementia. Not suffering from severe and debilitating chronic physical disease based on the information in the patient's file (such as cancer, hemodialysis, multiple sclerosis, etc.) Preparation and favorable physical and mental conditions of the patient to participate in the intervention

Exclusion criteria:

Refusal to continue participating in the study (during the study) Occurrence of unexpected physical or mental problems during study Inability to actively participate in the treatment process (for reasons such as slowness of thinking, slowness of speech, etc.)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, cluster controlled randomization method is used, where hospital departments (instead of individuals) will be considered as the randomization unit. In this study, random assignment of departments in the hospital will be done by someone outside the study using randomization software. In other words, the numbers of the sections will be entered into the randomization software, and this software will place the sections in one of the intervention or control groups completely randomly and by coding. The reason for choosing the cluster randomization method is to prevent and protect against data contamination that can occur in the randomization of people.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to blind and prevent possible bias, interpretation of questionnaires and data entry and analysis will be done by someone outside the study. Also, the Beymazer clinical caregiver does not know how to assign people and the type of training of people. In order to prevent data contamination in this study, hospital departments will be randomized instead of individuals, and in fact, department numbers will be entered into the randomization software, and this software will be completely random and by coding the departments into one of two groups. control or intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in the Research of Nursing and Midwifery, Management and Medical Information-Shiraz

Street address

School of Nursing and Midwifery, Nemazee Square, Zand St., Shiraz, Iran

City

shiraz

Province

Fars

Postal code

71936-13119

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.059

Health conditions studied

1

Description of health condition studied

major depressive disorder

ICD-10 code
F33.2
ICD-10 code description
Major depressive disorder, recurrent severe without psychotic features

Primary outcomes

1

Description
positive and negative affect
Timepoint
Before and immediately after the intervention
Method of measurement
PANAS Emotional Experiences Questionnaire

Secondary outcomes

1

Description
life satisfaction
Timepoint
before and immediately after intervention
Method of measurement
satisfaction with life scale

2

Description
suicidal ideation
Timepoint
before and immediately after intervention
Method of measurement
suicidal cognition scale

Intervention groups

1

Description
Intervention group: Receiving three sessions of positive psychotherapy through virtual reality, including teaching positive psychotherapy modules such as forgiveness, kindness and gratitude. These trainings for the intervention group will be done by virtual reality glasses and software designed specifically for these glasses. By using these glasses, the patient will be placed in a 3D and virtual environment and will also hear the voice of the psychotherapist who communicates with him through the headset. The content of the mentioned century will be played three times for the patient on different days and the patient will complete the questionnaires before and after the intervention.
Category
Other

2

Description
Control group: Receiving three sessions of positive psychotherapy including modules of kindness, gratitude and forgiveness in person and face to face.The patient will receive the mentioned trainings by the project's partner, a senior psychiatric nursing student, in person and in three sessions. These patients will also complete the questionnaires before and after the end of the intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne Sina Hospital
Full name of responsible person
Kimia Bahman
Street address
Shiraz, Hafez street, 8th Street
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2

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpoor

Street address
Zand St., Central Building of Shiraz University of Medical Sciences, 7th floor, Vice Chancellor for Research and Technology
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7134814336
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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz University of Medical Science

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
Dr Maryam Shaygan
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Iran, Shiraz, Namazi Square, Namazi Teaching Hospital, Fatemeh PBUH School of Nursing and Midwifery, Building 3, 2nd Floor, Community-based Psychiatric Care Research Center
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Person responsible for scientific inquiries

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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

Anonymous study data will be shared in correspondence with the project manager

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Systematic reviews and meta-analyses

From where data/document is obtainable

Contact via email

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

After obtaining permission from the security unit and the university's vice chancellor for research, the data will be made available to the individual.

Comments