Sex hormones, cognition, and the role of cardiovascular and psychological factors: a study in elderly transgender women and men receiving long-term gender-affirming hormone therapy in comparison with cis men and women from the LASA cohort.

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

Summary

ID

NL-OMON50025

Source
ToetsingOnline

Brief title
Cognition in elderly transgender individuals

Condition

- Other condition

Synonym
gender dysphoria, gender incongruence

Health condition

patienten met genderdysforie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular status, Cognition, Gender-affirming hormone therapy, Psychological status

Outcome measures

Primary outcome

Endpoints that are of particular interest to this study and have been studied within the LASA framework include: general cognitive functioning (Mini-Mental State Examination), coding task, 15-word test (immediate and delayed recall), letter and category fluency, GIT, and number series (forward and backward). An exhaustive list of items that are part of the general LASA data collection can be found in Huisman et al (2011), and Hoogendijk et al. (2016), attached.

Secondary outcome

The following variables will be investigated as mediators: 1) psychological factors including depressive symptoms (CES-D) and anxiety (HADS-A), self-esteem/efficacy questionnaire, life satisfaction and (history of) psychiatric/psychological help, and 2) social factors including loneliness (De Jong-Gierveld & Kamphuis Loneliness Scale) and discrimination, and 3) cardiovascular parameters including self-report on cardiovascular disease,

diabetes, stroke and high blood pressure, medication use, health-related behaviour (smoking, alcohol consumption, sleep), BMI and blood pressure (2x). In addition, the following demographic information will be gathered: sex/gender, age, region in the Netherlands, marital status, housing, spirituality, socioeconomic status, feelings of masculinity/femininity. Information regarding contentment with medical treatment(s), body satisfaction, and sexuality will be collected as well.

Study description

Background summary

The number of individuals seeking (medical) help for gender dysphoria has strongly increased. Medical help may consist of gender-affirming hormone therapy (GHT), which could potentially have beneficial effects on cognition. However, increased cardiovascular risk (CVR) and psychological problems among transgender individuals could negatively influence cognition. Long-term GHT effects on cognition in the rising number of elderly transgender individuals are unknown.

Study objective

We aim to (1) assess differences in cognitive performance between trans women (male assigned at birth with female gender identity), trans men (female assigned at birth with male gender identity), cis (non-trans) men, and cis women; (2) determine whether differences in cognition could be explained by differences in CVR and psychological factors between these groups.

Study design

Cross-sectional observational study.

Study burden and risks

The data collection encompasses a face-to-face interview, consisting of validated questionnaires and including among others cognitive tests, and a self-administered questionnaire. The interview takes about 1.5 hours. The self-administered questionnaires are handed out by the interviewers and are

sent back in a stamped envelope by the respondents. Interviews take place at the respondent*s home address.
Contents of the interview and questionnaire include aspects of physical, emotional, social and cognitive functioning. We consider the most burdensome aspects of the data collection the general cognitive functioning, because these may be confronting to respondents. All data collection is completely observational and non-invasive. In general, there are no risks associated with participation in the study, but for frail older adults the data collection might be more burdensome. If participants indicate that they feel it is too burdensome beforehand, they will be excluded from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >55 years
Diagnosis of gender dysphoria
Continued and consistent use of GHT for at least 10 years
Currently in treatment at the Center of Expertise on Gender Dysphoria (i.e., last clinical appointment <2 years ago)

Exclusion criteria

No sufficient understanding of the Dutch language
Subjects that indicate on forehand to be too frail for full participation in the study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2020

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	NL72669.029.20