Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Ṡhohaday 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

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
Phone
+98 34 3213 3151
Fax
Email
e.movahed@ssu.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
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