Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of aversive therapy using virtual reality on drug craving, depression and self-efficacy in patients under methadone maintenance treatment `

Protocol summary

Study aim

Investigating aversion therapy using virtual reality on cravings, depressive symptoms and self-efficacy of addiction withdrawal in patients undergoing maintenance treatment with methadone in 2014

Design

It is agreed with all 99 patients that during the 12 weeks of the intervention, . Acker has a positive addiction test with any type of drug. , will be excluded from the study and will be analyzed with the Intention-to-Treat protocol. All the people who enter the study, in addition to the demographic questionnaire, the momentary craving measurement questionnaire (DDQ); Bramson addiction withdrawal self-efficacy questionnaire; Beck depression questionnaire; They are completed and measured once before entering the study and once after 12 weeks of the study.

Settings and conduct

Kashan Medical Sciences

Participants/Inclusion and exclusion criteria

Conditions for entering the study: Clients should visit the clinic at least once a week Clients are on a fixed dose of methadone maintenance treatment for at least 3 months or more Clients are willing to participate in the project and complete the treatment consent form Have at least reading and writing literacy Have the ability to speak and communicate Absence of severe vision and hearing problems Absence of severe and frequent headaches No history of mental illness, epilepsy and malignant diseases Suffering from all types of phobias Suffering from symptoms of stimulant use and drug poisoning Under the treatment of a psychiatrist specialist for all kinds of cognitive and psychosomatic disorders

Intervention groups

Then the people will be randomly divided into 3 groups receiving methadone and people receiving methadone and psychological counseling of the center, individual undergoing aversion therapy intervention with virtual reality (VR), and methadone.

Main outcome variables

Consequences of cravings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240429061588N1**
Registration date: **2024-05-01, 1403/02/12**
Registration timing: **prospective**

Last update: **2024-05-01, 1403/02/12**
Update count: **0**

Registration date

2024-05-01, 1403/02/12

Registrant information

Name

Nasim Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2237 9431

Email address

drsadeghi6@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2024-05-30, 1403/03/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of aversive therapy using virtual reality on drug craving, depression and self-efficacy in patients under methadone maintenance treatment `

Public title
The effect of virtual reality in the treatment of addiction
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Clients should visit the clinic at least once a week Age 25 to 55 years Clients are on a fixed dose of methadone maintenance treatment for at least 3 months or more Clients are willing to participate in the project and complete the treatment consent form Have at least reading and writing literacy Have the ability to speak and communicate Absence of severe vision and hearing problems Absence of severe and frequent headaches No history of mental illness, epilepsy and malignant diseases Do not have any type of phobia Do not suffer from the symptoms of stimulant use and drug poisoning Not under the treatment of a psychiatrist for all kinds of cognitive and psychosomatic disorders
Exclusion criteria:
Unwillingness to cooperate at any stage of the plan Urine test for morphine, amphetamine and hashish is checked three times for each person during the study, and if the test is positive, the person is excluded from the study. Having psychotic symptoms Pregnant women Use of special psychiatric or neurological drugs affecting cognition, such as antipsychotics
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
After the purposeful selection of samples, the randomization of the division of groups is done using Random allocation software and based on the table of random numbers. Also, the website (https://www.sealedenvelope.com) is a useful site for generating a random sequence for randomization of It is a block type; And it will be comparable.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research Faculty of Medicine and Dentistry - Kashan University of Medical Scienc
Street address
Ghotb ravandi Blv,
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2024-04-07, 1403/01/19
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1403.007

Health conditions studied

1

Description of health condition studied
Substance Use disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
DDQ momentary consumption craving measurement - in the consumption craving questionnaire, the number 0 indicates the absence of an experience or feeling and the number 5 indicates the maximum presence of an experience or feeling.
Timepoint
12 weeks
Method of measurement
All people who enter the study, in addition to the demographic questionnaire, the momentary craving measurement questionnaire (DDQ); Bramson addiction withdrawal self-efficacy questionnaire; Beck depression questionnaire; They are completed and measured once before entering the study and once after 12 weeks of study. The virtual reality intervention was done once a week for about 6 minutes for the people who entered this part of the study; And the exams and the process of

increasing or decreasing the points are finally checked and compared. In this way, the score of each person subjected to instrumental intervention is known at the end of each week, and it is announced to them.

