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PATHWAYS

REC Reference: 25/LO/0500

Participant Information Sheet for Parents/Legal Guardians

We would like to invite you and your child to take part in this research called **PATHWAYS TRIAL**

- Before you decide if you would like you and your child to take part, it is important you know why the research is being done and what it will involve for you and your child.
- Please read this information carefully and discuss it with your child.

Take as much time as you need.

- Write down any questions on the notes page at the end and ask us if there is anything that you do not understand. A doctor will talk to you and your child about the trial and can help answer your questions.
- It is up to you and your child whether you take part or not. If you or your child do not take part in the trial, your child's doctor will continue to take care of your child as they have done in the past.
- If your child takes part in the trial, either of you can decide to stop taking part at any time without giving a reason.

If you have any questions about the trial, please contact:

Study Doctor (**Insert local details**)

Research Nurse (**Insert local details**)



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1. Why are we doing this trial?

Gender incongruence is when an individual's gender identity does not match their sex registered at birth. Puberty can be a difficult time for children and young people with gender incongruence, as the physical changes they experience may not align with their gender identity.

During puberty the body starts to produce sex hormones, such as testosterone or oestrogen, which act as chemical messengers, triggering the development of secondary sex characteristics. These changes can include breast development, growth of facial and body hair, or deepening of the voice, depending on the individual's sex assigned at birth.

Doctors have sometimes prescribed a treatment called 'gonadotropin releasing hormone analogues (GnRHa)', also known as puberty suppressing hormones or puberty blockers, to young people experiencing gender incongruence. GnRHa temporarily stops the body from releasing sex hormones. This means that whilst a young person is taking GnRHa they will not continue to experience the physical changes normally occurring during puberty. GnRHa is licensed for use in younger children who go through puberty when they are too young, known as precocious puberty, however, it is not licensed to be prescribed for gender incongruence because it hasn't been carefully tested to find all the benefits and possible harms.

Puberty suppressing hormones may provide young people with gender incongruence time to explore their gender identity without worrying about their body starting to change. Doctors have thought this might help young people to focus more on things that improve their quality of life, like their interests, school, friendships and relationships. However, there is currently limited evidence to show whether these outcomes are consistently achieved when young people take GnRHa.

Doctors and other people have also been worried about possible risks associated with GnRHa. These include decreased bone strength, making young people more likely to have fractures. But we don't know how likely this is and whether bone strength returns to normal when young people stop



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GnRHa or go on to other treatments for gender incongruence like cross-sex hormones. There are also concerns that GnRHa might affect brain development and learning, based on findings from animal studies, however it is not yet known whether similar effects occur when young people take GnRHa for gender incongruence. There might be other benefits and harms from GnRHa doctors are not yet aware of. That is why it is very important to study both its physical and psychological effects carefully.

Due to the lack of robust, long-term research on the effectiveness and safety of puberty suppressing hormones, doctors in the UK are not able to prescribe GnRHa to children or young people with gender incongruence. Currently, this treatment can only be accessed within the context of a research study. The aim of this research is therefore to better understand how young people experience this treatment, by finding out how it affects their quality of life, mental and physical health and how they feel about their bodies and their gender. It will also look at learning and brain development. For all of these areas, the research will look to see if these get better, stay the same or get worse - we won't know until we complete the study.

2. Why are my child and I being asked to take part?

The doctors and other professionals caring for your child in the Gender Service will have discussed GnRHa with you and your child, including the possible advantages and disadvantages. You and your child have been invited to take part in the PATHWAYS TRIAL because you, your child, your child's care team, the doctors at the Gender Service, as well as a national multi-disciplinary team think that it might be helpful for your child to have treatment with puberty suppressing hormones (GnRHa). The doctors caring for your child have checked this opinion with other doctors, called the national multidisciplinary team.

3. How will the treatment be tested?



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Usually, when a treatment is used for a new reason, a type of experiment called a randomised controlled trial (RCT) is done to see whether it works well and is safe to use. This means your child will be allocated one of two groups by chance. One group will start the treatment right away, and the other group will start after 12 months. This helps us compare the two groups to see how the treatment works - what is helpful and what are the side effects.

