

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of family-centered neuropsychological training interventions on reducing stress, marital incompatibility, drug craving and cognitive-emotional regulation of married drug-dependent clients

Protocol summary

Study aim

The aim of the current research is to show what therapeutic methods exist to reduce stress, marital incompatibilities, drug addiction and cognitive-emotional regulation, and that family-oriented neuropsychological training interventions reduce stress, marital incompatibility, drug addiction. Drugs and cognitive-emotional regulation of married clients dependent on drugs are effective.

Design

Clinical trial with control group, with factorial groups, single-blind, randomized, on 30 patients. A table of random numbers was used for randomization.

Settings and conduct

The study site was a hospital, patients admitted to the neuropsychiatric department, obtaining informed consent and placing them in two experimental and control groups. One-sided blinding that they are unaware of how to receive or not receive the treatment package of the other group.

Participants/Inclusion and exclusion criteria

1- having the diagnostic criteria of substance dependence based on DSM-5, 2-The person suffering from addiction must be at least 18 years old and at most 40 years old; 3-The level of education of the person suffering from addiction should be at least elementary; 4-The person is not taking antipsychotic drugs (such as haloperidol) and does not have bipolar or dissociative disorder.

Intervention groups

Experimental group: receiving the combined techniques of training sessions Control group: They will receive the usual treatment and will not participate in the researcher's training sessions.

Main outcome variables

Neuropsychological, family-oriented, stress, marital incompatibilities, drug addiction, cognitive-emotional

regulation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231204060264N1**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Hanieh Goli Rostami

Name of organization / entity

University of Tehran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of family-centered neuropsychological training interventions on reducing stress, marital incompatibility, drug craving and cognitive-emotional regulation of married drug-dependent clients

Public title
The effect of family-centered neuropsychological training interventions on reducing stress, marital incompatibility, drug craving and cognitive-emotional regulation of married drug-dependent clients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Having the diagnostic criteria of substance dependence based on DSM-5 The person suffering from addiction must be at least 18 years old and at most 40 years old The education level of the person suffering from addiction should be at least elementary The person is not taking antipsychotic drugs (such as haloperidol) and does not have bipolar or dissociative disorder
Exclusion criteria:
 Taking psychiatric drugs Not cooperating with the therapist Not doing the main tasks

Age
From **18 years** old to **40 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Available sampling method was used. Randomization method: simple randomization Randomization unit: cluster Randomization tool: table of random numbers In the first step, using available sampling, first the hospital was selected, then in the next step, married drug-dependent patients admitted to the neuropsychiatric department of the hospital were selected, and after the necessary explanations about the objectives of the research and the stages of the research, and obtaining consent With the knowledge of the participants, they were randomly assigned to the experimental and control groups using a table of random numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants were blinded. They will know that they have participated in a study, but they will not know how to receive or not receive the treatment package of the other group.

Placebo
Not used

Assignment
Factorial

Other design features
Designing a treatment protocol and package that is a combination of four treatments.

Secondary Ids

1

Registry name
000

Secondary trial Id
0

Registration date
2023-12-07, 1402/09/16

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University
Street address
 Shahid Chamran Highway - Jalal Al Ahmad St. - opposite Koi Nasr, Dr. Kardan St
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 Tehran
Province
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Postal code
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Approval date
2023-07-18, 1402/04/27

Ethics committee reference number
IR.UT.PSYEDU.REC.1402.037

Health conditions studied

1

Description of health condition studied
Addicted to drugs

ICD-10 code
F19

ICD-10 code description
Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Primary outcomes

1

Description
Stress: means the sum of scores that the respondents will get from answering questions 1 to 14 of Everly and Girdano's (1980) questionnaire.

Timepoint

The beginning of the study (before the start of the intervention) and after the end of the intervention and 90 days after the end of the intervention.

Method of measurement

Standard stress questionnaire

2

Description

Marital incompatibility: refers to the sum of scores that respondents will get from answering questions 1 to 32 of Spanier's (1976) questionnaire.

Timepoint

The beginning of the study (before the start of the intervention) and after the end of the intervention and 90 days after the end of the intervention.

Method of measurement

Marital incompatibility standard questionnaire

3

Description

Craving for drug use: it means the sum of scores that respondents will get from answering questions 1 to 14 of Franken, Hendricks, and VandenBernick (2002) questionnaire.

Timepoint

The beginning of the study (before the start of the intervention) and after the end of the intervention and 90 days after the end of the intervention.

Method of measurement

Standard substance craving questionnaire

4

Description

Cognitive regulation of emotion: it means the sum of the scores that the respondents will get from answering questions 1 to 36 of the Granfsky, Kraij and Spinhoven (2001) questionnaire.

Timepoint

The beginning of the study (before the start of the intervention) and after the end of the intervention and 90 days after the end of the intervention.

Method of measurement

Standard questionnaire of cognitive emotion regulation

Secondary outcomes

1

Description

Stress: means the sum of scores that the respondents will get from answering questions 1 to 14 of Everly and Girdano's (1980) questionnaire.

Timepoint

After the completion of the intervention and 90 days after the completion of the intervention.

Method of measurement

Standard stress questionnaire

2

Description

Marital incompatibility: refers to the sum of scores that respondents will get from answering questions 1 to 32 of Spanier's (1976) questionnaire.

Timepoint

After the completion of the intervention and 90 days after the completion of the intervention.

Method of measurement

Marital incompatibility standard questionnaire

3

Description

Craving for drug use: it means the sum of scores that respondents will get from answering questions 1 to 14 of Franken, Hendricks, and VandenBernick (2002) questionnaire.

Timepoint

After the completion of the intervention and 90 days after the completion of the intervention.

Method of measurement

Standard substance craving questionnaire

4

Description

Cognitive regulation of emotion: it means the sum of the scores that the respondents will get from answering questions 1 to 36 of the Granfsky, Kraij and Spinhoven (2001) questionnaire.

Timepoint

After the completion of the intervention and 90 days after the completion of the intervention.

Method of measurement

Standard questionnaire of cognitive emotion regulation

Intervention groups

1

Description

Intervention group: Family-centered neuropsychological therapy training for ten sessions

Category

Treatment - Other

2

Description

Control group: They will undergo the usual medical care and will not participate in the researcher's training sessions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar educational research and treatment center

Full name of responsible person

Dr Mohammad Kermani

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Golestan town, Amin Blvd., Kosar Medical Research Training Center

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Sponsors / Funding sources

1

Sponsor

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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?

No

Title of funding source

Semnan 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

University of Tehran

Full name of responsible person

Hanieh Goli Rostami

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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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

Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable