

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of Education Interventional base on Extended Health Belief Model to Antiretroviral adherence in HIV/AIDS patients

Protocol summary

Summary

This study will be conducted on AIDS patients who are referred to the Behavioral Disease Counseling Center of Qom who receive antiretroviral drugs. In this study, the criteria for entry are patients who do not follow appropriate treatments. These patients include people who receive less than 95% of their prescribed medication. Then they are randomly divided into two groups of control and intervention. Each group consists of 36 people. A researcher-made questionnaire whose validity and reliability were confirmed by the Panel of Experts and Will be available to both groups. The initial and main consequence of this study is to increase treatment compliance in patients with AIDS, and its secondary implications include increased sensitivity and perceived severity, increased awareness of the barriers and benefits of treatment, and the impact of social protection in adherence to treatment, which ultimately leads to Patients' self-efficacy is the regular use of medications. Attendance criteria for patients receiving at least 2 years of AIDS treatment and exit criteria include the death of a patient or the imprisonment or migration of patients under study. For the intervention group, 3 educational sessions will be based on the structures of the developed Health Belief Model on AIDS and its treatment, and finally, the pre-test and post-test will be analyzed.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017020432386N1**

Registration date: **2017-10-20, 1396/07/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-20, 1396/07/28

Registrant information

Name

Javad Yadegari

Name of organization / entity

Qom University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-02-09, 1395/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Education Interventional base on Extended Health Belief Model to Antiretroviral adherence in HIV/AIDS patients

Public title

Effectiveness of Education Interventional base on Extended Health Belief Model to Antiretroviral adherence in HIV/AIDS patients

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria The drug received less than 23 time in the last 2 years; Willingness to participate in this research project; No prison record in the past two years; Treatment began more than two years Exit criteria any reason that a person is not able to cooperate during the study and conviction to prison during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The randomization in this study is based on names blocking from the Drug Availability Office at the Behavioral Disease Advice Center. The number of names of the patients receiving the drug was 217, which divided into 72 blocks of 3, respectively. From 1 to 3, one number was randomly selected and was selected with 3 other names, so that 72 patients were selected in this study. .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Saheli Avenue

City

Qom

Postal code

Approval date

2016-07-02, 1395/04/12

Ethics committee reference number

IR.MUQ.REC.1395.33

Health conditions studied

1

Description of health condition studied

Aids

ICD-10 code

B23

ICD-10 code description

Acute HIV infection syndrome

Primary outcomes

1

Description

Adherece to Antiretroviral Treatment

Timepoint

One month befor intervention and 3 month after

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Social Suport

Timepoint

One month befor intervention and 3 month after

Method of measurement

Questionnaire

2

Description

Perceived Susceptibility

Timepoint

One month befor intervention and 3 month after

Method of measurement

Questionnaire

3

Description

Perceived Severity

Timepoint

One month befor intervention and 3 month after

Method of measurement

Questionnaire

4

Description

Perceived Barriers

Timepoint

One month befor intervention and 3 month after

Method of measurement

Questionnaire

5

Description

Perceived Benefits

Timepoint

One month before intervention and 3 months after

Method of measurement

Questionnaire

6

Description

Perceived Self efficacy

Timepoint

One month before intervention and 3 months after

Method of measurement

Questionnaire

Intervention groups

1

Description

In the intervention group, 3 training sessions were held. The first session was for an hour and about the immune system's function. The second session was for an hour and about the general AIDS. The third session was for one hour for antiretroviral drugs and their complications. All of these sessions were based on the health belief model.

Category

Other

2

Description

no intervention in control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Behavioral Disease Counseling Center

Full name of responsible person

Javad Yadegari

Street address

Nirouhah, Nabovat sq, Qom

City

University of Medical Science

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Gharlipour Zabiholah

Street address

Saheli avenue

City

Qom

Grant name

ندارد

Grant code / Reference number

Does not have

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

Yes

Title of funding source

Qom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qom University of Medical Science

Full name of responsible person

Javad Yadegari

Position

Master Student

Other areas of specialty/work

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Qom

Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*