Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effect of occupational therapy intervention in area of leisure on occupational performance and balance in abstinent person with substance use disorders

Protocol summary

Study aim

Investigation the effect of occupational therapy intervention in area of leisure on occupational performance and balance in abstinent person with substance use disorders

Design

The clinical trial is a single blind , with parallel groups, and divided into two groups as a block randomization.

Settings and conduct

The interventions will be implemented in a group and within a period of 2 months. According to the nature of the interventions, and if necessary facilities are available, recreation centers (Enghelab Cultural and Sports Complex) are the main place to provide these interventions.

Participants/Inclusion and exclusion criteria

1- Absence of central nervous system diseases 2- Minimum period of abstinence from any substance and alcohol for a period of 15 days 3- Age range of 18-50 years 4- Absence of any psychiatric diagnosis based on DSM-5 diagnostic criteria 5- Absence of obvious movement problems 6- No history of head injury with loss of consciousness or seizures 7- Not taking drugs that disrupt the central nervous system

Intervention groups

1- Conventional interventions :which are usually the administration of agonist drugs such as methadone and buprenorphine. There will also be regular medical and psychological counseling sessions. 2- Leisure time interventions: In this intervention method, the leisure-based intervention group is presented with a list of leisure occupations and asked to choose the ones of interest. The selected leisure will be considered as therapeutic interventions and will be carried out according to the schedule.

Main outcome variables

1- Occupational balance, which is an experience of having a sufficient amount (neither too much nor too little) of occupation in sufficient variety that is accompanied by a feeling of satisfaction in the individual. 2- Occupational performance, which is the level of participation of a person in daily life occupations.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010806N11**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **retrospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

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Malahat Akbarfahimi
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of occupational therapy intervention in area of leisure on occupational performance and balance in abstinent person with substance use disorders

Public title

leisure and substance use disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of central nervous system diseases (stroke, multiple sclerosis, Parkinson's, etc., according to observations and medical records) Minimum period of abstinence from any substance and alcohol for a period of 15 days Age range of 18-50 years Absence of any psychiatric diagnosis based on DSM-5 diagnostic criteria Absence of obvious movement problems (according to observation and medical record) No history of head injury with loss of consciousness or seizures (according to observation and medical record) Not taking drugs that disrupt the central nervous system (medical history and doctor's confirmation)

Exclusion criteria:

Substance abuse The person's unwillingness to answer questions or attend the intervention session Receive cognitive rehabilitation treatments at the same time

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of the block randomization type. Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. In this clinical trial, we will have blocks of equal size (blocks of 4 including 2 people in the conventional treatment group, 2 people in the leisure-based intervention). All the people in the two groups received the conventional interventions of addiction treatment centers, while the second group also received leisure timed interventions. At first, 4 blocks were prepared as (AABB, ABAB, ABBA, BBAA, BABA, BAAB). Then 12 of these blocks are randomly selected and people are assigned to two groups B and A; And this work continues until the completion of the blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the evaluator in all three stages of evaluation (before interventions, after interventions and follow-up) is unaware of the study groups. The research team and the participants are aware of the research groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway, next to the milad hospital

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Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-11-02, 1401/08/11

Ethics committee reference number

IR.IUMS.REC.1401.623

Health conditions studied

1

Description of health condition studied

Substance use disorders

ICD-10 code

F19.1

ICD-10 code description

Other psychoactive substance abuse

Primary outcomes

1

Description

occupational balance score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up

period

Method of measurement

Occupational balance questionnaire

2

Description

occupational performance score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Occupational performance questionnaire

Secondary outcomes

1

Description

leisure score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Leisure time questionnaire

2

Description

Quality of life score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Quality of life questionnaire(36-Item Short-Form Health Survey)

3

Description

drug craving score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Drug desire questionnaire

4

Description

Executive function score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Dysexecutive questionnaire

5

Description

Time management score

Timepoint

1- Before the start of the intervention, 2- After the end of the interventions, 3- After the two-month follow-up period

Method of measurement

Assessment of Time management skills questionnaire

Intervention groups

1

Description

Control group: This group receives the conventional interventions of drug cessation centers. Treatment measures of withdrawal centers in our country are usually prescription of agonist drugs such as methadone and buprenorphine to reduce withdrawal symptoms and drug cravings. Also, weekly medical and psychological consultation and examination sessions will be held for this group. During this research, there will be no interference in these interventions and the participants will take medicine according to the doctor's order and will participate in their meetings in the weekly schedule.

Category

Rehabilitation

2

Description

Intervention group: In addition to the conventional interventions of drug cessation centers, this group also receives leisure time interventions. The aim of leisure time intervention is to provide occupation in order to improve the individual's performance. In this intervention method, a list of leisure occupations is presented and they are asked to select the ones they like. The selected cases will be considered as therapeutic interventions and will proceed according to the schedule. The steps of designing and carrying out leisure time interventions are as follows: 1- Preparation of the list of leisure time occupations: In order to prepare the list of leisure time occupations, a library study will be done to check the available evidence and documentation in the field of types and ways of implementing leisure time occupations. Also, the results of the evaluations (Nottingham Leisure Questionnaire) are used to check people's leisure time interests. After gathering the information, the opinions of experts will be considered during meetings to finalize the leisure activities. In addition to the mentioned cases, the results of the qualitative evaluation of the research participants (results from the interview and the COPM test) will be considered in choosing the final list of leisure occupations. It is attempted that as much as possible the leisure occupations presented in the final list are socially and culturally acceptable, accessible, affordable, feasible and safe. 2- Selection of occupations: After preparing the final list of leisure time occupations, during a group meeting with the presence of all members of the

intervention group, 9 occupations agreed upon by the group members will be selected as intervention. Elections will be based on the number of people's votes, and any activity that has the majority vote will be selected as an intervention. Finally, a table to specify the time and place of these interventions is compiled and adjusted with the consensus of all members of the intervention group and is provided to the people. 3- How to carry out the intervention: after choosing the occupations (interventions) and scheduling them, the implementation phase begins. The number of intervention sessions is 12, sessions 1, 2 and 12 will be in person or online and in line with education, and in the other 9 sessions The group does their chosen leisure activity. The interventions will be implemented in a group and within a period of 2 months. According to the nature of the interventions, and if necessary facilities are available, recreation centers (enghelab Cultural and Sports Complex) are the main place to provide these interventions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Chavan Occupational Therapy Center

Full name of responsible person

Zahra Morovati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Malahat Akbafahimi

Position

Master degree Occupational therapy- PhD of Cognitive neuroscience Science

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
After the end of the study, all data can be shared after de-identifying people.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
The data will be available to researchers of academic and scientific institutions.
Under which criteria data/document could be used
If possible, further statistical analysis of the data will be available .
From where data/document is obtainable
Dear Mrs. Dr. Malahat Akbarfahimi. Iran University of Medical Sciences - Faculty of Rehabilitation - Department of Occupational Therapy
What processes are involved for a request to access data/document
Sending an e-mail to Dr. Malahat Akbarfahimi.
Comments