

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The acceptability and effectiveness of a mobile-health intervention to improve adherence to treatment and medication for people living with HIV

#### Protocol summary

##### Study aim

The aim of this study is to assess the acceptability and effectiveness of a mobile-health intervention to improve adherence to treatment and medication for people living with HIV. The intervention will use text-messaging to provide support and counselling to patients. Adherence to anti-retroviral therapy will be measured through self report and clinical outcomes.

##### Design

This is a single-blinded (investigator blinded) Randomised Controlled Trial, with two parallel groups.

##### Settings and conduct

This trial will be based in the HIV/AIDS clinic in Iran. The investigators will be blinded to allocation of participants, however due to the nature of the intervention the participants cannot be blinded to the receiving of the intervention.

##### Participants/Inclusion and exclusion criteria

Patients will be eligible if they are 1) already receiving ART treatment, 2) aged 18 years or above, 3) own or have sufficient access to a mobile phone (shared access is allowed if access is daily and the phone owner agrees to participate), 4) are able to sufficiently operate a cell phone to communicate using mobile-messaging (help by a partner is sufficient for patients with reading and/or writing difficulties).

##### Intervention groups

Mobile messages will be sent to the intervention group to provide personalized support through counseling and reminders to improve adherence to medication. Adherence will be measured via self report, and confirmed through CD4-cell count and viral load tests.

##### Main outcome variables

Adherence to HIV treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100601004076N23**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **prospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

##### Registration date

2019-03-09, 1397/12/18

##### Registrant information

##### Name

Minoos Mohraz

##### Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6694 7984

##### Email address

minoomohraz@ams.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-04, 1398/01/15

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The acceptability and effectiveness of a mobile-health intervention to improve adherence to treatment and medication for people living with HIV

## Public title

MHealth for Antiretroviral adherence

## Purpose

Health service research

## Inclusion/Exclusion criteria

### Inclusion criteria:

All PLHIV will be eligible to participate if they are receiving ART aged 18 years or above own or have sufficient access to a mobile phone are able to sufficiently operate a cell phone to communicate using mobile-messaging (help by a partner is sufficient for patients with reading and/or writing difficulties)

### Exclusion criteria:

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Investigator
- Outcome assessor

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization procedure will follow CONSORT guidelines and occur after study enrollment and baseline data collection. The study will use a free web-based program for randomizing (e.g. SealedEnvelopeTM [www.sealedenvelope.com/freerandomiser/v1/](http://www.sealedenvelope.com/freerandomiser/v1/)). This will reduce the potential for allocation bias through correct sequence generation and allocation concealment. Researchers will notify participants about their allocation individually. Allocation of other participants will not be disclosed in order to reduce contamination bias.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Data collectors will be blinded to the participant allocation. However, due to the nature of this study, double blinding will not be possible as participants will know their allocation to the intervention group.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Tehran University of Medical Sciences

##### Street address

Central building of TUMS, Ghods St, Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

0123456789

#### Approval date

2018-11-10, 1397/08/19

#### Ethics committee reference number

IR.TUMS.VCR.REC.1397.558

## Health conditions studied

### 1

#### Description of health condition studied

HIV

#### ICD-10 code

B20

#### ICD-10 code description

Human immunodeficiency virus [HIV] disease

## Primary outcomes

### 1

#### Description

Adherence to HIV treatment

#### Timepoint

Every week

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Vira Load

#### Timepoint

At the end of intervention

#### Method of measurement

Lab Test

### 2

#### Description

CD4 Cell Count

#### Timepoint

At the end of the intervention

#### Method of measurement

Lab test

## Intervention groups

### 1

#### Description

Intervention group: Mobile messages will be sent to the intervention group to provide personalized support through counseling and reminders to improve adherence to medication. Adherence will be measured through self-report, and confirmed through CD4 and viral load tests.

#### Category

Behavior

### 2

#### Description

Control group: Adherence to the medication among the control group will be measured through self-report, and confirmed through viral load and CD4 cell tests. However, the control group will not receive the intervention through mobile messaging.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iranian Research Centre for HIV / AIDS

##### Full name of responsible person

Dr. Minoos Mohraz

##### Street address

The Department of Infectious and Tropical Diseases, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

14-19-733141

##### Phone

+98 21 6658 1583

##### Email

minoomohraz@ams.ac.ir

##### Web page address

<http://ircha.tums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Minoos Mohraz

##### Street address

Iranian Research Center for HIV/AIDS, Imam Khomeini Hospital, Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

0123456789

##### Phone

+98 21 6641 9661

##### Email

minoomohraz@ams.ac.ir

##### 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

##### Full name of responsible person

Minoos Mohraz

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Iranian Research Center for HIV/AIDS (IRCHA), Imam Khomeini Hospital

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Tehran

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Tehran

##### Postal code

1956865432

##### Phone

+98 21 6694 7984

##### Email

ircha@tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Vira Ameli

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Public Health

**Street address**

Iranian Research Center for HIV/AIDS, Imam Khomeini Hospital

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**Phone**

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**Other areas of specialty/work**

Public Health

**Street address**

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**City**

Tehran

**Province**

Tehran

**Postal code**

1123565479

**Phone**

+98 21 6658 1583

**Email**

vira.ameli@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to the possibility of unauthorized copying and duplication of the shared data, it is not possible to publish the data set

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Vira Ameli

**Position**

researcher

**Latest degree**

Ph.D.