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Longitudinal outcomes of gender identity in children

Submission date 13/12/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2019	**Overall study status** Completed	
Last Edited 21/05/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Emerging data from several countries suggests that gender diversity in children and young people (CYP) is more common than previously thought (1.2% to 2.7%). This is reflected in the significant increase in referrals reported in gender clinics across a number of countries, including in the UK. While not all gender-diverse CYP will experience gender dysphoria (that is, the distress associated with a mismatch between the sex assigned at birth and gender identity), some do. The available evidence suggests that gender dysphoria is further associated with a range of negative mental and physical health outcomes, including depression, anxiety, suicidality and substance abuse. Current treatment in the NHS for CYP experiencing 'Gender dysphoria' is aimed at alleviating dysphoric feelings and improving psychological wellbeing. However, the evidence base on which the current treatment protocols are based is widely acknowledged to be both limited and shifting. A particular gap in the evidence, both in the UK and internationally, relates to children/younger adolescents presenting to services for which there is minimal research evidence to inform questions regarding likely trajectories and outcomes particularly in the context of: a) physical treatments (e.g. hormone blockers to suppress the onset of puberty); b) social transition (where a child presents to other people as a member of the 'opposite' gender in all contexts) and; c) co-occurring ASD. The aim of this study is to understand the key issues children, young people and their families face when accessing Gender Identity Development Services (GIDS). The researchers wish to understand more about the factors that lead some children to experience ongoing distress about their gender development while for others their distress subsides over time. They are also interested in the factors that influence whether a young person will choose to have medical treatment with hormone blockers to pause puberty or not. This is an important question for the NHS as most young people who opt for hormone blocking treatment to suppress puberty will later choose to have further treatment with hormones to enable them to transition to their preferred gender. The researchers are particularly keen to know more about how the decisions young people and their families make later affect their quality of life, physical health and psychological wellbeing.

Who can participate?

Patients aged 3-13 referred to the UK's Gender Identity Development Service (GIDS)

What does the study involve?
Young people and their families are interviewed about their experiences and the outcomes that matter to them and how this may or may not change over time.

What are the possible benefits and risks of participating?
The UK GID service for children and young people is the largest such service in the world and this study will be the largest study of its kind to date. It is anticipated that there will be great interest in the findings in the UK and elsewhere and that the study will generate much needed evidence about outcomes for young people and their families and thereby enable services to provide better, more individualised care. Although there is no immediate benefit to participating, this programme of research will provide new knowledge on how to best support young people who are concerned about their gender and provide good specialist care. Making as accurate an assessment as possible at a younger age has profound implications for the psychological and physical wellbeing of the individual but also for the cost to the NHS and public funds. The results will make it much clearer when to start intervening at a young age and the predictors for those who decide not to continue with physical or social transition. It will also provide new knowledge on how services might bring about optimal outcomes in terms of health and quality of life. It will help to answer the questions that Children and Young People and their families pose when first seeking help and will assist services to offer sensitive and appropriate care. While participants may be talking about difficult life experiences that may cause distress, no risks are foreseen.

Where is the study run from?
Tavistock & Portman NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2019 to May 2025

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
260379

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HS&DR 17/51/19, IRAS 260379

Study information

Scientific Title
Outcomes and predictors of outcome for children and young people referred to UK gender identity development services: a longitudinal investigation

Acronym
LOGIC

Study objectives
The research questions are:
1. What is the profile of children and younger adolescents referred to Gender Identity Development Services (GIDS)?
2. What proportion of children and younger adolescents, aged 3-13 years, referred to these services:
2.1. Experience ongoing gender dysphoria;
2.2. Go on to have physical treatment; and what are the predictors of such occurrences?
3. What is the impact of a) physical treatment b) social transition c) co-occurring autism on physical health, psychological wellbeing, Quality of Life, peer and family relationships and cost to the NHS and other public services?
4. What is the experience of children and their families over time referred to GID services?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study will be submitted for ethical review to a London-based Research Ethics Committee by February 2019 - pending

Study design
Prospective longitudinal mixed-methods design with a single centre

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Gender identity development in children and young people

Interventions
This study will employ a mixed-methods longitudinal design. It will consist of both quantitative assessments and qualitative interviews at three timepoints.

Participants will be firstly recruited to participate in quantitative assessments on gender dysphoria and gender identity; status with regard to social transition; physical health; mental health and psychological wellbeing; Autism Spectrum Disorder; cognitive development; quality of life; peer and family relationships; socio-cultural and demographic factors; Adverse Childhood Experiences; and health care and societal costs.

In addition to this quantitative assessment, 40 families will be invited to take part in interviews to explore their first-hand accounts of living with issues of gender identity, and their experiences of health services and therapies.

Intervention Type
Other

Primary outcome(s)
Gender Dysphoria

Baseline assessments and interviews will take place between June 2019 and November 2020. Timepoint 1 (first follow-up) assessments and interviews will take place between June 2020 and November 2021. Time point 2 assessments and interviews will take place between June 2021 And November 2022. We are currently in the process of deciding on our measures and designing our topic guides. We will be able to update you on the measures used by June.

Key secondary outcome(s))
Physical/endocrine Intervention and Mental Health; Behavioural and Emotional Functioning; and Quality of Life.

Completion date
31/05/2025

Eligibility

Key inclusion criteria
Participants must:
1. Be aged 3-13 years at the time of referral to the UK's Gender Identity Development Service (GIDS)

2. Have received parental consent
3. Have English language comprehension
4. Live in the UK

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
13 years

Sex
All

Key exclusion criteria
Participants must not:
1. Be aged 14 years or older

All participants must have parental consent and reasonable fluency in English

Date of first enrolment
05/06/2019

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Tavistock & Portman NHS Foundation Trust
Tavistock Centre, 120 Belsize Lane
London
United Kingdom
NW3 5BA

Sponsor information

Organisation
Tavistock & Portman NHS Trust (via NOCLOR)

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
We would like to make it possible for others to access such data but will need to review this once the study is completed, in consultation with our funders, the NIHR.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes