Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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

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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
Negetive 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
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Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Afshin Zarghi
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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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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