

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 Parents/Carers

We invite you and your child 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 and your child.
- Please take time to read the following information carefully. Discuss it with your GP, your child's GP, or friends and relatives if you wish.

Summary of important things that you need to know:

- We want to understand more about the impact of different types of chronic pain on health and well-being, how this changes over time, and which treatments are used.
- 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 child's current or future care at GOSH.
- In this research study we will use information from your child's medical records. We will only use information that we need for the study.
- Everyone involved in this study will keep your child's 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 your child's data for future research.
- We will make sure no-one can work out who your child is from the reports we write.
- The following information pack tells you more about this. Your child will also receive an Information Sheet.
- 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 extra questions or need longer to decide.
- 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.
- Your child will not need any extra tests or any extra hospital visits as part of this research.
- You and your child may also be asked to consider additional research studies related to the management or assessment of chronic pain during your Pain Clinic care. If so, you will receive separate information at a later time.

PART ONE

What is the purpose of the study?

The aim of the study is to find out more about the effects that chronic pain has on children and families.

We want to address the following questions:

- What types of chronic pain affect children?
- How much does chronic pain affect emotions and activities and school, and how does this change over time?
- What type of treatments are used for chronic pain, and how many hospital, GP or healthcare provider visits are needed?
- What is the impact and potential costs (e.g., time off work, travel to appointments) for the family?

Why have I been invited?

All young people aged 8-18 years who are referred to the Pain Clinic at Great Ormond Street Hospital, and their parents, are being invited to take part in this study.

Great Ormond Street Hospital is one of the largest paediatric research centres in Europe. Hospital and research staff are committed to involving as many young people as possible in research studies so we can:

- understand more about illness during childhood, and how it effects current and future well-being
- assess responses to current management and treatments
- have data to compare our practice with new interventions or with other centres.

Do I have to take part?

We will describe the study and go through this Information Sheet. Your child will also receive an Information Sheet and will have the chance to ask additional questions. If you agree to take part, we will ask you to sign a consent form and your child to sign an assent form (or a consent form if they are 16 years or older) indicating that they also understand what is involved. You are free to withdraw yourself and your child from the study at any time, without giving a reason. Any current or future clinical care your child receives at GOSH will not be affected in any way by your withdrawing from the study.

What will happen if we take part?

- Your child would be one of over hundreds of young people who are referred to the GOSH Pain Service who will be helping us with this study.
- The study will take place at Great Ormond Street Hospital.

Usual care at Pain Clinic:

- Your child will be assessed by a multidisciplinary team that includes Pain Consultants, Clinical Nurse Specialists (CNS), Physiotherapists and Psychologists.
- Information about your child's pain, general health and physical activities, previous illnesses, previous and current treatments, and medical investigations or tests will be entered into their clinical record.
- When you attend the Pain Clinic outpatient appointment, you and your child will also be asked to complete a set of questionnaires. These will ask about your child's pain and quality

of life, whether or not you or your child experience feelings of anxiety or sadness, how your child copes with pain, and whether they have any problems sleeping.

- These questionnaires help the Pain Team assess the impact of chronic pain, and how this changes with time.
- When you attend follow-up Pain Clinic appointments, you and your child will tell the team about any changes in the pain, which treatments or interventions have been helpful, and complete the same questionnaires.

Where will the research take place?

- After your appointment, a member of the research team will be available to answer questions about the study, either in person or online, or they can arrange to call you.
- It is up to you and your child to decide to join the study.
- If you and your child 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 access your child's GOSH medical records and retrieve information collected at their Pain Clinic appointments. This will include their age, information about their medical history, their pain, treatments that have been used, and the questionnaires you and your child completed at clinic or online via MyGOSH.
- To further assess changes over time, you may 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. Your child 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 child's pain clinic visits and from their medical record for this research project.
- Information from their medical record will include their hospital number.
- We will keep a linking file that contains the hospital number and the anonymous code number that will be used to label your child's data. People will use this information to check the records to make sure that the research is being done properly.
- People who do not need to know who your child is will not be able to see your child's name or contact details.
- We will keep all information about your child safe and secure.
- We will store your child's information with their 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 from you and your child's 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 child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we have already collected.
- We need to manage your child's data and 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 your child.
- If you and your child agree to take part in this study, you will have the option for 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?

This study will not alter your child's usual care, and your child will not be asked to complete any extra tests.

What are the possible benefits of taking part?

We cannot promise the study will help you or your child directly, but the information we get from this study will help improve our understanding of chronic pain in children. The results will also help us identify which treatments or interventions work best, and what factors could increase the risk of developing long-term pain.

PART TWO

What if there is a problem?

Taking part in this study will not alter your child's usual clinical care.

If you have concerns about your child's pain while they 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 and your child agree to longer-term follow-up when your child is no longer a patient at GOSH, and you raise issues about any ongoing pain that is affecting your child, 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 Chief Investigators (Prof Suellen Walker or Dr Glyn Williams) or other members of the research team who will do their best to answer your questions. It is highly unlikely that taking part in this study could harm you and/or your child.

Every care will be taken in the course of this study. However, in the unlikely event that you (or your child) are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (Great Ormond Street Hospital NHS Foundation Trust) negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Prof Suellen Walker who is the Chief Investigator for the research:

Name: Prof Suellen Walker Designation: Consultant
Department: Hummingbird Ward, Level 7 Southwood Building, Great Ormond Street Hospital;
Tel: 0207 813 8268

The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you or your child have been approached or treated by members of staff, or about any side-effects experienced due to participation in the research, the normal National Health Service complaints mechanisms are 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

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

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

- watch this video: www.youtube.com/watch?v=VII6V1MgZgY
- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- seeing how research data is managed at GOSH: www.gosh.nhs.uk/about-us/about-gosh-drive/
- by asking one of the research team
- by sending an email to Suellen.Walker@gosh.nhs.uk or anna.fieldwalker@gosh.nhs.uk
- by ringing us: 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 you and your child's 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 has funded the study?

The study is being 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. You can leave a message if there is no-one in the office and you wish us to call back. 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.