Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
Age
From **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 and Midwifery
City
Tehran
Province
Tehran
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
Street address
Tohid Square, Dr.Mirkhani St, School of Nursing and Midwifery
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f_farnam@yahoo.com

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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1419733181

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Email
mahdieh.d20@gmail.com

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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Assistant Professor in Tehran University of Medical Sciences

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Ph.D.

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Person responsible for updating data

Contact

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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