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PATHWAYS HORIZON: A longitudinal observational study

Submission date 30/07/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/08/2025	**Overall study status** Ongoing	
Last Edited 13/08/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The PATHWAYS study aims to find out how the NHS can best support children and young people with gender incongruence. Gender incongruence is when a person feels their gender identity differs from the sex that they were given at birth. Some people with gender incongruence want their bodies to be more like their gender identity.
In the UK, specialist gender services have been set up to support children/young people with gender incongruence including talking therapies and sometimes medical treatments. However, there are gaps in our understanding about how identity and feelings develop for young people with gender incongruence as they grow up and what treatment is helpful.

PATHWAYS Horizon will include all young people attending a UK NHS Gender Service who want to take part, and their parents. It will track young people's physical, social and emotional well-being, and the care and support they receive over time.

The study aims to find out about the needs of young people with gender incongruence and how services can help and support them and their families, and will provide new and important evidence that will help young people with gender incongruence, along with their parents and health professionals, to make informed choices about the care and support options that are most likely to be helpful.

Who can participate?
All children and young people (CYP) attending the CYP Gender Service across the UK.

What does the study involve?
The study will involve the completion of a number of questionnaires assessing the emotions, behaviours, quality of life, mental health, and the overall impact of gender incongruence from the perspective of the CYP, and from the perspective of their parent/guardian.

What are the possible benefits & risks of participating?
Benefits: The benefits of participation include contributing to valuable research that aims to improve the care and support for CYP with gender incongruence. Participants will receive better supervision and more visits, which may enhance their overall care. The study's findings will

provide evidence that can inform better clinical practices and policies, ultimately benefiting the wider community.
Risks: The potential risks include emotional distress, intrusion, inconvenience, breach of confidentiality, discomfort from assessments, changes to lifestyle, and potential misunderstandings. These risks are considered minimal and manageable with appropriate measures in place.

Where is the study run from?
King’s College London (UK)

When is the study starting and how long is it expected to run for?
December 2024 to January 2031

Who is funding the study?
National Research Collaboration Programme (NRCP) (UK)

Who is the main contact?
PATHWAYSEnquiries@kcl.ac.uk

Study website
https://www.kcl.ac.uk/research/pathways

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Emily Simonoff

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
350909

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 66901

Study information

Scientific Title
Puberty suppression And Transitional Healthcare with Adaptive Youth Services (PATHWAYS): a longitudinal observational study

Acronym
PATHWAYS HORIZON

Study objectives
Primary objectives:
1. To improve the understanding of the care needs and holistic developmental journeys of all CYP attending NHS Gender Services.
2. To understand how the developmental trajectories and short – to medium-term outcomes of CYP with gender incongruence are influenced by differences amongst CYP and their life experiences.

Secondary objectives:
1. To improve understanding of how care options are experienced by CYP and their parents /carers/legal guardians..
2. To develop a novel interview-based outcome measure that focuses on CYP's aspirations and goals from gender care.
3. To explore similarities and differences in the holistic perspectives of CYP and their parents /carers/legal guardians to gain a comprehensive understanding of how gender incongruence affects CYP.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/07/2025, London - City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048124; cityandeast.rec@hra.nhs.uk), ref: 25/LO/0251

Study design
Longitudinal observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Internet/virtual

Study type(s)
Quality of life

Participant information sheet
https://www.kcl.ac.uk/research/pathways

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

Interventions
Participants are recruited from the NHS Children & Young People's Gender Services (CYP-GS). They can consent to the study in clinic or remotely from home. The CYP's parent/caregiver may also consent to participate in the study alongside their CYP.

Once enrolled, at the Baseline visit, medical history and demographic data relating to the CYP will be collected. Questionnaires can be completed by CYP and/or their parents/caregivers, with the appropriate consent.

Participants will receive questionnaires on an annual basis for the duration of the funding period, which means they may complete the questionnaires in total between three and six annual occasions.

Questionnaires are completed via an online survey platform, unless one of the following applies: CYP is under 12, CYP or parent/caregiver has a neurodevelopmental condition or learning disability, English is the CYP or parent/caregiver's second language, and or/personal preference. If these circumstances apply, the research team can support the completion of the questionnaires.

