

# 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)

##### Phone

+98 21 6691 1296

##### Email address

a\_dehghanm@sina.tums.ac.ir

##### 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.

##### City

Tehran

##### Province

Tehran

##### Postal code

14-19-733141

##### Phone

+98 21 6658 1583

##### Email

a\_dehghanm@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahraian

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1417614411

##### Phone

+98 21 6697 0178

##### Fax

+98 21 6648 6500

##### Email

Research@ut.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**

Dr Seyd Ali Dehghan Menshadi

**Position**

Associate Professor

**Latest degree**

Master

**Other areas of specialty/work**

Infectious diseases

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

14-19-733141

**Phone**

+98 21 6119 2047

**Email**

a\_dehghanm@sina.tums.ac.ir

## Person responsible for scientific 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**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

14-19-7331411

**Phone**

+98 21 6119 2047

**Email**

a\_dehghanm@sinam.tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyd Ali Dehghan Menshadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

14-19-733141

**Phone**

+98 21 6658 1583

**Email**

a\_dehghanm@sina.tums.ac.ir

## 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