Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Guided smartphone-based treatment for patients in opioid maintenance treatment in Iran - transdiagnostic treatment for substance use and common mental disorders

Protocol summary

Study aim
To examine the effectiveness of a newly designed, culturally adapted, gender-sensitive, smartphone-based intervention based on a community-based reinforcement approach, motivational interviewing, and cognitive-behavioral therapy in patients undergoing opioid maintenance treatment with methadone and buprenorphine in Iran.

Design
After a detailed gender-sensitive iterative pilot and validation process, the final PROMPT version (Study arm 1) will be compared with OAT as usual (Study arm 2) in a randomized controlled trial (RCT) within 400 opioid-dependent patients at eight treatment centers.

Settings and conduct
Patients in the 8 addiction treatment center in Tehran who are under the treatment, were randomly assigned to the intervention group (OAT+smartphone intervention) and control group (OAT) based on the designed protocol.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: To provide written informed consent; Minimal age of 18 years; Positive urine test for morphine or tramadol; Diagnosis of opioid dependence (ICD-11); Stabilization on methadone or buprenorphine for at least 2 weeks and maximum 8 weeks; Ownership of a smartphone; Internet access; Good command of Persian; Appropriate geographical access to the study site in Tehran. Exclusion Criteria: Concurrent dependence on other substances (except nicotine); Current severe or acute psychiatric diseases.

Intervention groups
The intervention group will receive an integrated Community Reinforcement Approach, motivational interviewing, and CBT-based guided smartphone intervention (PROMPT) added to OAT as usual. The control group will receive OAT as usual, as in the intervention group, but without the smartphone intervention.

Main outcome variables
1-Percentage of negative urine tests for illicit, non-prescribed use of opioids 2- Retention in treatment and study

General information

Reason for update
Change planning for implementation

Acronym

IRCT registration information
IRCT registration number: **IRCT20170702034844N8**
Registration date: **2021-02-21, 1399/12/03**
Registration timing: **prospective**

Last update: **2025-12-22, 1404/10/01**
Update count: **2**

Registration date
2021-02-21, 1399/12/03

Registrant information

Name
Alireza Noroozi

Name of organization / entity
Iranian National Center for Addiction Studies (INCAS)

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-12-23, 1404/10/02

Expected recruitment end date
2026-12-23, 1405/10/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Guided smartphone-based treatment for patients in opioid maintenance treatment in Iran - transdiagnostic treatment for substance use and common mental disorders

Public title
Guided smartphone-based treatment for patients in opioid maintenance treatmen
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Written informed consent Minimal age of 18 years Stabilization on methadone or buprenorphine dosage for at least 2 weeks and a maximum of 8 weeks Ownership of a smartphone Good command of Persian Appropriate geographical access to the study site in Tehran Internet access Positive urine test for morphine or tramadol Opioid dependence based on ICD-11
Exclusion criteria:
Diagnosis of concurrent dependence on other substances (except nicotine) Current severe or acute psychiatric disorders.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants, after completing baseline assessment, will be randomized by an automated computer program into either the treatment or control group in a 1:1 ratio.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research School of Medicine - Tehran University of Medical Sciences
Street address
Building No. 1, Faculty of Medicine, First Floor, Office of the Vice Chancellor for Research, Ghods St., Enghelab St
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Postal code
1635713366
Approval date
2020-11-03, 1399/08/13
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.714

Health conditions studied

1

Description of health condition studied
Moderate to severe opioids use disorder
ICD-10 code
F11.2
ICD-10 code description
Opioid dependence

Primary outcomes

1

Description
The percentage of negative urine tests for illicit, non-prescribed use of opioids
Timepoint
Baseline and months 1 to 12
Method of measurement
Urine rapid test

2

Description
Retention in treatment and study
Timepoint
Months 1, 2, 3, 6, and 12
Method of measurement
Self-report and treatment record

Secondary outcomes

1

Description
Days of opioid use during last 7 days

Timepoint
Baseline and months 1 to 12
Method of measurement
Self-report Timeline Follow Back Questionnaire

2

Description
Days of street-drug use during last 7 days
Timepoint
Baseline and months 1 to 12
Method of measurement
Self-report TLFB Questionnaire

3

Description
Severity of opioid dependence
Timepoint
Baseline and months 1, 2, 3, 6 and 12
Method of measurement
Rapid urine test

4

Description
The longest period of abstinence from the illicit opioids
Timepoint
Months 1, 2 and 3
Method of measurement
Urine rapid test

5

Description
Score of communicable disease risk-taking behaviors
Timepoint
At the baseline and 3-, 6- and 12-month follow-up.
Method of measurement
Blood-borne Virus Transmission Risk Assessment Questionnaire BBV-TRAQ

6

Description
Score of perceived stress
Timepoint
At the baseline and 3-, 6- and 12-month follow-up.
Method of measurement
Perceived Stress Scale

7

Description
Score of depression
Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
Patient Health Questionnaire

8

Description
Score of anxiety
Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
Generalized Anxiety Disorder Questionnaire

9

Description
Score of Trauma
Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
International Trauma Questionnaire for PTSD

10

Description
Score of Alcohol Use Disorder
Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
Alcohol Use Disorder Identification Test (AUDIT-C Questionnaire)

11

Description
Score of Nicotine Dependence
Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
Fagerstrom Test for Nicotine Dependence Questionnaire

12

Description
Number of missed OAT appointments
Timepoint
Months 1, 2, 3, 6 and 12
Method of measurement
Physician report

13

Description
Score of Client Satisfaction
Timepoint
Months 1, 2, 3, 6 and 12
Method of measurement
Client Satisfaction Questionnaire

14

Description
Score of psychological treatment negative effects
Timepoint
Months 1, 2, 3, 6 and 12
Method of measurement
Negative Effects Questionnaire

15

Description
HIV results test

Timepoint
At the baseline and 3-, 6- and 12-month follow-up
Method of measurement
Blood Test

Intervention groups

1

Description
Intervention group: The intervention group will receive an integrated community reinforcement approach, motivational interviewing, and cognitive, behavioral treatment-based guided smartphone intervention (called PROMPT for Promoting Recovery in Opioid Maintenance and Psychosocial Treatments) added to opioid maintenance treatment (OMT).
Category
Behavior

2

Description
Control group: Control group will receive opioid maintenance treatment with methadone or buprenorphine based on national protocols.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian National Center for Addiction Studies' Clinic
Full name of responsible person
Alireza Noroozi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Swiss Research Institute of Public Health and Addiction (ISGF)
Full name of responsible person
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Konradstrasse 32 8005 Zurich, Swiss Research Institute of Public Health and Addiction ISGF, a WHO Collaborating Centre, associated with the University of Zurich
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Web page address
https://www.isgf.uzh.ch/de.html
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Swiss National Science Foundation
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
CH
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iranian National Center for Addiction Studies (INCAS)
Full name of responsible person
Alireza Noroozi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Eisa Naghizadeh

Position
Clinical psychologist (addiction therapist)

Latest degree
Master

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
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
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
It is planned to share IPD, study protocol and report of the clinical study.

When the data will become available and for how long
IPD will be shared after completion of the data gathering phase. Study protocol will be available within 3 months after successful registration of the trial. Report of the clinical study will be finalized at the end of study

To whom data/document is available
Clinical researchers

Under which criteria data/document could be used
IPD will be available for researchers who are conducting review studies. The study protocol and report will be published as English articles.

From where data/document is obtainable
Email to the individual who is responsible for scientific inquiries of this project

What processes are involved for a request to access data/document
It will be responded after processing within the project team.

Comments