SUPPORTED BY NIHR National Institute for Health and Care Research

South London and Maudsley NHS Foundation Trust

KING'S College LONDON

PATHWAYS Frequently Asked Questions (FAQs)

What is the PATHWAYS research?

The PATHWAYS research study aims to find out how the NHS can best support children and young people with gender incongruence. Gender incongruence is when a person's gender identity does not match their sex registered at birth. In recent years we have seen a very large increase in the number of children and young people experiencing gender incongruence, and we don't know why, or what their needs are. The PATHWAYS research study will explore the needs of children and young people attending the NHS Children and Young People's Gender Services and will help to shape the services in the future to better support young people and their families.

What is PATHWAYS HORIZON?

PATHWAYS HORIZON is the largest part of the PATHWAYS study. It is an observational research study, which is when researchers ask questions to understand people's thoughts, feelings or experiences, without the participants receiving any additional interventions within the study. Taking part in PATHWAYS HORIZON will not affect any interventions or care that young people and their families receive from the Gender Services.

This study has now received all the approvals it needs to start.

What are the other parts of the PATHWAYS research?

The PATHWAYS research will look comprehensively at the impact of different types of support for young people who are experiencing gender incongruence and have been referred to the NHS Children and Young People's Gender Services. There are four parts to the PATHWAYS study:

- **PATHWAYS HORIZON** is a longitudinal observational study of all young people attending the NHS Children and Young People's Gender Services who want to take part. It is the largest part of the PATHWAYS study, and will explore the wellbeing of young people, including their mental and physical health and experiences, and how these change (or not) as they grow up. This study has now received all necessary regulatory and ethics approvals and will begin recruiting participants soon. It will be open to all young people attending the NHS Children and Young People's Gender Services, with over 3000 young people expected to take part.
- **PATHWAYS TRIAL** focusses on the effects of puberty suppressing hormones on young people's physical, social and emotional well-being. It involves young people who want to delay puberty and whose parents and Gender Service agree with this treatment option.
- **PATHWAYS CONNECT** will look at young people's thinking and brain development, and will follow both those who are, and are not, taking puberty suppressing hormones.
- **PATHWAYS VOICES** involves speaking to young people about their experiences of living with gender incongruence and of their care in the NHS Children and Young People's Gender Services including, for some, taking puberty suppressing hormones. We will talk to young people and parents/caregivers several times while they are attending the Services. We will also find out from staff working within the Services about what they think helps.

All parts of the study have been designed to meet rigorous scientific and ethical standards.

Why do we need PATHWAYS HORIZON?

Some people have asked whether we need a new study of children and young people with gender incongruence or whether we could just follow up people who previously attended gender services. There are several reasons why we need a new study. First, the group of young people attending Gender Services now is more diverse in their experiences and characteristics than has been in previous studies. Second, the model of care in the new Children and Young People's Gender Services is different from what children and young people received in the past. It is important that we understand the care needs of young people in the context of the current services. Finally, PATHWAYS HORIZON will look at a wider range of outcomes, because young people and their parents/caregivers told us many different aspects of their lives were important to think about in relation to gender incongruence.

PATHWAYS HORIZON is the largest study in the world of young people attending gender services, with over 3000 young people expected to take part, along with their parents/caregivers. It is at least 10 times larger than any other study that has been conducted so far. It has been designed to meet high scientific and ethical standards. PATHWAYS HORIZON will look at a wide range of psychological, social and behavioural outcomes, to provide a much better understanding of young people's wellbeing and needs.

What does taking part in PATHWAYS HORIZON involve?

In this study children, young people and their parents/caregivers will be asked to complete questionnaires so that we can understand more about how the children or young people feel and behave, including how they feel about their gender and body. They will also be asked about their daily lives, their relationships, friends/peers, family, school or other activities.

Who can take part in PATHWAYS HORIZON?

Children and young people are eligible to take part in PATHWAYS HORIZON if:

- They are under 18.
- They have had at least a first appointment with the NHS Children and Young People's Gender Services.

Do children or young people attending the NHS Children and Young People's Gender Services, and their parents have to take part?

No. It is up to the children, young people, and their parents/ caregivers whether they would like to take part.

Anyone taking part in PATHWAYS HORIZON can stop taking part at any time, if it no longer feels right for them. They do not need to give a reason. If someone does not want to take part, or if they decide to stop taking part in the study, it will not affect the care the child or young person receives at the Gender Services, or anywhere else in the NHS.

How will young people and their parents/caregivers be contacted about PATHWAYS HORIZON?

