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Does a theory and evidence-based approach to implementation increase the uptake of photobiomodulation in U.K. children's cancer centres?

Submission date
27/06/2025

Recruitment status
Recruiting

Registration date
30/06/2025

Overall study status
Ongoing

Last Edited
22/09/2026

Condition category
Cancer

[ ] 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
Most children with cancer are treated with chemotherapy. Eight in every ten of these children develop a sore mouth, which can involve extensive, painful ulceration. For some, this prevents eating and drinking.

Children may require hospitalisation to receive painkillers and nutrition through a drip. Ulcers can delay cancer treatment which can lower the chances of curing their cancer. Children tell us that these ulcers harm their quality-of-life.

When receiving chemotherapy, a special red light can be shone into the mouth, which reduces the risk of painful ulcers by about half. We call this photobiomodulation, or PBM for short. PBM is recommended by many national and international guidelines. However, in early 2022 only two U.K. children's hospitals delivered this treatment. We don't know why hospitals are not using PBM or how best to support hospitals to start delivering this treatment.

We want to explore why PBM isn't widely used. We will then work with different groups to create a collection of resources and strategies, which can be adapted to local context, to help children's cancer centres start to deliver PBM.

Who can participate?
We will ask children with cancer, their parents, professionals involved in delivering chemotherapy, and NHS managers and commissioners what they think would help and hinder PBM services.

What does the study involve?
We will use the information from these conversations to create resources to help these groups of people understand, deliver and get the most benefit from PBM. We will use implementation-science approaches to make sure the resource is based on theories tested through rigorous

research. We will test our theory and research-based resource with a range of children's cancer hospitals. We will evaluate whether our resource helps increase PBM use and ask professionals about their experience in starting a PBM service with this resource.

What are the possible benefits and risks of participating?
Taking part in the SPOT-LITE study may help improve care for children with cancer by contributing to the development of tools that support wider use of a treatment called photobiomodulation (PBM). While there are no direct health benefits for participants, their involvement could lead to better services for others in the future. Participants will receive gift vouchers and travel reimbursement as a thank you for their time. The main risks are minimal but may include emotional discomfort when discussing past experiences with cancer treatment. Children will be supported by a parent or carer during interviews, and all participants can skip questions or stop at any time. Healthcare professionals involved in testing the new resources may have additional meetings and tasks, but these are designed to be flexible and manageable.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2022 to September 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Claudia Heggie, C.Heggie@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Claudia Heggie

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Additional identifiers

Integrated Research Application System (IRAS)
336518

Central Portfolio Management System (CPMS)
61158

National Institute for Health and Care Research (NIHR)
303289

Study information

Scientific Title
SPOT-LITE: Study of PhOTobiomodulation impLementation for mucosiTis managEment in childrEn

Acronym
SPOT-LITE v1.0

Study objectives
AIM: To identify determinants of implementation of photobiomodulation services for children and young people to increase uptake, sustainability, and mucositis management

OBJECTIVES:
To:
1. Explore the barriers and facilitators to implementation of photobiomodulation services at CYP, parent, HCPs, commissioner levels (Work-package 1)
2. Co-create an implementation package for use by stakeholders at all levels of implementation (Work-package 2)
3. Test and evaluate the implementation package in children’s hospitals at different stages of implementation (Work-package 3)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/05/2024, Yorkshire & The Humber – South Yorkshire REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 2071048075; southyorks.rec@hra.nhs.uk), ref: 24/YH/0080

Primary study design
Interventional

Study design
Interventional non randomized and qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children's cancer and mucositis

Interventions
Participants are involved in one of three work-packages:

1. Work-package 1: Participants (healthcare professionals, commissioners, equipment manufacturers, and child-parent dyads) take part in a one-time qualitative interview to explore barriers and facilitators to implementing photobiomodulation (PBM). There is no follow-up. Duration: approximately 60 minutes.

2. Work-package 2: Stakeholders (including healthcare professionals, parents, children, and others) participate in co-design workshops to design an implementation package for PBM. These are collaborative sessions, not formal research participation. There is no follow-up. Duration: 2–3 hours per workshop.

