



Patient Information Sheet for Young People Age 10-12

A study about children with a hip condition called Perthes

Chief Investigator: Professor Daniel Perry

Hello.

We would like to invite you and your family to take part in a study called the **Op Non-STOP Study**.

The study will compare two different types of treatment for your hip problem.

If you would like to join the study it is important that you understand why we are doing this study and what it would involve for you.

If you would like more information, please ask your parent or guardian, or one of the doctors or nurses looking after you.

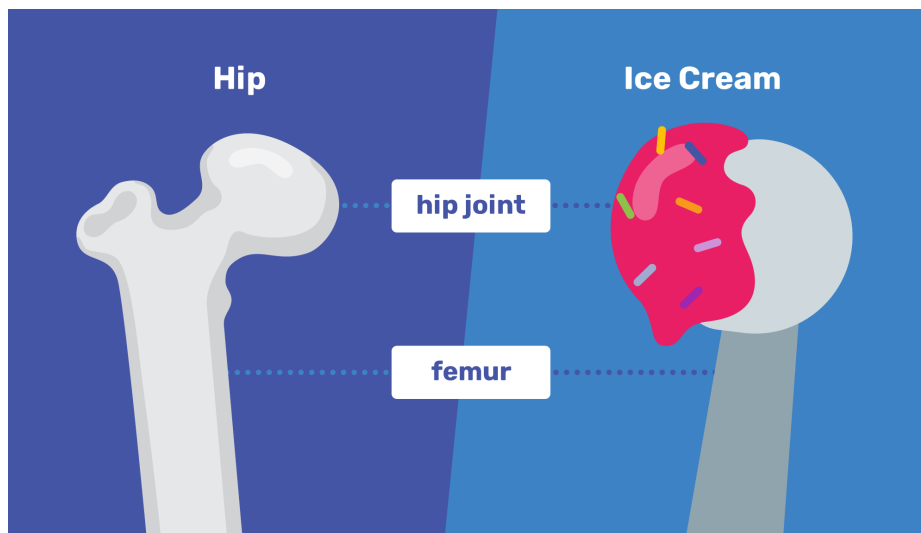
Further details of the study can be found in the parent version of the information leaflet given to your parent/guardian, and also online at www.opnonstop.org.

The study is led by Professor Daniel Perry, who is a Consultant Children's Orthopaedic Surgeon specialising in the treatment of Perthes' Disease at Alder Hey Children's Hospital in Liverpool, and Mr Nicolas Nicolaou, who is a Consultant Children's Orthopaedic Surgeon at Sheffield Children's Hospital.

1) WHAT IS THE OP NON-STOP STUDY?

The study is trying to find the best way to treat the problem you have with your hip bone—called Perthes' Disease.

A handy way to make sense of what is happening to you, is to imagine that your hip joint is an ice-cream. You can picture your round hip joint bone is like ice-cream ball. And, the ice-cream ball is inside an ice-cream scoop (the hip socket). When your leg moves, the ball moves around in the socket.



Living with Perthes' disease means something happens in your hip so it does not receive enough blood and nutrients. You can think of this like someone takes the ice-cream out of the freezer for a while. The ice-cream (i.e. your hip bone) melts and becomes soft and flattens out. After a while, the blood and nutrients return to your hip, which is like putting the ice-cream back into the freezer. When the ice-cream re-freezes it stays in the shape it was when it melted. So, your hip joint bone might harden in a flattened shape. If the hip joint bone is flat then it does not fit as smoothly into your hip socket, which can be painful and stop you doing the things you love.

At the moment, doctors don't know what the best thing to do is to make the hip grow back like a nice round ice cream. Some doctors think we should do “enhanced physiotherapy” which is where we teach you lots of ways to keep your hip moving – like rolling the ice cream within in the scoop to ensure it stays smooth helping the hip to grow back in a round shape.

Other doctors think we should do “surgical containment” which means doing an operation on your hip. This operation would change the shape of the bone to try to help the the ball grow back in the round shape of the socket.

2) WHY ARE YOU ASKING ME?

You have been given this information sheet because your hip is affected by Perthes' Disease. Your doctor believes that each of the treatments above could help you, though no doctor knows which of the treatments is the best.

We are asking lots of children and young people in the country who have the same condition as you if they will think about taking part in the Op Non-STOP Study.

3) WHAT TREATMENT WILL I GET?

