

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Cognitive -behavioral interventions on Family violence and its Consequences in Transgender people

Protocol summary

Study aim

Determining the effect of Cognitive-Behavioral Interventions on family Violence and its Consequences in Transgender People.

Design

Randomized clinical trial with parallel groups

Settings and conduct

50 transgender people with inclusion criteria will be selected via the Internet (Twitter and Instagram). DASS-21, and Rosenberg self-esteem questionnaires will be completed by transgenders and the CTSP questionnaires by their parents, and self report family violence checklist will be given to transgenders to complete for 30 days. The transgender people will be divided into two groups. Cognitive-behavioral interventions will be sent in 8 one-hour online sessions to parents of intervention group. Immediately after the education sessions, the CTSP questionnaire will be completed by the parents. 2 months after the end of the cognitive-behavioral sessions, other questionnaires will be given to transgender people again.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Defenitive diagnosis of Gender dysphoria by Psychiatrist of Forensic Medicine, Living in a home with parents or guardians, Trangender's and his/her parents or guardian's Willingness to participate in the study, Age over 12 years, Being the victiom of family violence; Exclusion Criteria: The transgender's and his/her parents or guardian's unwillingness to participate in the study absence in more than 1 education session

Intervention groups

cognitive-behavioral interventions will be performed on parents or guardian's of transgenders. These training sessions will be held via internet for the parents of the intervention group.

Main outcome variables

The main outcome of this study is family violence, which means physical, psychological, verbal, and sexual violence perpetrated by a transgender's parent or

guardian.

General information

Reason for update

1-we found that the researcher-made questionnaire was not suitable for measuring family violence against transgender people, so the method of measuring the family violence variable was changed to a daily checklist for measuring violence completed by a transgender for 30 days. 2-Also, since sampling has not started yet, the sampling date was changed. 3- Due to the prevalence of Covid-19 virus, training sessions will be held online, so the sample people will be divided into 2 intervention groups (who receive online training sessions) and a control group. 4-In addition to the Iranian Gender dysphoria Association, sampling will also include transgender support pages on Instagram and Twitter.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120609009975N7**
Registration date: **2020-03-08, 1398/12/18**
Registration timing: **prospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **1**

Registration date

2020-03-08, 1398/12/18

Registrant information

Name

Farnaz Farnam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4217

Email address

fz.farnam@gmail.com

Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2021-03-01, 1399/12/11

Expected recruitment end date

2021-06-01, 1400/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cognitive -behavioral interventions on Family violence and its Consequences in Transgender people

Public title

Effects of Cognitive -behavioral interventions on Family Violence and its Consequences

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Defenitive diagnosis of Gender dysphoria Living in a home with parents or guardians Transgender person's Willingness to participate in the study Parent's or guardian's of Trangender willingness to participate in the study Age over 12 years Being a victim of family violence

Exclusion criteria:

The transgender person's unwillingness to participate in the study Parent's or guardian's of Transgender unwillingness to participate in the study Absence in more than 1 training session

AgeFrom **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **1**

For each transgender person participating in the study, at least one parent or guardian of the individual will be included in the study for cognitive behavioral intervention.Open in Google Translate

Randomization (investigator's opinion)

Randomized

Randomization description

We will study 50 transgender youth, who will gather from the list of trangender people of the Gender dysphoria association and through Internet. An announcement about this study will first be posted on the Transgender support pages in Instagram and Twitter. The subjects will then randomly divided into intervention and control group by using random block size of four .There are 6

modes for blocks, including: TTCC, TCTC, TCCT, CCTT, CTTC, and CTTC for random allocation by blocking and assigning subjects to 2 intervention (T) and control (C) groups. By using the computer we create random numbers; For numbers 1, Compound 1 (CTTC), For numbers 2 , compound 2 (CCTT), for numbers 3 , compound 3 (TCCT), for numbers 4 compound 4 (TCTC), for numbers5 Compound 5 (CTTC) and for numbers 6 Compound 6 (TTCC) will be used.

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**

School of Nursing and Midwifery & Rehabilitation -
Tehran University of Medical Sciences

Street address

Tohid square, Dr.Mirkhani street, school of Nursing
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Province

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Postal code

1419733171

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.TUMS.FNM.REC.1398.201

Health conditions studied**1****Description of health condition studied**

Gender Dysphoria

ICD-10 code

F64.9

ICD-10 code description

Gender identity disorder, unspecified

2**Description of health condition studied**

family Violence

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

family violence

Timepoint

Before intervention, 2 months after the end of the intervention

Method of measurement

Self Report of family violence checklist

2

Description

Depression

Timepoint

Before intervention , 2 months after the end of the intervention

Method of measurement

Depression- Anxiety- Stress Scale (DASS-21)

3

Description

Anxiety

Timepoint

Before intervention , 2 months after the end of the intervention

Method of measurement

Depression- Anxiety- Stress Scale (DASS-21)

4

Description

Stress

Timepoint

Before intervention , 2 months after the end of the intervention

Method of measurement

Depression- Anxiety- Stress Scale (DASS-21)

5

Description

Self-esteem

Timepoint

Before intervention , 2 months after the end of the intervention

Method of measurement

Rosenberg Self-esteem Questionnaire

Secondary outcomes

1

Description

parents's conflict tactics

Timepoint

Before intervention ,immediately after the intervention

Method of measurement

Conflict tactics scale parents (CTSP)

2

Description

High-risk behaviors

Timepoint

Before intervention , 2 months after the end of the intervention

Method of measurement

High-risk behaviors questions of demographic questionnaire

Intervention groups

1

Description

Intervention group : They will be subjected to 8 one-hour online sessions cognitive-behavioral intervention. The first two sessions included information on changing parents' Cognitive of gender dysphoria and violence, and next sessions included training to change violent behavior, anger and calm control, speech skills training, empathy skills, conversation skills, resolution skills, emotion control, stress management.

Category

Behavior

Recruitment centers

1

Recruitment center**Name of recruitment center**

Instagram and Twitter/ Iranian gender dysphoria association

Full name of responsible person

Farnaz Farnam

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research of Tehran University of Medical Science

Full name of responsible person

Mohammad Ali Sahraian

Street address

Tohid Square, Nosrat st, Tehran, Reproductive Health
Department, Tehran University of Medical sciences

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Web page address

http://fnm.tums.ac.ir

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 of Tehran University of
Medical Science

Proportion provided by this source

50

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**

Tehran University of Medical Sciences

Full name of responsible person

Mahdieh Damanpak

Position

Master Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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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Assistant Professor in Tehran University of Medical
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Person responsible for updating data**Contact****Name of organization / entity**

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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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We're going to publish the results and not distribute the

data

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available