

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of intervention based on working memory rehabilitation on reducing craving for drugs

#### Protocol summary

##### Study aim

The effect of working memory rehabilitation treatment with methadone on drug craving in people with a history of opium use and its derivatives.

##### Design

A clinical trial with a control group, randomized by sampling method available on 50 patients. SPSS software is used for randomization.

##### Settings and conduct

At the Addiction Treatment Center, after placing the subjects in the desired groups, each subject was first repeated by the WHO Questionnaire of Periodicity and Consumption and Quality of Life and the severity of substance dependence and three subtests of mental control. The figures will be evaluated forward and reverse and the learning of Wechsler memory associations will be measured and their craving will be measured. Immediately after the evaluation of the first session, working memory training will be performed. The number of sessions is 10 and it takes place twice a week, which will cover a total of 5 weeks. In each training session, the person performs working memory exercises.

##### Participants/Inclusion and exclusion criteria

A history of at least 12 months of opioid use disorder based on DSM-5 diagnostic criteria prior to treatment. • Age 18 to 50 years. • Male gender. • Cycle education.

##### Intervention groups

Cognitive rehabilitation treatment

##### Main outcome variables

Craving rate; The degree of dependence on substance use; Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210220050424N1**

Registration date: **2021-05-26, 1400/03/05**

Registration timing: **prospective**

Last update: **2021-05-26, 1400/03/05**

Update count: **0**

##### Registration date

2021-05-26, 1400/03/05

##### Registrant information

###### Name

Seyyede faeghe Alipoor poori

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3239 3363

###### Email address

faeghe.ap1995@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-30, 1400/03/09

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intervention based on working memory rehabilitation on reducing craving for drugs

##### Public title

The effect of working memory rehabilitation on reducing craving

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Subjects should have a history of methadone use of at least one year. Subjects must have at least a degree in the cycle. Subjects should be eager to attend and attend meetings.

### **Exclusion criteria:**

Subjects have illness and psychotic symptoms. Subjects are less than 18 years old and more than 50 years old. Subjects should be absent for more than two sessions.

## **Age**

From **18 years** old to **50 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 university of social welfare and rehabilitation sciences

##### **Street address**

No 149, ammar 5 street, komeyl gharbi 7 street, salehin place, Babol Town, Mazandaran Province

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

۴۷۱۵۷۱۵۹۳۴

#### **Approval date**

2021-05-15, 1400/02/25

#### **Ethics committee reference number**

IR.USWR.REC.1400.013

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Addiction

#### **ICD-10 code**

F11

#### **ICD-10 code description**

Opioid related disorders

## **Primary outcomes**

### 1

#### **Description**

The primary outcome can be a craving score in craving questionnaires

#### **Timepoint**

For the experimental group for 5 weeks and two sessions per week and for the control group, the post-test is performed 5 weeks after the pre-test.

#### **Method of measurement**

Craving Questionnaire, Periodic Craving Questionnaire,

## 2

### **Description**

The primary consequence may be the improvement in quality of life following the rehabilitation of working memory.

### **Timepoint**

For the experimental group for 5 weeks and two sessions per week and for the control group, the post-test is performed 5 weeks after the pre-test.

### **Method of measurement**

World Health Organization Quality of Life Questionnaire, Revised Wechsler Memory Scale

## 3

### **Description**

The primary consequence may be a reduction in the severity of substance dependence.

### **Timepoint**

For the experimental group for 5 weeks and two sessions per week and for the control group, the post-test is performed 5 weeks after the pre-test.

### **Method of measurement**

substance dependence severity scale

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: Working memory rehabilitation treatment, After placing the subjects in the target groups, each of the subjects was first repeated the questionnaires by means of periodic cravings and cravings questionnaires and quality of life of the World Health Organization and the severity of substance dependence and three sub-tests of mental control. Forward and reverse and learning Wechsler memory associations will be evaluated and their craving will be measured. Immediately after the evaluation of the first session, working memory training is done. The number of sessions is 10 sessions and it takes place twice a week for a total of 5 weeks. In each training session, the person performs working memory exercises. The person will have freedom of action in the order of presenting the exercises, but he must do all the exercises completely in each session. The amount of time for each exercise is 3 to 4 minutes. Each training session is 1 hour for each subject, taking into account the rest time. The program is step-by-step and adaptive, so that in each effort, process and difficulty of the program, each individual's capacity and ability is matched separately. In fact, the degree of difficulty in each exercise is classified from 1 to 9, and the person can choose the desired degree of difficulty at the beginning of each exercise and start training from that degree, but after starting the exercise, the degree of difficulty Auto goes higher and allows you to use the maximum working memory capacity for more practice.

The software provides the user with the amount of points earned as feedback from the exercise And for each correct attempt, 20 points are added to the total points, and for each error attempt, 10 points are deducted, and if you get 100 points, the difficulty level of the training is one degree. increase. This training program is designed in such a way that in each part, by providing appropriate visual and auditory feedback and recording the scores and execution time of each stage, the person is guided step by step and helps to improve his working memory.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: Control group members; First, they were assessed by the World Health Organization's periodic cravings and cravings and quality of life questionnaires and the severity of substance dependence and three subtests of mental control, repetition of forward and reverse digits and learning Wechsler memory associations and the amount of craving. They will be measured and pre-tested, after 5 weeks without any intervention, they will be measured again by the same instruments and the post-test will be performed.

### **Category**

Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

rahe sabz center

#### **Full name of responsible person**

Dr.Ahmad Bagherpoor

#### **Street address**

Shahid Soleymani square

#### **City**

Babol

#### **Province**

Mazandaran

#### **Postal code**

4715715934

#### **Phone**

+98 11 3239 3363

#### **Email**

Faeghe.ap1995@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

University of social welfare and rehabilitation sciences

#### **Full name of responsible person**

Hamidreza Khanke

#### **Street address**

Daneshjoo Blvd, Evin, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713871

**Phone**

+98 21 2218 0083

**Email**

pr@uswr.ac.ir

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

Yes

**Title of funding source**

University of social welfare and rehabilitation sciences

**Proportion provided by this source**

1

**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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

seyyede Faeghe Alipour pouri

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

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**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**

The data is analyzed as a group and there is no need to publish the data individually.

**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**

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

**Title and more details about the data/document**

It is not necessary to share data separately because they are analyzed in groups. Group data analysis can be shared.

**When the data will become available and for how long**

Access period starts 6 months after printing

**To whom data/document is available**

Researchers in academic institutions after completing and publishing the dissertation

**Under which criteria data/document could be used**

Only if you are trustworthy and follow moral principles

**From where data/document is obtainable**

ایمیل : faeghe.ap1995@gmail.com

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

After completing the work and defending the dissertation and publishing the article, they can contact the researcher by email.

**Comments**