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HRA PROTOCOL COMPLIANCE DECLARATION

This protocol has regard for the HRA guidance and order of content

TITLE PAGE

- Full study title:

SPOT-LITE: Study of PhOTobiomodulation impLementatIon for mucosiTis managEment in children

- Short study title:

SPOT-LITE

- Protocol Version Number

Draft version v1.0 – 16/1/2024

RESEARCH REFERENCE NUMBERS

IRAS: 336518

Funder Number: NIHR Doctoral Research Fellowship Round 9. Award Reference: NIHR303289.

Sponsor Reference Number: 2024-NCT03

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Funder(s)	Direct funding: National Institute of Health and Care Research, Doctoral Research Fellowship Round 9 Award Reference: NIHR303289. Funding in kind: Recruitment, facilities and PPI support received from matched funding from Candlelighters Children's Cancer Charity. Charity No: 1045077
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Committees	Project Advisory Group

STUDY SUMMARY

Study Title	Study of PhOTobiomodulation impLementatIon for mucosiTis managEment in children
Internal ref. no. (or short title)	SPOT-LITE
Study Design	Mixed methods **Work-package 1:** Qualitative semi-structured interviews will be undertaken with diverse stakeholders in photobiomodulation implementation. **Work-package 2:** Co-creation of an implementation package with a diverse group of stakeholders. **Work-package 3:** Mixed-methods evaluation of implementation package at three children's cancer centres. Data collection consisting of lightning reports, quantitative patient-reported outcome measures and qualitative focus groups.
Study Participants	**Work-package 1**: Qualitative semi-structured interviews with an anticipated 20 healthcare professionals, commissioners and equipment manufacturers and 5 dyads of children and young people (CYP) and their parents. **Work-package 2:** A co-design group will be formed, consisting of cancer care commissioners, healthcare professionals (HCPs - dentists, dental nurses and therapists, doctors, nurses), patients and parents, equipment manufacturer representatives, and healthcare

	researchers. Up to 20 stakeholders will be involved, including at least five parents and CYP, and at least one member of each named professional group across different geographical locations. **Work-package 3:** Three children's cancer centres will be purposively sampled to ensure: different photobiomodulation implementation stages in relation to the Rogers Adoption Curve (early majority, late majority, laggards), different geographical areas, different number of eligible cases, different cancer treatments, and, presence or absence of specialist Paediatric Dental teams. Lead clinicians will be recruited from these sites who will take part in lightning reports and will oversee collection of treatment and anonymised patient data for outcome evaluation as part of a locally registered service evaluation. Up to eight healthcare professionals, purposively sampled by professional role, will be recruited at each children's cancer centre to take part in a focus group at six months.
Planned Size of Sample (if applicable)	**Work-package 1:** 20 healthcare professionals and 5 CYP & Parent Dyads (n=10). **30 participants.** **Work-package 3:** Three children's cancer centres sampled by site; one lead clinician and up to seven further healthcare professionals to be recruited at each site for focus groups. **24 participants.**
Follow up duration (if applicable)	Not applicable for work-packages 1 & 2. For work-package 3, focus groups planned at six months following implementation to evaluate sustainment of knowledge and services.
Planned Study Period	30 months from ethical and HRA approvals, up to September 2026
Research Question/Aim(s)	RESEARCH QUESTION: Does a theory and evidence-based approach to implementation increase the uptake of photobiomodulation in U.K. children's cancer centres? AIM: To identify determinants of implementation of photobiomodulation services for children to increase uptake, sustainability, and mucositis management

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute of Health and Care Research	Funding in Round 9 of Doctoral Research Fellowships – awarded to Chief Investigator as a personal award C Heggie. Funding commenced October 2023 to cover: project costs, salary and training plan of Chief Investigator. Award reference: NIHR303298, value £457,522
Candlelighters Children's Cancer Charity	**Charity Number: 1045077** Non-financial support for patient and public involvement: facilities, advertisement through Candlelighters mailing lists, networks and social media. Non-financial support for recruitment of children and parents into research: advertisement through Candlelighters mailing lists, networks and social media. Equivalent to £2,100 matched funding

ROLE OF SPONSOR AND FUNDER

The University of Leeds acts as the Sponsor for this study and assumes overall responsibility for the initiation and management of the study.

