ISRCTN91641999 https://doi.org/10.1186/ISRCTN91641999

Feasibility of a new paediatric pain rehabilitation programme

Submission date
19/07/2024

Recruitment status
Recruiting

Registration date
12/08/2024

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Signs and Symptoms

[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
One in twenty teenagers experience chronic pain that lasts many months and affects their activities, mood, sleep and ability to go to school. These young people often need extra healthcare and are referred to pain clinics. At Great Ormond Street Hospital (GOSH) Pain Clinic, a specialist team (doctors, nurses, physiotherapists, psychologists) sees children and their families. A plan is made to help manage the pain, with treatment and follow-up at separate outpatient appointments. An intensive pain rehabilitation programme (PPRP) that combines all treatments at the same time can be more effective for some young people. An interdisciplinary team work together to deliver group and individual sessions for young people and parents/carers each day over several weeks. This study aims to test PPRP as a treatment option within the GOSH Pain Service. The study plans to find out more about how effective PPRP is, which parts work best, which children are helped the most and whether the timing of PPRP makes a difference.

Who can participate?
Children and young people aged 11-18 years with chronic pain and pain-related disability (low quality of life, school attendance, and/or mood)

What does the study involve?
Patients and families who agree will be randomly allocated to either Early PPRP (start within 1-3 months) or continue usual Pain Clinic care until Deferred PPRP (start within 6-9 months). The young person and a parent/carer will attend Monday to Friday for 3 weeks of care that includes: pain education; psychology, physiotherapy, and occupational therapy; parental support and skills training. The team will ask young people and parents how well the different timings work and to fill in questionnaires about how pain affects their activities, mood and thoughts, and health care needs. The questionnaires will be repeated 3 and 6 months later to check how participants and families are doing.

What are the possible benefits and risks of participating?
Potential benefits from participating in the PPRP are an increase in quality of life for young people with pain, and an increased ability to live alongside and manage their pain, as well as benefits to parents/carers such as feeling better equipped to help their young person manage their pain.

Participants may feel distress or emotional effects related to answering questions about chronic pain and mental health, or related to an increase in physical activity. The programme's intensity and attendance for 3 weeks may raise issues related to separation from other family members or peers. The PPRP intervention team (psychologists, clinical nurse specialists, physiotherapists, occupational therapists) have clinical skills to identify and assess risk for participants and manage this by i) addressing these within group and/or individual sessions during the PPRP timetable; ii) adjusting individualised plans as needed; or iii) withdrawing the participant from the intervention and returning them to usual Pain Clinic care if this is needed clinically, or according to participant/family preference.

Where is the study run from?
The study will be run at GOSH (UK)

When is the study starting and how long is it expected to run for?
January 2024 to February 2027

Who is funding the study?
GOSH Charity (UK)

Who is the main contact?
Prof. Suellen Walker, suellen.walker@gosh.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
343593

Protocol serial number
24NC06, Charity Grant Ref: W1167C

Study information

Scientific Title
PIIPeR Trial: Impact of Paediatric Intensive Interdisciplinary Pain Rehabilitation for children with chronic pain and pain-related disability: Feasibility of recruitment to a randomised trial

Acronym
PIIPeR-F

Study objectives
1. Recruitment to a study evaluating an intensive interdisciplinary paediatric pain rehabilitation programme (PPRP) that incorporates randomisation to early entry into the PPRP (within 1-3 months following referral to pain clinic) or usual care until deferred/delayed entry into the PPRP (6-9 months following referral to pain clinic) is feasible and will be acceptable to CYP and parents.

2. It is feasible to deliver a standardised interdisciplinary programme, and participants and parent /carers will attend sessions throughout a 3-week programme.

3. It is feasible to collect patient- and parent-reported outcomes (PROMs) that assess multiple domains of pain-related disability, and health care/family costs, at several timepoints (first and last day of 3-week intervention, 3 and 6 month follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2024, London - Central Research Ethics Committee (3rd Floor 3 Piccadilly Place, London Rd, Manchester, M1 3BN, United Kingdom; Tel: N/A; londoncentral.rec@hra.nhs.uk), ref: 24/LO/0680

Study design
Single-site randomized within-cohort feasibility study

Primary study design

Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic pain in young people aged 11-18 years old

Interventions
This is a single-site randomized within-cohort feasibility study (interventional) with 2 years duration. Following referral and usual interdisciplinary assessment at Great Ormond Street Hospital Chronic Pain Clinic, children fulfilling eligibility criteria will be offered recruitment to a Paediatric Pain Rehabilitation Programme (PPRP) with randomisation using computer-generated block randomisation to PPRP-Early (within 1-3 months of recruitment) or usual care until PPRP-Delayed (6-9 months post recruitment).

2 randomised arms:
• "Active Arm" = Early (enter PPRP 1-3mo following recruitment)
• "Control arm" = Deferred (enter PPRP 6-9mo following recruitment)

Intervention:
• 3-week intensive PPRP delivered by an interdisciplinary team (clinical psychologists, physiotherapists, occupational therapists, advanced nurse practitioners, paediatric pain physicians)
• daily timetabled sessions for participant and parent/carer(s)
Follow-up:
• They will be followed up at 3 and 6 months post PPRP with completion of patient- and parent-reported outcomes.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcomes as of 16/12/2025:
1. Recruitment rate: number of CYPs referred to GOSH Pain Service who fulfil eligibility criteria consenting to enter the study measured using the screening and recruitment logs at Day 1 PPRP
2. Time-frame adherence: proportion of enrolled participants for whom it was feasible to enter the PPRP within the designated time-frame (1-3 months for Early, 6-9 months for Delayed)
3. Treatment completion rate, defined as the proportion of enrolled participants completing the 3-week PPRP, measured using the study Attendance Log on Day 19 PPRP (immediate post-intervention)
4. Follow-up rate, defined as the proportion of enrolled participants who “attend” the online 3 months and 6 months post-PPRP assessments, measured using the study Attendance Log at 3 and 6 months post-PPRP

Previous primary outcomes:
1. Recruitment rate: number of CYPs referred to GOSH Pain Service who fulfil eligibility criteria consenting to enter the study measured using the screening and recruitment logs at Day 1 PPRP
2. Treatment completion rate, defined as the proportion of enrolled participants completing the 3-week PPRP, measured using the study Attendance Log on Day 19 PPRP (immediate post-intervention)

3. Follow-up rate, defined as the proportion of enrolled participants who “attend” the online 3 months and 6 months post-PPRP assessments, measured using the study Attendance Log at 3 and 6 months post-PPRP

Key secondary outcome(s))

Current secondary outcomes as of 16/12/2025:
Intervention:
1. The number of deviations by PPRP clinical staff from program timetable and/or content (with reasons recorded and potential contributing/mitigating factors) and number of essential elements delivered ('dose delivered') measured using study records at one timepoint; attendance by participant and parent/carer throughout 3-week PPRP ('dose received').
2. The acceptability of study design, by the participant, parent/carer, clinical care team, and PPRP staff, measured using qualitative interview on Day 1 of the PPRP and at the 3-month follow-up
3. Participant and parent-reported satisfaction, measured using at Treatment Satisfaction Scale (NRS 0-10), measured on Day 19 (i.e., final day) of the PPRP and the 3-month follow-up
4. The identification and reporting of adverse events, measured using official reports as detailed in the protocol at one timepoint

Data Collection:
1. The proportion of complete datasets: Case Report Form, PROMs and questionnaires, and physical assessments, measured by calculating the number of complete datasets versus the number of incomplete datasets, measured on Day 1 and Day 19 of PPRP, and at 3 months and 6 months post-PPRP
2. The feasibility of calculating health and social care resource use and wider societal impact including days off school, measured using the Child and Adolescent Service Use Schedule (CA-SUS) on Day 1 of PPRP and at the 6-month post-PPRP follow-up.
3. The feasibility of calculating quality-adjusted life years measured using the Child Health Utility instrument 9 Dimensions (CHU-9D) on Day 1 of the PPRP and at 6-months post-PPRP