Secondary outcomes

1

Description
It has no variable consequences
Timepoint
They are completed and evaluated once before entering the study and once after 12 weeks of the study
Method of measurement
Beck Depression Inventory (BDI) This questionnaire, which contains 21 questions, was created by Beck et al. in order to measure the feedback and symptoms of depressed patients. The drug was designed and used by Bramson (1999), it consists of 16 questions. According to Bramson's instructions regarding how to score, the answers were determined in the form of seven options and using a Likert scale (one point for each scale) as follows: 1-definitely no 2-probably no 3-maybe no 4- I can't say 5-Maybe yes 6-Possibly yes 7-Definitely yes The score range of this questionnaire was between 16 and 112.Scores are measured and compared once before the start of the study and once after 12 weeks

Intervention groups

1

Description
Intervention group: 33 study intervention participants are justified for a period of 12 weeks not to change their normal physical and nutritional activities during this period of study. Patients are evaluated once a week by a free urine addiction test and the patients' non-slip test by a trained expert. is controlled.This intervention can be done with virtual reality glasses. Therefore, its tools are a three-dimensional display similar to the combination of large glasses with a hat. There are two very small monitors in it that cover a wide field of viewThe visualization for this intervention in this software is not adapted and has an atmosphere that reminds of the conditions for consuming morphine, heroin, or hashish, and is covered with old clothes and sitting and messy dishes that create a feeling of numbness and discomfort. It induces the person and the possibility and conditions of abstinence and staying away from substances are embedded in it.The main character who is a patient of addiction, by choosing the right and folding clothes, arranging the room, has a clean house, he knows that he has done abstinence, and also by destroying the tools of use, he adds to the score of the user, if the patient is towards drug use and touching the tools with the intention of use. Broad misses the chance to score from it. And the troubling images of Trustak will also see the condition of a patient with severe addiction and its side effects, which is disgusting and will receive strange and scary sounds .
Category
Treatment - Devices

2

Description
Intervention group: The second intervention: 33 addiction patients who receive psychological counseling during the study period, the discussions are conducted by a counselor. The psychological counselor is a senior psychology expert who has completed MMT methadone therapy, CBT and schema therapy.
Category
Lifestyle

3

Description
Intervention group: Intervention group: Third intervention: 33 patients using methadone with a routine dose in maintenance treatment are subjected to methadone intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Methadone addiction treatment center under the supervision of the vice president of Kashan Universit
Full name of responsible person
Dr.Nasim Sadeghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
All the financial resources of this research were independently provided by the researcher Dr. Nasim Sadeghi. International Pardis University is non-profit and has not accepted any fees.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Fateme Sadat Ghoreishi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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 materials related to the research and documents that can be published in the form of a full article will be published in the open ACCESS journal, only the names of the participants in the research will be avoided.

When the data will become available and for how long

Information and processing will be available in magazines from January 2025

To whom data/document is available

All people interested in the science of addiction and virtual reality

Under which criteria data/document could be used

This study can be used with the aim of preventing the waste of time and money resources on addiction treatment and virtual reality and metaverse projects that are not yet complete or have not been completed. During the pilot implementation of this plan, the shortcomings and problems in the implementation are identified and investigated so that the next study plan can be completed. The pilot of this study is a very good option to evaluate the performance of the system, because this type of study can be implemented at a faster rate and at a lower cost in the future.

From where data/document is obtainable

Contact the Correspondents via email

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

The request is sent to the responsible author via e-mail. After consulting with the professor or the first person of the article, the author provides the authorized data

Comments

Hoping to prevent and treat addiction