4. What will happen if my child and I take part?

Finding out about the research

The first step is to carefully read this information sheet, take time to think about what you have read and ask any questions. If you would like your child to take part, a doctor will ask you and your child some questions to make sure you understand why the trial is being done, what will happen if your child takes part, and what might be good or bad about your child starting treatment with puberty suppressing hormones (GnRHa). You and your child will have already discussed this with your doctors, but it is important that you ask about anything you want to, and that all your questions are answered.

Agreeing to take part

If you and your child would like to take part, and you agree for your child to take part, we will ask you to sign a consent form, to confirm that you agree to participate, and to confirm on behalf of your child that they agree to participate. You will be given a copy of this form to keep.

We will also ask your child to sign a form to say that they agree to take part.

Finding out which group your child is in

A computer programme will randomly pick whether your child is in Group 1 or Group 2:



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Group 1: This group will start the treatment straight away, called the **'immediate'** group.

Group 2: This group will wait 12 months before starting the treatment, called the **'delayed'** group.

A doctor at the Gender Service will tell you which group your child has been given. No one in the study will pick their own group, as this needs to be selected at random for the research to work.

Treatment

There are several different drugs that can be used to suppress puberty. The main one we will use in PATHWAYS TRIAL is called Triptorelin. We may use other drugs, or give your child Triptorelin in different doses and frequencies, depending on how they respond. The other drugs we might use are called Leuprorelin and Goserelin. If we change your child's treatment, we will discuss it with you and your child first, and explain why we think it is a good idea.

The puberty suppressing hormone is given by an injection. The treatment lasts for 6 months, so your child will receive the injection once every 6 months after starting the treatment. A specialist nurse or doctor will explain this to you and your child before they are given the treatment.

Depending on how your child feels during the 6 months and how their body has responded, a doctor may suggest your child changes to an injection that lasts for 3 months or 1 month.

Safety checks and scans

A doctor will ask you and your child some questions about your child's mental health before they start the treatment. We recommend keeping physically active, such as walking and running, whilst your child is in the trial. This will help them to maintain a healthy weight and strong bones.



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To make sure it is safe for your child to take part, they will need to have some tests and measurements taken at the clinic, including blood and urine tests, height, weight, heart rate, blood pressure, and a pregnancy test if your child was female sex at birth. These may have already been done by your child's doctor but your child may need to have these tests done again when they are due to start treatment, to make sure it is still safe for your child to take part. We will repeat these tests once every 6 months whilst your child is taking the treatment.

Before starting the trial a doctor or specialist nurse will have looked at your child's body to check their physical health and what stage of puberty they are at. This is called a Tanner Stage Assessment. We don't know if the benefits and side effects of GnRH α are the same at all stages of puberty, so we want to find out whether this makes a difference. If your child is in the delayed group, they will have this assessment again when they are due to start the treatment. A chaperone will always be present during your child's Tanner Stage Assessment.

Blood and urine tests

During the trial, your child will need to have blood and urine tests to ensure that it is safe for them to continue. The amount of blood required is about 2 tablespoons, and the urine needed is roughly 1/3 of a cup. After the samples are collected, they will be clearly labelled with your child's name, date of birth, and NHS number to prevent any mix-ups. The samples will then be sent to the hospital laboratory, where they will be tested. Once the tests are completed, lab or medical staff will carefully check the results for accuracy before entering into the hospital system and destroying the samples. The doctor will then review these results as part of your child's care.

Bone imaging

Your child will also be asked to have 2 types of bone imaging. The first scan is called a DEXA, or bone density scan. During the DEXA scan they will lie down on a padded table for around 15 minutes whilst a scanner moves over their body. The DEXA scan is important for doctors to know



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how strong your child's bones are during the treatment. The second scan is called a bone age X-Ray, which takes an X-Ray image of your child's left hand. The bone age X-Ray helps doctors to see how your child's bones are growing.

The effects of puberty-suppressing hormones (GnRHa) on foetal (baby in the womb) development and reproductive cells are not yet fully understood. For this reason, it is important to avoid pregnancy during treatment. If your child was female at birth and is or might be sexually active with a person of the opposite sex, your child will need to use effective barrier contraception (such as a male or female condom, diaphragm or cervical cap) as a precaution throughout the treatment period to prevent pregnancy and against infections. If your child stops puberty suppression treatment, they will need to continue to use this contraception until their periods return. Your child's doctor or a specialist nurse will be able to discuss alternatives with you and your child.

