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Early-onset trans-sensitive therapy as part of gender dysphoria care

Submission date	Recruitment status	[ ] Prospectively registered
14/04/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/10/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/10/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosocial support can be provided at an early stage of gender-identity assessment and gender gender-affirming treatment process. The aim is to assess the effects of an early-onset trans-sensitive psychotherapy on the well-being of individuals seeking gender-affirming treatment.

Who can participate?
Study participants are non-treated patients referred to the Outpatient clinic for Assessment of Gender identity during the autumn of 2020.

What does the study involve?
In this pilot RCT study, an early-onset trans-sensitive therapy is integrated into gender dysphoria care. A naturalistic clinical sample of 60 consecutive individuals seeking gender affirming treatment is randomly allocated into two groups: one group received early therapy, while the other underwent the standard assessment process. The primary outcome investigates general health, and the secondary outcome looks at mental well-being, both using validated scales.

What are the possible benefits and risks of participating?
The possible benefits can be better coping with stress, increased wellbeing and readiness for self-reflection during the assessment process. Possible risks can be investment of time with no benefits, and the insufficiency of time-limited therapeutic intervention, if there are psychiatric disorders or psychosocial problems that would require other types of interventions.

Where is the study run from?
Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?
May 2020 to December 2026

Who is funding the study?
Helsinki University Hospital (Finland)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
Nil known

Study information

Scientific Title
The changing diagnostics and the clinical picture of gender dysphoria: Evaluation and effectiveness of the treatments

Acronym
GDDGTREAT32

Study objectives
The early timing of a short trans sensitive psychotherapeutic intervention, before diagnostic and gender reassignment procedures will be better than the same intervention later in the process (treatment as usual)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/05/2020, Helsinki and Uusimaa Hospital District Ethics Committee II (Keskuskirjaamo PL 200, Marjaniementie 74, Iiris-Keskus, Helsinki, 00029 HUS, Finland; +358 40359 4618 ; eettinen.toimikunta@hus.fi), ref: HUS/2924/2018

Study design
Randomized controlled trial within a naturalistic cohort

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gender dysphoria

Interventions
An early intervention-subsample of a naturalistic gender dysphoria cohort. Patients referred for diagnostics and treatment of Gender dysphoria at the University Hospital outpatient clinic are randomized to two groups: An early waiting list-intervention and treatment as usual (the same intervention later in the clinical process)

Participants are randomized 1:1 to receive either 10 sessions of individual early onset trans-sensitive therapy or the standard evaluation protocol. The aim is to offer the early intervention to the participants while queuing for the assessment. The randomization is conducted with the sealed envelope method.

Intervention Type
Behavioural

Primary outcome(s)
General health measured using the Finnish version of the General Health Questionnaire (GHQ) at baseline and approximately 6 months after. Exact dates in a naturalistic clinical study.

Key secondary outcome(s))

Mental well being measured using the Short Warwick-Edinburgh Mental Well-being Scale, before and after the early psychotherapeutic waiting-list intervention, and at the endpoint of the assessment procedure

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Non-treated patients referred to outpatient clinic for assessment of gender identity
2. Aged 18 years or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
An ongoing gender reassignment treatment, or only a consultative assessment

Date of first enrolment
01/08/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
PB 250
Helsinki
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00029 HUS

Sponsor information

Organisation
Helsinki University Hospital

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsingin ja Uudenmaan Sairaanhoitopiiri

Alternative Name(s)
Helsinki University Central Hospital, HUS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Finland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study are not expected to be made available due to privacy and data protection. The sample is a small, naturalistic clinical sample, and the data are derived from patient files.

IPD sharing plan summary
Not expected to be made available