

# 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  
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 9138813944  
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**Fax**  
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**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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 Ebrahimzadehzs@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**  
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Mashhad University of Medical Sciences  
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## 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