



PATHWAYS HORIZON INTENSIVE '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 HORIZON INTENSIVE and what taking part in the study involves. This 'Easy Read' document is a simplified version of the scientific protocol for PATHWAYS HORIZON INTENSIVE. PATHWAYS TRIAL, CONNECT and HORIZON INTENSIVE 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 HORIZON INTENSIVE.

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 CONNECT can be found here:

<https://www.kcl.ac.uk/ioppn/assets/pathways/connect/pathways-connect-easy-read.pdf>

What is PATHWAYS HORIZON INTENSIVE?

The PATHWAYS programme will follow and compare two groups: one group of young people taking part in PATHWAYS TRIAL, who are receiving puberty suppressing hormones, and another group called PATHWAYS HORIZON INTENSIVE, who are not receiving puberty suppressing hormones.

PATHWAYS HORIZON INTENSIVE is called this because it will include young people who are taking part in PATHWAYS HORIZON but are being studied more closely.

The young people taking part in PATHWAYS HORIZON INTENSIVE will complete the same measurements and scans as the young people taking part in PATHWAYS TRIAL, but less often.

This means that as well as the questionnaires that will be completed as part of PATHWAYS HORIZON, people taking part in PATHWAYS HORIZON INTENSIVE will also complete physical health measurements and scans, and cognitive assessments.

Why is this important?

Gender incongruence is when someone's gender doesn't match the sex they were registered at birth. Puberty can be a difficult time for young people with gender incongruence. This is because their body starts to change in ways that don't match how they feel inside.

Many different treatments are used to help young people with gender incongruence, including psychological support, voice training and medical treatment to help with related concerns, such as periods. There is currently not enough research to understand how young people experience these different treatments and who may benefit from them.

One of these treatments is puberty suppressing hormones- a medication used to pause puberty. PATHWAYS HORIZON INTENSIVE will explore the physical, social and emotional wellbeing of young people who are not receiving puberty suppressing hormones. Another part of the PATHWAYS programme- PATHWAYS TRIAL will explore the physical, social and emotional wellbeing of young people who are receiving puberty suppressing hormones.

This will help us understand more about the impact of puberty suppressing hormones on how young people feel, think and learn and how they grow and develop.

Who can take part in PATHWAYS HORIZON INTENSIVE?

A group of the young people already taking part in PATHWAYS HORIZON will be invited to take part in PATHWAYS HORIZON INTENSIVE. This group of young people will be specifically chosen because they share similar characteristics to the young people taking part in PATHWAYS TRIAL. They will be roughly 'matched' to the young people taking part in PATHWAYS TRIAL on things like birth-registered sex, age, Autism or ADHD traits and which NHS Gender Service they received care from.

As an example, if 40% of the young people taking part in PATHWAYS TRIAL are birth-registered males, then around 40% of the young people taking part in PATHWAYS HORIZON INTENSIVE will also be birth-registered males.

This matching will help make sure that differences between the groups are because of the treatment, not because of other things, like age.

The young people's parents/caregivers will also be invited to complete questionnaires.

How many people will take part in PATHWAYS HORIZON INTENSIVE?

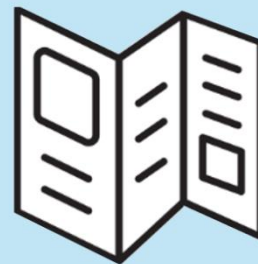
PATHWAYS HORIZON INTENSIVE will include 300 of the young people who are already taking part in PATHWAYS HORIZON.

What will happen if someone takes part?

Finding out about the research

Researchers will ask some of the young people taking part in PATHWAYS HORIZON if they want to take part in PATHWAYS HORIZON INTENSIVE. As this group should be similar to the young people taking part in PATHWAYS TRIAL, only some young people will be asked.

The young person and their parents/legal guardians will receive a Participant Information Sheet with details about taking part in HORIZON INTENSIVE and who to contact if they have any questions.



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.



Physical measurements and scans

The young person will be asked to have a series of physical health measurements and scans, including:

- Blood and urine samples
- Height and weight
- Blood pressure
- Heart rate and heart activity



Bone scans

The young person will also be asked to have 2 types of bone scan, one to check how strong their bones are, and the other to check how their bones are growing.

They will complete these measurements and scans 2 times in total- once when they start HORIZON INTENSIVE, and again 2-years later.

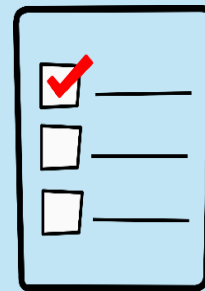
They will get a voucher worth £15 every time they complete their physical health measurements and scans.

Online questionnaires

The young person and their parent/caregiver will be asked to complete questionnaires once a year, for up to 5 years. This means if they join the study early on, they will complete questionnaires 5 times in total. If they join later on, they will complete questionnaires 3 times in total. The questionnaires will ask about:

- The young person's emotions and behaviours
- How they feel about their gender and body, and what stage of puberty they think they are at (young person only)
- Their relationships with others (young person only)
- Their daily life with friends, family, education and other activities

These questionnaires will take around an hour to complete, and both the young person and their parent/caregiver will get a voucher worth £20 every time they complete them.



Measuring thinking, learning and memory (cognitive assessments)

The cognitive assessments are short puzzles and tasks that tell us about how the young person learns, thinks and solves different problems. For example, they might be shown some pictures and after a short break be asked to tell the researchers what they saw, to see what they can remember.

These take about two hours, and the young person can take breaks. Young people taking part will be asked to complete cognitive assessments in the clinic, 2 times in total- first when they start HORIZON INTENSIVE, and again 2-years later.

They will get a voucher worth £30 every time they complete their cognitive assessments.



Young people and their parents/caregivers will get money back for travel and other costs for taking part.

What if someone wants to stop taking part?

Anyone taking part can choose to stop participating in PATHWAYS HORIZON INTENSIVE at any time and they do not need to give a reason.

If a young person decides to stop taking part in PATHWAYS HORIZON INTENSIVE, they can continue taking part in PATHWAYS HORIZON if they want to.

How will researchers analyse the data?

The findings of this research will be joined with the findings from other PATHWAYS projects, including PATHWAYS TRIAL and PATHWAYS CONNECT. PATHWAYS TRIAL is a study looking at the same outcomes among children and young people who are taking puberty suppressing hormones. PATHWAYS CONNECT is a brain imaging study looking at how the brain develops in some of the young people taking part in PATHWAYS HORIZON INTENSIVE and PATHWAYS TRIAL.

By comparing the young people taking part in PATHWAYS TRIAL and PATHWAYS HORIZON INTENSIVE, the researchers can understand more about the effects of puberty suppressing hormones, including the impact on young people's physical, social and emotional wellbeing, and whether any change are due to puberty suppressing hormones.

Who is funding PATHWAYS HORIZON INTENSIVE?

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 HORIZON INTENSIVE?

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.