

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The assessment of the effect cognitive-behavioral consultant in reproductive health of women with HIV referred to Imam Khomeini Consultation Center for Clients with Risky Behaviors in Tehran city in 1395

Protocol summary

Summary

The present study is a randomized control trial, parallel, not blinded, designed With assessment of the effect cognitive-behavioral consultant in reproductive health of women with HIV. Researchers after obtaining permission from the authorities feeder every days of the week to visit to Imam Khomeini Consultation Center for Clients with Risky Behaviors, and after explaining the purpose of the study and the consent of the participants has started sampling has available, In this study 126 patients with the HIV virus are into two groups, Intervention (get consultation) and control group (receiving routine care). Inclusion criteria can be noted from the women in the age range between 15-45 years, The ability to read and write and having sex. Exclusion criteria include failure to attend counseling sessions over three sitting and severe addiction and severe psychiatric disorder who are not able to answer questions. Number eight 50-minute sessions of cognitive-behavioral counseling for the intervention group will be held. The implications of this study include the quantity of physical and acceptance of HIV disease, increase compliance with the disease, increase responsible behavior towards illness, Reduce instability in life, increase self-awareness, enhance the quality of reproductive health and reducing anxiety and depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101920719N3**

Registration date: **2017-04-19, 1396/01/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

Sara Esmaelzadeh Saeieh

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research chancellor of Alborz University of Medical Sciences

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the effect cognitive-behavioral consultant in reproductive health of women with HIV referred to Imam Khomeini Consultation Center for Clients with Risky Behaviors in Tehran city in 1395

Public title

The effect consultant in reproductive health of women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria consisted of women in the age range between 15-45 years, The ability to read and write, lack of severe addiction to substances that do not have the ability to respond to questions, No history of severe psychological disorders, Lack of advanced stages of disease, Having sex. Exclusion criteria included Lack of consultation sessions over 3 sitting, disinterest To participate in research, having severe addiction to substances that do not have the ability to respond to questions and Severe psychiatric disease.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Research chancellor of Alborz University of Medical Sciences

Street address

Taleghani Square Taleghani Blvd North - the administrative settlement - alborz University of Medical Sciences

City

Karaj

Postal code**Approval date**

2017-03-04, 1395/12/14

Ethics committee reference number

Abzums.Rec.1395.150

Health conditions studied**1****Description of health condition studied**

Human immunodeficiency virus [HIV] disease

ICD-10 code

B20

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes**1****Description**

Reproductive health

Timepoint

Before and A month after the intervention

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Anxiety

Timepoint

Before and a month after consultation

Method of measurement

Questionnaire

2**Description**

Depression

Timepoint

Before and a month after consultation

Method of measurement

Questionnaire

3**Description**

Stress

Timepoint

Before and a month after consultation

Method of measurement

Questionnaire

Intervention groups**1****Description**

In the intervention grope: 8 sessions of cognitive-behavioral counseling for two days a weak(Sunday and Wednesday) for 50 minutes to be held which including reproductive health, sexuality, responsible behavior, fertility, coping with illness, psychological problems, health problems related to pregnancy and social

problems.
Category
Behavior

2

Description

Control group: In this group, except for routine care, there is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Consultation Center for Clients with Risky Behaviors

Full name of responsible person

Sara Esmaelzadeh

Street address

Imam Khomeini hospital, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research chancellor of Alborz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Noori Sepehr

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Azimieh Sq.,Research chancellor of Alborz University of Medical Sciences,Karaj,Alborz.

City

karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research chancellor of Alborz 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

Research chancellor of Alborz University of Medical Sciences

Full name of responsible person

Katayoon Salehi

Position

A graduate student in consultation on midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sara Esmaelzadeh

Position

PHD in Reproductive Health/Faculty member

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Person responsible for updating data

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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