The treatments are:

1. Enhanced Physiotherapy (we call this "Active Containment")– Involving exercises to keep the hip moving – like rolling the ice cream within in the scoop to ensure it stays smooth helping the hip to grow back in a round shape.
2. Surgical Containment – Involving surgery to change the shape of the bone to try to help the hip ball grow back in the round shape of the socket.



The best way to compare the treatments is to fairly make two groups of children/young people who are similar. One group will have enhanced physiotherapy (active containment) and the other will have containment surgery. You can't choose the treatment, and neither can the doctors. When we have groups of patients who are as similar as possible, we can then compare them in the best possible way.

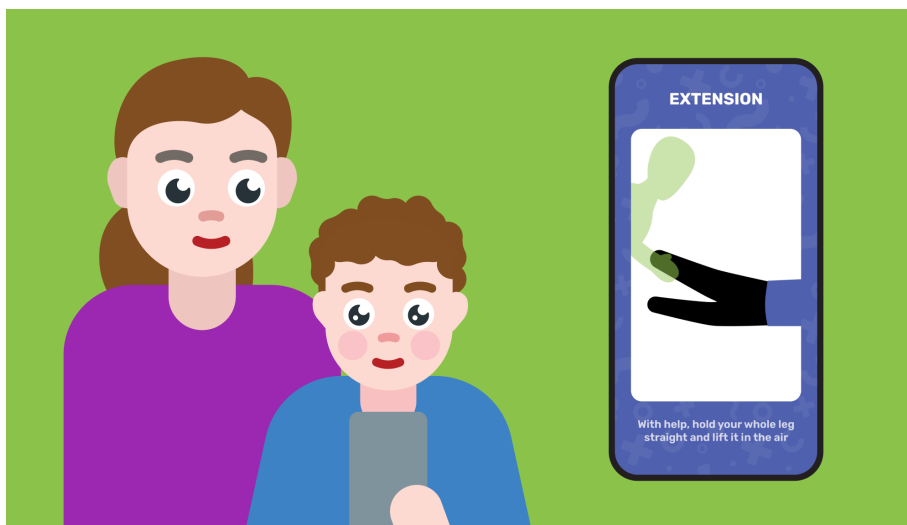
4) DO I HAVE TO SAY YES?

No, you don't. If you decide to say no, nobody will mind and you, your parents, doctors and nurses can talk about what treatment you will have.

5) WHAT WILL HAPPEN IF I SAY YES?

Your parent or guardian will need to sign a consent form to agree to you taking part and then one of your doctors or nurses will ask if you would like to sign a form called an "Assent Form". This is just to say that you understand the study and what will happen.

Your parent or guardian will be sent a copy of the form to keep, as well as this information leaflet.



Then you will have some questions to answer with your parent or guardian. The questions will be about what activities you can do and how much pain you have. After this, treatment will be decided fairly.

If you get put in the enhanced physiotherapy group

If you get put in the enhanced physiotherapy group, you will spend time with a physiotherapist who has been taught lots about Perthes' Disease. They will teach you about Perthes' disease and teach you special exercises, make contact with a physiotherapist close to your home and will show you and your family a website and a mobile app that has lots of information about Perthes' Disease and reminders about how to best look after your hip. You will need to take medicine to help you manage your pain and a physiotherapist will assess you to see what walking aid(s) you may need.

If you get put in the surgical containment group.

If you are part of the surgical containment group, the doctors and nurses will plan to bring you to hospital for an operation. Your doctors will tell you the operation details clearly, though you will be put to sleep with special medicine, so you can't feel anything. All children with Perthes' disease have pain and take painkillers, but surgery will make the hip hurt more for a few weeks, so you will have extra medicine to help you manage your pain. After surgery you may not be able to put any weight on your hip for six weeks. You will be introduced to a physiotherapist who will help you with your recovery and will assess you to see what walking aid(s)/wheelchair you may need. You will normally be in hospital for a few of days after surgery and you may go home in a type of plaster cast.

For Everyone

Whilst you recover from Perthes' disease, we will ask you how you are doing as your hip re-grows. We'll ask you questions eight times during the 3-years of the study to make sure we know how you are doing while you continue to grow.

The questions will be sent to the mobile phone or e-mail address that your family tells us to.

The care from your doctors will be the same as if you did not take part in the study.

6) WHO WILL KNOW I'M IN THIS STUDY?

You will be given a identification number and any information that you give us will be linked only to this number. This means that only the people who are treating you, or who need to contact you, will know who you really are.

7) WHAT HAPPENS IF I CHANGE MY MIND?

You can change your mind at any time and we will stop contacting you. If you do change your mind please ask your parent or guardian to let your doctor or one of the research team members know.