

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 51 3711 2721

Email address

farshad.sheybani@gmail.com

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

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۷۷۸-۹۹۱۹۱

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, Iadan 18 Ave, Vakilabad Blv, Mashhad, Iran

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9179974359

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Email

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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 Mohebaty

Street address

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MouhebatyM@mums.ac.ir

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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farshad Sheybani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Psychology

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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