

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Planning, Implementing and Evaluating the Impact of an Empowerment Program Based on Information, Motivation and Behavioral Skills (IMB) Model on Adherence to Treatment Regimen Patients with positive HIV in the Behavioral Disease Counseling Center

#### Protocol summary

##### Study aim

Determination of the Impact of an Empowerment Program Based on Information, Motivation and Behavioral Skills (IMB) Model on Adherence to Treatment Regimen Patients with Positive HIV in the Behavioral Disease Counseling Center

##### Design

Clinical trial is double blind, randomized with intervention and control groups. Using random number table, we select the 3 digits on the left side of the table, which are smaller than 122, and assign them one by one to the intervention and control groups.

##### Settings and conduct

There is a Behavioral Diseases Counseling Center in Kerman city for HIV positive patients. We use two qualitative and quantitative methods. First, we conduct the qualitative method using face-to-face interview until saturation point. In quantitative method, using the allocation of people to the two groups A and B, we randomly place the patients in two groups. Educational interventions used in the group are scenario, group discussion and posters. Men and women sessions will be held separately for at least 20 training sessions in parks, sports club and Behvarzi institute. Participants are not aware of the allocation of people in each group as well as the educational intervention, and the evaluators and the data monitoring committee are not aware too.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria People over the age of 18 HIV Positive Antiviral drugs used for 6 months Willingness to participate in the study Exclusion criteria They have severe motor disabilities They don't have reading and writing skills

##### Intervention groups

Intervention group: " Educational intervention based on information, motivation and behavioral skills model.

Using group discussion, scenario, projection, and practical demonstration. "Control group:" routine care

##### Main outcome variables

Adherence to the diet; Adherence to the drug regimen Adherence to the motor program; CD4

#### General information

##### Reason for update

##### Acronym

0

##### IRCT registration information

IRCT registration number: **IRCT20181112041616N1**

Registration date: **2018-12-12, 1397/09/21**

Registration timing: **retrospective**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

##### Registration date

2018-12-12, 1397/09/21

##### Registrant information

##### Name

Ehsan Movahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3213 3151

##### Email address

e.movahed@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-10-23, 1396/08/01  
**Expected recruitment end date**  
2018-11-21, 1397/08/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Planning, Implementing and Evaluating the Impact of an Empowerment Program Based on Information, Motivation and Behavioral Skills (IMB) Model on Adherence to Treatment Regimen Patients with positive HIV in the Behavioral Disease Counseling Center

**Public title**  
Impact of an Information, Motivation and Behavioral Skills (IMB) Model on Adherence to Treatment Regimen

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

People over the age of 18 HIV positive Antiviral drugs used for 6 months Willingness to participate in the study

**Exclusion criteria:**

They have severe motor disabilities They don't have reading and writing skills

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **122**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The researcher used a simple randomized method. The random unit is HIV positive patients. The instrument is through allocating two groups of A and B In the random sequence, first we use the convenience sampling method. The questionnaire is completed for all people referring to the Behavioral Disease Counseling Center on different days of the week until the sample size is reached. Codes of 1 to 122 are considered for each questionnaire. In the next step, we will consider two groups of A and B, then we put the even numbers in group A and the odd numbers in group B, and finally we will consider the intervention and control groups. Hiding random allocation: In this method, without knowing the names of the two groups, after the individuals are

assigned to both groups, a group is called the intervention and the other is called control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher does not inform the participants of the number of individuals, individual characteristics and intervention in each group, which makes all those involved in the study think that all participants receive intervention, although some do not receive it. In our study, only the researcher knows the allocation of the two groups, but the participants, evaluators and the data monitoring committee are not aware of the type of assigned intervention. Another useful way is that the evaluator is selected from outside the treatment team. Given that the researcher is aware of the type of intervention devoted to the participants in the study, this awareness cannot affect the data analysis.

