

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of Behavioral Self-Regulation Counseling on HIV Treatment Adherence Delivered by Phone

Protocol summary

Study aim

Determining the effectiveness of telephone behavioral self-regulatory counseling on adherence to treatment in HIV patients

Design

In this research, 40 patients referring to voluntary and counseling center for HIV will be chosen purposefully and a code will be allocated to each one of them. Then, patients randomly will divide into two control and intervention groups. Block randomization and intervention is group counseling

Settings and conduct

It is a randomized controlled clinical trial without blinding. Setting and conduct: voluntary and counseling testing center of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Entry requirements Over 18 years HIV positive File formation between 2016 and 2017 in the Behavioral Diseases Counseling Center of Imam Khomeini Hospital Adherence to treatment less than 95% Familiarity with using a mobile phone No entry conditions Dissatisfaction Has a psychotic disorder and is receiving psychiatric medication

Intervention groups

The intervention group performs five educational and therapeutic sessions, counseling intervention (one in-person counseling session in person and four telephone counseling sessions in a week in between with a self-regulatory approach) and also measures their adherence in each course. Be. The control group received the national protocol and measured the level of adherence to treatment in each period.

Main outcome variables

The main messages of our study are the presence or absence of adherence to treatment and the degree of adherence to it.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040037N2**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **prospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Seyed Ali Dehghan maneshadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6691 1296

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Behavioral Self-Regulation Counseling on HIV Treatment Adherence Delivered by Phone

Public title

Effect of Behavioral Self-Regulation Counseling on HIV Treatment Adherence Delivered by Phone

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

People must be over 18 years old to participate in the project. Participants must be HIV positive and have a folder and receive medication at the Behavioral Diseases Counseling Center of Imam Khomeini Hospital between 2016 and 2017. The rate of adherence to drug therapy in participants should be less than 95%. Participants should be know with how to use a cell phone and send text messages.

Exclusion criteria:

People who are not satisfied with participating in this project. People who, in addition to HIV, have a psychotic disorder and are taking psychiatric medication.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, because the sample size is 40 people, this amount is less than 100. If people are divided into 2 groups by simple random method. According to the law of tap and line randomization, the number of taps and lines may not be equal in the two groups. Therefore, the Block-Randomization method is used. The sample size calculated in this study is 40 people. Therefore, 10 blocks of 4 people are formed and 5 blocks are randomly assigned to each group. As a result, the balance between the two groups is assigned to one group of 20 people and the other 20 people to the second group. A simple random method is used to assign people to each block. This means that people are placed in one of these blocks based on a table of random numbers.

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 of Tehran University of Medical Sciences

Street address

Central Office of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.149

Health conditions studied

1

Description of health condition studied

Human immunodeficiency virus

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Adherence for Treatment

Timepoint

At the beginning of the study (before the intervention) at the end of the study and 2 weeks, 4 weeks and 2 months after the completion of the study.

Method of measurement

Measure adherence to treatment based on self-report and include in the Adherence measurement formula.

Secondary outcomes

1

Description

increase of self-regulation

Timepoint

At the beginning of the study (before the intervention) at the end of the study and 2 weeks, 4 weeks and 2 months after the completion of the study

Method of measurement

Self-Regulation questionnaire, this questionnaire was prepared by Miller & Brown(1999) for measure self-

regulating components.

Intervention groups

1

Description

Intervention group:20 HIV-positive participants In the intervention group we hold 5 consultation sessions based on self- regulation.The time of each session is 45 minutes. After being in the intervention group, it tests, which includes two questionnaires: the degree of adherence to treatment and increasing self-regulation skills in the individual, because if you want to do the treatment accurately and treat the person in the field of your skills, it will determine Be. After people have taken their antiretroviral drugs, they are asked to do so for 10 weeks (until their last telephone consultation) each day they buy their drugs to avoid the mobile number they are considering for the plan. Taken, send SMS. The number of unused pills of all participants is measured each week and recorded in the relevant form. After the last telephone counseling session for the intervention group, follow-up to adhere to the treatment for individuals for a period of two weeks - four weeks - and two months later by telephone with each participant. At the end, participants are assessed for their adherence to treatment and self-regulatory skills, and the pre-test and post-test results are compared.

Category

Behavior

2

Description

Control group:20 people who are HIV-positive in the control group they will receive just routine voluntary and counseling protocol for HIV consultation. After placing the people in the control group, the pre-test, which includes two questionnaires, the amount of adherence to treatment and the level of self-regulatory skills in the person, is taken from them to determine the exact score of adherence to treatment and his total score in self-regulatory skills. After people receive their antiretroviral drugs, they are asked to immediately send a text message to the mobile number provided for the plan for 10 weeks each day they take their medication. The number of unused pills of all participants is measured each week and recorded in the relevant form.After the last telephone counseling session for the intervention group, follow-up to adhere to the treatment for individuals for a period of two weeks - four weeks - and two months later by telephone with each participant. At the end, participants are assessed for their adherence to treatment and self-regulatory skills, and the pre-test and post-test results are compared.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Behavioral Disease Counseling Centers

Full name of responsible person

Dr Seyd Ali Dehghan Menshadi

Street address

The Department of Infectious and tropical Disease, Imam Khomeini Hospital, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research, Central Campus of the University of Tehran, 16 Azar St., Islamic Revolution Square, Tehran

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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

Dr Seyd Ali Dehghan Menshadi

Position

Associate Professor

Latest degree

Master

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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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

No information available.

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available