Online questionnaires

Your child will be asked to complete some questionnaires. These will ask about:

- Their emotions and behaviours
- How they feel about their gender and body
- Their relationships with others
- Their daily life with friends, family, education and other activities

We also want to find out how you think your child is getting on. As a parent or caregiver, you will also be asked to complete a number of questionnaires. These will ask about:

- Your child's emotions and behaviours
- Your child's daily life with friends, family, education and other activities

These questionnaires can be answered on a phone, tablet or laptop. If you or your child would like assistance in completing these



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questionnaires, we can help you via phone or video call, or in-person at one of your child's clinic visits.

We will ask you and your child to do most of these questionnaires once a year (including after the trial ends, for up to 5 years altogether) and they will take around an hour to complete.

We will ask you and your child to complete some of these questionnaires more often, two will be completed 7 times in total, 1 will be completed 5 times in total.

After you complete the questionnaires, you or your child might want to talk about your thoughts and experiences. There is an option to let us know that you would like a researcher to contact you.

Young people might worry that the answers they give could affect whether they stay on GnRHa. We know that young people's emotions and experiences change, depending on what is happening in their lives. Your child's treatment will not be stopped if you or your child tell us about their difficult feelings or experiences.

Cognitive assessments

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

We will ask your child to complete them with one of the researchers in clinic, whenever possible on the same day as one of your child's existing appointments. This will take about 2 hours, but your child can have as many breaks as they need.

We will ask your child to do these cognitive assessments once a year (3 times in total). Your child will get a voucher worth £30 every time they complete the cognitive assessments.

Continuing the treatment



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3 months into the trial: A doctor or researcher will call your child to check how they are feeling.

6 months: Only if your child is in the immediate group – you and your child will visit the clinic for your child’s safety checks. If a doctor is happy for your child to continue, they will continue the treatment.

9 months: A doctor or researcher will call your child, again to check how they are feeling.

12 months: You and your child will visit the clinic for your child’s safety checks and scans. If your child is in the immediate group, they will only have a bone age X-Ray if the doctor thinks they need to. If they are in the immediate group and the doctor is happy for your child to continue, they will continue the treatment. If your child is in the delayed group, they will also have their Tanner Stage Assessment. If the doctor is happy for your child to start the treatment, they will start the treatment at this point.

15 months: A doctor will call your child, again to check how they are feeling.

18 months: You and your child will visit the clinic for your child’s safety checks and scans. If the doctor is happy for your child to continue, they will continue the treatment.

21 months: A doctor will call your child, again to check how they are feeling.

24 months: The final in person clinic visit during treatment is at 24 months, where your child will repeat their safety checks and scans, to make sure they are still safe and well. They will only have a bone age X-Ray if the doctor thinks they need to.

What happens when my child’s treatment in the trial ends?

When the trial ends, your child’s doctor will talk to your child and you about how they have found the treatment in terms of their quality of life, mental and physical health and their experience of their gender and



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body. Your child and you will discuss the next steps in their care, what their options are, and what they would like to do. These might include staying on GnRHa, stopping the treatment, or going on to another treatment. It is not possible to know what their treatment plan will look like at the end of the trial, as this will depend on several factors, including their experience of GnRHa, their mental and physical health, and their future preferences. We also do not know whether results from the trial more generally may be showing that there are significant harms from this treatment, which could mean it is not a good idea to say on GnRHa.

If your child wants to say on GnRHa and you and their doctor in the Gender Service agrees that they may continue to benefit from it, their care will be reviewed again by the national multidisciplinary team, who need to agree that your child should stay on GnRHa. If they don't agree, they will give you reasons why they think this is not the right ongoing care for your child. If they make that decision and your child's circumstances change so the reasons no longer apply, your child's doctor can ask for another review of your child's care.

If your child stays on GnRHa, their care will need to be reviewed by the national multidisciplinary team every year while they are on it, to check it is still the right treatment for them.