**Placebo**

Not used

**Assignment**

Other

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**

Shohaday Gomnam Blvd., Faculty of Health., Yazd Town

**City**

Kerman

**Province**

Kerman

**Postal code**

7618746864

**Approval date**

2017-07-30, 1396/05/08

**Ethics committee reference number**

IR.SSU.SPH.REC 1396.83

**Health conditions studied**

1

**Description of health condition studied**

HIV

**ICD-10 code**

D89.9

**ICD-10 code description**

Disorder involving the immune mechanism, unspecified

## 2

### **Description of health condition studied**

Adherence to Nutrition

### **ICD-10 code**

D51.9

### **ICD-10 code description**

Vitamin B12 deficiency anaemia, unspecified

## 3

### **Description of health condition studied**

HIV

### **ICD-10 code**

D82.9

### **ICD-10 code description**

Immunodeficiency associated with major defect, unspecified

## 4

### **Description of health condition studied**

Adherence to Physical Activity

### **ICD-10 code**

Z89.9

### **ICD-10 code description**

Acquired absence of limb, unspecified

## **Primary outcomes**

### 1

#### **Description**

Adherence to drug regimen

#### **Timepoint**

Adherence to drug regimen before and 3 months after the intervention

#### **Method of measurement**

Adherence to the drug regimen based on the AACG drug compliance questionnaire and the self made information, motivation and behavioral skills questionnaire

### 2

#### **Description**

Adherence to nutrition regimen

#### **Timepoint**

Adherence to nutrition regimen before and 3 months after the intervention

#### **Method of measurement**

Adherence to the diet based on a nutrition questionnaire and a researcher-made questionnaire of information, motivation and behavioral skills

### 3

#### **Description**

Adherence to physical activity regimen

#### **Timepoint**

Adherence to physical activity regimen before and 3 months after the intervention

#### **Method of measurement**

Adherence to the physical activity program based on

Beck questionnaire and self made information, motivation and behavioral skills questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: "The intervention is based on at least 20 training sessions (60 minutes per session according to the participants' viewpoints) within 16 weeks for treatment adherence behavior using information, motivation and behavioral skills model. Due to stigma and shame, sessions will be held separately for men and women for more participation of people. Considering that drug adherence, nutrition and exercise are intended, according to the opinion of male participants, two sessions were held in parks and forests to do a variety of exercises and walking as well as the use of equipment inside parks and create a sense of pleasure in people and the third session is conducted inside the counselling center until reaching 20 sessions. In the women's group, 10 sessions of the aerobics class will be held at the club (according to women's opinion) and 4 sessions will be held inside the women's park and 8 sessions of nutrition and medication classes will be held at the Behvarzi institute while holding aerobic classes. The 8 training sessions are as follows: The first and second sessions will be held to increase knowledge and information for 2 weeks. The third and fourth sessions will be held to increase motivation for two weeks using group discussion and lectures, posters, pamphlets, and PowerPoint: Motivation construct consists of three parts. Individual motivation, social motivation and perceived sensitivity (perception of risk). 1-Individual motivation: Using brainstorming and projection in all possible outcomes in a training session and evaluating outcomes (group discussions on all possible outcomes). SMS or MMS are used to send messages at appropriate times (message timing control) for creation of individual motivation. Social motivation: holding sessions in the parks, doing exercises, and involving all people will bring more people together and approval of friends and family. The 5th, 6th and 7th sessions are used to increase behavioral skills within 3 weeks. Behavioral skills consist of two parts: 1. Increasing self-efficacy, which is a powerful strategy for behavioral development. 2. Performing objective skills for correct behavior in 2 or 3 sessions. Role playing of people and encouraging them with rewards (in cash and non-cash) give them the opportunity to get self-confidence and learn skills. The eighth session is held one month after the seventh session for the purpose of follow up and review of presented materials.

#### **Category**

Behavior

2

**Description**

"Control group:" routine care

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Behavioral Disease Counseling Center

**Full name of responsible person**

Ehsan Movahed

**Street address**

Shohaday Gomnam Blvd., Yazd Town, near Azad University

**City**

Yazd

**Province**

Yazd

**Postal code**

7618746864

**Phone**

+98 34 3213 3151

**Email**

e.movahed@ssu.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Shohady Gomnam Blvd, Yazd town, near Azad University

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Phone**

+98 35 3820 9138

**Fax**

+98 35 3820 9119

**Email**

e.movahed@ssu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Ehsan Movahed

**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Shohaday Gomnam Blvd., Yazd Town., near Azad University

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Phone**

+98 35 3820 9138

**Email**

e.movahed@ssu.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Ehsan Movahed

**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Shohaday Gomnam Blvd., Yazd Town., near Azad University

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Phone**

+98 34 3213 3151

**Fax**

**Email**

e.movahed@ssu.ac.ir

**Phone**

+98 34 3213 3151

**Fax**

**Email**

e.movahed@ssu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Ehsan Movahed

**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

**Street address**

Shohaday Gomnam Blvd., Yazd Town., near Azad University

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

## 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**

HIV patients were reluctant to share data

**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**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available