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# Evaluating mental health and psychological wellbeing drop-in services at paediatric hospitals

**Submission date**
22/11/2022

**Recruitment status**
No longer recruiting

**Registration date**
09/12/2022

**Overall study status**
Completed

**Last Edited**
16/04/2025

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Young people with chronic illness are up to nine times more likely to have mental health disorders than the general population. However, many children are not able to access Child and Adolescent Mental Health Services. This project builds on a previous research study at a paediatric hospital which increased access to evidence-based psychological treatment for children and young people with mental health needs. A drop-in mental health centre was set up in a paediatric hospital, which served as a single point of access for evidence-based low-intensity psychological interventions, signposting and onward referrals. There was a significant positive impact of attending the drop-in centre on symptoms and quality of life for children, parents, and siblings. The next stage of this study aims to evaluate the national roll-out of drop-in mental health centres and services in paediatric hospitals across the UK.

Who can participate?
Patients aged 5-25 years old, and families of patients at participating hospitals who have been receiving care for 6 months or more

What does the study involve?
The study involves an assessment call with a practitioner to assess mental health and wellbeing needs. Depending on clinical need, young people and their families will either receive a low-intensity psychological intervention, a referral to other services in their hospital or signposting to other services or resources. Families are asked to complete standardised questionnaires at baseline and at 6-month follow-up.

What are the possible benefits and risks of participating?
The project aims to benefit families' mental health and improve access to mental health support. We do not foresee any risks in taking part but answering some of the baseline and follow-up questionnaires may cause some emotional distress.

Where is the study run from?
The study is run by UCL Great Ormond Street Institute of Child Health (UK) and open at multiple paediatric hospitals and services across the UK

When is the study starting and how long is it expected to run for?
October 2021 to June 2024

Who is funding the study?
1. Beryl Alexander Charity (UK)
2. Great Ormond Street Hospital Children's Charity (UK)

Who is the main contact?
Anna Roach, anna.roach@annafreud.org

### Study website
https://www.ucl.ac.uk/child-health/research/population-policy-and-practice-research-and-teaching-department/champp/psychological-18

# Contact information

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Principal Investigator

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### Type(s)
Public, Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
213733

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
16HN11, IRAS 213733, CPMS 52414

## Study information

### Scientific Title
Clinical effectiveness of drop-in mental health services at paediatric hospitals: A non-randomised multi-site study

### Study objectives
A mental health and wellbeing drop-in service delivering low-intensity psychological interventions at paediatric hospitals improve emotional and behavioural outcomes for children and parents.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 14/12/2016, London – Riverside (Meeting held by video conference via Zoom; +44 (0) 207 104 8150, (0)207 104 8013; riverside.rec@hra.nhs.uk), ref: 16/LO/1915

### Study design
Multicentre interventional non-randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Non randomised study

### Study setting(s)
Hospital

### Study type(s)
Quality of life

### Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

### Health condition(s) or problem(s) studied

Mental health support for families of children with chronic conditions

## Interventions
This is a single-arm trial with no control group.

Referral methods:
Participants will be referred using different pathways depending on which hospital they attend. They can self-refer to the project, using a QR code or email address which is available on study posters. Alternatively, they can be referred by their clinician, who, after gaining families' consent to contact, can share their details with the study team, who will get in touch with more information and details for the next steps and consent process.

Observations for all groups:
All participants will fill out baseline measures after consenting to be part of the study. Baseline measures include demographic information, the Strengths and Difficulties Questionnaire, the Pediatric Quality of Life Questionnaire, and for those aged 12 years old and above the Patient Health Questionnaire-9 (PHQ-9) and Generalised Anxiety Disorder Assessment (GAD-7). Following this, all families will have an assessment call with a trained low-intensity therapist to allocate them to the most appropriate treatment. For those for which it is clinically appropriate, low-intensity cognitive behavioural therapy (CBT) interventions, such as guided self-help, will be delivered to families as 30-minute sessions over 4/6 weeks. For families with concerns that can not be appropriately treated with CBT (either mental health needs are too severe, or they have a specific need best addressed elsewhere), they will be referred to other services, such as CAMHS or can be signposted to specific support services.

Follow-up for all groups:
All participants will complete follow-up questionnaires, 6 months after completing their baseline questionnaires. Questionnaires will include the Strengths and Difficulties Questionnaire, the Pediatric Quality of Life Questionnaire, and for those aged 12 years old and above the PHQ9 and GAD7. At follow-up, all participants will also be asked to complete the Centre Satisfaction Questionnaire.

## Intervention Type
Behavioural

## Primary outcome measure
Parent-reported emotional and behavioural problems measured using the total score on the Strengths and Difficulties Questionnaire (SDQ) at baseline and 6 month follow-up

## Secondary outcome measures
1. Parent-reported quality of life measured using the Paediatric Quality of Life (PedsQL) total score at baseline and 6 month follow up
2. Child-reported emotional and behavioural problems measured using the total score on the SDQ at baseline and 6 month follow up
3. Child-reported quality of life measured using the PedsQL total score at baseline and 6 month follow up
4. Child-reported low mood measured using the Patient Health Questionnaire-9 (PHQ-9) total score at baseline and 6 months
5. Parent-reported low mood measured using the PHQ9 total score at baseline and 6 months

6. Child-reported anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) total score at baseline and 6 months
7. Parent-reported anxiety measured using the GAD7 total score at baseline and 6 months

### Overall study start date
04/10/2021

### Completion date
30/06/2024

## Eligibility

### Key inclusion criteria
Aged between 5-25 years old and has been a patient at a participating paediatric hospital within the last 6 months or be a carer/family member/sibling of such patients

### Participant type(s)
Mixed

### Age group
Mixed

### Lower age limit
5 Years

### Upper age limit
25 Years

### Sex
Both

### Target number of participants
180 (30 per site)

### Total final enrolment
120

### Key exclusion criteria
Participants must not have been currently under the care of psychology services within their hospital

### Date of first enrolment
16/11/2022

### Date of final enrolment
04/01/2024

## Locations

### Countries of recruitment

England

United Kingdom

**Study participating centre**
**Cambridge and Peterborough NHS Foundation Trust**
Elizabeth House
Fulbourn Hospital
Cambridge Road
Cambridge
United Kingdom
CB21 5EF

**Study participating centre**
**University College London Hospitals NHS Foundation Trust Hq**
250 Euston Road
London
United Kingdom
NW1 2PG

**Study participating centre**
**Hinchingbrooke Hospital (hinchingbrooke Healthcare Trust)**
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

**Study participating centre**
**Sheffield Childrens Hospital**
Western Bank
Sheffield
United Kingdom
S10 2TH

**Study participating centre**
**Leeds Teaching Hospitals NHS Trust**
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

**Study participating centre**
**Peterborough City Hospital**
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
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PE3 9GZ

# Sponsor information

**Organisation**
Great Ormond Street Hospital for Children NHS Foundation Trust

**Sponsor details**
Great Ormond Street
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WC1N 3JH
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research.governance@gosh.nhs.uk

**Sponsor type**
Hospital/treatment centre

**Website**
http://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

### Funder Name
Beryl Alexander Charity

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

### Intention to publish date
01/08/2025

### Individual participant data (IPD) sharing plan
The data will be made available upon request by a bona fide research team. Contact person: Anna Roach anna.roach@annafreud.org

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol article | | 09/05/2024 | 10/05/2024 | Yes | No |
| Results article | | 14/04/2025 | 16/04/2025 | Yes | No |