

PiCCoLO: Paediatric Chronic pain Clinic LOngitudinal cohort
Evaluating the effects of chronic pain and how these change with time in young people
attending GOSH Pain Clinic

Participant Information Sheet for Young People aged 16-18

We invite you to take part in a research study.

- Before you decide, we would like you to understand why the research is being done and what it would involve for you.
- Please take time to read the following information carefully. Discuss it with your family if you wish.

Summary of important things that you need to know:

- We want to understand the effect that chronic pain has on young people's health and well-being and how this changes with time and treatment.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect your current or any future care you may receive at GOSH.
- In this research study we will use information from your medical records. We will only use information that we need for the research study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- At the end of the study we will save the data (in case we need to check it) and you may agree for us to use the data for future research.
- We will make sure no-one can work out who you are from the reports we write.
- The following pages tell you more about this.
- If you are interested, one of our research team will go through the information sheets with you and describe the study in more detail. This should take about 30 minutes, but more time will be available if you have any extra questions or need longer to decide to take part.
- You can decide to leave the study at any time, without giving a reason. Your treatment at the hospital will not be affected in any way.
- You will not be required to do any extra tests or come to any extra hospital visits as part of this research.

PART ONE

What is the purpose of the study?

The aim of the study is to find out more about the effect chronic pain has on the health and well-being of children and young people and how this changes with time. We also want to know which treatments work best for young people with pain.

Why have I been invited?

Young people aged 8-18 years who attend the Pain Services Clinic at Great Ormond Street Hospital, and their parents or carers, are being invited to take part in this study.

What will happen if I take part?

- You will be one of hundreds of young people helping us with this study.
- The study will take place at Great Ormond Street Hospital.

Usual care at Pain Clinic:

- At your Pain Clinic hospital appointment you will see a multidisciplinary pain team that includes a Pain Consultant, Clinical Nurse Specialist, Physiotherapist and Psychologist.
- Information about your pain, general health and physical activities, and previous treatments will be entered into your hospital record by the pain team.
- As part of your usual appointment, you will also fill in some questionnaires about your pain, your quality of life, whether or not you experience feelings of anxiety or sadness, and how you cope with pain. The Pain team use this information to understand more about your pain and how best to manage it. If you agree to join the study, we will also collect this information from your hospital records.
- After your appointment, a member of the research team will be available to answer questions regarding the study, either in person or online. If you and your parent/carer agree, you will be asked to complete the necessary consent forms. This can be done in person at the first appointment, over the phone, or online through a secure videocall (MyGOSH).
- We will ask you to sign a form indicating that you understand what is involved and agree to join the study, and also ask your parent or carer to sign a consent form. If you haven't had a chance to read the information sheets before the day of your appointment but have discussed the study with the researcher and would like to provide consent on the day, there will be a 48-hour "cooling off" period where we won't look at your data, and you may change your mind and let us know that you don't want to join the study.
- You will be assigned a coded Study Number that will be used in place of your name, and your confidentiality will be safeguarded.

Where will the research take place?

We will access your GOSH medical records and retrieve information collected at your Pain Clinic appointments. This will include your age, information about your medical history, your pain, treatments that have been used, and the questionnaires you and your parent/carer completed at clinic or online via MyGOSH.

To further assess how things can change over time, you will be asked if you agree to be contacted by the research team at 2 further time points (3 and 5 years following your first visit to Pain Clinic). A questionnaire will be completed via telephone or online at a time that is

convenient for you. You may no longer be receiving care at Pain Clinic at these times, and you are free to decline these additional follow-up questionnaires.

How will we use information about you?

- We will need to use information collected at your pain clinic visits and from your medical record for this research project.
- Information from your medical record will include your hospital number.
- We will keep a linking file that contains your hospital number and the anonymous code number that will be used to label your data. People will use this information to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will only have a code number.
- We will keep all information about you safe and secure.
- We will store your information with your code number in a database managed by the GOSH Digital Research Environment team.
- Once we have finished the study, we will keep the data so we can check the results. Data about you and from your questionnaires will be analysed at GOSH and will be accessed only by the researchers working on the study.
- All data will be kept securely for 25 years in compliance with data policies (Data Retention Policy and Data Protection Act).

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option for your saved data to also be used in future research.

What will happen to the results of this study?

- The results will be published in medical journals and be presented at scientific conferences so that other health care providers can learn from this work.
- We will write our reports in a way that no-one can work out that you took part in the study.
- If you wish to receive a newsletter with an anonymous summary of the group results, you can indicate this on your consent form.

Are there any risks in taking part?

We will not be asking you to do any extra tests outside of what usually happens in a clinical appointment. You may feel a bit upset when answering questions about your experiences with pain; if this is the case, within the usual care pathway, any concerns will be raised with the clinical care team and you will be signposted to your named nurse. For the 3- and 5-year follow-up questionnaires, if you are no longer under the care of the Pain Service team, we would encourage your parents/guardians to contact your GP and we will signpost you to appropriate available resources if you experience any distress and/or concern.

What are the possible benefits of taking part?

We cannot promise the study will help you directly, but the information we get from this study will help us learn more about how pain affects children and young people. The results will also help us identify factors that could increase the risk of developing long-term pain in future studies.

PART TWO

What if there is a problem?

Taking part in this study will not affect your usual clinical care.

If you feel distressed or have new questions about your pain while you are being managed by the Chronic Pain Clinic, you will have contact details for a Pain Clinical Nurse Specialist or you can contact the team via MyGOSH. If you agree to longer-term follow-up when you are no longer a patient at GOSH, and answering the questionnaires makes you feel distressed or you have new questions, we will suggest that you contact your GP for advice. We will also send a current copy of the GOSH Pain Education booklet which includes website links to resources for self-management of pain and distress.

If you 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.

Every care will be taken in the course of this study. If you suspect that an injury is the result of the Sponsor's (Great Ormond Street Hospital) negligence then you may be able to claim compensation. After discussing with your parents, please make the claim in writing to Dr Suellen Walker who is the Chief Investigator and who will then pass the claim to the Sponsor's Insurers:

Name: Suellen Walker

Designation: Consultant

Hospital/Department: Great Ormond Street Hospital

Tel: 020 7905 2382

The normal National Health Service complaints mechanisms are also available to you. You can contact the Patient Advice and Liaison Service (PALS) at Great Ormond Street Hospital:

Email: pals@gosh.nhs.uk

Tel: 020 7829 7862

Participant Information Sheet – 16-18 year old
IRAS: 340388 R&D No: 24PC03

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- Watch this video:
www.youtube.com/watch?v=VII6V1MgZgY or scan the QR code →
- At www.hra.nhs.uk/information-about-patients/
- Read our leaflet available from
www.hra.nhs.uk/patientdataandresearch
- See how research data is managed at GOSH:
www.gosh.nhs.uk/about-us/about-gosh-drive/
- Ask one of the research team by sending an email to
Suellen.Walker@gosh.nhs.uk
or Anna.Fieldwalker@gosh.nhs.uk
- Ring us at Hummingbird Ward at GOSH on 0207 8138268



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 your interests. This study has been reviewed by the West of Scotland REC 4 Committee, the NHS Health Research Authority and the GOSH Research and Development Office. The study can only commence when all the necessary approvals are in place.

Who is funding the study?

The study is funded by Great Ormond Street Hospital Charity.

Further information:

If you have questions about the study, the research team can be contacted at Hummingbird Ward, Great Ormond Street Hospital Tel: 0207 813 8268. The Chief Investigator Dr Suellen Walker can also be contacted via e-mail: suellen.walker@gosh.nhs.uk.

Thank you very much for your interest in this study.