

The CELLOS Study: What is important to measure after children have planned operations for orthopaedic conditions affecting the leg from hips to toes?

INFORMATION SHEET FOR PARTICIPANTS AGED 12-15 YEARS OLD

*If you need an audio or translated copy of this sheet,
please let the research team know at CELLOS.study@ndorms.ox.ac.uk*

1. Introduction

You are being invited to take part in a research project called the CELLOS Study. Before you decide if you would like to join in, it's important to understand what the study is about, why we're doing it and what it would involve for you.

Please read and think about this leaflet carefully. Please feel free to talk to your family, friends, or the researchers about it if you want. If anything isn't clear or you have more questions you can ask your parent or carer to email us. We can answer any questions.

2. Why is this research being conducted?

To help with a problem in their leg, children sometimes need a planned surgery to the bones and muscles of their legs. This includes surgeries from the hips to the feet. When a child needs to have surgery, a surgeon chooses which is the best operation for them. They use research studies to decide which is the best operation.

Researchers measure things before and after the surgery to see whether the surgery has worked. But sometimes researchers measure different things. One study might measure if the children can walk further after surgery. Another study might measure if the children take part more in school after surgery. Because the studies have measured different things, it is sometimes hard for the surgeons to tell which operation is best.

To help this, we want to know what researchers should measure before and after surgery. This will make sure that researchers always measure the same things. It will also make sure what researchers measure is important.

We want to know what is important for children who are having the surgery. We would like to speak to you and your parent or carer.

3. Why have I been invited to take part?

We have invited you to take part because you:

- Had planned orthopaedic leg surgery (surgery to the bones or muscles of your leg). This surgery happened while you were under 18 years old. If you have not had this surgery, you will have it soon.
- Are between the ages of 8 and 25 years old.
- Are currently living in England, Wales or Northern Ireland.

4. Do I have to take part?

No. It is up to you. You can stop by telling your parent or carer. You do not have to give a reason. Nothing bad will happen to you.

You can also ask to have the recording of your conversation with the researcher erased. The deadline for this is 14 days after your conversation with the researcher. After 14 days your data will be analysed with others. This means we can't erase your conversation, but you could still withdraw.

5. What will happen to me if I take part?

We would like to speak to you. Your parent or carer will also be there. We want to know your opinion about what researchers should measure before and after surgery. We will speak to about 25 people in total.

We will ask your parent or carer to complete a 'consent to be contacted' form. This tells us you are interested in taking part. We will use these forms to pick people to speak to.

If you are picked, we will let your parent or carer know. We will speak to them about what is the best time to meet you.

You can choose how to meet the researcher. We can meet you online or in person. If you choose to meet online, we will use Microsoft Teams. If you choose to meet in person, you can choose where you meet the researcher. We can meet you at your home, or somewhere nearby such as a community centre. We can also meet somewhere fun like a zoo or science centre. This will depend on what we can book near you.

If you are meeting in person, we will bring a form for you and your parent or carer to sign. If you are meeting online, we will send your parent or carer online forms to complete. When you fill in this form, it tells us you are happy to take part.

The conversation will take about one hour. We will only need to speak to you once. If you need to take a break, you can let the researcher know. They will be more than happy to help.

We will ask you and your parent/carer questions about:

- Your surgery.
- What you were hoping would change after surgery.
- What you have found did change after surgery.
- Why these changes were important to you.
- You might be told about some other kids. You will be asked what you think researchers should measure in their situation.

We might use some cartoon cards, or ask you to draw some pictures. This might help us understand more about your surgery. What you say during the conversation will be audio recorded.

6. What are the possible advantages and disadvantages or risks in taking part?

Joining in will not help you, but it might help other kids in the future.

You might find the questions we are asking upsetting. This is more likely if you had a bad experience with surgery. If you get upset, you ask the researcher to change question. You can stop at any time.

7. Expenses and payments

After the meeting, you will be offered a £20 gift voucher. This is a thank you for taking part.

8. What information will be collected and why?

The conversation will be recorded using two voice recorders. One will be a backup, in case the other does not work.

This recording will be turned into writing. Once it has been checked the recording will be erased. We will then look at what people said to see what people though researchers should measure.

9. Will the research be published? Could I be identified from any publications or other research outputs?

What we find out will become a book for a degree at the University of Oxford. We want to tell researchers the results of this study. This will make sure they measure the right things in future research studies. To tell researchers the results, we'll write articles, do presentations and make an information pack for researchers. We'll also make an animated video. We might use a quote from you when we are telling other people about the results. We also might use any pictures you draw with us. We won't use your name. We will try our best to make sure people don't know they are your words or pictures.

If you would like to see the video or read about what we find out, ask your parent or carer. They can find the results on our Twitter (X) page @CELLOSstudy.

10. Will anybody know I am taking part?

We will keep your information private. This means we will only tell those who have a need or right to know that you are taking part. This will include the research team, people helping with the research, and your parent/guardian.

If you tell us that you or someone you know is being hurt, we will need to pass that information on to the relevant agencies. We will let you know if we need to do this. Other than these people, we will only share information without your name.

11. What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller and is responsible for looking after your information and using it properly. We will be using information from you in order to undertake this study and will use the minimum personally identifiable information possible.

We will store any research documents with personal information, like consent forms, securely at the University of Oxford for five years after the end of the study as part of the research record. We will keep any other identifiable information for a maximum of three months after the study has finished. This will include your contact details.

A company will help us turn your conversation recording into a writing. If you need a translator, we will use a company who does translations. Before we talk to you, both companies will sign a contract to say that they will keep what you said secret.

If you have been recruited to this study through Oxford University Hospitals NHS Foundation Trust (OUH), the OUH will use your name and NHS number to oversee the quality of the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>

You can find out more about how we will use your information by contacting the study team at CELLOS.study@ndorms.ox.ac.uk

12. Who has reviewed this research?

Before any research involving people can start, it has to be checked. A Research Ethics Committee makes sure that it is OK for the research to go ahead. This study has been checked by the Research Ethics Committee in Harrow (London). The reference code for the committee is 24/PR/0719.

13. What if there is a problem or something goes wrong?

If you are not happy because of something that happened in the study, please talk to your parent or carer. They will let the researcher know.

Thank you for reading this information.