







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

Submission date 22/11/2022	Recruitment status No longer recruiting	 Retrospectively registered
Registration date 09/12/2022	Overall study status Ongoing	 Protocol added
Last Edited 10/05/2024	Condition category Mental and Behavioural Disorders	 SAP not yet added
		 Results not yet expected
		 Raw data not yet expected
		 Record updated in last year

Plain English Summary

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 December 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.21@ucl.ac.uk (UK)

Study website

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

Contact information

Type(s)

Principal Investigator

Contact name

Prof Roz Shafran

Contact details

30 Guildford Street
London
United Kingdom
WC1N 1EH
+44 (0)7596890672
r.shafran@ucl.ac.uk

Type(s)

Public

Contact name

Miss Anna Roach

Contact details

30 Guildford Street
London
United Kingdom
WC1N 1EH
+44 (0)7596890672
anna.roach.21@ucl.ac.uk

Type(s)

Scientific

Contact name

Miss Anna Roach

Contact details

30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)7596890672
anna.roach.21@ucl.ac.uk

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 hypothesis

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

Condition

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

Overall study end date

31/12/2024

Eligibility

Participant 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

Participant exclusion criteria

Participants must not have been currently under the care of psychology services within their hospital

Recruitment start date

16/11/2022

Recruitment end date

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
United Kingdom
PE3 9GZ

Sponsor information

Organisation

Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details

Great Ormond Street
London
England
United Kingdom
WC1N 3JH
+44 (0)20 7405 9200
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-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

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