Figure 1 on page 10 shows what will happen in the immediate start group.

Figure 2 on page 11 shows what will happen in the delayed start group.

Long-term follow-up

36 months: We would like to understand your child's experience long-term and see how they are doing after receiving treatment. Whatever their treatment decision at the end of the trial, we will ask your child to complete the full set of questionnaires again and to visit the clinic for a DEXA Scan at 36 months.



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48 months: The final clinic visit is at 48 months, where we will ask your child to have a DEXA Scan and complete the final set of questionnaires.

As much as possible, we will arrange your child's study visits for when you are coming to see the specialist nurse or doctors to review your child's treatment. If that isn't possible, we can be flexible when arranging study visits to find a date and time that suits you and your child best. If you arrange a visit and you and your child can no longer make it, that is ok, we can arrange another time for you.

We will reimburse your costs for attending research appointments, including your and your child's travel and meals on days when your child has a cognitive assessment.



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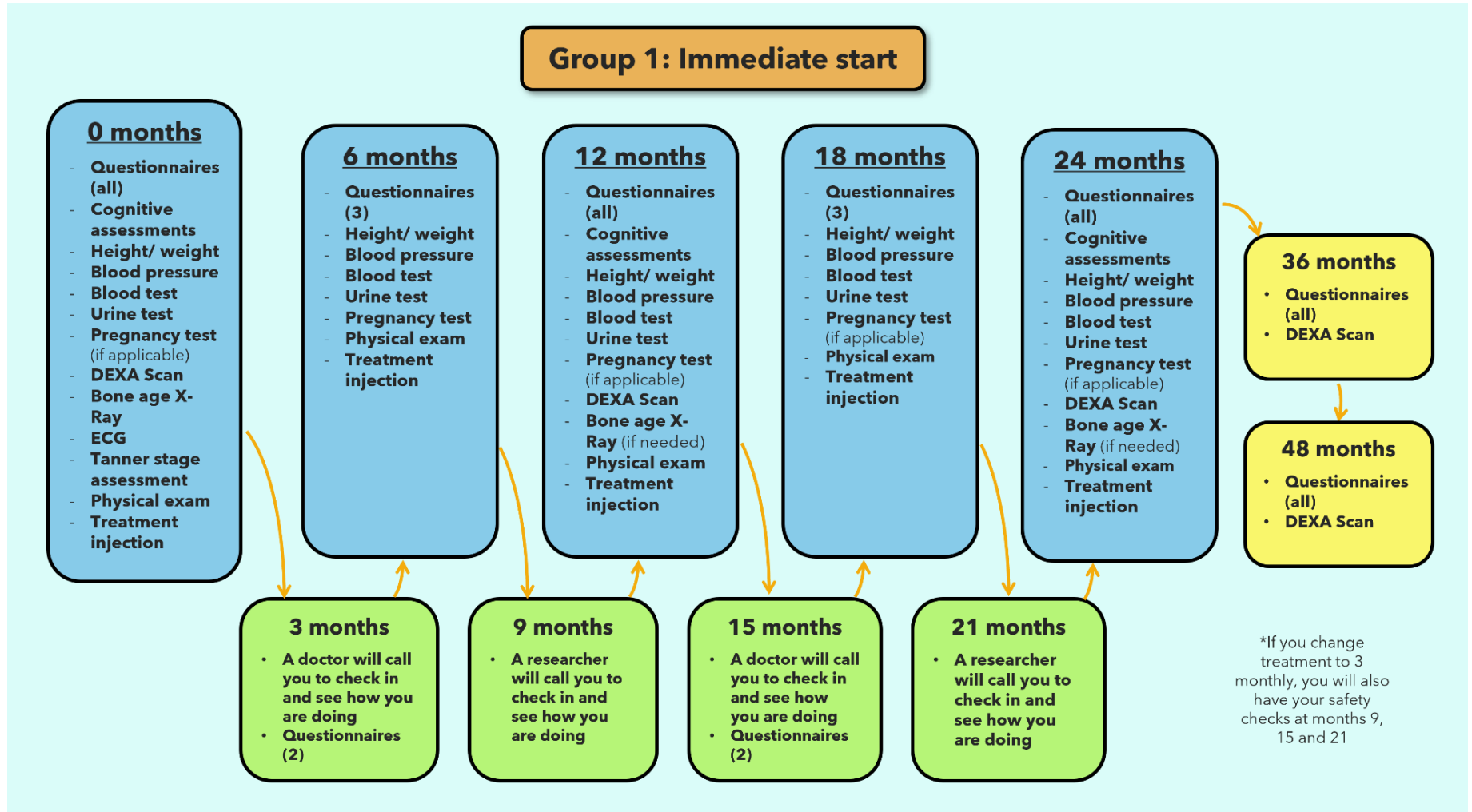


