A Randomized Clinical Trial Protocol, Parallel-Group Study to Determine the Effect of Cognitive-Behavioral Therapy on Family Violence and Its Consequences in Transgender Youth.

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Study protocol

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Abstract

Background

Family violence against transgender people is a common issue and affects their mental health. Very few if any interventions have been designed to reduce family violence against transgender youths. This RCT will evaluate the efficacy of cognitive-behavioral therapy for transgender's parents on their violent behavior towards their children and on transgender youth's mental health.

Methods

This study is a randomized controlled trial that will be conducted on 50 transgender youths with selected inclusion criteria in Iran. Intervention will be undertaken on the parents or guardians of these transgender youths, in eight 1-hour online sessions for intervention group to increase their knowledge of gender dysphoria, to help control their anger regarding their offspring's gender dysphoria and to learn manage stressful situations. Primary outcomes that will be measured in this study include frequency of family violence towards transgender youths, depression, anxiety, stress, self-esteem, suicidal thoughts and suicide attempts in transgender youth and secondary outcome is parental conflict resolution tactics before and after intervention.

Discussion

To the best of our knowledge, this is the first RCT on family violence against transgender youth in world and in Iran. Findings will help to provide better education for transgender's parents to reduce violence against their children.

Results

N/A

Conclusion

N/A

Trial registration

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Plain English Summary

Transgender people are one of the special minorities in society. These people are not sufficiently accepted by the community and families yet, and so there is a lot of violence against them in the community, school and family. Family violence is one of the most common issues that transgender people face and can lead to depression, stress, low self-esteem, suicidal thoughts, drug abuse, running away from home

and high risk behaviors. So far, several studies have been conducted on the prevalence of family violence against transgender people and its effects on their mental health but very few if any interventions conducted to reduce violence against these youths by working with potential perpetrators of violence. The main aim of this study is to test the efficacy of Counseling sessions for abusive parents on frequency of family violence against their transgender children and their mental health.

Background

Gender identity is defined as the feeling of being male or female that corresponds to one's gender(1). There is usually a harmony between sex and gender identity, but sometimes these two items are incompatible(2). According to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), “the incongruity between a person's experienced gender and the gender assigned to him or her at birth” leads to “Gender Dysphoria,” a term that replaced the previous “Gender Identity Disorder” in order to avoid stigma(1, 3).

The prevalence of gender dysphoria in trans women ranges from 0.005–0.014% and in trans men from 0.002–0.003%. Since not all adults seek hormonal and surgical treatment at specialized clinics, this rate is probably underestimated(3).

Transgender people face a lot of problems include lack of social support, community rejection, physical and family violence. Among this problems, family violence is a common issue (1, 4–7).

Family violence is defined as any act or omission by people who are cohabitating or living together as a family that results in serious injury to other members of the family. Family violence has several distinct subgroupings, such as child abuse, intimate partner abuse and elder abuse(8).

Many transgender are not accepted by their families because of the religious atmosphere and fear of disgrace and harassment of neighbors and other members of society, and they constantly treat their children with violence(9). A 2010 study found that 60% of transgender people are subject to domestic violence(10). According to a report in Iran, parents support their transgender child in only 30% of cases; in 10% of cases, parents do not care about this issue and choose to ignore it, but in 70% of cases parents deal with anger and repression or are saddened to hear their child's demand for gender reassignment. These parents usually do not accept their child's problems or respond with inhumanity, anger and resentment to the child(2). In qualitative studies conducted by the research team (under submission), many of the problems faced by these individuals in society stem from violence and a lack of family support(11).

Although transgender people are a minority of the population, this population is increasing, and these individuals, like other individuals in the community, have the right to reproductive health(3). A number of studies reported high level of family violence against transgender youth, that can be lead to suicidal thoughts, drug abuse, running away from home and high risk behaviors; but very few if any interventions has been conducted to reduce violence against these youths by working with potential perpetrators of

violence.(10, 12) To the best of our knowledge, this study is the first RCT on family violence against transgender youth in the world and in Iran.

