

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)

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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

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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 updating data

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Name of organization / entity

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Full name of responsible person

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Latest degree

Master

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