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Paediatric chronic pain clinic cohort

Submission date
31/05/2024

Recruitment status
Recruiting

Registration date
06/06/2024

Overall study status
Ongoing

Last Edited
12/09/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In England, 17.8% adolescents self-report chronic pain at multiple body sites, with 5-6% experiencing moderate-severe chronic pain that adversely effects school attendance, physical, emotional and family function, and increases health care utilisation. Children and young people referred to the GOSH Chronic Pain Clinic are assessed by a multidisciplinary team (pain specialist, clinical nurse specialist, physiotherapist and clinical psychologist). Parents and patients complete a range of validated questionnaires at each clinic visit related to pain, quality of life, mood, pain coping, school and physical activities. These outcome data assess the impact of pain and pain-related disability, help to inform management, and monitor response over time.

Who can participate?
We wish to recruit all children aged 8-18 years attending their first appointment at GOSH Pain Clinic to a longitudinal cohort study.

What does the study involve?
Parental consent and child assent/consent will be sought and all participants will. be assigned an anonymised study number. Participant study number, clinical and demographic data, medication and health care utilisation, questionnaire results collected at pain clinic, and details of pain treatment/interventions will be entered into a database. Data is information obtained as part of pain clinic assessment and follow-up, and there will be no alteration in usual clinical care. In addition, participants will be able to opt in or out of additional follow-up and completion of questionnaires following discharge from pain clinic at 3 and 5 years following initial assessment.

What are the possible benefits and risks of participating?
We cannot promise that the study will help participants directly, but the information we get from the 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.
We will not be asking participants to do any extra tests outside of what usually happens in a clinical appointment. They may feel a bit upset when answering questions about their experiences with pain; if this is the case, within the usual care pathway, any concerns will be raised with the clinical care team and they will be signposted to their named nurse. For the 3- and 5-year follow-up questionnaires, if they are no longer under the care of the Pain Service team, the young person's parent/guardian will be encouraged to contact the young person's GP

and they will be signposted to appropriate available resources if they experience any distress or concern.

Where is the study run from?
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2024 to September 2034

Who is funding the study?
Great Ormond Street Hospital Charity (UK)

Who is the main contact?
Dr Anna Fieldwalker, a.fieldwalker@ucl.ac.uk
Prof. Suellen Walker, suellen.walker@ucl.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340388

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
24PC03, IRAS 340388

Study information

Scientific Title
Paediatric Chronic pain Clinic LOngitudinal cohort (PiCCoLO) study

Acronym
PiCCoLO

Study objectives
In England, 17.8% adolescents self-report chronic pain at multiple body sites, with 5-6% experiencing moderate-severe chronic pain that adversely effects school attendance, physical, emotional and family function, and increases health care utilisation. This study will collect observational data from young chronic pain patients who are referred to Great Ormond Street Hospital.
We aim for this observational study to contribute to:
- ongoing review of our current practice within the context of a prospective research study, which will build on
our previous work utilising audit methodology to retrospectively retrieve patient outcome data
- improved understanding of the impact of chronic pain and response to different types of intervention
- identifying potential factors associated with poor outcome that may be targets for intervention and quality improvement projects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/05/2024, West of Scotland REC 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 24/WS/0048

Study design
Longitudinal observational cohort study

Primary study design

Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
To follow

Health condition(s) or problem(s) studied
Paediatric chronic pain patients

Interventions
The study aims to describe and quantify the type and impact of chronic pain in CYP, and the degree and duration of change throughout usual care. It is routine practice at Great Ormond Street Hospital (GOSH) Pain Clinic to collect Patient- and Parent-Reported Outcome Measures (PROMs) at each clinic appointment. These are uploaded into the electronic medical record (EPIC). Results are reviewed by the multidisciplinary clinical care team and used to: i) assess pain and pain-related disability; ii) inform a biopsychosocial formulation and management plan; and iii) collection at subsequent appointments facilitates monitoring of treatment response.

The research team will prospectively collect clinical data, PROMs scores, and information regarding interventions (type, frequency, how delivered) throughout the usual 2-year clinical management pathway at Chronic Pain Clinic. While selected data have been previously retrieved retrospectively for clinical audits and annual reviews of practice, prospective data collection in as many patients as possible will facilitate more comprehensive analyses. This will allow establishment of trajectories of pain-related disability, improvement, and/or response to treatment, and to benchmark this against other centres.

Enrolment in this study will not alter usual clinical care. In addition, patients and families will have the option to consent or decline follow-up following discharge from pain clinic (3 and 5 years post initial referral) and to provide additional details regarding health care utilisation and family financial burden of care.

Intervention Type
Other

Primary outcome measure
Overall well-being (quality of life) measured using the Paediatric Quality of Life Inventory (PedsQL Core Domains V4, total score, Child Versions (ages) & Parent version) at each clinic visit, and at 3 and 5 years post referral for participants consenting to longer follow-up.