Figure 1- A flowchart showing what will happen in the immediate start group



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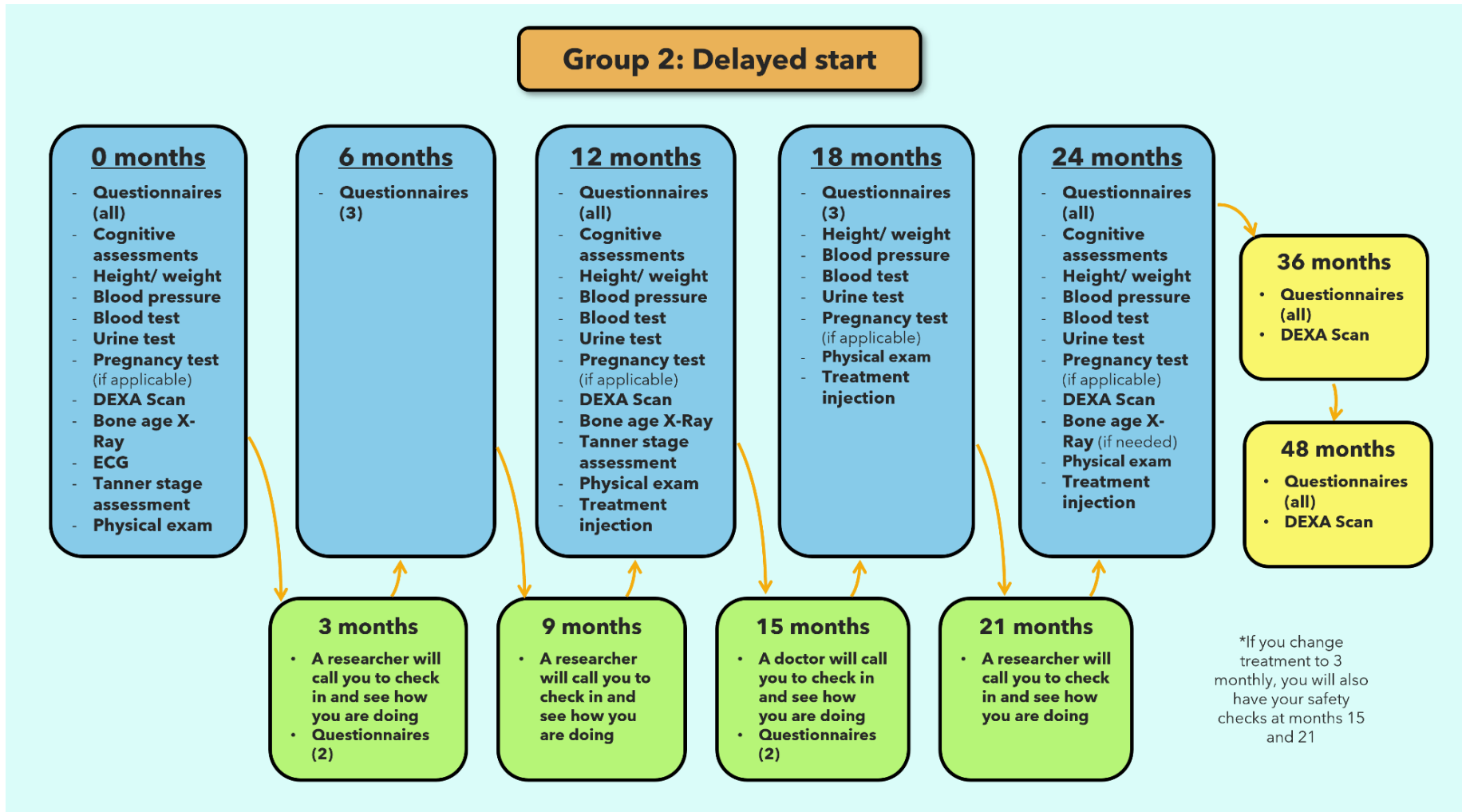


Figure 2- A flowchart showing what will happen in the delayed start group



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5. What might be good about taking part?