Method/design

Aim:

Research Hypothesis

1. CBT can reduce family violence perpetrated by parents or guardians towards transgender youths.

Primary Objective:

1. The main primary objective is the frequency of family violence towards transgender youth before and after intervention.
2. Other primary objectives are depression, anxiety, stress, self-esteem, suicidal thoughts and suicide attempts changes in transgender youths before and after intervention.

Secondary Objectives:

1. The secondary objective is comparing the parents' conflict resolution tactics in the relation to transgender youths before and after intervention.

Study design:

This trial is designed as a parallel randomized, controlled trial with block randomization and 1:1 allocation ratio. All ethical and scientifical requites of this protocol has been reviewed and approved by Tehran University of Medical Sciences at 2020-02-18.

Study setting

The exact prevalence of gender dysphoria in Iran is not determined. Based on a survey that recorded the subjects referred to the Tehran Psychiatric Institute (TPI) from 2002 to 2009 with a diagnosis of gender dysphoria by two independent psychiatrists, the prevalence of Gender dysphoria in Iran considered 1:141000 (referral population considered people aged between 15 and 44) (13). Iran is one of the first Islamic countries where gender reassignment has been legalized since 1964 and was second only to Thailand for the most gender reassignment surgeries in 2008 (14). But despite the legality of gender reassignment, transgender youth are still not sufficiently accepted in society due to cultural and religious pressures ; and society, family, friends, school, and co-workers perpetrate violence and discrimination against transgender people. The steps for obtaining allowance of gender reassignment surgery for transgender people in Iran are as follows: Request to Family Court; refer the person to the Legal Medicine Organization (LMO) by court; evaluate hormonal and karyotype tests and at least 12 counseling sessions with an expert psychiatrist in LMO; approve gender dysphoria diagnosis by psychiatrist and then

reapproved in LMO Commission with attendance of an expert group and refer accepted request to the court again for final decision. Only after this approval, the transgender youth can change their identity card, have the desired sex cloths and undergo gender reassignment surgery (although many of them have started hormone therapy many years sooner by private physician or by own).

Participants

We will study 50 transgender youth, who will gather through Internet from October 2020 to January 2021.

An announcement about this study will first be posted on the Transgender support pages in Instagram and Twitter. Inclusion criteria for transgender youths are the definitive diagnosis of Gender Dysphoria; aged between 16-30 years; living in a home with parents or guardians; transgender youth's and their parents' willingness to participate in the study and being a victim of family violence, which is investigated through one question "Have you experienced any physical, emotional, verbal or sexual violence from your family in the past 4 months?" from transgender individual. The only exclusion criterion is transgender parents' unwillingness to attend classes during the intervention process. The eligible participant who intend to participate in the study will apprise of the nature of the trial. Verbal and written informed consent will obtain prior to randomization. The participants will be randomized to intervention and control groups by using randomized block design with four block sizes with a 1:1 allocation ratio. Study outcomes will be measured through self-report questionnaires.

Randomization

The sample size of this study was calculated based on the most similar available article titled: "individual cognitive behavioral treatment and family therapy for physically abused children and their offending parents: A comparison of clinical outcomes" (15). Based on the mean and standard deviation of this article and also with α=0.05 and power 1-β 0.90 and considering a 20% drop, the total sample size required for each group is 25 people.

$$n_1 = n_2 = \frac{(S_1^{\,2} + S_2^{\,2})(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(\overline{X}_1 - \overline{X}_2)^2} \qquad \mathrm{N1} = \mathrm{N2} = \frac{(62+4.52)(1.96+1.28)2}{(9-3.6)2} = 21$$

For concealment and implementation mechanism, FF will generate allocation sequence and opaque sealed envelopes will be received by recruiters (MD). The randomization code will not release until the participant has been recruited into the trial. All people who give consent for participation and who fulfill the inclusion criteria will be randomized. Intervention sessions will be done by one of research team member (MD) who is not involved in randomization and not in assessing the outcomes of the study.

Complete blinding is not possible due to the nature of the intervention. Neither participants nor staffs can be blinded to allocation. An employee outside the research team will analyze data. Therefore, in this study

outcome assessor will be blinded.