The National Institute of Health and Care Researcher acts as the funder of the study.

ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS

1) **Project Advisory Group:**

An advisory group has been established to provide methodological support throughout. Biannual meetings are planned throughout the project. The Project Advisory Group consists of academics, patient and public involvement representatives and commissioners:

- PhD supervisory team:
    - Professor Carl Thompson, Professor of Applied Health Research with Expertise in Implementation Science
    - Professor Bob Phillips, Professor of Paediatrics and Evidence Synthesis Honorary Consultant in Paediatric Oncology
    - Professor Peter Day, Professor of Children's Oral Health, University of Leeds,
- Patient and Public Involvement (PPI) representatives

    - Hayley McGee is a bereaved parent whose daughter Elsa experienced life-threatening mucositis during her cancer treatment. She has contributed to our previous PPI and has experience in contributing to research through the charity Alice's Arc.
    - A flexible approach to representation of children and young people with experience of cancer is planned, to allow for changes in their lives throughout cancer treatment.
- PPI expertise:
    - Professor Sue Pavitt, Translational and Applied Health Research
- Candlelighters Family Liaison Representative
    - Natalie Kisby
- Qualitative methods expertise
    - Dr Kara Gray-Burrows, Psychologist and Lecturer in Behavioural Sciences & Complex Intervention Methodology
    - Dr Amrit Chauhan, Qualitative Researcher with interest in Behaviour Change
- Health Economist
    - Professor Chris Bojke will inform data collection relating to drivers of cost and benefit required for creation of an economic model
- Commissioner
    - Dr Julia Chisholm, National Specialty Advisor for Children and Young People's Cancer at NHS England and Children and Young People's Cancer Clinical Reference Group member.
- Statistician:
    - Michelle Collinson, a statistician who leads the Cancer & Palliative Care Complex Intervention portfolio for the Leeds Clinical Trials and Research Unit

2) Patient and Public Involvement Group

- Hayley McGee, bereaved parent with lived experience of having a child with mucositis
- Flexible approach to child and young person involvement planned (see below)

To ensure the voice of CYP with cancer is central to this project, PPI involvement is costed throughout the research to remunerate contributors for time and expenses, following INVOLVE guidance.

The research is supported by Candlelighters, a charity dedicated to supporting families of children diagnosed with cancer within Yorkshire. Their family support team, headed up by Natalie Kisby, will support PPI recruitment and activities, and dissemination (equivalent to a £2,100 in matched funding). Haylee McGee is a bereaved parent who contributed to our preliminary PPI. She has agreed to join my project advisory group, alongside Natalie and a CYP representative, to provide input and lived experience.

A child and their family's life can be subject to significant change, particularly during cancer treatment. Insights from other research projects led by my supervisor Prof Phillips have highlighted a need for a responsive model of research involvement, sensitive to the life stage of CYP. Therefore, engagement is planned throughout, with different representatives likely to contribute at different time points and to different activities. Our PPI representatives have highlighted the importance of flexibility to reduce time burden, including use of email and video conferencing as alternatives to face-to-face meetings. Research involving CYP with cancer relies on the ability to contact families and Candlelighters' support has proven invaluable in engaging these families.

Following an initial training event to support representatives in their contribution, biannual meetings with eight PPI representatives are scheduled throughout the research project. Initial PPI consultation has occurred to support finalisation of the study protocol, topic guides and documents. Infographics will be created following PPI meetings to demonstrate impact on research design, these will be disseminated as the fellowship progresses. In addition to biannual meetings, consultation will occur with smaller PPI subgroups for: website content design, qualitative research training and analysis, video co-creation and dissemination event planning.

