Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of mobile application (Neuro-Rehab App)including working memory training and inhibitory control training in opioid craving impulse control, and cognitive function of patients with opioid use disorder undergoing methadone maintenance treatment

Protocol summary

Study aim
investigating the effectiveness of mobile application (Neuro-Rehab App) including working memory training and inhibitory control training in opioid craving impulse control, and cognitive function of patients with opioid use disorder undergoing methadone maintenance treatment

Design
Two arms parallel group Randomized trial, superiority, with blinded outcome assessment

Settings and conduct
In Mashhad's educational research and treatment center for drug use disorders and addictive behaviors, the temptation to use test, the reading of Wechsler's impulsivity and Bart's scores are taken by a person who is not aware of the groupings. The application will be provided to the intervention group and how to work with it will be explained to them.

Participants/Inclusion and exclusion criteria
Age between 18 to 49; history of opium use; having smartphone with android system at least 6; Being under methadone maintenance treatment

Intervention groups
After placing the participants in the target groups, an interview session is conducted with the intervention group. The application will be provided to them and they will be asked to practice it for at least 60 to 90 minutes a week for 4 weeks.

Main outcome variables
Impulsivity Craving Working memory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171031037145N3**
Registration date: **2023-09-22, 1402/06/31**
Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**
Update count: **0**

Registration date
2023-09-22, 1402/06/31

Registrant information

Name
Farshad Sheybani

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3711 2721

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of mobile application (Neuro-Rehab App)including working memory training and inhibitory

control training in opioid craving impulse control, and cognitive function of patients with opioid use disorder undergoing methadone maintenance treatment

Public title
Effects of mobile app cognitive rehabilitation on addiction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a smart phone Undergoing methadone maintenance treatment Eager to participate in this study
Exclusion criteria:
Age out of range 18 to 49 years Having diseases such as Down syndrome Gender other than male, female, or trans
Age
From **18 years** old to **49 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
This is how the research is randomized: The first step is to create a random sequence. In this research, simple randomization will be used. Randomization based on a single sequence of random allocations is called simple randomization. The randomization unit in this study is individual. There are various randomization tools for this type of randomization, which in this research uses a table of random numbers. Random number table is a set of numbers that are generated without a pattern and with a specific order and in a completely random way and have become a table. Here's how to make a random sequence: First, read the numbers We specify that two are from above. Numbers can be considered for different groups. Here, even numbers obtained from this table are assigned to the control group and odd numbers to the intervention group. Then we place our fingers on one of the numbers in the table and act according to the described process (ie we move upwards 2) and record the numbers and assign them to the control or intervention group according to their individuality or evenness. Let's. The next step, called concealment, refers to the method used to execute random sequences on subjects so that the assigned group is not known before the individual is assigned To hide in this study, opaque sealed envelopes or random sequences will be used. In this method, a random sequence is performed, which is done here by a table of random numbers. Then, based on the sample size (50 people), a number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the envelope lids are glued and placed in a box, respectively. At the beginning of the registration of the subjects, according to the order of entry of the eligible participants into the study, one of the envelopes was opened in order and the assigned group of the participant was revealed.
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 of Mashhad University of Medical Sciences
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri ۹۴) – Mashhad - Iran
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Approval date
2022-04-24, 1401/02/04
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.018

Health conditions studied

1

Description of health condition studied
Opioid related disorders
ICD-10 code
F11
ICD-10 code description
Opioid related disorders

Primary outcomes

1

Description
Impulsivity
Timepoint
Before starting the study and after the end of the study
Method of measurement
Barrett impulsivity questionnaire

Secondary outcomes

1

Description
Comparison of the average latency of the correct response (average response time) in the attention game in the first week with the average speed of the correct response in the attention game in the fourth week
Timepoint
Percentage ratio of incorrect answers to all answers in the attention and concentration game of the Neuro-Rehab application
Method of measurement
The information about the amount and performance of the participants is recorded in the central server and the necessary comparisons of the performance are made by the server manager

Intervention groups

1

Description
Intervention group: The neuro rehab application will be available to them for four weeks, and before that, how it works will be explained to them in a training session with two exercises of the application. And the participants will be advised to practice it for at least 60 to 90 minutes a week in order to get the most benefit. The application exercises, which are mainly based on strengthening working memory and inhibitory control, are adjusted to reduce their difficulty according to the performance of the participants.
Category
Rehabilitation

2

Description
Control group: They only receive methadone maintenance treatment.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad's educational research and treatment center for drug use disorders and addictive behaviors
Full name of responsible person
Reza Emran
Street address
No 26, ladan 18 Ave, Vakilabad Blv, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Mohebati
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Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri ۹۴) – Mashhad - 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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Reza Emran
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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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
Not applicable
Informed Consent Form
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the main outcome or similar can be shared.
When the data will become available and for how long
1 month
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to facilitate further research
From where data/document is obtainable
Correspondence with the person responsible for the research at the following address:Reza.emran66@gmail.com
What processes are involved for a request to access data/document
This process is done only by e-mail and a response will be given within a week.
Comments