Intervention:

50 eligible transgender youths will be assigned to intervention and control group. For assessing main primary objective (frequency of family violence), all transgender youths will complete the family violence self-report checklist daily for 1 month as a pre-test tool and again for 1 month as a post-test (2 months after ending intervention). For other primary outcomes, DASS-21 and Rosenberg self-esteem questionnaires will be sent via an internet website for transgender youth as pre-test and also as post-test. After completing the pre-tests by transgender youths, their parents will be invited to the study for CBT intervention. For assessing secondary outcome, the parents will complete Conflict Tactics Scales; Parent-child version (CTSPC) as pre-test and at the end of intervention as post-test. After receiving pre-test questionnaires, our intervention (CBT) will begin on the parents of the transgender youths. Parents in the intervention group will attend eight 1-hour online group therapy sessions. and for better modification these sessions will be held in four 2-hour sessions, if parents could not attend in eight sessions. Two months after last session of intervention, post-test questionnaires will be sent to transgender youths.

The first session of intervention contains information for increasing the parent's/guardian's awareness of nature of gender dysphoria, with talking about the history of gender dysphoria in Iran and the world, the theoretical causes and risk factors, different reactions of parents, expressing the research team's sympathy with the parents because of their sadness and concerns.

The second session contains the problems faced by transgender youth, consequences of lack of family and community support and examples of successful transgender youth.

The third session includes an overview of existing counseling and treatments and health care needs before and after gender reassignment.

The fourth session will be about the definition of violence, family violence and anger symptoms.

The fifth and sixth sessions contains anger management strategies, relaxation, and home exercises and the seventh and eighth sessions include speech and discussion skills training, empathy skills, conflict resolution skills and stressful conditions management.

For ethical consideration, control group will receive all meeting's content after ending intervention.

Outcomes measurement

Primary Outcome Measures:

1. Family violence against transgender youth: The main primary outcomes of this study is the family violence against transgender youth that will be assessed by a research-made daily self-report checklist completed by transgender youths for 1 month prior and also 2 months after intervention. In

our research, family violence means the frequency of physical, psychological, verbal, and sexual violence perpetrated by a transgender parent or guardian.[16]

2. Depression, anxiety and stress: To determine these outcomes the standard questionnaire of Depression Anxiety Stress Scale (DASS -21) will be used. It has 21 items and each item is scored on a 4-point Likert scale ranging from 0 (“did not apply to me at all”) to 3 (“applied to me very much”). [17-19]
3. Self-esteem: Self-esteem will be determined by the standard questionnaire of Rosenberg Self-Esteem scale (RSES)[20], that has the score range between of 0–30, where a score of less than 15 may indicate problematic low self-esteem. It is a ten item Likert-type scale with items answered on a four-point scale—from strongly agree to strongly disagree. The scale measures global self-worth by measuring both positive and negative feelings about the self.[21]
4. Suicide thought and attempt: This outcome will be determined by two questions ““How many times have you seriously considered suicide in the last 4 months? Never/once/ 2-3 times/4 times or more” and “How many times have you committed suicide in the last 4 months? Never/once/ 2-3 times/4 times or more”.

Secondary outcome measures:

1. Parental conflict resolution tactics: This outcome will be assessed by the Conflict Tactics Scales; Parent-child version (CTSPC). The basic form of CTSPC consists of 22 items divided into three scales: non-violent discipline, psychological aggression, and physical assault. The latter is further split into three subscales according to severity, which is respectively called corporal punishment, physical maltreatment, and severe physical maltreatment. The questionnaire also contains supplementary scales on disciplinary methods, neglect, and sexual abuse in the preceding week.[22]

Adherence:

1. Researchers will call the transgender youth once a week to remind them to fill out the family violence self-report checklist in pre-test and post-test period.
2. Researchers will call the transgender youth’s parents once a week to review any issues arising from the previous session, and reminding next session.
3. Researchers will answer parents’ sub-questions about contraception, sexual disorders and reproductive health at the end of the sessions to encourage them to continue meetings.
4. Researchers help participants to use internet websites for data collection.

