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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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
213733

Central Portfolio Management System (CPMS)

52414

Protocol serial number
16HN11

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

Primary study design
Interventional

Study design
Multicentre interventional non-randomized controlled trial

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 Years

Upper age limit
25 Years

Sex
All

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
United Kingdom

England

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

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, greatormondSt, GOSH

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Beryl Alexander Charity

Results and Publications

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?
Results article		14/04/2025	16/04/2025	Yes	No
Protocol article		09/05/2024	10/05/2024	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes