

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Investigating the effectiveness of immersive virtual reality based relaxation in reducing the stress of substance abuse patients undergoing detoxification

Protocol summary

Study aim

Investigating the effectiveness of immersive relaxation based on virtual reality in reducing the stress of substance abuse patients undergoing detoxification

Design

Clinical trial with repeated measures, parallel-group, single-blinded, randomized on 60 patients, random list generator app used for randomization

Settings and conduct

A clinical trial will take place in a university medical center using a single-blind sampling method. Participants will be informed of the study's objectives, but will not be told which scenes they will be watching. Invited individuals will be screened for eligibility, with those meeting the criteria randomly assigned to one of three groups of 20 people. The first group will watch nature scenes for 12 minutes using virtual reality, while the second group will watch city scenes for the same duration. The third group will take a pre-test and post-test with timing equivalent to the first two groups. Questionnaires will be administered before and after viewing the scenes, alongside recording of physiological data.

Participants/Inclusion and exclusion criteria

Age between 18-50 years, no neurological disorders, absence of psychotic disorders, and being under detoxification from opioid substances

Intervention groups

During the study, nature scenes were displayed for 12 minutes to the intervention group, while the control group viewed city scenes for the same duration through a virtual reality device. Additionally, a third group underwent pre-test and post-test assessments, as well as physiological recordings, without being exposed to the virtual reality device, using the same timing as the other two groups.

Main outcome variables

Intensity of perceived stress; scores of positive and negative affects; heart beat; skin conductance; Abdominal breathing rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220316054306N2**

Registration date: **2023-09-16, 1402/06/25**

Registration timing: **retrospective**

Last update: **2023-09-16, 1402/06/25**

Update count: **0**

Registration date

2023-09-16, 1402/06/25

Registrant information

Name

Shahab Lotfinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

lotfiniashahab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-27, 1402/06/05

Expected recruitment end date

2023-09-13, 1402/06/22

Actual recruitment start date

2023-08-27, 1402/06/05

Actual recruitment end date

2023-09-13, 1402/06/22

Trial completion date

empty

Scientific title

Investigating the effectiveness of immersive virtual reality based relaxation in reducing the stress of substance abuse patients undergoing detoxification

Public title

Investigating the effectiveness of virtual reality based relaxation in reducing the stress

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-50 years Do not have any neurological disorders Do not have any psychotic disorders Being under detoxification

Exclusion criteria:**Age**

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A code will be assigned to the people entering the study, and then each code will be randomly assigned to a group using the random list generator tool.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the participants were blinded in this study, but both groups were given an explanation of the purpose. However, they were unaware of the difference in the virtual reality images they received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethic committee of Shahid Beheshti University of

Medical Science

Street address

Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2023-08-27, 1402/06/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.303

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

Opioid abuse

ICD-10 code

F11.10

ICD-10 code description

Opioid abuse, uncomplicated

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

Negative and positive affects based on scores on positive and negative affect schedule

Timepoint

Before and after intervention

Method of measurement

Positive and Negative Affect Schedule

2**Description**

Perceived stress score

Timepoint

Before and after intervention

Method of measurement

Cohen's perceived stress scale

3**Description**

Heart rate

Timepoint

During 12 minutes of intervention

Method of measurement

Procomp-5 with ECG/EKG sensor

4**Description**

Abdominal breath rate

Timepoint

During 12 minutes of intervention

Method of measurement

Procomp-5 with respiration sensor

5**Description**

Skin conductance

Timepoint

During 12 minutes of intervention

Method of measurement

Procomp-5 with Skin Conductance sensor

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Relaxation-based virtual reality. The patients have been using a virtual reality device to view nature scenes for 12 minutes.

Category

Treatment - Devices

2**Description**

Control group: Intervention group: Relaxation-based virtual reality. The patients have been using a virtual reality device to view city scenes for 12 minutes.

Category

Other

3**Description**

Control group: The patients in this group received the pre-test and post-test with the same timing as the intervention group, but without using the virtual reality device.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Taleghani Hospital

Full name of responsible person

Shahab lotfinia

Street address

Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahab

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sam Kianimoghadam

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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

Undecided - It is not yet known if there will be a plan to make this available