Previous secondary outcomes:
Intervention:
1. The number of deviations by PPRP clinical staff from program timetable and/or content (with reasons recorded and potential contributing/mitigating factors) and number of essential elements delivered ('dose delivered') measured using study records at one timepoint
2. The acceptability of study design, by the participant, parent/carer, clinical care team, and PPRP staff, measured using qualitative interview on Day 1 of the PPRP and at the 3-month follow-up
3. Participant and parent-reported satisfaction, measured using at Treatment Satisfaction Scale (NRS 0-10), measured on Day 19 (i.e., final day) of the PPRP and the 3-month follow-up
4. The identification and reporting of adverse events, measured using official reports as detailed in the protocol at one timepoint

Data Collection:
1. The proportion of complete datasets: Case Report Form, PROMs and questionnaires, and physical assessments, measured by calculating the number of complete datasets versus the number of incomplete datasets, measured on Day 1 and Day 19 of PPRP, and at 3 months and 6 months post-PPRP
2. The feasibility of calculating health and social care resource use and wider societal impact including days off school, measured using the Child and Adolescent Service Use Schedule (CA-

SUS) on Day 1 of PPRP and at the 6-month post-PPRP follow-up.
3. The feasibility of calculating quality-adjusted life years measured using the Child Health Utility instrument 9 Dimensions (CHU-9D) on Day 1 of the PPRP and at 6-months post-PPRP

Completion date
20/02/2027

Eligibility

Key inclusion criteria
1. CYP aged 11-18 years with chronic pain (>3 months duration) following referral to, and multidisciplinary assessment at, the GOSH Chronic Pain Clinic. Eligibility will not be influenced by biological sex, gender, ethnicity, or socioeconomic grouping.
2. Willing and able to provide written informed Participant consent/assent and Parental consent
3. Fulfil at least 3 of the 4 criteria:
3.1. Significant pain-related disability (PedsQL quality of life total score <70)
3.2. High levels of pain catastrophising (Pain Catastrophizing Scale score > 20)
3.3. School attendance <90%
3.4. Psychological (Pediatric Index of Emotional Distress score >20) and/or physical (specialist physiotherapy assessment of reduction in mobility and muscle strength) comorbidity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
11 years

Upper age limit
18 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unwilling/unable to provide written informed Participant consent/assent and/or Parental consent
2. Non-engagement and/or not willing to accept biopsychosocial formulation and management plan
3. Major psychological or psychiatric illness (personality disorder, severe depression, eating disorder) that requires specific therapy
4. Other acute intercurrent illness/infection that precludes involvement in group activities or

ability to attend full-time Participant Timetable
5. Parent/carer unable to attend for joint and parallel Parent Timetable
6. Severe limitation of mobility due to an intercurrent medical condition that precludes involvement in group activities (based on the clinical history and medical and physiotherapy assessment)
7. Any primary psychological disorder likely to interfere with engagement with the intervention including, but not limited to: externalising conduct disorder, chronic fatigue syndrome, functional neurological disorder, and eating disorders (based on clinical psychology assessment at Chronic Pain Clinic and by PPRP clinical staff).
8. Significant limitations in understanding written and verbal English that would preclude the participant's engagement in group activities and verbal discussions. As patients referred to GOSH Pain Clinic are usually attending UK schools, this exclusion would be rare. Parental language barriers are relative exclusion criteria. In line with current clinical practice, information for parents and consent can be obtained with interpreters, and some educational material can be translated from English. The extent to which parental understanding of verbal English would limit engagement in parent sessions and skills training would be assessed on an individual basis.

Date of first enrolment
20/08/2024

Date of final enrolment
20/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
London
England
WC1N 3JH

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Great Ormond Street Hospital Charity

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be available on reasonable request to the corresponding author, subject to approval by the investigative team. Regarding access to the study protocol, full study report, anonymised participant-level dataset and statistical code for generation of results will also be available upon reasonable request to the Chief Investigator, Professor Suellen Walker, suellen.walker@gosh.nhs.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	22/10/2025	16/12/2025	No	No