Concomitant care:

Parents or guardians who are enrolled in the study will be warned to not attend any family counseling from sampling and for 2 months after the intervention.

Statistical methods

Outcomes:

The intervention group will be compared against control group and also both groups will be compared before and after intervention. Data analysis will be performed with SPSS 21. At the first description of the data (in percentage and frequency, mean and standard deviation) will be provided. And then by using Independent T-test (examining the questionnaire scores in terms of binary variables such as the study group and gender), paired t-test (Study before and after intervention in one group), Pearson correlation test (for correlating questionnaire scores and quantitative variables such as age), ANOVA and Tukey post hoc tests (Analysis questionnaire scores and categorical variables such as job and economic status), Chi-square test (Relationship of two qualitative variables such as the relationship between levels of mental health and family violence with gender, marital status, etc.) will be analyzed.

Additional analyses:

For qualitative variables and quantitative variables with a cut-off point, logistic regression and quantitative numerical variables, linear regression will be used.

Analysis population and missing data:

Outcome data obtained from all participants are included in the data analysis, regardless of protocol adherence. If there is missing data in an internet-based questionnaire, the questionnaire will be returned to the person to complete. Finally, if there is missing data, statistical methods of single imputation and multiple imputations will be used.

Abbreviations

Cognitive-behavioral therapy (CBT)

Tehran Psychiatric Institute (TPI)

Legal Medicine Organization (LMO)

Conflict Tactics Scales; Parent-child version (CTSPC)

Depression Anxiety Stress Scale (DASS -21)

Rosenberg Self-Esteem scale (RSES)

Declarations

Ethics approval and consent to participate:

The study was approved by the research ethics committee of Tehran University of Medical Sciences on the 18th of February 2020 (IR.TUMS.FNM.REC.1398.201). (Ethical document attached)

This study was found to be in accordance with the Declaration of Helsinki and national norms and standards for conducting Medical Research in Iran. Participants have to provide written informed consent for participation in the trial before screening.

Consent for publication:

Not applicable

Availability of data and materials:

The data will be available from the corresponding author on reasonable request.

Access to data

MD and FF will be given access to the cleaned data sets. To ensure confidentiality, data dispersed to project team members will be blinded to any identifying participant information.

Data management

Electronic files of participants will be stored in numerical order and stored in a secure and accessible place and manner. Participant files will be maintained in storage for a period of 2 years after completion of the study.

Formal committee and Interim analysis:

This trial does not have a data monitoring committee and any stopping guidelines.

Harms:

It seems that our RCT does not have any adverse effects on participants

Auditing:

Auditing will be done by the Tehran University of Medical Sciences.

Competing interests:

We have no conflict of interest to declare.

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Authors' contributions:

FF (Farnaz Farnam): she is grant holder and contributes in conception and design of the study, design and conduct of intervention, resolve the problems during the project, coordination with related organization, final analysis, interpretation of data, revise and approve final report and papers

MD (Mahdieh Damanpak): she contributes in design of the study and conduct of the intervention, coordination with related organization, writing the first draft of the proposal and papers, data interpretation

PK (Parisa Khodakhah): she contributes in the sampling and design the content of intervention.

Protocol amendments:

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the participants or may affect participants' safety, including changes of study objectives, study design, participant population, sample sizes, study procedures, or significant administrative aspects will be notified to the Ethics Committee of Tehran University of Medical Sciences.

Consent or assent:

To acquire informed consent comprehensible information about the research will be provided in writing to the participants to ensure that they understand the purpose and methodology of the research and are fully satisfied with the study. The researcher will also explain all the necessary information to the study participants. Participants can discuss with the researcher if they have any questions, so that nothing will be left vague to them. Written informed consent will be maintained until the end of the study.

Ancillary studies:

Participants complete consent for the use of their data (without the name) in future research under the supervision of FF.

Confidentiality:

All study-related information will be stored electronically. Each participant will have his or her code to fill out forms and questionnaires; therefore, all reports, data collection, process, and administrative forms will be identified by a coded number only in order to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All files containing data will be protected by password and no one except the researcher will have access to it.

