A web based cognitive behavioral therapy that addresses gender dysphoria, gender minority stress and suicidality among gender minority youth. A Randomized Control Trial

Published: 09-12-2024
Last updated: 18-01-2025

Research question:To what extent is a web-based, Cognitive Behavioral Therapy (CBT) specially designed for young gender diverse youth in the Netherlands, an effective treatment to reduce their suicidality? Are there gender, sex assigned at birth,...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57183

Source
ToetsingOnline

Brief title
CBT for Trangender Youth who feel Suicidal

Condition

- Other condition

Synonym
suicidal ideation, suicidality

Health condition

suicidaliteit en minderheidsstress

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cognitive behavioral therapy, Minority stress, Suicidality, Transgender

Outcome measures

Primary outcome

Main study parameters for primary objectives are suicidal ideation and

behavior, depression, gender minority stress, genderdysphoria and coping.

Secondary outcome

Main study parameters for secondary objectives are thwarted belongingness and

perceived burdensomeness. Secondary parameters are explicit rejection due to

gender identity.

Study description

Background summary

The high rate of suicidality among transgender and gender diverse youth (hereafter "gender diverse") is a serious mental and public health issue. Gender diverse youth have a 7-10-fold risk of suicidality. Adolescence and young adulthood are peak periods for mental health problems among gender diverse people: 93.0% of first suicide attempts in this group occur before the age of 25.
The mechanisms that can explain the increased suicidality of gender diverse youth occur from within a 1) gender minority stress framework and a 2) gender dysphoria framework. These frameworks show that gender minority individuals can experience internal and external stress, as well as dysphoria around their gender identity. (Testa et al., 2015).
Trying to understand what is happening in relation to their gender identity and

seeking confirmation of their gender identity, both internally and from their environment (where rejection often takes place), enhances youth*s psychological complaints and suicidality. The proposed
treatment therefore aims to address the combined burden of having suicidal thoughts, experiencing gender minority stress and gender dysphoria, and offer helpful coping skills.

Study objective

Research question:
To what extent is a web-based, Cognitive Behavioral Therapy (CBT) specially designed for young gender diverse youth in the Netherlands, an effective treatment to reduce their suicidality? Are there gender, sex assigned at birth, age (and ethnicity) differences when comparing transgender males, transgender females and non-binary young people?

Objective: Primary objectives. We aim to investigate: (1) the extent to which a web-based CBT specifically developed gender diverse youth, aged between 16 and 28, is more effective in reducing a) suicidal ideation, b) depression, and c) gender minority stress than treatment as usual. And (2), we aim to investigate the extent to which this web-based CBT helps to decrease participants* maladaptive coping strategies and increase participants* adaptive coping strategies for dealing with minority stress and suicidality.
Secondary objectives. We aim to investigate if: (3) there are group differences in intervention effects. And (4) suicidal ideation is reduced through decreasing thwarted belongingness and perceived burdensomeness.

Study design

We will utilize a single blind randomized controlled trial: participants will be randomly assigned to either the control condition (treatment as usual) or the experimental condition. Participants are blind to the condition.
Study population Gender diverse youth aged 16 - 28 with suicidal ideation or suicidal behavior. Youth who are unsure about their gender identity will also be able to participate. The experimental and control condition will be delivered by approximately 15 psychologists from 113 Suicide Prevention.
The experimental condition is a web-based CBT intervention. This treatment consists of 12 weekly chat or phone sessions of approximately an hour with a psychologist.

The control condition is the treatment as usual delivered by psychologist from 113 Suicide Prevention. In the treatment as usual participants also receive 12 weekly chat sessions of approximately an hour.
The difference between the experimental condition and the control condition consists of the focus and contents on *genderdyphoria, gender minority stress, and coping with these aspects*, which is only visible in the experimental

condition.

Main study parameters/endpoints:
Main study parameters for primary objectives are suicidal ideation and behavior, depression, gender minority stress, genderdysphoria and coping. Main study parameters for secondary objectives are thwarted belongingness and perceived burdensomeness. Secondary parameters are explicit rejection due to gender identity.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There is no added risk for participants participating in one of our conditions compared to the treatment as usual condition as provided by 113 to this population. Research shows that participating in a randomized controlled trial aimed at reducing suicidality does not increase the risk of suicide (Huisman & Kerkhof, 2017). In addition, in both conditions participants receive treatment for their suicidal ideation by trained psychologists. However, in the experimental condition, we have a specific focus on genderdyphoria, gender minority stress, and coping with these aspects*. In the study (and different from treatment as usual), participants (in both conditions) are asked to complete a total 60-92 items at four times points: before the first session (T0; 92 items), after the seventh session (T1; 60 items), after the last session (T2; 60 items) and three months after the last session (T3; 80 items). The questions ask, among other things, about suicidal ideation, gender dysphoria coping and minority stress. Research showed that answering questions regarding suicidality does not increase suicidal ideation (Huisman & Kerkhof, 2017), and therefore does not pose a risk to participants.

Study burden and risks

There is no added risk for participants participating in one of our conditions compared to the treatment as usual condition as provided by 113 to this population. Research shows that participating in a randomized controlled trial aimed at reducing suicidality does not increase the risk of suicide (Huisman & Kerkhof, 2017). In addition, in both conditions participants receive treatment for their suicidal ideation by trained psychologists. However, in the experimental condition, we have a specific focus on genderdyphoria, gender minority stress, and coping with these aspects*. In the study (and different from treatment as usual), participants (in both conditions) are asked to complete a total 60-92 items at four times points: before the first session (T0; 92 items), after the seventh session (T1; 60 items), after the last session (T2; 60 items) and three months after the last session (T3; 80 items). The questions ask, among other things, about suicidal ideation, gender dysphoria coping and minority stress. Research showed that answering questions regarding suicidality does not increase suicidal ideation (Huisman & Kerkhof, 2017), and therefore does not pose a risk to participants.

Contacts

Public
Rijksuniversiteit Groningen

Grote Kruisstraat 2/1
Groningen 9733TG
NL
Scientific
Rijksuniversiteit Groningen

Grote Kruisstraat 2/1
Groningen 9733TG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- A subject is aged between 16 - 28 years old.
- A subject identifies as one of the identities we classify under *gender diverse* (see 4.1) or is not sure about their gender identity.
- A subject is having suicidal ideation
[Nb: if subjects already follow a therapy elsewhere, we will include them but within the sessions also gives them tools to discuss their suicidal thoughts with their current mental healthcare provider]

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Subjects who are in acute suicidal crisis. They will be able to discuss this with their 113 therapist when they have a meeting scheduled, or they contact the crisis chat of 113 Suicide Prevention. All potential subjects are informed of this at several points in the online registration environment, and in the recruitment material. It will be discussed with the participants if it still feasible and sensible to continue their enrolment in the therapy.
- Subjects who seem to be confused or mentally incapacitated The assessment of an individual's eligibility to participate will be made by the therapist in consultation with their supervisor. Those unable to follow therapy will be excluded.
- - When a subject starts or is already enrolled in new therapy somewhere else, the psychologist decides together with the participant if this therapy continues. Participants who do attend other therapy more frequently than once every three weeks will be excluded or that the 113 therapy will be finished.

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	132
Type:	Anticipated

Ethics review

Approved WMO Date:	09-12-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85970.018.23