Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of virtual self-care education on quality of life in HIV positive patients

Protocol summary

Study aim
Determining the Effectiveness of Self-Care Training with Network Method Virtual on the quality of life of HIV positive patients in Tehran

Design
40 subjects in control group and 40 patients in intervention group will be divided into quasi-random method. The grouping will be based on the file number. It will first draw between the couple's number and the individual. The first group will be intervention group and the second group will be control group.

Settings and conduct
The study population was HIV positive patients referred to Behavioral Disease Counseling Centers in Tehran. 5 Behavioral Counseling Centers in Tehran will be selected. The study is single-blind and the participants are blinded.

Participants/Inclusion and exclusion criteria
Entry requirement: 1. A definitive diagnosis of HIV and having a file at the counseling center 2. Not having severe cognitive impairments such as mental retardation 3. Access to smartphone and internet 4. Age range from 18 to 45 years 5. Having informed consent 6. Minimum literacy skills 7. No addiction 8. No chronic diseases such as hepatitis, tuberculosis, etc.

Intervention groups
The intervention and control groups will complete the MQOL-HIV questionnaire. The intervention group will then receive audio and text files of virtual self-care skills training. Training will be for 4 weeks. The questionnaire will be completed again by the participants 2 weeks after the training and the information will be analyzed.

Main outcome variables
Quality of life of HIV-positive patient

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190924044872N1**
Registration date: **2019-10-04, 1398/07/12**
Registration timing: **prospective**

Last update: **2019-10-04, 1398/07/12**
Update count: **0**

Registration date
2019-10-04, 1398/07/12

Registrant information

Name
Anna Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
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Email address
anna.amini@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-05, 1398/07/13

Expected recruitment end date
2019-10-12, 1398/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of virtual self-care education on quality of life in HIV positive patients

Public title
The effect of virtual self-care education on quality of life

in HIV positive patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1.A definitive diagnosis of HIV and having a file at the counseling center 2.Not having severe cognitive disorders, such as mental retardation 3. Smartphone and Internet access 4. Age range 18 to 45 years 5. Having informed consent 6. Minimum literacy 7. No addiction 8. Lack of other chronic diseases such as hepatitis, tuberculosis, etc.

Exclusion criteria:

Lack of continuous communication with the researcher

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of medical school of Islamic Azad University of Tehran

Street address

No. 6, Block 16, Kanoon Ave., Share Ziba Blvd., ayatollah kashani, Tehran

City

Tehran

Province

Tehran

Postal code

1487953186

Approval date

2018-10-30, 1397/08/08

Ethics committee reference number

IR.IAU.TMU.REC.1397.227

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

The quality of life of HIV-positive patients is measured by the standard MQOL-HIV questionnaire.

Timepoint

Questionnaires will be completed before intervention and 2 weeks after training.

Method of measurement

MQOL-HIV

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 40 HIV positive patients will complete the questionnaire. The group will then receive audio and text files for 4 weeks of self-care virtual training. The questionnaire will be completed again by this group within 2 weeks of completion of training.

Category

N/A

2

Description

Control group: 40 HIV-positive patients who did not receive education. This group will also be provided with training to follow ethics.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

مركز مشاوره بيماريهاي رفتاري والفجر

Full name of responsible person

Dr. Lesan Pezashki

Street address

West Shahid Dastgheib, Ostad Moein Boulevard, Azadi Ave.

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2

Recruitment center
Name of recruitment center
شبکه بهداشت و درمان شمیرانات
Full name of responsible person
بهرخ محمود زاده
Street address
at the beginning of Shariati Street, Qods Square
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Shemiranat@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Akram Peyman
Street address
School of Nursing, University of Science and Research, University Square, Simon Bolivar Ave.
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1477893855
Phone
+98 21 4486 5154
Email
akrampeyman@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad university
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
Islamic Azad University
Full name of responsible person
Anna Amini
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Clinical reports will be presented in paper form.

When the data will become available and for how long
Since 1399

To whom data/document is available
Researchers and students in academic institutions

Under which criteria data/document could be used
Any kind of ethical statistical analysis is allowed

From where data/document is obtainable
anna.amini@yahoo.com

What processes are involved for a request to access data/document
Send request and full justification for use of information to researcher

Comments