3. Work-package 3: Healthcare professionals at three children's cancer centres test the implementation package. This includes:
- Fortnightly "lightning report" meetings for the first 3 months.
- Collection of anonymous clinical and patient-reported data.
- A focus group at 6 months to assess sustainability and impact.
Total observation and follow-up duration for Work-package 3 is 6 months.

Intervention Type
Other

Primary outcome(s)
A mixed-methods approach following the triangulation convergence model is planned, where qualitative findings will be compared to quantitative findings to aid interpretation and improve validity. The key outcome of interest will be successful implementation of photobiomodulation, with experiences determined by qualitative and quantitative data.

Key secondary outcome(s)
1. Treatment uptake barriers and facilitators, and need for adaptation, are measured using qualitative semi-structured interviews guided by the Consolidated Framework for Implementation Research (CFIR) during work-package 1
2. Stakeholder feedback on implementation resources from co-design workshops over course of 3 months during work-package 2
3. Reach of photobiomodulation is measured using service-level data on the proportion of eligible children and young people receiving treatment at months 1-6 of work-package 3
4. Severity of mucositis is measured using the World Health Organization Mucositis Grading Scale at months 1-6 of work-package 3
5. Patient-reported mucositis symptoms are measured using the Children's International Mucositis Evaluation Scale (ChIMES) at month 1-6 of work-package 3
4. Implementation experience is measured using the Stanford Lightning Report Method at fortnightly intervals during the first 3 months of implementation in work-package 3
6. Healthcare professional-reported implementation outcomes are measured using qualitative focus groups guided by the RE-AIM framework at 3-6 months in work-package 3
8. Implementation package usability is measured using qualitative data from lightning reports and focus groups during months 1-6 in work-package 3
10. Feasibility of outcome data collection is measured using completion rates of WHO mucositis grading and ChIMES forms at months 1-6 of work-package 3

Completion date
30/09/2027

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 22/09/2026:

Work-Package 1: Qualitative Interviews
1. Children and Young People
1.1. Children and young people aged 6–17
1.2. Experience of cancer treatment or haematopoietic stem cell transplant
2. Parents
2.1. Individuals with parental responsibility for children meeting the above criteria
3. Healthcare Professionals
3.1. Doctors
3.2. Nurses
3.3. Dentists
3.4. Dental nurses
3.5. Play therapists
4. Wider Stakeholders in Photobiomodulation
4.1. Industry representatives
4.2. Charity representatives
4.3. Commissioners
4.4. Other stakeholders involved in photobiomodulation treatment and NHS implementation
4.5. Note: Sampling will evolve iteratively as analysis progresses

Work-Package 2: Co-Design
1. Children and Young People (same as 1.1–1.2 above)
2. Parents (same as 2.1 above)
3. Healthcare Professionals (same as 3.1–3.5 above)
4. Wider Stakeholders in Photobiomodulation (same as 4.1–4.5 above)

Work-Package 3: Testing of Implementation Package at Children's Cancer Centres
1. Children's Cancer Centres
1.1. Principal Treatment Centres within the Children's Cancer and Leukaemia Group
1.2. Clinician leads selected based on:
1.2.1. Stage of photobiomodulation implementation (Rogers Adoption Curve)
1.2.2. Geographical area
1.2.3. Number of eligible cases
1.2.4. Presence or absence of specialist Paediatric Dental teams
2. Healthcare Professionals
2.1. Doctors
2.2. Nurses
2.3. Dentists
2.4. Dental nurses
2.5. Play therapists
2.6 Any other allied health professional involved in delivery of children's cancer or transplant care

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Previous key inclusion criteria:

Work-Package 1: Qualitative Interviews
1. Children and Young People
1.1. Children and young people aged 6–17
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2.5. Play therapists

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children and young people outside of the specified age range
2. Parents and healthcare professionals lacking capacity to consent

Date of first enrolment
03/05/2024

Date of final enrolment
01/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
The Christie NHS Foundation Trust
550 Wilmslow Road
Withington
Manchester
England
M20 4BX

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

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Individual participant data (IPD) sharing plan

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?
Protocol file	version 3.0	11/02/2025	30/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes