

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determine the effect of preconception counseling based on motivational interview on knowledge, attitude, and pregnancy related behavior among women in reproductive age suffering from HIV

Protocol summary

Study aim

Determine the effect of preconception counseling based on motivational interview on knowledge, attitude, and pregnancy related behavior among women in reproductive age suffering from HIV

Design

Controlled clinical trial with parallel groups, without blinding, with sample size of 30, randomized via permuted block method

Settings and conduct

Researcher will refer to four centers (Mashhad1(Imamhadi), Mashhad2 (Basij), Mashhad3 (Resalt), Mashhad5 (Vahdat)) of behavioral and infectious diseases in Mashhad and will select cases consequently from women who have the inclusion criteria. Then will randomly allocate participants to the intervention and control groups through the permuted block method using Random Allocation Software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: HIV-infected women; Age 15 to 49 years; Married; Sexual activity during last 6 months; Written informed consent to participate in project; Writing and reading literacy; ability to get pregnant. Non-inclusion criteria: hysterectomy; menopause; pregnancy; addiction; occurrence of unpleasant accidents in the last 6 months

Intervention groups

Intervention group: three 60-90 minute weekly preconception counselling sessions with the use of motivational interview. Control group: routine cares, i.e., contraceptive counselling, gynecology examination if necessary and conducting annual Pap smear test

Main outcome variables

Knowledge, attitude, and pregnancy related behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049722N1**

Registration date: **2021-02-17, 1399/11/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-17, 1399/11/29**

Update count: **0**

Registration date

2021-02-17, 1399/11/29

Registrant information

Name

Motahare Mohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3521 4325

Email address

mohammadimt972@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine the effect of preconception counseling based on motivational interview on knowledge, attitude, and pregnancy related behavior among women in reproductive age suffering from HIV

Public title

The effect of preconception counseling on knowledge, attitude, and pregnancy related behavior

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

HIV-infected women Age 15 to 49 years Married Sexual active since last 6 months Written informed consent to participate in project Writing and reading literacy Capable of conception Refer to counselling centers of septic and behavioral diseases in Mashhad city Having contact number

Exclusion criteria:

History of hysterectomy Menopause Pregnancy Addiction Occurrence of unpleasant accidents in the last 6 months

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Researcher will refer to four centers (Mashhad1(Imamhadi), Mashhad2 (Basij), Mashhad3 (Resalt), Mashhad5 (Vahdat)) of behavioral and infectious diseases in Mashhad and will select cases consequently from women who have the inclusion criteria. Then will randomly allocate participants to the intervention and control groups through the permuted block method using Random Allocation Software.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research; Mashhad University of Medical Sciences; Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9188667656

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.055

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

Z21

ICD-10 code description

Asymptomatic human immunodeficiency virus [HIV] infection status

Primary outcomes

1

Description

Knowledge

Timepoint

before the intervention, immediately and four weeks after the intervention

Method of measurement

Knowledge questionnaire

2

Description

Attitude

Timepoint

before the intervention, immediately and four weeks after the intervention

Method of measurement

Attitude researcher-made questionnaire

3

Description

Behavior

Timepoint

before the intervention, immediately and four weeks after the intervention

Method of measurement

Behavior researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three sixty-to-ninety minute weekly preconception counselling sessions with the use of motivational interview.

Category

Behavior

2

Description

Control group: routine cares, i.e., contraceptive counselling, gynecology examination if necessary and conducting annual Pap smear test

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Navid Tandorosti counselling center

Full name of responsible person

Dr. Sepehri

Street address

Navid Tandorosti counselling center, inside health center number 2, near the Vahdat park, at the beginning of Vahdat boulevard, Panjrah district.

City

Mashhad

Province

Razavi Khorasan

Postal code

9185684538

Phone

+98 51 3365 7731

Email

Aids@mums.ac.ir

2

Recruitment center

Name of recruitment center

Mashhad 1 Behavioral and infectious diseases counselling center

Full name of responsible person

Dr. Karimian

Street address

First of Imam Hadi 12 street, Imam Hadi Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9185684538

Phone

+98 51 3691 3199

Email

Aids@mums.ac.ir

3

Recruitment center

Name of recruitment center

Mashhad 5 Behavioral and infectious diseases counselling center

Full name of responsible person

Dr. Yaghobi

Street address

No. 19, Mostafakhomeini 14 street, Basij 52 road, Basij highway

City

Mashhad

Province

Razavi Khorasan

Postal code

9185684538

Phone

+98 51 3341 7012

Email

Aids@mums.ac.ir

4

Recruitment center

Name of recruitment center

Mashhad 3 Behavioral and infectious diseases counselling center

Full name of responsible person

Ms. Beheshti

Street address

Near the Siloo, Resalat 14 street, Resalat street

City

Mashhad

Province

Razavi Khorasan

Postal code

9185684538

Phone

+98 51 3271 5242

Email

Aids@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Darabi Mahboob

Street address

Gharishi building; Khorasan Razavi University of Medical Sciences, Daneshgah street

City

Mashhdsd
Province
 Razavi Khorasan
Postal code
 9138813944
Phone
 +98 51 3841 3007
Fax
 +98 51 3841 3006
Email
 Bahreynimh@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Mashhad 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
 Academic

Person responsible for general inquiries

Contact
Name of organization / entity
 Mashhad University of Medical Sciences
Full name of responsible person
 Dr. Samira Ebrahimzade Zagmi
Position
 Assistant professor
Latest degree
 Ph.D.
Other areas of specialty/work
 Midwifery
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Person responsible for scientific inquiries

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Full name of responsible person
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Other areas of specialty/work
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 Ebrahimzadehzs@mums.ac.ir

Person responsible for updating data

Contact
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 Mashhad University of Medical Sciences
Full name of responsible person
 Motahare Mohamadi
Position
 Student
Latest degree
 Bachelor
Other areas of specialty/work
 Midwifery
Street address
 No. 67, Azade 5 street, Fallahi 2 Ave, Ghasem Abad
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9184146953
Phone
 +98 51 3521 4325
Email
 mohammadimt972@mums.ac.ir

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
 Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
 Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to
make this available