Intervention Type
Other

Primary outcome measure
Mental health status and well-being quantitatively assessed using the KIDSCREEN-10 questionnaire at baseline and annually for up to 5.5 years

Secondary outcome measures
1. Quality of life is measured using the KIDSCREEN-52 at baseline and annual follow-up assessments for up to 5.5 years
2. Severity of gender-related distress is measured using the Utrecht Gender Dysphoria Scale – Gender Spectrum (UGDS-GS) at baseline and annual follow-up assessments for up to 5.5 years
3. Anxiety and depression symptoms are measured using the Revised Children's Anxiety and Depression Scale (RCADS) at baseline and annual follow-up assessments for up to 5.5 years
4. Suicidal ideation and non-suicidal self-injury are measured using the Ask Suicide-Screening Questions (ASQ) at baseline and annual follow-up assessments for up to 5.5 years
5. Post-traumatic stress disorder (PTSD) symptoms are measured using the Adolescent Primary Care Traumatic Stress Screen (APCTSS) at baseline and annual follow-up assessments for up to 5.5 years
6. Behavioural and functional difficulties are measured using the Child Behavior Checklist (CBCL) and the Youth Self-Report (YSR) at baseline and annual follow-up assessments for up to 5.5 years
7. Body image dysphoria is measured using the Body Image Dysphoria Scale (BIS) at baseline and annual follow-up assessments for up to 5.5 years

8. Emotional dysregulation is measured using the Difficulties in Emotional Regulation Scale (DERS-18 for CYP and DERS-29 for parents) at baseline and annual follow-up assessments for up to 5.5 years
9. Eating problems are measured using the SCOFF at baseline and annual follow-up assessments for up to 5.5 years
10. Sexual attraction and sexual behaviours are measured using items from the Avon Longitudinal Study of Parents and Children (ALSPAC) at baseline and annual follow-up assessments for up to 5.5 years
11. Hospitalisations are measured using hospital records at baseline and annual follow-up assessments for up to 5.5 years
12. Social transition status is measured using the Social Transition Status form developed for the PATHWAYS-HORIZON study at baseline and annual follow-up assessments for up to 5.5 years
13. Experiences with therapeutic options are measured using service records and participant report at baseline and annual follow-up assessments for up to 5.5 years
14. Parental support is measured using the Parental Support (PAGES) questionnaire at baseline and annual follow-up assessments for up to 5.5 years

Overall study start date
01/12/2024

Completion date
31/01/2031

Eligibility

Key inclusion criteria
1. The Child or young-person (CYP) has an accepted referral to CYP-Gender Services (CYPGS), or has already attended an appointment at a CYPGS.
2. The CYP is awaiting or has received their first appointment with the service at the time of completing baseline measures.
3. Valid assent/consent has been obtained:
- For CYP under the age of 16 at recruitment providing self-reports:
--Parent/legal guardian gives consent for them to participate AND
--CYP gives assent to participate. CYP is deemed to have capacity to consent by their clinician and gives consent to participate.
- For CYP 16 years and above providing self-report information:
--CYP gives consent to participate. OR
--Personal Consultee gives consent for the CYP to participate if the CYP lacks capacity to consent.
-For parent-reported measures for CYP under the age of 16 at recruitment:
-- Parent/legal guardian consents to their own participation to provide parent-reported measures.
For parent-reported measures for CYP 16 years and over at recruitment:
-- Parent/legal guardian consents to their own participation to provide parent-reported measures and CYP consents to parent/legal guardian completing measures.

Participant type(s)
Patient, Service user

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
3600

Key exclusion criteria
1. Child or young-person (CYP) did not attend a first appointment at CYP gender services.
2. CYP is deemed unsuitable in the opinion of the investigator for clinical or other reasons.

Date of first enrolment
01/09/2025

Date of final enrolment
31/01/2031

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Alder Hey Children's Hospital Trust
E Prescot Rd
Liverpool
United Kingdom
L14 5AB

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
Maudsley Hospital, Denmark Hill
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United Kingdom
SE5 8AZ
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PATHWAYSEnquiries@kcl.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Organisation
King's College London

Sponsor details
Strand Building Strand Campus, Strand
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PATHWAYSEnquiries@kcl.ac.uk

Sponsor type
University/education

Website
https://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Research Collaboration Programme

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

Publication and dissemination plan
Planned publication in peer-reviewed scientific journals and presentations at scientific and community-facing conferences. Whenever a peer-reviewed manuscript is accepted for publication, we will provide an accessible, easy-read version (confirmed with our lived experience Advisory Groups). These will be made widely available, including through the NHS Children and Young People Gender Services. Primary and secondary outcomes will be published in journals within 12 months of the end of the trial.

Intention to publish date

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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