TransMind

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This mixed-methods pilot study will explore the effects of a group-based MBI on body and emotional awareness in TGD individuals by collecting both quantitative measures and qualitative experiences on an adapted gender-inclusive MBI program. ...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57529

Source
Onderzoeksportaal

Brief title
TransMind

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- Psychiatric disorders NEC

Synonym
Gender dysphoria, psychological distress

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Psychosocial intervention

Explanation

N.a.

Outcome measures

Primary outcome

Primary outcomes include self-ratings of body awareness on the Multidimensional Assessment of Interoceptive Awareness (MAIA) and emotion regulation on the Difficulties Emotion Regulation Scale (DERS).

Secondary outcome

Secondary outcomes include self-report measures of perceived stress,rumination, alexithymia, experiential avoidance, positive and negative affect, emotional well-being, mindfulness skills, self-compassion, and decentering.

Study description

Background summary

Transgender and gender diverse (TGD) individuals experience an incongruence between their natal sex and gender identity that can cause deep discomfort known as gender dysphoria (GD). In recent years, the number of individuals who identify as TGD has increased markedly, particularly among younger age groups. This has led to a growing demand for specialized transgender healthcare and long waiting times (>3 years). Prolonged waiting for transgender care is associated with psychosocial distress, poorer health, and increased healthcare consumption. Moreover, it can exacerbate mental health problems such as depression, anxiety, and suicidality, which are prevalent in this population. Given that many TGD individuals do not feel comfortable or “at home” in their body, the vulnerability to mental problems may stem from impaired body awareness and interoceptive ability, which is essential for emotion regulation. Mindfulness-based interventions (MBIs) have been shown to improve mental health, promote interoceptive ability, and enhance emotional resilience, and could thus be a valuable (early) intervention option for people with GD.

Study objective

This mixed-methods pilot study will explore the effects of a group-based MBI on body and

emotional awareness in TGD individuals by collecting both quantitative measures and qualitative experiences on an adapted gender-inclusive MBI program.

Study design

In this pilot study, we will offer an 8-week MBI entitled Mindfulness-Based Cognitive Therapy for Life (MBCT-L), adapted in language for use in an adult gender-diverse population and co-facilitated by a trainer with lived experience. Participants will be recruited through TGD social networks. A combination of qualitative and quantitative data will be acquired to explore the effects of mindfulness training. Participants will be interviewed before and after the training to collect qualitative data on their experience with the training protocol, the group-based format and effects on body/interoceptive awareness and emotion regulation (co-primary outcomes), well-being, rumination, perceived stress, positive and negative affect, alexithymia, self-compassion and mindfulness skills.

Intervention

We will offer an 8-week mindfulness program (MBCT-L) that was developed by the University of Oxford Mindfulness Centre. It will be adapted in language for use in a gender-diverse population (18 - 50 years of age). Two trainers will teach the program, including one person with lived experience and one clinician. The training program follows a standardized protocol based on mindfulness-based cognitive therapy (MBCT) but applicable for use in a non-clinical population. The training program consists of 8 weekly 2-hour group sessions and one silent day. The program includes mindfulness exercises, elements from cognitive therapy, psychoeducation, and gentle physical exercises. In between sessions, participants are encouraged to practice at home for approximately 30 minutes/day.

Study burden and risks

The risks and discomforts associated with participation in this study are estimated as low. The main burden for participants consists of repeated non-invasive assessments. Benefits for participants include the opportunity to participate, free of charge, in a mindfulness program adapted for the TGD population. An indirect benefit of this pilot study is the potential to inform and provide a base for a larger study aimed at improving transgender care during the waiting period.

Contacts

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Trial sites

Trial sites in the Netherlands

Radboud Universitair Medisch Centrum
Target size: 12

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Trans and gender-diverse individuals who have received or are currently receiving medical transgender care.
2. Age between 18 and 50 years.
3. Provide written informed consent.
4. Adequate mastery of English or Dutch language.
5. Sufficient proficiency in English to complete questionnaires.

Exclusion criteria

1. Moderate to severe mental health problems, based on questionnaire DSM-XC scores above 2 [Mild symptoms] on a 5 point (0-4) Likert scale.
2. Recent (less than 5 years ago) participation in an 8-week mindfulness program

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2025
Enrollment:	12
Duration:	3 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	01-05-2025
Application type:	First submission
Review commission:	METC Oost-Nederland

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
Research portal	NL-009231