

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of education based on empowerment model on anxiety and quality of life among transsexual clients undergoing hormone therapy

Protocol summary

Study aim

The main objective of the project: To determine the effect of empowerment based education on the anxiety and quality of life of transgender patients under hormone therapy

Design

Clinical trials with community based and pragmatic control group, with parallel groups, without blindness, randomized

Settings and conduct

This study is based on an empowerment model based education, conducted at the Tehran Welfare Center. It is based on education based on the empowerment model (perception of threat, problem solving, learning participation, and evaluation) with the presence of clients in the form of training sessions, question and answer, and group discussion in 5 axes (definition of the nature of the disease, factors affecting the incidence of sexual illness and its severity, The ways of diagnosis and treatment, the long process of treatment, and the problems surrounding it), with emphasis on drug therapy and the impact of the treatment process and complications.

Participants/Inclusion and exclusion criteria

Entry requirements: • Having a diagnosis of transient disorder based on DSM-5 diagnostic criteria for sexual dysfunction • The absence of diagnosed psychological illness • Not having physiological disorders of the genitalia • Being at least 18 years old and up to 35 years (ie, the client is within the adult age range). • At least 6 months of taking hormonal medications

Intervention groups

In this research, the control group receives the routine training, and the intervention in test group is based on the training based on the empowerment model (threat perception, problem solving, training participation and evaluation) which is conducted by training sessions, question and answer and group discussion

Main outcome variables

Anxiety; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181013041321N1**

Registration date: **2018-11-08, 1397/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-08, 1397/08/17**

Update count: **0**

Registration date

2018-11-08, 1397/08/17

Registrant information

Name

maryam asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7790 7620

Email address

ma88mrp@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-27, 1397/08/05

Expected recruitment end date

2018-11-26, 1397/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	continue this until the sample size is completed.
Scientific title	Blinding (investigator's opinion)
The effect of education based on empowerment model on anxiety and quality of life among transsexual clients undergoing hormone therapy	Not blinded
Public title	Blinding description
The effect of education based on empowerment model on anxiety and quality of life	Placebo
Purpose	Not used
Education/Guidance	Assignment
Inclusion/Exclusion criteria	Parallel
Inclusion criteria:	Other design features
Having a diagnosis of transgender disorder based on DSM-5 diagnostic criteria for sexual dysfunction (diagnosis is done by psychologists and psychiatrists and recorded in the patient file) The absence of diagnosed psychological illness Not having physiological disorders of the genitalia Complete the informed consent form for participation in the study Being at least 18 years old and up to 35 years (ie, the client is within the adult age range) Pass at least 6 months of taking hormonal medications Lack of participation in similar specialized studies simultaneously Having the minimum level of fifth grade primary education or having the ability to read and write	Secondary Ids
Exclusion criteria:	empty
Non-cooperation until the end of the plan Abandonment in training sessions more than a meeting	Ethics committees
Age	1
From 18 years old to 35 years old	Ethics committee
Gender	Name of ethics committee
Both	Research Ethics Committee of Tehran University of Medical Sciences
Phase	Street address
N/A	Sixth Floor., Central Organization of the University., Qods St., Keshavarz Blvd
Groups that have been masked	City
No information	Tehran
Sample size	Province
Target sample size: 90	Tehran
Randomization (investigator's opinion)	Postal code
Randomized	1419733171
Randomization description	Approval date
The Researcher starts sampling after referring to the welfare organization and passing the administrative procedures and observing the ethics principles and obtaining written consent. Sampling is done by continuous sampling. At first, a list of qualified applicants is provided, starting with the latest case file, and if they are eligible, they are entered in the list to complete the required sample size. After completing the allocation list of the samples in two groups, the control group and the intervention group are randomly assigned using four blocks design. Thus, the letter A is considered for the intervention group and the letter B is considered for the control group. Then, all the permutation combinations of the letters A, A and B, B, six different combinations, are written (AABB for digit 1, ABBA for digit 2 ...), and from digits 1 to 6 a digit is randomly selected (for example, if The digit 2 was chosen. The concept is that the first person in the experimental group is the next two in the control group and the fourth in the test group), and we	2018-04-08, 1397/01/19
	Ethics committee reference number
	IR.TUMS.FNM.REC.1397.020
	Health conditions studied
	1
	Description of health condition studied
	Transsexual patients
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	1
	Description
	Quality of Life Score in SF-36 questionnaire
	Timepoint
	At the beginning of the study (before the intervention) and then three months after the intervention.
	Method of measurement
	Quality of Life Measurement: A Short Form Questionnaire 36 _Questions Of Quality Of Life
	2
	Description
	Anxiety

Timepoint

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

Method of measurement

Spielberger Anxiety Inventory

Secondary outcomes

empty

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

Intervention group: The training is based on an empowerment model (perception of threat, problem solving, learning participation and evaluation) with the presence of clients through training sessions, question and answer, and group discussion in 5 axes (definition of the nature of the disease, factors affecting the incidence of sexual illness and severity, ways of diagnosis and Treatment, long process of treatment and problems surrounding it) with an emphasis on drug therapy and the extent of the treatment process and complications.

Category

Prevention

2**Description**

Control group: Routine training of Tehran Welfare Center

Category

Prevention

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

Tehran Welfare Center

Full name of responsible person

Maryam Asadi

Street address

Shahid Zolfaghari Well Being Center., Takhty street.,
Moalem Square., West Yaft Abad

City

Tehran

Province

Tehran

Postal code

1371789631

Phone

+98 21 6669 2332

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+98 21 6663 3408

Email

info@behzisti.gov.ir

Web page address

<http://tehran.behzisti.ir/Portal/Home>

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

Research and Technology Department., 6th floor.,
Central University of the University., Quds St.,
Keshavarz Blvd

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+98 21 8163 3698

Email

itcenter@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir>

Grant name**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**

Tehran University of Medical Sciences

Full name of responsible person

Fariba Tabari

Position

science Committee

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery., Dr Mirkhani St.,
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Full name of responsible person

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ma88mrp@gmail.com

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