

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of group counselling versus no counselling on quality of life, knowledge and attitude toward HIV/AIDS among HIV-positive women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of group counselling versus no counselling on quality of life, knowledge and attitude toward HIV/AIDS among HIV-positive women. **Design:** A randomized clinical trial. **Setting and conduct:** The eligible HIV-positive women who will refer to Shohada Health Center during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 18 to 65 years; HIV-positive women. **Exclusion criteria:** Advanced AIDS; Sever mental disorders. **Intervention group:** Routine care plus group counselling once a week for 60 minutes in four successive weeks. **Control group:** Just routine care. **Primary outcome:** (a) assessing quality of life using standard WHOQOL-Brief questionnaire before intervention and 4 weeks after that; (b) assessing knowledge toward HIV/AIDS using standard questionnaire before intervention and 4 weeks after that; (c) assessing attitude toward HIV/AIDS using standard questionnaire before intervention and 4 weeks after that. **Randomization:** Random assignment of the patients to the intervention and control groups through drawing of lots. **Blinding:** Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201711199014N202**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counselling versus no counselling on
quality of life, knowledge and attitude toward HIV/AIDS
among HIV-positive women: a randomized clinical trial

Public title

Effect of group counselling versus no counselling on
quality of life, knowledge and attitude toward HIV/AIDS
among HIV-positive women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; HIV-positive women. Exclusion criteria: Advanced AIDS; Severe mental disorders.

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-10-28, 1396/08/06

Ethics committee reference number

IR.UMSHA.REC.1396.500

Health conditions studied

1

Description of health condition studied

HIV-positive

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Assessing quality of life

Timepoint

Before intervention and 4 weeks after that

Method of measurement

Using standard WHOQOL-Brief questionnaire

2

Description

Assessing knowledge toward HIV/AIDS

Timepoint

Before intervention and 4 weeks after that

Method of measurement

Using standard questionnaire

3

Description

Assessing attitude toward HIV/AIDS

Timepoint

Before intervention and 4 weeks after that

Method of measurement

Using standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care plus group counselling once a week for 60 minutes in four successive weeks.

Category

Other

2

Description

Control group: Just routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Health Center

Full name of responsible person

Akram Mohammadi Gheisar

Street address

Takhti Ave. Shohada Health Center

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan
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**

School of Nursing and Midwifery

Full name of responsible person

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Position

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Department of Epidemiology

Full name of responsible person

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Position

Professor of Epidemiology

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Web page address**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