

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Investigating the effect of educational-behavioral interventions on the reproductive and sexual health needs of transgender women

#### Protocol summary

##### Study aim

Determining the effect of educational-behavioral interventions on safe sexual behaviors, sexual satisfaction, sexual function and body image

##### Design

Controlled, randomized trial without blinding is done on 70 participants and randomization is implemented by R statistical software.

##### Settings and conduct

The researcher receives a list of all transgender women by referring to the Iranian Transgender Support Association. Eligible individuals are divided into control and intervention groups. Standard questionnaires of sexual satisfaction, sexual function, body image satisfaction and safe sexual behaviors are completed before the intervention and 3 months after the educational intervention by both control and intervention groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: transgender women who have been hormonally or surgically adapted from man to woman and are willing to participate in the study and have a sexual partner and sexual intercourse. People who stop participating in the study Exclusion criteria: Unwillingness to participate in the study.

##### Intervention groups

For the intervention group, there are 4 online training sessions, 2 hours per session and 2 sessions per week. The educational content of the intervention group includes 1- sexually transmitted diseases and AIDS 2- Sexual cycle and sexual problems 3- Mental body image 4- Tests, screening examinations and prevention of high-risk sexual behaviors. The control group receives the routine training of the association and the usual psychological counseling. The content of the training package are provided to the control group after completing the second stage questionnaires.

##### Main outcome variables

Safe sexual behaviors, sexual satisfaction, sexual

function and body image satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201114049379N1**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

##### Registration date

2021-01-13, 1399/10/24

##### Registrant information

##### Name

Azar Nematollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3633 3128

##### Email address

nematolah@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the effect of educational-behavioral interventions on the reproductive and sexual health needs of transgender women

### Public title

Investigating the effect of educational-behavioral interventions on the reproductive and sexual health needs of transgender women

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Transgender women who have been adapted from male to female by hormonal or surgical methods  
Transgender women who have sexual partner and sexual intercourse  
Transgender women who want to participate in the study

#### Exclusion criteria:

Reluctance to participation in the study

### Age

No age limit

### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 70

### Randomization (investigator's opinion)

Randomized

### Randomization description

The list of eligible transgender women is received from Iranian Transgender Support Center. Considering that the type of treatment for reassignment gender surgery may affect the results of our study, to consider this variability in the sample, first people are divided into two groups according to the type of treatment received (hormone therapy or hormone therapy + surgery). Randomization is done separately in each of these two groups using R software. In each treatment group, the zero codes of the software are assigned to the control group and the codes of one software are assigned to the educational intervention group.

### 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 Tehran University of Medical Sciences

##### Street address

School of Nursing and Midwifery, East Nusrat Street, Tohid Square, Tehran

##### City

Tehran

##### Province

Fars

##### Postal code

1419733171

#### Approval date

2019-06-23, 1398/04/02

#### Ethics committee reference number

IR.TUMS.FNM.REC.1398.052

## Health conditions studied

### 1

#### Description of health condition studied

Transgender women

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Score of safe sexual behavior in the standard Safe Sex Behaviors Questionnaire (SSBQ)

#### Timepoint

At the beginning of the study (before the start of the study) and 3 months after the intervention

#### Method of measurement

Safe Sex Behaviors Questionnaire (SSBQ) (Dilorio, et al., 1993)

### 2

#### Description

Sexual Satisfaction Score in The Global Measure of Sexual Satisfaction Questionnaire

#### Timepoint

At the beginning of the study (before the start of the study) and 3 months after the intervention

#### Method of measurement

The Global Measure of Sexual Satisfaction Questionnaire(Kelli-an Lawrance)

### 3

#### Description

Sexual function in the standard Female Sexual Function Index Questionnaire (FSFI -6)

#### Timepoint

At the beginning of the study (before the start of the study) and 3 months after the intervention

**Method of measurement**

Female Sexual Function Index Questionnaire (FSFI -6)

**4****Description**

Body image satisfaction score in the standard body image satisfaction questionnaire

**Timepoint**

At the beginning of the study (before the start of the study) and 3 months after the intervention

**Method of measurement**

Souto and Garcia Standard Satisfaction With Body Image Questionnaire

**Secondary outcomes**

empty

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

Intervention group: For the intervention group, 4 online training sessions are held, each session lasts 2 hours and 2 sessions per week using the lecture method, question answering method and slide show. The educational content of the intervention group includes 1- Wids sexually transmitted diseases 2- Sexual cycle and sexual problems 3- Mental body image 4- Tests and examinations Screening and prevention of high-risk sexual behaviors

**Category**

Behavior

**2****Description**

Control group: The control group receives the routine training of the association and the usual psychological counseling. The content of the training package are provided to the control group after completing the second stage questionnaires.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Iranian Transgender Support Center

**Full name of responsible person**

Parisa Khodakhah

**Street address**

second floor, Toloo Bi-neshanha society center, Shahid Salehi Alley, Before the exit of Imam Ali North, Shahid Mahallati Highway East to West

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Sahraeian

**Street address**

Deputy of Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

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**Grant name**

Grant number 98-3-100-43201.

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Azar Nematollahi

**Position**

Faculty of Midwifery, School of Nursing and Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Health

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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Ph.D.

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**Contact**

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**Position**

Faculty member of midwifery, School of Nursing and  
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**Latest degree**

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**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**

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