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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**
30/06/2025

**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 2026

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

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
336518

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 61158, NIHR303289

# 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

### Study design
Interventional non randomized and qualitative

### Primary study design
Interventional

### 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

## Phase
Not Specified

## 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
30/09/2026

## Eligibility

### Key inclusion criteria
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

### Participant type(s)

Patient

**Healthy volunteers allowed**
No

**Age group**
Mixed

**Sex**
All

**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**
01/07/2026

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Addenbrookes**
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

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

**Study participating centre**

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

# 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**
The current data sharing plans for this study are unknown and will be 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? |
|---|---|---|---|---|---|
| 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 |