THE CELLOS STUDY: INFORMATION SHEET FOR HEALTHCARE PROFESSIONALS

WHAT IS THE CELLOS STUDY?

Overall, the CELLOS Study will investigate what are the most important outcomes and outcome measurement tools for children's elective lower limb orthopaedic surgery. We are interviewing parents, children, paediatric orthopaedic surgeons and nurses and allied health professionals.

In the interview, you will be asked what outcomes are important. Examples of outcomes might include pain, participation in sport, range of movement. You will also be asked about what outcome measurement tools you think are useful or use. Examples of outcome measurement tools include the 10 metre walk test or the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C).

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been invited to take part because: 1) You are a Paediatric Orthopaedic Surgeon, Paediatric Orthopaedic Nurse, Occupational Therapist, Podiatrist, Physiotherapist or Prosthetist/Orthotist. 2) You have at least two years of clinical practice. 3) Your current role involves working with children who have had elective lower limb orthopaedic surgery. 4) Your current role is within the UK including Northern Ireland.

WHAT HAPPENS IF I DECIDE TO TAKE PART?

You will have one interview with a researcher online using Microsoft Teams. This will be arranged at a time convenient to you. This interview will be audio recorded and will take approximately 45 minutes.

DO I HAVE TO TAKE PART?

No, it is your choice to take part. If you choose not to, it will not affect your employment.

If you decide to take part and change your mind during the project, you can withdraw. You don't have to give a reason.

WHAT ARE THE ADVANTAGES AND DISADVANTAGES?

There are no immediate benefits if you take part. We hope this research will improve evidence for children's lower limb surgery.

This interview will take approximately 45 minutes of your time.

We do not anticipate any further advantages or disadvantages.

YOU CAN FIND MORE DETAILED INFORMATION ABOUT THE CELLOS STUDY BY READING THE REST OF THIS INFORMATION SHEET

The CELLOS Study: Development of a core outcome set for children's elective lower limb orthopaedic surgery

INFORMATION SHEET FOR HEALTHCARE PROFESSIONALS

If you need an audio or translated copy of this sheet, contact: 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 whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. Why is this research being conducted?

Surgeons use research findings to decide which surgery is most appropriate for children who need elective lower limb orthopaedic surgery. However, there are some problems with the existing research which surgeons rely on. Some studies only measure functional outcomes, like the range of movement in a joint. This does not consider other outcome domains which might be important. For example: self-esteem, engagement in school, or access to services. Some studies also use unverified tools to measure these outcomes. This makes it hard to compare research findings to support surgeons.

To address this, the CELLOS study is developing a core outcome set for children's elective lower limb orthopaedic surgery. A core outcome set is an established list of outcomes that should be measured and reported in all clinical trials. The aim is to improve consistency between studies. This will improve the evidence base supporting treatment.

We want to speak to children and young people, parents/carers and healthcare professionals to find out what outcomes are important. This will be used to write a survey for people to vote on the most important outcomes.

3. Why have I been invited to take part?

We have invited you to take part because you:

- Are a Paediatric Orthopaedic Surgeon, Paediatric Orthopaedic Nurse, Occupational Therapist, Podiatrist, Physiotherapist, Prosthetist or Orthotist.
- You have at least two years of clinical practice.
- Your current role includes working with children who have had elective lower limb orthopaedic surgery, at any stage of rehabilitation.
- Your current role is within the UK including Northern Ireland.

4. Do I have to take part?

No. It is up to you to decide. You can choose to withdraw from the study by telling us. You do not have to give a reason. This will not affect your employment or legal rights. If you chose to withdraw, your contact details will be erased. You will no longer be contacted about the study.

You can also ask to have the recording or transcript of the conversation erased. The deadline for this is 14 days after your conversation with the researcher. After this time your data will be analysed with others. This means it will no longer be possible to remove your data, but you could still withdraw.

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

We would like to speak to you about what outcomes are important. We are planning to speak to up to 25 people overall. This will also include children, young people and parents/carers.

We will ask you to complete a 'consent to be contacted' form. This tells us you are interested in taking part and will collect some information about you. We would like to speak to different types of people. This will help us make sure we understand a wide perspective. We will use the information you share to decide who we should speak to.

If you are selected to be interviewed, we will send you a consent form to complete before the interview to tell us you have read this sheet, and that you are happy to take part. The interview will be arranged at a time convenient to you. It will be held over Microsoft Teams. You will be sent a link to join at the correct time and date. This interview will take about 45 minutes. If you need to take a break, you can let the researcher know. They will be more than happy to accommodate. This conversation will be audio recorded.

We will ask you questions about:

- What outcomes you believe are important.
- What outcome measurement tools you use or believe are important.
- You will be told about some example patients. You will be asked what outcomes would be important for those patients and what outcome measurement tools you might use.

We don't expect you to have an expertise in outcomes or measurement tools. Your understanding of the patient group is sufficient to take part.

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

There are no immediate benefits for participating in the research. However, we hope that this project will improve the research evidence for children's elective lower limb orthopaedic surgery.

This interview will take approximately 45 minutes of your time. We do not anticipate any further disadvantages.

7. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

The interview will be audio recorded using two encrypted digital recorders. One will serve as a backup.

This recording will be turned into a written transcript. Once it has been checked the recording will be erased. The transcripts will be analysed to see what outcomes were identified as important. These will also be analysed to understand why these outcomes are important.

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

The findings from the research will be written up as a thesis for a DPhil at the University of Oxford. A copy of the thesis will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available.

In addition, several academic publications, conference presentations, an information pack for researchers, an animated video and reports in charity magazines will be developed.

We would like your permission to use direct quotations in any research outputs. The quote will be published under a pseudonym (fake name) and all identifiers removed. Every effort will be made to maintain your confidentiality.

If you wish to read a summary of the findings of this research study, one will be published on the study X(Twitter) page: @CELLOSstudy

9. Will my participation be kept confidential?

Yes. All study records and data will be identified only by a code. We will only use your name, email address or telephone number where this is necessary to contact you. Information that can identify you will only be held securely by Doctoral Investigator (Eileen Morrow) for the purposes of the study. Confidentiality will be maintained as far as it is possible. Unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies. We would discuss it with you first.

Responsible members of the University of Oxford, regulatory authorities and relevant NHS Trusts may be given access to data. This is for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

10. 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 only in order to undertake this study and will ask you 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 about you for, such as contact details, for less than three months after the study has finished.

A third-party transcription service will be used to turn your interview into a written manuscript. If you require a translator for your interview, a third-party translator service will be used. Prior to their involvement, any third-party suppliers will sign a contract which shall include that they 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 will use your information by contacting the study team at CELLOS.study@ndorms.ox.ac.uk

11. Who is funding the research?

This study has been funded by the National Institute for Health and Care Research (NIHR) Doctoral Clinical Academic Fellowship.

12. Who has reviewed this research?

This research has received sponsorship from the University of Oxford (reference: PID 17847).

This research has also received a favourable opinion from the Harrow Research Ethics Committee (reference: 24/PR/0719).

13. Who do I contact if I have a concern about the research or I wish to complain?

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.

Thank you for considering taking part.