We do not know whether the treatment may help your child.

By taking part in this study, you and your child may help us learn more about what children and young people with gender incongruence find good or not so good about puberty suppressing hormone (GnRHa) treatment. This information might help young people, parents and doctors in the future make decisions about this treatment.

6. Risks or possible risks of taking part in the study

Taking part in this study means your child will receive medicines called puberty blockers (GnRH analogues). These medicines are already used for other conditions, like early puberty, and most side effects are mild and go away when treatment stops. Common short-term effects include headaches, hot flushes, tiredness, mood changes, and soreness where the injection is given. Some people may feel more anxious or low in mood, so we will check in with your child regularly about how they are feeling.

There are also some less common but important risks. These medicines can affect your child's bones by slowing down bone strength development. We will monitor your child's growth and bone health during the study. Rarely, a condition called idiopathic intracranial hypertension (IIH) can happen, which causes severe headaches, vision problems, or ringing in the ears. If your child notices these symptoms, you must tell your child's doctor straight away. There is also a very small chance of changes in heart rhythm, especially if your child takes certain other medicines, so we will check your child's health history and may do an ECG (heart tracing) if needed.

Some risks may not show up until later in your child's life. These include possible effects on:

- Fertility (your child's ability to have children in the future if they go on to have cross sex hormones like testosterone or oestrogen). It is important that your child talks to the doctors in the clinic about the options they have for their fertility in the future. These choices would



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include being referred to a fertility specialist to discuss storing eggs or sperm.

- Bone health (risk of weaker bones or fractures later)
- Sexual development and function
- Memory and thinking skills (we do not yet know if there is an effect)

Because these changes can take years to appear, we will ask for your permission to keep in touch with your child after the main study ends and, if you agree, link to your child's NHS health records. This helps us understand the long-term effects and keep you safe. You can say no to this and your child still take part in the main study.

Your child can stop taking part at any time. If they do, we will ask if we can still collect information about your child's health to help make the study results useful for others.

7. What might not be good about taking part?

Whilst on the treatment, your child might notice changes to their body or how they feel. Your child might feel more sad or anxious, or struggle to sleep. Your child might feel sick or have an allergic reaction to the treatment, but this is less likely.

A doctor or nurse will talk to your child regularly over the phone and at the clinic to check if they are having any of these side effects, but if your child feels unwell at any point, please let the doctor know on **[insert local telephone number]**.

The scans your child will have to check that their bones are healthy will expose them to radiation.

If you take part in this study you will have DEXA scans of your spine and hips and x-rays of your Left Hand/Wrist. Some of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.



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We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to you.

When answering the questionnaires, you or your child might find some questions upsetting or difficult to answer. We can discuss this with you or your child if it is helpful. Remember that you or your child telling us that questions are difficult or upsetting to answer will not change your child's treatment in the trial.

Taking a blood sample is generally a safe procedure, however there are some potential risks. This includes: mild discomfort caused by the needle, bruising around the puncture site, bleeding (usually minor and short-lived), dizziness or fainting (especially with phobia of needles), and infection, which is incredibly rare whilst following proper procedures.

It may not always be possible to arrange your child's clinic visits outside of school hours, however, we will do our best to schedule their appointments in a way that minimises any disruption to their education.

8. Do my child and I have to take part? What if we change our minds?

No, it is up to you and your child whether your child takes part or not. If either of you change your mind about taking part, you or your child can stop the research at any time, without giving a reason. If either of you decide you want to stop taking part, your child's care in the Gender Service or anywhere else will not change in any way. If your child wants to stop taking GnRHa, your child's doctors will talk with you and your child about other treatment choices they have.