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Figures

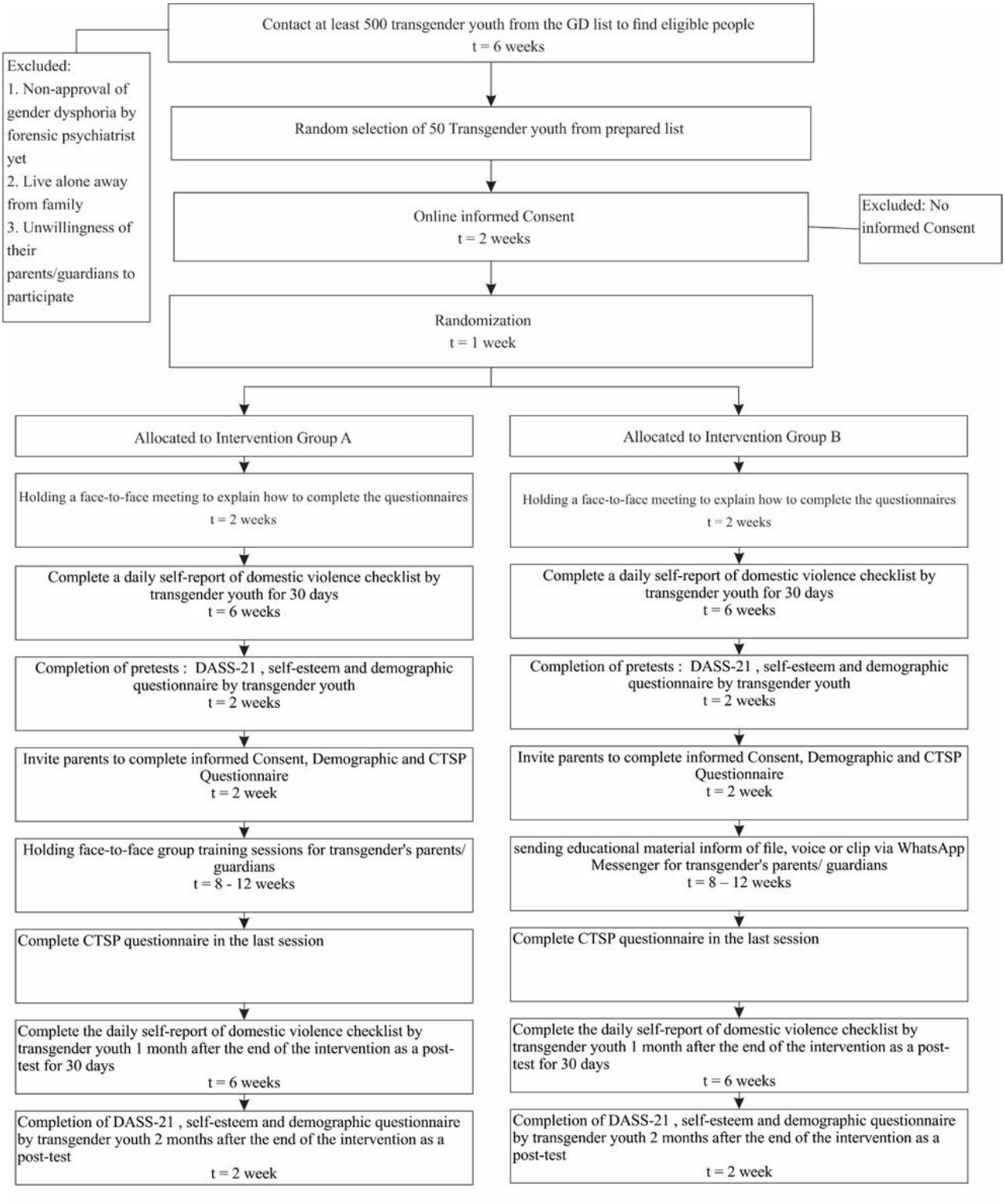

Figure 1

Participant timeline. Time schedule of enrolment, interventions, assessments, and visits for participant.