Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Teaching Dialectical Behavior Therapy Skills on resilience and reducing internalized transphobia of transgender people

Protocol summary

Study aim
Determining the effectiveness of teaching dialectical behavior therapy skills on the resilience of transgender people. Determining the effectiveness of dialectic behavior therapy skills training on reducing internalized transphobia in transgender people.

Design
Semi-experimental before-after type with single groups, convenience sampling, on 18 transgender individuals.

Settings and conduct
Due to the cooperation of this plan with the forensic medicine, the place of the treatment sessions will be in one of the government hospitals approved by the forensic medicine.Referrals will be given explanations about the plan and purpose of its implementation, the optionality of participating in the study and the absence of additional fees. The sample members are selected from among the people who are eligible in terms of Inclusion and exclusion criteria. Dialectical behavioral therapy skills training program will be implemented in 10 sessions and two sessions per week.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Verification of transgender identity by the Forensic Medicine Commission 2- Ability to understand therapeutic content 3- Minimum Middle school education 4- Age 18 to 50 years 5- Completing the informed consent form 6- Life in Iran exclusion criteria: 1- acute medical, psychiatric or surgical diseases.

Intervention groups
In this method, each person will be his own control and there is no separate control group. The intervention group is among transgender people. Dialectical behavior therapy skills training program is presented in 10 sessions, these skills are divided into 4 general categories of mindfulness skills, distress tolerance, emotional regulation and effective communication, and each of them is divided into two basic and advanced levels.

Main outcome variables
Resilience; internalized transphobia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230801058999N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effectiveness of Teaching Dialectical Behavior Therapy Skills on resilience and reducing internalized transphobia of transgender people

Public title
The effect of teaching dialectical behavior therapy skills in transgender people

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of gender dysphoria based on DSM5 in the medical record, this term is considered equivalent to transgender identity in this study. Ability to understand therapeutic content Minimum Middle school education Age 18 to 50 years Complete the informed consent form life in Iran

Exclusion criteria:
History of active phase of acute medical or psychiatric diseases in the last 6 months

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad Univesity of Medical Sciences

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Central Organization of Qurashi Building, University Street

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Approval date
2023-06-21, 1402/03/31

Ethics committee reference number
IR.MUMS.REC.1402.081

Health conditions studied

1

Description of health condition studied
Transgender people

ICD-10 code
F64.0

ICD-10 code description
Gender identity disorders Transsexualism: A desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inapprop

Primary outcomes

1

Description
Resilience

Timepoint
before the start of the study, the day of the end of the training and 1 month after the completion of the training

Method of measurement
Connor and Davidson Resilience Questionnaire

2

Description
Internalized Transphobia

Timepoint
before the start of the study, the day of the end of the training and 1 month after the completion of the training

Method of measurement
The 8-item subscale of internalized transphobia from the Minority Stress and Resilience Questionnaire of Testa et al.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Transgender people referring to the Transgender Center of Ibn Sina Mashhad Hospital and Mashhad Forensic Medicine in 1402-1403. This research will be done as a semi-experimental before-and-after type. And each person will be his own control. The sample members are selected by

a simple random method. After selecting the participants, the training program of dialectical behavior therapy skills will be implemented on the experimental group in 10 sessions of 90 minutes, twice a week, under the supervision of the relevant professor, and in each session 20 People will participate and the patients will be asked to complete the tasks that are needed to consolidate the training and better effectiveness of the treatment. Connor and Davidson Resilience Questionnaire (CD-RISC) and internalized transphobia (IT) will be administered before the intervention (day zero) and at the end of the training as a post-test to ensure the stability of the results over time one month later. The results of the treatment are followed up after the sessions. The content of the dialectical behavior therapy training sessions: first session: stating the rules of group therapy sessions; including the purpose of holding the meetings, the duration and number of meetings, the conditions for exiting the meetings and answering the questions of the participants in this field. The definition of the term dialectic and the principles and methods underlying thinking and behavior in the dialectical behavior therapy approach, familiarization and explanation of pervasive awareness and emotional, rational and logical states of mind. The second session: the centrality of teaching the basic skills of distress tolerance; including relaxation and self-soothing, turning attention from self-harming behaviors to pleasurable activities, leaving the situation and diverting attention to another issue The third session: the centrality of teaching advanced distress tolerance skills; Among them, visualizing a safe place, living in the present moment, discovering individual values, accepting fundamentals, formulating new coping strategies and coping plans in stressful situations. The fourth session: the centrality of teaching the fundamental skills of mindfulness; Among them, neglecting and mindfulness and practicing it. The fifth session: the centrality of teaching advanced skills of mindfulness; Among them, the wise mind, fundamental acceptance and initiatory mind, judgments and labels, non-judgment and everyday experience, the application of mindfulness in relationships and daily life, and recognizing and examining the obstacles ahead in performing mindfulness exercises. The sixth session: focusing on the fundamental skills of emotional regulation; Among them, the recognition of emotions and the process of emotion regulation, overcoming the obstacles to experiencing healthy emotions, reducing physical vulnerability to disturbing emotions and increasing the experience of positive emotions. The seventh session: focusing on teaching advanced emotional regulation skills; including, paying mindfulness to emotions without judging them, how to face positive and negative emotions, acting against strong emotional desires and problem solving The eighth session: focusing on the fundamental skills of effective communication; Among them, recognizing passive-aggressive behavior, compatibility between my desires and the desires of others, proportionality of individual desires and needs, learning key interpersonal skills and knowing the obstacles to their use. Session 9: Focusing on education Advanced effective communication skills; including identifying demands, adjusting the intensity of demands, bold draft, bold listening, saying no, and how to negotiate and analyze interpersonal problems. The 10th session: summarizing and reviewing what was presented in the entire sessions, evaluating the amount of results obtained from the sessions and the therapeutic goals of the content of the sessions based on McKay, Wood and Brantley behavioral therapy techniques.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

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1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

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

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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

Title and more details about the data/document
All data can be shared after de-identifying people.

When the data will become available and for how long
Access starts 6 months after results are published

To whom data/document is available
The data will be accessible to the editor-in-chief of the journal in which the article was published and to the researchers working in academic and scientific institutions if they provide valid reasons.

Under which criteria data/document could be used
It can be used if valid reasons are presented to the

responsible author.

From where data/document is obtainable

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What processes are involved for a request to access data/document

After sending the request by mentioning the reasons to the entered emails, the authors will send the data file or the data access code which is registered in valid databases to the applicant after checking and if they agree with this request.

Comments