For you or your child to stop taking part in the study, please email the research team [\(insert local PATHWAYS researchers' email\)](#) or contact your child's Gender Service.

9. Who is organising and funding the trial?



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This project (NIHR167530) is funded by the National Research Collaboration Programme, an NHS England and National Institute for Health and Care Research (NIHR) partnership. The research was reviewed by independent scientists before this funding was given. The views expressed are those of the author(s) and not necessarily those of NHS England, NIHR or the Department of Health and Social Care.

The PATHWAYS TRIAL is co-sponsored by King's College London (KCL) and South London and Maudsley NHS Foundation Trust (SLaM). The trial is coordinated by the King's Clinical Trials Unit (KCTU) and monitored by the Kings Health Partners Clinical Trials Office (KHP-CTO), to ensure the trial is being done properly, in line with regulations.

10. Is the trial ethical?

All research in the NHS is looked at by a group of people, called a Research Ethics Committee (REC), before the study begins, to make sure it is safe and fair for the people taking part. This research has been approved by the Health Research Authority (HRA) and given a favourable opinion by an NHS Research Ethics Committee.

The research is also overseen by two committees, a Data Monitoring Committee (DMC), and a Programme Steering Committee. These committees are made up of people who are independent from the research team and the funders, and are separate to the HRA and REC. The DMC will check the data and highlight any concerns in relation to the quality of data (such as the amount of missing information) and any concerns about the safety or well-being of participants. The Programme Steering Committee will include at least two lay members with lived experience, as well as scientists, and will advise of the study progress overall.

11. How will mine and my child's personal information be used?

We will need to use information from you, your child, your child's tests and scans, and your child's medical records for this research project.



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This information will include your child's:

- Initials
- Name
- Date of Birth
- Sex Registered at Birth
- Contact Details (phone number & email address)
- NHS Number

This information will also include your:

- Name
- Contact Details (phone number & email address)

People will use this information to do the research or to check your child's records to make sure that the research is being done properly. People who don't need to know who you or your child are will not be able to see your or your child's name or contact details. Your and your child's data will have a unique code number instead.

King's College London and SLaM NHS Trust are the sponsors of this research.

King's College London and SLaM are responsible for looking after your and your child's information. We will share your and your child's information related to this research project with the following types of organisations:

- Non-commercial research organisations
- Higher education institutions (universities)
- Healthcare assessment providers

We will keep all information about you and your child safe and secure by:

- Following strict guidelines concerning the use and storage of personal information, compliant with the General Data Protection Regulation (2018) and the Data Protection Act (2018) in UK law, to keep the information that you and your child provide safe and private.
- Unless you give us permission, your or your child's information won't be shared with anyone outside of the research team.



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If we are worried about your child's safety, we may contact your child's clinical care team or GP, but we'll talk to you and your child first.

- At the start of the trial, you and your child will be given a unique code number or participant identification number (PIN). Your and your child's research data will be stored under this unique number.
- Only members of the research team who need to know who you and your child are will be able to see your personal details (name, email address and/or phone number).
- Your and your child's research data will be stored under a secure server. The secure server will be password-protected and only authorised members of the local trial team, staff at KCTU, KCL, and KHP-CTO will be given access.
- During the trial, authorised staff outside of your child's care team will need to see information about your child and view their personal and medical records. This is done to check the trial is being done properly.
- Your and your child's data will be processed so neither you nor your child can be directly identified from it.

12. International transfers

We may share or provide access to data about you and your child with researchers outside of the UK for research related purposes to:

- Conduct collaborative research
- Create larger combined datasets for further analysis
- Maximise the impact of the research
- Improve the quality of research in this area globally
- Set up your child's profile on Q-interactive for completing cognitive assessments

If this happens, we will only share the data that is needed. We will also make sure you and your child can't be identified from the data that is shared where possible. This may not be possible under certain circumstances - for



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instance, if your child has a rare illness, it may still be possible to identify them. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Non-commercial research organisations
- Higher education institutions (universities)
- Healthcare assessment providers

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your and your child's data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give the same level of protection to personal data it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We make sure other organisations have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators if there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>.



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13. How will information about me and my child be used after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you or your child took part in the study.

