Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Developing a clinical guideline for treatment of sex addiction and comparing its efficacy in individuals with and without a history of stimulant use.

Protocol summary

Study aim
Comparison of the effectiveness of the clinical guideline for the treatment of sexual addiction disorder in individuals with and without a history of stimulant use.

Design
A clinical trial with a control group, with factorial groups, one-way blind, randomized. A random number table was used for randomization.

Settings and conduct
This research will be conducted in Isfahan. Among the people who received a diagnosis of sexual addiction disorder based on a clinical interview and a hyper sexual behavior inventoy (HBI), 60 people were selected and placed in intervention and comparison groups. Then developed clinical guideline is implemented. After the performance, the subjects will be evaluated again with HBI and the results will be analyzed using the analysis of variance test with repeated data. In order to blind the study, after compiling the guideline, we use a placebo for the comparison groups. For this purpose, a similar intervention will be designed and presented for these groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include receiving a diagnosis of sexual addiction disorder and stimulant use disorder, and exclusion criteria include mental retardation, psychotic symptoms, bipolar disorder, acute suicidal ideation, opioid use, drug use, and any organic disorders such as a history of head trauma. Along with anesthesia, seizures, brain tumors, etc., which have led to cognitive and psychological disorders.

Intervention groups
Therapeutic guideline is administered for intervention groups and not for comparison groups. Subjects are randomly divided into intervention and comparison groups based on a table of random numbers. After the implementation of the guide, its effectiveness is compared in the two intervention groups and based on this, research hypotheses are confirmed or rejected.

Main outcome variables
Hyper sexual behaviors, Sexually addictive behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200905048628N1**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

Registration date
2021-01-01, 1399/10/12

Registrant information

Name
Arash Javaheri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3521 9079

Email address
ajavaheri68@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-30, 1399/09/10

Expected recruitment end date
2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing a clinical guideline for treatment of sex addiction and comparing its efficacy in individuals with and without a history of stimulant use.

Public title

Comparison of the effectiveness of the clinical guide for the treatment of sexual addiction disorder in individuals with and without a history of stimulant use

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

receiving a diagnosis of stimulant use disorder receiving a diagnosis of sexual addiction disorder

Exclusion criteria:

Existence of mental retardation Symptoms of psychosis Bipolar disorder Acute thoughts of suicide Opioid use Drug use Having any organic disorders such as a history of head trauma with anesthesia, seizures, brain tumors, etc., which has led to cognitive and psychological disorders.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People who enter the study are assigned to different groups based on the method of Balance Block Randomization. Mr. Arash Javaheri, a PhD student in addiction studies with a master's degree in clinical psychology, is in charge of randomization. When Mr. Javaheri evaluates the inclusion and exclusion criteria and obtaining informed consent, the people go to the receptionist of the medical center, who has a randomization table. The names of these people are recorded in the randomization table, respectively. A card is then given to the person with the randomization table code and the person's name written on the card. Subjects are required to carry this code with them whenever they refer for intervention or follow-up, and this is the basis for recording information in subsequent visits. The randomization method is simple and individual randomization unit. Using Excel software, the design consultant epidemiologist designed and plotted a balanced four-block table for study.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the study, after compiling the guide, we use a placebo for the comparison group, for this purpose, a similar intervention will be designed and presented for this group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Iran University of Medical Sciences

Street address

Room 503, Fifth Floor, Central Staff Building of Iran University of Medical Sciences, between Chamran and Sheikh Fazlollah, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.IUMS.REC.1399.945

Health conditions studied

1

Description of health condition studied

sexual addiction disorder, stimulant use disorder

ICD-10 code

F52.8

ICD-10 code description

Other sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

People who have a score of 53 or higher in the Hypersexual Behavior Inventory

Timepoint

Measuring the score of the Hypersexual Behavior Inventory before the intervention (pre-test), after the intervention (post-test) and 2-month follow-up

Method of measurement
Hypersexual Behavior Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: People with sexual addiction disorder; According to the handbook for guideline development (World Health Organization, 2012) and based on literature review, the clinical guide for the treatment of sexual addiction disorder in the form of 10 sessions of 90 minutes and one month follow-up will be developed and implemented as compilations of guidelines. The treatment will be done in the form of group therapy.
Category
Treatment - Other

2

Description
Intervention group 2: People with sexual addiction disorder and stimulant use disorder; According to the handbook for guideline development (World Health Organization, 2012) and based on literature review, the clinical guide for the treatment of sexual addiction disorder in the form of 10 sessions of 90 minutes and one month follow-up will be developed and implemented as compilations of guidelines. The treatment will be done in the form of group therapy.
Category
Treatment - Other

3

Description
Control group 1: People with sexual addiction disorder; For the control group, the placebo will be presented in the form of books and educational videos in the field of treatment of sexual addiction disorder.
Category
Placebo

4

Description
Control group 2: People with sexual addiction disorder and stimulant use disorder; For the control group, the placebo will be presented in the form of books and educational videos in the field of treatment of sexual addiction disorder.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid TC center
Full name of responsible person
Reyhaneh Mansouri Tehrani
Street address
5 km from Mahmoud Abad Road, Isfahan University of Technology Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Abbas Motevalian
Street address
Fifth Floor, Central Staff Building of Iran University of Medical Sciences, between Chamran and Sheikh Fazlollah, Hemmat Highway
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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
Arash Javaheri

Position
Phd student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Unit 3, Moghadam Building, next to Imam Hossein Mosque, Golestan Alley, Alley 69 (Shahid Zamani), Jay St.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be 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
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