Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Divergent Effects of Opium Tincture Step-down Tapering (DST) versus Methadone Maintenance Treatment (MMT) on Sexual Function in Men with Opium Use Disorder: Evidence from a Comparative Trial

Protocol summary

Study aim

This study compared the effects of gradual stepwise treatment with opium tincture (DST) and methadone maintenance treatment (MMT) on sexual functioning in married men with opium dependence, given concerns about sexual dysfunction associated with opioid substitution therapy.

Design

A phase III, randomized, open-label, parallel-group controlled clinical trial involving 60 patients. Simple randomization was performed using a lottery method

Settings and conduct

A four-group quasi-experimental study with a pretest–posttest–follow-up design was conducted among 60 married men with opium use disorder recruited through purposive sampling at Shafa-ye Sabz Treatment Center. Participants were randomly allocated to four groups of 15 each: gradual stepwise treatment (DST), cognitive behavioral therapy (CBT), methadone maintenance treatment (MMT), and a control group. Treatment readiness, sexual functioning, and self-control were assessed at three time points: pretest, posttest, and follow-up.

Participants/Inclusion and exclusion criteria

Opium dependence, male gender, married status, no severe psychosis or cognitive impairment, no concurrent treatment, informed consent, regular attendance, and adherence to medication protocol. Premature treatment discontinuation, incomplete questionnaires at any assessment, and use of other substances during treatment.

Intervention groups

DST group (Dezhakam Step Time; gradual stepwise reduction) MMT group (Methadone Maintenance Treatment) CBT group (Cognitive Behavioral Therapy) Control group (without structured intervention)

Main outcome variables

Treatment Readiness: All three interventions (DST, CBT, and MMT) were equally effective. Sexual Functioning: DST was superior to all other groups; MMT showed worse outcomes than the control group. Self-Control: Only CBT was effective; DST showed no significant advantage.

General information

Reason for update

Acronym

DST,MMT

IRCT registration information

IRCT registration number: **IRCT20261018071471N1**
Registration date: **2026-10-19, 1405/07/27**
Registration timing: **retrospective**

Last update: **2026-10-19, 1405/07/27**
Update count: **0**

Registration date

2026-10-19, 1405/07/27

Registrant information

Name

Ali Shaker Dolgh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3344 0094

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ali.shaker2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-24, 1404/11/04

Expected recruitment end date

2026-06-25, 1405/04/04

Actual recruitment start date

2026-01-25, 1404/11/05

Actual recruitment end date

2026-06-28, 1405/04/07

Trial completion date

2026-06-29, 1405/04/08

Scientific title

Divergent Effects of Opium Tincture Step-down Tapering (DST) versus Methadone Maintenance Treatment (MMT) on Sexual Function in Men with Opium Use Disorder: Evidence from a Comparative Trial

Public title

The Effects of Opium Tincture Administered Through a Stepwise Gradual Reduction Method and Methadone on Sexual Function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Opium dependence diagnosed through a clinical interview in accordance with the DSM-5-TR criteria male gender being married absence of severe psychotic disorders or cognitive impairment no history of simultaneous participation in other similar treatment programs provision of informed consent and commitment to regular attendance o use of pharmaceutical medications outside the assigned treatment protocol

Exclusion criteria:

Severe psychotic disorders or cognitive impairment a history of concurrent participation in other similar treatment programs use of pharmaceutical medications outside the assigned treatment protocol

Age

From **20 years** old to **65 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple randomization. Four study groups were formed, and the four study conditions, including gradual stepwise treatment (DST), cognitive behavioral therapy (CBT), methadone maintenance treatment (MMT), and the control condition, were subsequently assigned to the groups by lottery. Randomization Unit: Study group. Randomization Tool: Lottery using paper slips bearing the names of the treatment conditions and the control condition. Random Sequence Generation: After the four participant groups had been formed, the names of the four study conditions, namely gradual stepwise treatment, cognitive behavioral therapy, methadone maintenance treatment, and the control condition, were written on separate paper slips. Each condition was then assigned to one of the four groups through a lottery-based procedure. Allocation Concealment: In this study, the treatment conditions were allocated to the groups through a lottery-based procedure. No separate procedure for allocation concealment was implemented apart from the lottery process.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Respected Ethics Committee of the Islamic Azad University, Urmia Branch

Street address

Department of Psychology, School of Humanities, Urmia Branch, Islamic Azad University, Urmia, West Azerbaijan Province, Iran

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Approval date

2026-04-21, 1405/02/01

Ethics committee reference number

IR.IAU.URMIA.REC.1405.013

Health conditions studied

1

Description of health condition studied

opioid sexual dysfunction

ICD-10 code

F11.181

ICD-10 code description

Opioid abuse with opioid-induced sexual dysfunction

Primary outcomes

1

Description

Total score on the Stages of Change Readiness and

Treatment Eagerness Scale (SOCRATES), comprising 19 items and three subscales: Recognition, Ambivalence, and Taking Steps. Responses are rated on a five-point Likert scale. Higher scores indicate greater readiness to change addictive behaviors.

Timepoint

Three assessments: baseline (before the intervention), post-test (immediately after completion of the three-month treatment period), and follow-up (at a specified interval after treatment completion)

Method of measurement

Self-report questionnaire completed by the participant in the presence of the researcher/therapist.

2

Description

Total score on the International Index of Erectile Function (IIEF), comprising 15 self-report items across five domains: erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. Total scores range from 0 to 75, with higher scores indicating better sexual functioning.

Timepoint

Three assessments: baseline (before the intervention), post-test (immediately after completion of the three-month treatment period), and follow-up (at a specified interval after treatment completion)

Method of measurement

Self-report questionnaire completed by the participant in the presence of the researcher/therapist.

3

Description

Total score on the Brief Self-Control Scale (BSCS), comprising 13 self-report items. Total scores range from 13 to 65, with higher scores indicating greater self-control/behavioral self-regulation.

Timepoint

Three assessments: baseline (before the intervention), post-test (immediately after completion of the three-month treatment period), and follow-up (at a specified interval after treatment completion).

Method of measurement

Self-report questionnaire completed by the participant in the presence of the researcher/therapist.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gradual Stepwise Reduction

Category

Treatment - Drugs

2

Description

Intervention group: Methadone Maintenance Treatment (MMT)

Category

Treatment - Drugs

3

Description

Intervention group: Cognitive Behavioral Therapy (CBT)

Category

Treatment - Drugs

4

Description

Control group: control

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa-ye Sabz Addiction Treatment Clinic

Full name of responsible person

Ms. Barkhordari

Street address

No. 948, 3rd Floor, Unit 12, Resalat Street, Farjam Street, Ayat Intersection, Sadaf Square.

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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
I had no source of funding.

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr.Ali.Shaker

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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

The data are recorded in written form on paper.

When the data will become available and for how long

Access will begin six months after publication.

To whom data/document is available

Researchers employed at academic and scientific institutions.

Under which criteria data/document could be used

There are no other specific conditions

From where data/document is obtainable

l.shabani.156@gmail.com

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

Please contact us only via email.

Comments