We will keep your and your child's study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

14. Will the research find anything important for my child's health?

During the course of this research project, previously unsuspected clinical findings about your child could be revealed. In the event that significant findings are revealed, a doctor will inform your child's GP and the study team. Where necessary, your child's local Gender Service and paediatric team will be informed, and there will be a discussion of the findings with you and your child to determine whether any further onward referrals are needed. A summary of the results of your child's scans will be sent to your child's GP and you will also receive a copy.

15. What are my choices about how mine and my child's information is used?

You or your child can stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have.

You have the right to ask us to remove, change or delete data we hold about you or your child for the purposes of the trial. We might not always be able to do this if it means we can't use your or your child's data to do the research. If so, we'll tell you why we can't do this.

If you and your child agree to take part in this study, you'll have the option to take part in future research using your and your child's data saved from this study.



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We're interested in finding out how your child is getting on in everyday life. To reduce the amount of information we need to collect from you directly, we'll seek your consent to:

- o Link your and your child's data, to UK health and education databases, held on secure platforms.
- o Share your and your child's data from the trial with other research groups in the future.

In both these instances, we would only share information about the trial and not information that could identify you or your child (e.g. names or contact details). Your and your child's identity will always be kept safe.

You don't have to agree to either of these, but it may help other young people with gender incongruence in the future.

16. How can I find out more about how mine and my child's information is used?

You can find out more about how we use your and your child's information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflets: <https://slam.nhs.uk/personal-information-gdpr>,
<https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>
- by emailing your local PATHWAYS research team:
 - o (Insert local PATHWAYS researchers' email)
- by sending an email to the data protection officers:
 - o Olenka Cogias, info-compliance@kcl.ac.uk (KCL)
 - o Claire Delaney-Pope, informationgovernance@slam.nhs.uk (SLaM).

by ringing us on **0207 848 7816**

17. Who will know that my child is taking part?



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We will need to let your child's GP know that you and your child are taking part in this trial as it is important for your child's healthcare. The researchers running the study and the team at the Gender Service will also know that you and your child are taking part.

We'll share the information you and your child give us during the study with the Gender Service, so they can see whether they are helping your child and other young people, unless you tell us not to.

18. What if something goes wrong?

If you or your child have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Insert local PATHWAYS researchers' email). If you remain unhappy and wish to complain formally, you can do this through the local Patient Advice and Liaison Service (PALS) on tel: (insert local PALS tel), email: (insert local PALS email).

If something does go wrong, and your child is harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

19. What will happen to the results of the trial?

The findings of this research will be linked with the findings from other PATHWAYS research projects. This will help us understand more about the experiences, emotions and development of children and young people with gender incongruence during puberty and adolescence. These other research projects include PATHWAYS HORIZON Intensive, a study looking at the same outcomes among children and young people who have not been prescribed puberty suppressing hormone treatment.

The findings of this research will be presented in internal reports, professional journals and at conferences. We will also publish our results in a way that is easy for the public to understand and make these available to



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everyone, including posting on the PATHWAYS website. We will send you and your child a newsletter at least twice a year to keep you informed about the study. Our patient advisory groups will help us to share the results in the best way.

It will not be possible to identify you or your child from any of the research reports or publications we write.

20. What other studies may my child and I be asked to take part in?

You and your child may be given information about a study called PATHWAYS CONNECT, which is a study looking at how the brain develops in some of the young people taking part in the PATHWAYS TRIAL.

You and your child might also be asked whether you want to take part in PATHWAYS Voices, where young people attending Gender Services and their families talk with a researcher about their experiences of care in the Gender Services.

It is up to you and your child whether you take part in PATHWAYS CONNECT or PATHWAYS VOICES. If you or your child decide not to take part, your child's care at the Gender Service will not change and it won't affect their treatment in the PATHWAYS TRIAL.

21. Who can I talk to about the trial?

You can ask any questions you have about the trial at any time by contacting:

[name of responsible person at site]

[address of site] Tel: [xxxxxxxxxxxx]

If you would like more information about you or your child participating in research, please contact:

[Name of local PALS]



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Tel: [xxxxxxxxxxx] Email: [email address if applicable] Website: [website if applicable]

Thank you for reading this information sheet and for considering taking part in this research