If a young person and their parent/caregiver are eligible to take part, then the Gender Service will contact them and ask them whether it is ok for a researcher to get in touch to tell them more about the PATHWAYS HORIZON study. If the young person or their parent/caregiver gives consent to be contacted, the research team will contact the young person or their parent/caregiver via email and send them a participant information sheet. The participant information sheet will explain in more detail what the study involves, to help them decide if they want to take part. They can also talk to a member of the research team before deciding whether to take part.

What will the study involve for participants?

Participants will be asked to complete a series of questionnaires. Usually participants will complete them online, on their own, but the research team will help all younger children to complete them. Anyone else, including young people and parents/caregivers, can ask for help from a researcher to complete questionnaires. The questionnaires will take about 45 minutes to one hour to complete, and participants will receive a voucher every year when they are completed.

What if a child or young person is discharged from the Gender Services?

PATHWAYS HORIZON would like to follow young people, whether or not they are still being seen in the Children and Young People's Gender Services. This includes those who turn 18 and go on to the adult Gender Services and those young people who stop attending the Gender Services.

Who is funding and overseeing the study?

The PATHWAYS research study is led by King's College London and co-sponsored by King's College London and the South London and Maudsley NHS Foundation Trust. NHS England commissioned and funded the study in partnership with the National Institute for Health and Care Research (NIHR). The study has undergone a comprehensive review of the science by independent scientists advising NIHR. These include independent academic peer reviewers and NIHR funding committee consideration. It has also undergone review by regulators and received approval from a Research Ethics Committee.

The research is overseen by two committees made up of people who are independent from the research team and the funders. A Data Monitoring and Ethics Committee will check the data and highlight any concerns in relation to the quality of data and any concerns about the safety or wellbeing of participants. The Programme Steering Committee will include at least two people with lived experience, as well as scientists, and will advise on the study progress overall.

How are participants' rights and privacy protected?

The study follows strict ethical and regulatory standards. This study has been reviewed and been given favourable opinion by London City and East- Health Research Authority (HRA) Research Ethics Committee (Reference: **25/LO/0251**).

All data will be managed according to the General Data Protection Regulation and Data Protection Act 2018, to make sure that participants' information remains safe and private. The data will also be managed according to the Health Research Authority guidelines found here: Patient data and research leaflet - Health Research Authority

At the start of the research, participants will be given a unique code number or participant identification number (PIN). The answers young people and their parents/caregivers give to questionnaires will be stored under this unique number, so it will not be possible for anyone outside of the research team to identify them from their questionnaires.

Who will have access to the research data?

Only the research team will have direct access to participants' answers. Personal information, like names, dates of birth or contact details, are kept separate from questionnaire responses. Everything that participants share is stored securely and handled in line with strict rules about privacy and data protection.

Unless participants give us permission, the answers they give to the questionnaires will not be shared with anyone outside of the research team.

Before participants take part in PATHWAYS HORIZON, we will ask the young people or their parents/ caregivers whether it is ok for their questionnaire responses to be shared with the Children and Young people's Gender Service. Participants' questionnaires won't be shared with the Gender Service unless they agree to this.

The questionnaires that participants will complete are commonly used in the Gender Services, so some people might find it helpful to share their responses with the Gender Service so that they don't have to repeat them.

The young people or their parents/caregivers will also be asked whether it is ok to share their questionnaire responses with other researchers in the future, once their personal details have been removed, so that it is not possible to identify them. Participants' questionnaire responses will only be used in future research if they agree to this.

What if there are concerns about a participant's safety?

If the answers that a young person or their parent/caregiver provide make us concerned about the young person's safety, we will share those responses with the young person's clinician at the Gender Service, or their GP, as a duty of care. We will let young people and/or their parents/caregivers know before we do this.

How long will the study take?

Recruitment will be open, meaning participants can join the study for the next 3.5 years. Children, young people and their parents/caregivers will be asked to complete questionnaires once a year, once they join the study. We will collect data over the study funding period (5.5 years), which means participants who join the study early on will be asked to complete questionnaires annually, up to five times. Those who join the study later may be asked to complete the annual questionnaires only twice.

How have the voices of people with lived experience been included in the PATHWAYS study and how will the study findings be shared?

We have consulted young people with lived experience and their parents/caregivers from early in the study's development. We will continue to involve our advisory board of young adults and parents throughout the study’s development, including when sharing our research findings.

PATHWAYS has Advisory Groups made up of young adults with lived experience as well as parents/caregivers. The Advisory Groups are convened by the National Children’s Bureau for the PATHWAYS research team.