Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Designing and clinical trial of a therapeutic intervention for codependency disorder among codependent wives of Iranian opioid and/or stimulant users

Protocol summary

Study aim
To compare the effectiveness of the integrated codependency intervention, Community Reinforcement and Family Training (CRAFT), and psychoeducation based on the Matrix protocol on codependency levels and quality of life among spouses of individuals with substance use disorder.

Design
A randomised block clinical trial with three arms of 14 participants each (total 42). To reduce bias, block randomisation was performed using the SealedEnvelope website. After informed consent, participants randomly select a sealed envelope, assigning them to one of the groups. Allocation of envelopes to study centers is done by simple randomization.

Settings and conduct
Select substance use treatment clinics in Isfahan and Tehran

Participants/Inclusion and exclusion criteria
Minimum age of 18 years, having a spouse undergoing treatment for substance use, no current or past substance use disorder or acute psychosis based on DSM-5 criteria, scoring at least 52.6 on the Spann-Fisher questionnaire, and willingness to participate with informed consent.

Intervention groups
1)Integrated codependency intervention consisting of 11 sessions covering case history, motivational interviewing, understanding addiction and maladaptive behaviours, codependent roles, breaking dysfunctional family cycles, managing obsessive thoughts, problem solving, and emotion regulation. 2)Standard CRAFT therapy; 3)Psychoeducation based on the Matrix model. All groups have an equal number and duration of sessions.

Main outcome variables
Codependency scale in participants

General information

Reason for update

Acronym
CODE-SPUD

IRCT registration information
IRCT registration number: **IRCT20250718066537N1**
Registration date: **2025-07-31, 1404/05/09**
Registration timing: **prospective**

Last update: **2025-07-31, 1404/05/09**
Update count: **0**

Registration date
2025-07-31, 1404/05/09

Registrant information

Name
Seyed Ramin Radfar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Designing and clinical trial of a therapeutic intervention for codependency disorder among codependent wives of Iranian opioid and/or stimulant users

Public title
Clinical Trial of Codependency Treatment in Spouses of Individuals with Substance Use Disorders

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum age of 18 years Having a husband who uses opioids and/or stimulants and has entered treatment No current or past history of substance use disorder based on DSM-5 criteria No current acute psychotic disorder based on DSM-5 criteria A minimum score of 52.6 on the Spann-Fischer Codependency Scale Willingness to participate in the study and complete the informed consent form

Exclusion criteria:
Illiterate

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the practical limitations in enrolling all participants in the intervention and control groups simultaneously, we use block randomisation to assign participants. A total of 42 eligible participants who signed the informed consent form will enrol in a clinical trial involving three intervention arms: 1)Integrated Codependency Intervention, 2)Community Reinforcement and Family Training (CRAFT), and 3)Psychoeducational Group Therapy based on the Matrix protocol. Participants were randomly allocated to one of the three groups using block randomisation with blocks of size three, generated by the SealedEnvelope.com online system to minimise the risk of bias. The randomisation list was generated using the website's simulation tool. Each unique participant ID, along with the corresponding assigned group, will be placed in a separate, sealed, and opaque envelope. After signing the consent form, each eligible participant was asked to randomly draw an envelope, which, once opened, revealed the participant's ID and assigned group. The allocation was then confirmed and documented according to the pre-generated randomization list. Envelope sets were distributed to study centers using simple randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Keshavarz Blvd, Ibn Sina St

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Tehran

Province
Tehran

Postal code
1461884513

Approval date
2023-09-12, 1402/06/21

Ethics committee reference number
IR.TUMS.TIPS.REC.1402.078

Health conditions studied

1

Description of health condition studied
Co dependency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Codependency scale

Timepoint
At study entry, at the end of the study, and at weeks 4, 8, and 12 following the study termination

Method of measurement
Spann-Fisher Codependency Scale

Secondary outcomes

1

Description
Quality of life

Timepoint

At study entry, at the end of the study, and at weeks 4, 8, and 12 following the study

Method of measurement

WHO-QOL-BREF Questionnaire

Intervention groups

1

Description

Intervention group: Implementation of the treatment package for the Integrated Intervention for codependent individuals

Category

Lifestyle

2

Description

Control group: Community Reinforcement and family therapy (CRAFT)

Category

Lifestyle

3

Description

Control group: The psychoeducation group based on the Matrix treatment protocol

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Andisheh Niayesh Clinic

Full name of responsible person

Seyed Ramin Radfar

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

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Recruitment center

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

Not applicable

Title and more details about the data/document

De-identified data collected from study participants will be entered into a secure database. After publication of the study results, these data will be made available upon reasonable request to the corresponding author, provided that all personally identifiable information has been removed to ensure participant confidentiality.

When the data will become available and for how long

Following the publication of the articles resulting from the study

To whom data/document is available

Access to the data or study documentation may be granted to researchers with relevant or overlapping research interests, provided they submit a reasonable justification for their request.

Under which criteria data/document could be used

No specific restrictions apply to the use of the data, provided the source is properly cited.

From where data/document is obtainable

Requests for data should be directed to the corresponding author of the article(s) resulting from the study.

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

Data or documentation requests must be submitted in writing via email to the corresponding author of the article(s) resulting from the study. The request should include a clear introduction of the applicant, institutional affiliation, purpose of the request, and specific details regarding the data or documents being sought. Upon receipt, the research team will review the request within 10 business days. If approved, de-identified data will be prepared and shared. The estimated timeframe from submission to data delivery is approximately 2 to 4 weeks, depending on the complexity of the request. Access will only be granted if the intended use aligns with ethical standards and ensures participant confidentiality. Proper citation of the original publication is required in any secondary use of the data.

Comments