Secondary outcome measures
Collected from each clinic visit, and extend outcome reporting to 3 and 5 years post referral for participants consenting to longer-term follow-up:
1. Pain intensity (using a 1-10 visual analogue scale [VAS]) (now, average last week, worst last

week)
2. Pain interference with daily living measured using the Paediatric PROMIS Pain Interference Short Form 8a
3. Physical function measured using the Physical function subscale of PedsQL (Child and Parent /Caregiver on behalf of child); physiotherapist assessment of muscle strength (MMT)
4. Psychosocial and family function measured using Emotional and Social domains of PedsQL (Child version & Parent/caregiver version relating to child)
5. Pain catastrophising measured using Pain Catastrophising Scale (PCS; child version and parent /caregiver version)
6. Child mental health measured using the Paediatric Index of Emotional Distress (PI-ED)
7. Parent/caregiver mental health measured using the Hospital Anxiety and Depression Scale (HADS)
8. School function/attendance measured using the school subscale of PedsQL, attendance reported at routine Pain Clinic appointments by child/parent and by the school (if latter available)
9. Pain-related disability measured using above-mentioned questionnaires, which form an overall view of pain-related disability
10. A case-report form (CRF), completed using patient notes collected onto EPIC following first assessment at Pain Clinic appointments, will capture:
10.1. demographics (age, sex, diagnosis)
10.2. pain: classification, distribution and duration of pain at primary site, pain at additional sites, spread, aggravating/relieving factors
10.3. medical history (current/prior illness, surgery, previous investigations)
10.4. details of pharmacological and multidisciplinary management methods, past and planned
11. For those who consent to follow-up at 3 and 5 years post referral, a follow-up CRF will collect directly from participants regarding:
11.1. Pain: classification, distribution and duration of chronic pain at primary site, additional pain sites
11.2. type and number of interventions and treatment response (i.e., pharmaceutical /multidisciplinary/intervention programmes), treatment response measured using Likert scale, "how much does this (intervention) help?: not at all; a little; some; a lot"
11.3. how pain interferes with mood, school, work, physical and social activity (using a Likert scale "never; almost never; sometimes; often; almost always")
11.4. methods of pain management and where these were learned
11.5. past visits to different healthcare professionals and burden on family, to measure cost of chronic pain on healthcare use (GP and hospital visits; medication use; investigations; interventions) and the family as a whole (e.g., economic burden of travel, parental time off work).

Overall study start date
31/05/2024

Completion date
01/09/2034

Eligibility

Key inclusion criteria
8 - 18 years old, referred to the GOSH chronic pain service

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Unwilling/unable to provide written informed Participant consent/assent and Parental consent
2. Outside of the stated age range (8 - 18 years).
3. If the parent/carer is unable to understand English, consent will be obtained only if a suitable interpreter can be sourced in line with usual clinical care. Children and Young People (CYP) who are unable to speak English or who are only managing school at a level less than usual for an 8-year old will be excluded as current versions of PROMs on EPIC are not available in multiple languages.

Date of first enrolment
01/11/2024

Date of final enrolment
01/11/2030

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital Central London Site
Great Ormond Street
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

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Great Ormond Street
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Sponsor type
Hospital/treatment centre

Website
https://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Great Ormond Street Hospital Charity

Alternative Name(s)
Great Ormond Street Hospital Children's Charity, GOSH Charity, GOSH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Results will be shared with other healthcare professionals and researchers via:
Monthly research updates to GOSH Pain Service
Presentations at national and international meetings
Existing teaching and training programmes (Faculty of Pain Medicine & RCPCH; GOSH Paediatric Pain Network meetings and Annual Paediatric Pain Symposium)
Public engagement activities, including ongoing presentations for GOSHCC and Donors
Multidisciplinary networks that include family and patient groups
Open-access peer-reviewed publications.

Study information can be discovered through ISRCTN, open-access publications, and conference presentations.

Participating investigators will have rights to publish study data. There are no time limits or review requirements on these publications.

Regarding participant notification of the study outcome(s), the PIS will include an agreement to additional follow-up which requires contact details (e.g., email address or telephone number), as well as an option to receive a final summary report via newsletter or publication.

Intention to publish date
01/09/2030

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Suellen Walker (suellen.walker@ucl.ac.uk).

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	12 - 15 year old version 0.5	20/05/2024	06/06/2024	No	Yes
Participant information sheet	16 - 18 year old version 0.4	19/05/2024	06/06/2024	No	Yes
Participant information sheet	8 - 11 year old version 0.6	20/05/2024	06/06/2024	No	Yes
Participant information sheet	Parent version 0.4	20/05/2024	06/06/2024	No	Yes
Protocol file	version 0.4	20/05/2024	06/06/2024	No	No