PATHWAYS CONNECT 'Easy Read' Study Description

Who is this article for?

This plain language study description is for anyone who would like to find out more about PATHWAYS CONNECT and what taking part in the study involves. This 'Easy Read' document is a simplified version of the scientific protocol for PATHWAYS CONNECT. The PATHWAYS TRIAL, CONNECT and HORIZON INTENSIVE studies were approved together under the same protocol, so we created separate Easy Read documents — one for each part of the PATHWAYS programme. You are currently reading the Easy Read study description for PATHWAYS CONNECT.

The Easy Read study description for PATHWAYS TRIAL can be found here: https://www.kcl.ac.uk/ioppn/assets/pathways/trial/pathways-trial-easy-read.pdf

The Easy Read study description for PATHWAYS HORIZON INTENSIVE can be found here: https://www.kcl.ac.uk/ioppn/assets/pathways/horizon/pathways-horizon-intensive-easy-read.pdf

What is PATHWAYS CONNECT?

PATHWAYS CONNECT is a research study that will explore brain development and changes over time in young people with gender incongruence who are attending the NHS Gender Service. The study will follow and compare young people enrolled in the PATHWAYS TRIAL, who are offered puberty suppressing hormones either immediately or after one year, and young people from PATHWAYS HORIZON INTENSIVE, who are not receiving puberty suppressing hormones. It will not follow everyone in these studies but a group from each.

Why is this important?

Gender incongruence is when someone's gender doesn't match the sex they were registered at birth. Young people with gender incongruence often feel especially distressed during puberty, because their body starts to change in ways that don't match how they feel inside.

Puberty suppressing hormones may reduce this feeling of strong dislike of the person's body and help young people with gender incongruence explore their gender identity more comfortably without feeling rushed or distressed by changes in their body. However, doctors and researchers don't yet know for sure what the benefits or risks of this treatment are. One of the main concerns is that puberty suppressing hormones might affect brain development, thinking and learning. There is not enough research to understand whether any changes happen, how big they might be, or if they return to normal after treatment stops. This is especially important because adolescence and puberty is a time of rapid brain development with big gains in memory, organisation, and abstract thinking.

To understand whether puberty suppressing hormones affect brain development, a research study needs to be done to compare young people receiving puberty suppressing hormones to those who are not. PATHWAYS CONNECT is the first study to explore this among young people with gender incongruence.

How will PATHWAYS CONNECT be done?

PATHWAYS CONNECT will recruit young people from two other PATHWAYS studies: TRIAL and HORIZON INTENSIVE. In the TRIAL study, half of the participants start puberty suppression treatment straight away, while the other half begin after 12 months. PATHWAYS CONNECT will include an equal number of young people from each of these two groups. It will also recruit a subgroup of young people who are not receiving puberty suppressing hormones, from PATHWAYS HORIZON INTENSIVE.

PATHWAYS CONNECT participants will have brain scans (magnetic resonance imaging, MRI) so that researchers can understand how the brain develops and whether it changes over time. To spot these changes, young people participating in both the PATHWAYS TRIAL and CONNECT will have the scans three times — at the start of the study, one year later, and again after two years. Young people participating in both HORIZON INTENSIVE and CONNECT will take part in brain scans twice — at the start of the study and after two years.

Who can take part in PATHWAYS CONNECT?

To take part in PATHWAYS CONNECT, a young person must be attending the NHS Gender Service. They must be enrolled either in PATHWAYS TRIAL or in PATHWAYS HORIZON INTENSIVE and agree to take part in CONNECT. This means the young person needs to meet inclusion criteria for whichever study they are part of. The young person's parent(s)/legal guardian(s) also needs to agree for the young person to take part.

Further, the young person must not have reasons why they cannot have MRI brain imaging (like metal implants in their bodies).

Because the brain scans will take place in London, both the young person and their parent(s)/legal guardian(s) need to agree to that as part of joining CONNECT.

More information on taking part (inclusion criteria) in PATHWAYS TRIAL and HORIZON INTENSIVE can be found here:

https://www.kcl.ac.uk/ioppn/assets/pathways/trial/pathways-trial-protocol.pdf

How many people will take part in PATHWAYS CONNECT?

PATHWAYS CONNECT will include 150 young people from PATHWAYS TRIAL — 75 who start treatment straight away and 75 who start 12 months later. It will also recruit 100 young people from HORIZON INTENSIVE.

How can a young person take part in CONNECT?

Agreeing to take part

If the young person and their parent/legal guardian agree for the young person to take part in the study, they will be asked to sign a form to say that they understand the research and what will happen, and that they both agree for the young person to take part. They can take as much time as they need to decide.

How will brain scanning be carried out?

Brain imaging (MRI)

TRIAL participants taking part in CONNECT need to have an MRI scan once a year (3 times in total), and the first scan should be performed before starting treatment.

HORIZON INTENSIVE participants taking part in CONNECT need to have an MRI scan once at the start of the research and again after 2 years (2 times in total).

The brain scans will take place in King's College London in South London, and the study will pay travel and related expenses for young people and a parent/caregiver as well as a £15 thank you voucher to young people for each scan.

Before the MRI scan, a radiographer will check for any contraindications (such as metallic implants or devices) and ensure the young person has no metal on or near them. The radiographer will explain what to do and answer any questions.

The scan itself takes no more than 60 minutes, and a parent or another trusted adult can stay in the room during the scan. The scan does not hurt, but lying still can be a little uncomfortable. It can also be noisy, with knocking or banging sounds, but the young person will be given earplugs and can talk to the radiographer through a speaker.

What if someone wants to stop taking part?

Anyone taking part can choose to stop participating in PATHWAYS CONNECT at any time and do not need to give a reason. They can also decide not to take part in CONNECT while continuing in the PATHWAYS TRIAL or HORIZON/HORIZON INTENSIVE studies.

How will researchers analyse the data?

To understand how the brain develops and grows during adolescence in young people enrolled in PATHWAYS CONNECT, researchers will look at brain scans from young people in each group. This will help them see how puberty suppressing treatment might affect brain development beyond the normal changes that happen with age. They'll compare how the brain's structure and activity change over time, taking into account each person's age, stage of puberty, and sex assigned at birth.

They'll also look at how thinking, memory and learning skills (cognitive functions) change over time and whether there are any differences between the groups. This will be done using cognitive assessments that young people will need to complete as part of the TRIAL and HORIZON INTENSIVE. The results will help researchers understand what factors might predict different outcomes for young people.

Who is funding PATHWAYS CONNECT?

The research is funded by the National Research Collaboration Programme (NRCP), a partnership between NHS England and the National Institute for Health and Care Research (NIHR).

Who is monitoring PATHWAYS CONNECT?

The research is led by King's College London and co-sponsored by King's College London and the South London and Maudsley NHS Foundation Trust.

The study has been carefully checked by independent scientists who advise the National Institute for Health and Care Research (NIHR). These include independent academic peer reviewers and NIHR funding committee consideration.

It has also been carefully checked by the Medicines and Healthcare products Regulatory Agency and received approval from a Research Ethics Committee.

The research is overseen by two groups of people who are independent from the research team and the funders. A Data Monitoring Committee will check the data and highlight any concerns they have about the quality of the data (such as the amount of missing information) and any concerns about the safety or wellbeing of people taking part.

The Programme Steering Committee will include at least two people with lived experience of being a gender diverse young person, or a parent/caregiver of a gender diverse young person, as well as scientists. The Programme Steering Committee will advise on the study's progress overall.