Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 it 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
Minoo Mohraz
Name of organization / entity
Iranian Research Center for HIV/AIDS, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 6694 7984
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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/). 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. Minoo Mohraz
Street address
The Department of Infectious and Tropical Diseases, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Minoo Mohraz
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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
Full name of responsible person
Minoo Mohraz
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Researcher
Latest degree
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Person responsible for updating data

Contact
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researcher
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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