

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

Submission date 14/04/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/10/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/10/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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?

Dr Katinka Tuisku, katinka.tuisku@hus.fi

Dr Niina Puustinen, niina.m.puustinen@hus.fi

Contact information

Type(s)

Scientific

Contact name

Dr Katinka Tuisku

Contact details

Helsinki University Hospital

PB 250

Helsinki

Finland

00029HUS

+358 504270354

katinka.tuisku@hus.fi

Type(s)

Scientific

Contact name

Dr Niina Puustinen

Contact details

Helsinki University Hospital

PB 250

Helsinki

Finland

00029HUS

+358 405440554

niina.m.puustinen@hus.fi

Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number

ClinicalTrials.gov number

Nil Known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet (languages: Finnish and Swedish)

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 measure

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.

Secondary outcome measures

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

Overall study start date

06/05/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

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

Finland

00029 HUS

Sponsor information

Organisation

Helsinki University Hospital

Sponsor details

PB250

Helsinki

Finland

00029HUS

+358 94711

HUSdg_1109003@hus.fi

Sponsor type

Hospital/treatment centre

Website

<https://www.hus.fi/en>

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsingin ja Uudenmaan Sairaanhoidopiiri

Alternative Name(s)

Helsinki University Central Hospital, HUS

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Finland

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2027

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