CELLOS Study: Delphi Survey Information Sheet for Children and Young People 16 Years and Older

Contact: CELLOS.study@ndorms.ox.ac.uk

What is the purpose of the study?

Surgeons use research findings to decide which surgery is the best. This includes for children who need elective (non-emergency) surgery to their legs, from their hips to their feet. However, there are some problems with the existing research which surgeons rely on. Some studies only measure how the child's leg moves after surgery. This does not consider other important outcomes from the surgery, like if the child can play more sport.

The CELLOS study is trying to improve this. We are trying to understand what the most important outcomes are for children who have non-emergency surgery to their legs. We are also trying to understand how researchers should measure these outcomes. We have made a list of outcomes which have been measured in previous studies. We have also done interviews with healthcare professionals, children and their parents or guardians. We would now like you to vote on which of these outcomes are most important.

This study includes a survey with up to four rounds. Some participants will be invited to participate in two further online workshops. In these workshops, we will discuss the results of the survey.

Why have I been invited?

About 150 people will take part in the survey. About 25 people will be invited to take part in each workshop.

We have invited you because you received elective surgery to your legs while you were under the age of 18 years old. This includes surgery from your hips to your feet. If you have not had surgery, but you are on a list to have surgery, we would like to hear from you also. We have invited you because you are currently between 8 and 25 years old.

Do I have to take part?

No, it is up to you. If you change your mind later, you can choose to withdraw from the study. You do not need to give us a reason. This will not affect your clinical care. You can take part in the survey without joining the online workshops. You can choose if you would like to be invited to the workshops when completing the consent form.

What will happen if I decide to take part?

After reading this information, you will complete a consent form to say you are happy to take part.

You will then complete the first round of the survey. We will ask you for some information about you. We will ask you to vote on what outcomes should be measured after children have non-emergency surgery to their legs. We will ask you if there are outcomes which are important to measure which are not on the list. Finally, we will ask you how you would measure the outcomes. The survey will take about 15 minutes to complete.

When we close the first round of the survey, we will look at how people have voted. We will use this information to change the survey. Outcomes will be removed if everybody agrees they are important, or not important. Outcomes which are suggested by participants will be added.

After these changes, you will be asked again to vote on the list of outcomes. We will repeat this until everyone agrees on all outcomes or until there has been four rounds of voting. If you don't complete a round you will be sent two reminder emails.

After the survey, two workshops will be held. In these, we will discuss the most important outcomes and how these outcomes should be measured. These workshops will include about 25 people. They will be held online using Microsoft Teams. They will be audio and video recorded using Microsoft Teams. You will be sent an optional online evaluation form after each workshop. You will be invited to an optional online chat before and after each consensus workshop to ask the researchers any questions. These will not be recorded. If you request in the consent form, you may be invited to join one or both workshops. We will let you know by email if you have been invited.

What are the advantages or disadvantages of taking part?

There are no immediate benefits if you take part. If you complete four rounds of the survey, it will take about one hour of your time. If you are invited to take part in an online workshop, these will take about four hours.

Will I be reimbursed for taking part?

If you take part an online workshop you will be offered a £75 gift voucher. This is a thank you for taking part.

Will my participation be kept confidential?

Yes. Information that can identify you will be held securely by Eileen Morrow (the Doctoral Investigator) for the purposes of the study. Responsible members of the University of Oxford and regulatory authorities may be given access to data for monitoring and/or audit of the study. They will ensure that the research is complying with applicable regulations.

What will happen if I don't want to carry on with the study?

If you chose to withdraw from the study, you will not be contacted about the study again. You can also ask to have your responses to the last survey round deleted. The deadline for this is seven days after the survey round closes. After this your data will be analysed. This means we will not be able to remove your data. The workshops will be analysed as a group. This means if you participate it will not be possible to remove your data, but you can still withdraw so you are not contacted again.

What will happen to the results of this study?

The findings will be written up as a thesis for a DPhil in Musculoskeletal Sciences at the University of Oxford. A copy will be deposited both in print and online in the Oxford University Research Archive where it will be open to the public. We will write academic articles, present at conferences, write an information pack for researchers and make an animated video to share the results. If you are interested in the reading the results, we will share a poster of the results and links to academic papers on our X (Twitter) page: @CELLOSstudy

We would like to use quotes from you in the results we share. The quote will be published under a pseudonym (fake name) and all identifiers removed. Every effort will be made to maintain your confidentiality.

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, such as 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.

The survey will be conducted using a secure online survey platform. We will store the data online until the end of this study. Once the study is finished, we will download it to the University of Oxford network drive and erase it from the online survey platform. The data from the survey will be anonymised when it is downloaded.

The workshop will be audio and video recorded using Microsoft Teams. The video file will be saved on the secure University of Oxford network drive in a password protected file, where only the research team can access it. It will be kept for five years along with the research data. A backup recording will be made with an encrypted digital recorder. This will be kept only until the video recording is checked. A company which hosts online meetings will be used. If anybody needs a translator, a company which provides translation will be used. Before the workshop, both companies will sign a contract to say that they will maintain participant confidentiality.

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 use your information by contacting

CELLOS.study@ndorms.ox.ac.uk

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions. They can be contacted at CELLOS.study@ndorms.ox.ac.uk

The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Eileen Morrow at Eileen.Morrow@ndorms.ox.ac.uk or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

Who is organising and funding the study?

The CELLOS study is sponsored by the University of Oxford. It is funded by the National Institute for Health and Care Research (NIHR) Doctoral Clinical Academic Fellowship.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Harrow Research Ethics Committee (reference 24/PR/0719).