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A study to evaluate how a new support program improves well-being in children and young people with sickle cell disease

Submission date 02/04/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/09/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/09/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sickle cell disease is a hereditary disorder of the blood. People living with sickle cell disease can face several challenges that impact their well being. This study aims to use a new support programme that combines psychology, education and nursing support combined with peer mentoring and use of digital technology to improve wellbeing.

Who can participate?
Young people with sickle cell disease aged 7-17 years(mentees). Adult patients with sickle cell disease (Mentors).

What does the study involve?
The study involves attending the hospital for 5 visits. At the first visit the participants will be introduced to the team and given some questionnaires to complete. Mentees will be provided with a hand held device with a preloaded APP to take home and given instructions to complete. Mentors will be given coaching training. During the visits there will be education and psychology sessions led by a specialist nurse and psychologist. During these visits adult mentors will be able to discuss their lived experience to support the young mentees with peer to peer support. Following these sessions a number of questionnaires will be completed to see if the support has made a difference to the mentees' well being.

What are the possible benefits and risks of participating?
The study aims to support young people with sickle cell disease in a holistic way to improve how the feel about their health. To fully benefit from the study, participants are encouraged to attend all sessions. This can be time consuming and potentially disruptive. Sometimes the discussions can make people sad as well as happy.

Where is the study run from?
Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2018 to September 2021.

Who is funding the study?
Grant received from Tower Hamlets Integrated Provider Partnership Staff Innovation Fund

Who is the main contact?
Banu Kaya, banukaya@nhs.net

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
217377

Study information

Scientific Title
An interventional study to evaluate impact on patient perceived well-being of an innovative model of biopsychosocial support for children and young people living with sickle cell disease

Acronym
BIOPS

Study objectives
Primary aim:
To assess the impact on perceived childhood bio-psycho-social well-being of using a package of biological, psychological and social support

Secondary aims:
To assess use, satisfaction and functionality of the package of intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/09/2017, London - Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; 44 (0)2071048181; chelsea.rec@hra.nhs.uk), ref: 17/LO/0900

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Sickle cell disease

Interventions
The intervention has three separate but related components:
1. Biological. A digital application (APP) will be used which would allow patients to record details of medical appointments, treatment plans, treatment adherence, fluid intake, exercise in a diary. The study participant will have the option of sending an email describing their progress. This may promote treatment adherence and improve both the patient's understanding of their condition and its treatment, as well as their confidence in managing their health. In recording details of hospital appointments, it is also hoped that the application may lead to a reduction in missed appointments, thereby reducing costs to services and potentially leading to better health outcomes for the patient. In addition, the application could provide medication reminders to promote treatment adherence. The application could also contain information about relevant websites and support groups patients could access. Usage of this data will be captured. At the end of the study feedback from patients will be used to design and commission a bespoke APP for routine use. The patients will gain a better understanding of their condition and health needs.

2. Psychological and educational. The model would offer two group interventions for this population. The first group would be a 3 x two-hour session (8 weeks apart) offered to seven to 13 year olds living with SCD. The session would utilise the skills of a Clinical Psychologist, Clinical Nurse Specialist, and mentor and would involve educating the children about their condition, answering questions about their condition, and discussing the psychological challenges of managing their condition, as well as strategies for addressing these.

The second would be a four-week group CBT intervention for 14 to 17 year olds living with SCD that would run over 3 sessions (2 hours each). This group would involve educating patients

about their condition and its treatment as well as providing a space to discuss the challenges of living with their condition and strategies for managing these. This would include addressing pain management and stigma and questions the young people might have about transition points and the future. The mentors would be a valuable resource to give a lived perspective on these issues to the young people in the group. The session would be attended by Clinical Psychologist, Clinical Nurse Specialist, and mentor. Additionally 2 personalised sessions with a mentor and Clinical Nurse Specialist will be organised for this older group.

3. Social. A mentorship scheme would recruit suitable adults living with SCD who would be asked to come to talk to and inspire young patients, and to provide them with ongoing social support for managing their condition. These mentors would be identified from the adult population accessing Haematology services at the Royal London Hospital, and would be provided with formal training in mentoring and coaching skills. These individuals would be assessed for suitability by the Haematology team and DBS checks organised. Additional support would be provided from the Haematology service in order to fulfil their roles as mentors. Not only will mentors provide additional peer support but it is felt that they will be particularly beneficial to patients who are more likely to identify with those who have been through experiences similar to their own.

Intervention Type
Mixed

Primary outcome(s)
1. Quality of life measured using CHQ-CF87 questionnaire at Baseline, then weeks 4, 12, 20, 28

2. Illness perception measured using brief illness perception questionnaire at Baseline, then weeks 4, 12, 20, 28

3. Self reported events measured using digital app at Baseline, then weeks 4, 12, 20, 28

4. Self reported pain scores measured using digital app at Baseline, then weeks 4, 12, 20, 28

5. Knowledgebase measured using SCD knowledge based questionnaire (non validated questionnaire) at Baseline, then weeks 4, 12, 20, 28

Key secondary outcome(s)
1. Usage of app, satisfaction measured using qualitative questionnaire / feedback survey at week 28

Completion date
29/09/2021

Eligibility

Key inclusion criteria
Mentees:
1. Informed consent and assent
2. Age 7-17 years
3. Primary diagnosis of sickle cell disease

Mentors:
1. Age over 18 years
2. Primary diagnosis of sickle cell disease
3. DBS clearance

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Any inclusion criteria not met
2. Severe cognitive deficit
3. Pregnancy
4. Severe recent acute illness (1 month)
5. Failed DBS clearance

Date of first enrolment
26/11/2018

Date of final enrolment
26/11/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London

England
E1 2ES

Sponsor information

Organisation
Barts Health NHS Trust

ROR
https://ror.org/00b31g692

Funder(s)

Funder type

Funder Name
Tower Hamlets

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available