3) Protocol Contributors

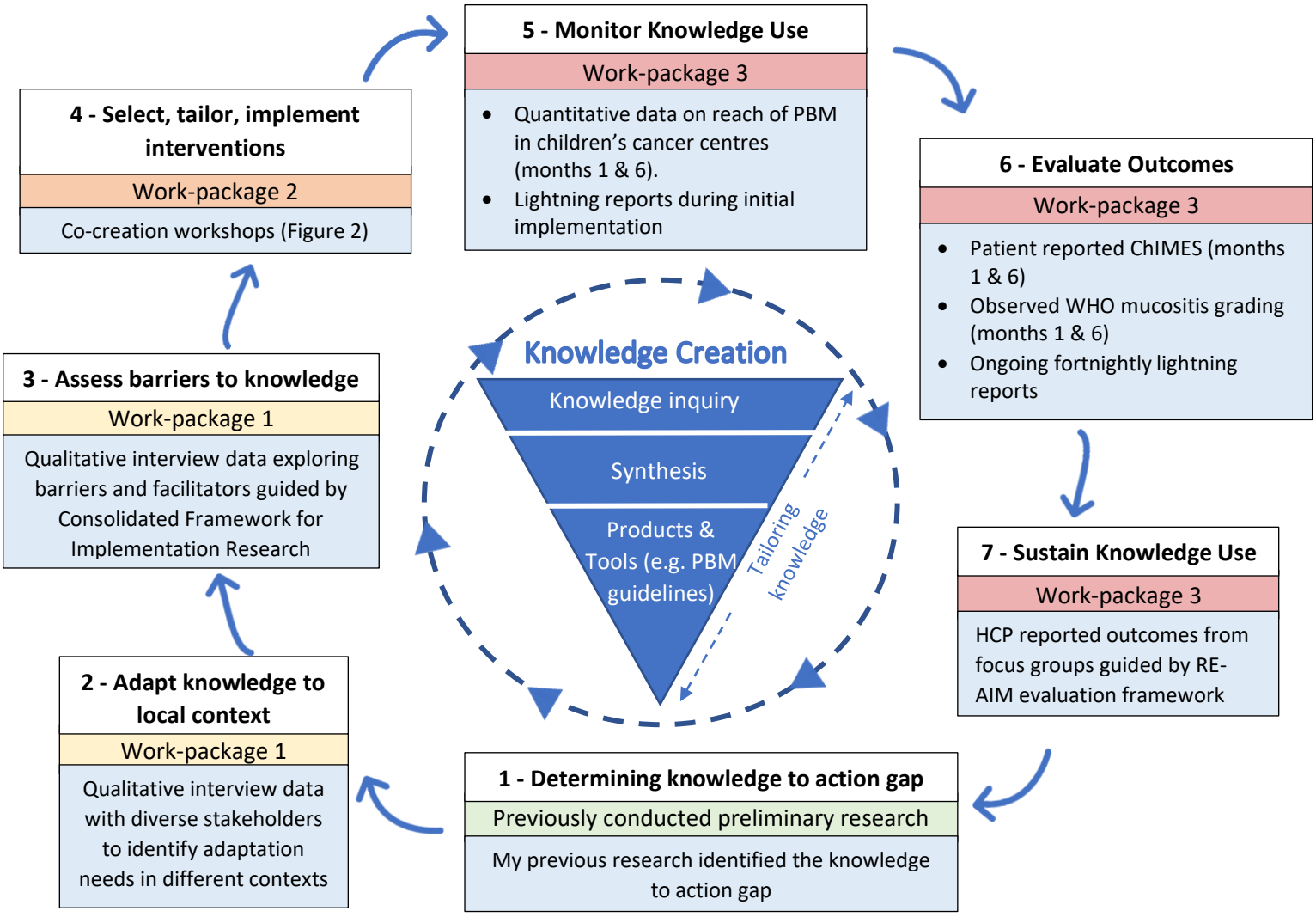
This protocol has been developed by the Chief Investigator (C Heggie), with support from the PhD Supervisory Team (Prof B Phillips, Prof C Thompson, Prof P Day) and qualitative researchers (AC, KG-B). Training and support in delivery of co-creation activities has been provided by Gemma Wheeler, co-designer and project manager at NIHR Children and Young People MedTech Co-operative.

The protocol has received external peer review, through the process of applying for competitive Doctoral Research Fellowship funding through the National Institute of Health and Care Research.

The protocol, ethics application and accompanying documents have been reviewed by the Project Advisory Group. Project outline was reviewed by PPI contributors prior to the funding application, and again prior to ethics consideration. Protocol and study documents have also undergone Sponsor review prior to submission for ethical approval.

KEY WORDS: Mucositis, Paediatric Oncology, Implementation, Photobiomodulation, Co-creation

SCHEMATIC OVERVIEW OF STUDY



1. BACKGROUND

THE DISEASE

An estimated 450,000 childhood cancer diagnoses occur globally each year,[1] with the U.K. recording 1,838 new diagnoses in 2018.[2] Childhood cancer has a high cure rate, with a five-year survival of 84% in 2012-2016.[3] Childhood cancers respond well to chemotherapy, and most children and young people (CYP) receive chemotherapy during their cancer treatment.[4] In the U.K., these intensive treatments are delivered in 20 principal treatment centres,[5] with some lower intensity treatments delivered in shared-care district general hospitals or Paediatric Oncology Shared Care Units (POSCUs).[6]

Oral mucositis affects up to 8 out of 10 CYP receiving chemotherapy,[7] usually within 3-10 days of initiating treatment and can persist for up to 3 weeks.[8] Mucositis has a significant biopsychosocial

impact on CYP.[9] In severe cases, CYP require hospitalisation for parental nutrition and pain-relief, delaying scheduled chemotherapy.[8] CYP who experience treatment delays and de-intensification of chemotherapy are at increased risk of treatment failure.[10] Preventing mucositis matters to patients, carers *and* oncology services; mucositis reduction minimises treatment disruption, reduces individual and societal costs and reduces burden of care.[11]

PREVENTION

A practical treatment that can prevent and reduce severity of mucositis is photobiomodulation (PBM), the application of red LED light or low-level laser to oral tissues during chemotherapy.[12] Our previous research identified that photobiomodulation is only available in 2 of 20 U.K. children's principal treatment centres.[13] The Pediatric Oncology Group of Ontario (POGO), a leading inter-professional group producing clinical practice guidance for Supportive Cancer Care for CYP, recommend the use of photobiomodulation for children at high risk of developing mucositis.[14-16]

THE PROBLEM

Photobiomodulation is a complex, multidisciplinary intervention, with several requisite interprofessional behaviours and skills that must interact in different contexts and settings for successful implementation. The latest MRC-NIHR framework for developing and evaluating complex interventions has a scope that goes beyond "effectiveness" to consider implementability, cost-effectiveness, transferability, and scalability in real world conditions. Using this effectively could help increase the uptake and reduce unwarranted variability in PBM implementation in principal treatment centres and children's cancer care more widely.[17]

Implementation research promotes the uptake of evidence-based practice into routine care and explores the influences on healthcare professional and organisational behaviour.[18] Research relating to implementation of complex interventions, such as photobiomodulation, in different contexts can provide the basis for generalisable resources to implement interventions in clinical service contexts.[19]

2. RATIONALE

HEALTHCARE NEED

CYP with cancer rank interventions addressing treatment side-effects as their second most important research priority in a James Lind Alliance priority setting exercise.[20] Managing side-effects is a key component of supportive cancer care delivered by multi-disciplinary teams.[21]

We have engaged CYP and their families in our patient and public involvement (PPI) groups using a "public science fair" stall and individual engagement sessions. Our PPI groups identified prevention of oral mucositis as highly important to CYP and their families. Families tell us oral mucositis can often be "the worst thing" about their child's cancer treatment, accompanied by feelings of "helplessness" when seeing their child unable to eat or drink.

Oral mucositis is most often managed with oral care advice, including oral hygiene instruction and maintaining hydration.[22] Mouthwashes such as chlorhexidine or benzydamine for pain relief and topical barrier gels are also used.[22,23] These treatments aim to relieve symptoms, rather than prevent mucositis. Our PPI representatives found mouthwashes were often "frustrating" and "impossible" to use when their mouths were painful. CYP and their parents tell us they want a viable treatment for preventing oral mucositis from happening during cancer treatment.

Photobiomodulation can prevent mucositis, or reduce its severity when it does occur.[24] Research shows that it is cost-effective in adults when compared to standard oral care, with an incremental cost-effectiveness ratio of $2868 and $4961 reported in two studies,[25,26] due to reduction in costs related to pain-relief, nutrition and hospitalisation. However, there is a paucity of economic evaluation in CYP.

RESEARCH GAP

This fellowship would fund empirical research and theoretical development exploring how best to implement photobiomodulation into U.K. children's cancer care and to co-create and test an implementation package. This would support implementation of photobiomodulation services and improve availability of this preventative treatment for CYP, reducing their risk of developing severe mucositis and the associated impact on cancer care and quality-of-life.

The implementation package would be transferrable and adaptable, able to support implementation of other evidence-based supportive cancer treatments in the future. Wider implementation of this complex intervention, supported by the fellowship results, would enable recruitment into clinical photobiomodulation trials.

This proposed research aims to test implementation theories in the novel context of children's supportive cancer care, to explore their value in developing other implementation interventions in this context. This aligns with the NIHR's focus on implementation science and knowledge mobilisation in their funding of advanced fellowships in the current recruitment round.[27]

This doctoral fellowship will enable my post-doctoral plans for conducting a hybrid randomised trial exploring both clinical and cost effectiveness and implementation.[28] Such a trial would aim to reduce uncertainty around degree of effectiveness of photobiomodulation in CYP and establish treatment parameters and regimes, whilst determining cost-effectiveness and evaluating implementation strategies in different contexts.

REVIEW OF EXISTING EVIDENCE

Photobiomodulation is an intervention with real potential clinical utility based on a growing evidence-base and subsequent recommendations for its use. An initial Cochrane review in 2011 found weak-evidence to support photobiomodulation use during chemotherapy.[29] In 2018, following literature review, NICE recommend photobiomodulation during chemotherapy or radiotherapy.[15] Similarly, the Mucositis Study Group of MASSC/International Society of Oral Oncology recommend photobiomodulation for patients undergoing haematopoietic stem cell transplant (HSCT) or receiving head and neck radiotherapy.[30,31]

In CYP, there are two notable systematic reviews with meta-analyses,[7] one published in 2021 by a team led by my supervisor Prof Phillips.[24] Meta-analyses showed an odds ratio of developing severe mucositis of 0.3-0.7 in the photobiomodulation groups compared to controls, depending on the time point analysed.[7,24] These estimates remain uncertain, through heterogeneity of trial design and varied implementation.

The POGO Mucositis Prevention Guideline Development Group recommend photobiomodulation for cooperative children receiving chemotherapy or HSCT.[14] This guidance was updated in 2021 to a strong recommendation, supported by high quality evidence in CYP.[16] Research gaps highlighted including the feasibility of treatment in CYP and uncertainty around economic evaluation, and ideal treatment

parameters such as wavelength, timing, duration. My previous research, described below, has shown that availability, unwarranted variations, feasibility, and acceptability of this evidence-based, recommended treatment for CYP can all be improved.

ALTERNATIVE TREATMENTS

There are few alternative treatments for mucositis prevention; cryotherapy (holding ice in the mouth throughout chemotherapy infusions) and keratinocyte growth factor (KGF) have the strongest evidence.[29] Studies supporting cryotherapy are in adult populations involving shorter duration chemotherapy regimens not commonly used in CYP, and a recent feasibility study found low compliance with cryotherapy among CYP.[32] Our PPI representatives felt this would have been "impossible" during chemotherapy infusions over several hours. Similarly, KGF is expensive, has an unknown toxicity profile, and there is a paucity of paediatric research in this area.[14] POGO therefore discourage routine KGF use in CYP.[16]

TIME AND RELEVANCE

Engagement from our PPI groups, and the CCLG with our survey, show this topic is of interest to CYP and children's cancer services. The proposed fellowship would use implementation theory to evaluate how best to address the implementation gap. Wider national and international implementation of photobiomodulation services will enable high-quality clinical trials of sufficient statistical power, to fine-tune treatment parameters and modalities and to improve certainty around effect size and economic evaluation in CYP, as highlighted as research gaps in the POGO guidance.[14] Additionally, wider availability of this preventative treatment for CYP undergoing cancer treatment will improve their quality-of-life and treatment outcomes.

3. THEORETICAL FRAMEWORKS

UNDERPINNING THEORIES

In implementation research, frameworks contain the theoretical constructs required for systematic application and the theoretical "lens" through which to study implementation.[33] Frameworks offer an evidence-based foundation for implementation research, promoting methodological rigour and transferability. Frameworks have differing purposes and uses.[34] Three frameworks are used in my planned research; each justified by their (project) function and the implementation question being addressed. Photobiomodulation provides a test-bed for evaluating and refining these frameworks and exploring their descriptive and predictive value in the novel context of supportive cancer care for children.

Knowledge to Action Framework (KTA)

The KTA is an iterative and dynamic process of knowledge creation and application for improving healthcare.[35] It is a social constructivist model, placing importance on social interaction and adaptation of research evidence into local context.[35] Social and local environmental influences were identified as contextual barriers to implementation in our previous survey research.[13] KTA offers an appropriate collaborative framework for this project, which aims to bring knowledge producers and users together to hasten and broaden adoption of PBM. It has a strong track record as a basis for developing multi-component interventions to support implementation - with 146 studies using the KTA in a 2014 systematic review.[35-37] In my fellowship, KTA provides the scaffolding surrounding the overarching project plan.

It provides a strategy for implementing photobiomodulation through seven phases outlined in the schematic diagram, with key phases outlined throughout the methods in *italics*.

Consolidated Framework for Intervention Research (CFIR)

The CFIR provides a framework for developing specific interventions to support implementation. The CFIR is a comprehensive framework, derived from 20 research sources from 13 different scientific disciplines.[38] The CFIR contains 39 constructs within five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, process of implementation.[38,39] The CFIR provides the framework to approach implementation research pre, peri and post-implementation.[38] It can be used to explore the conditions in which implementation has succeeded or failed, and identify modifiable factors to support implementation.[40] The CFIR will be used in work-package 1 to explore previous implementation experiences, to explore *why* implementation succeeds or fails.

RE-AIM Framework

The RE-AIM framework is used to evaluate implementation outcomes (*who,what,where,when)*.[40] It provides a practical, systematic approach to evaluating implementation interventions and has been utilised in a wide variety of clinical, community and corporate settings.[34,40-42] The RE-AIM framework considers five key domains of Reach, Effectiveness, Adoption, Implementation and Maintenance. It provides a more practical approach for planning and evaluating practice change interventions when compared to the CIFR.[40] RE-AIM will be used for implementation evaluation in work-package 3.

PREVIOUS WORK

My previous survey research on provision of photobiomodulation to CYP in the UK through the CCLG has *evaluated the knowledge to action gap*.[13] I have led the formation of a national collaborative of Paediatric Oncologist and Paediatric Dentists in this area. These existing relationships support purposive sampling and recruitment for our planned research.

4. RESEARCH QUESTION, AIM AND OBJECTIVES

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

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)

5. METHODS

Work-package 1: Qualitative interviews with stakeholders in photobiomodulation implementation.

Study design: Qualitative semi-structured interviews will be undertaken with diverse stakeholders in photobiomodulation implementation. Interviews will explore *adaptation in different local contexts* and *assessment of barriers and facilitators to use*, the next phases of the KTA framework (Schematic Overview).

Ethical approval and consent: Ethical approval will be obtained through the NHS Research Ethics Committee (REC) with sponsorship from the University of Leeds. All potential participants will receive an invitation email, information sheet and consent form. Where snowball sampling occurs, existing participants will mail their colleagues who will copy in the research team. Participation is voluntary and participants have the right to withdraw from the interview at any time.

Data collection and analysis:

Topic guides will be created with the project advisory group (including PPI representatives) and be responsive to emerging findings. Qualitative interviews will be semi-structured with open-ended questions to enable novel responses to be captured. Further questions will explore different CFIR domains to establish their relevance as well as their context.

Qualitative interviews will be audio recorded, assigned a code identifier, professionally transcribed verbatim and undergo framework analysis using NVivo software. The framework, matrices and initial coding will be guided by the CFIR, using a hybrid deductive (theory-driven) and inductive (data-driven) analytic approach.[43,44] Transcripts will be coded with an experienced qualitative researcher (AC & K G-B) providing sense-checks, face validity, consistency and reflexivity on coding choices. Codes will be discussed with our PPI panel representatives and project advisory group throughout analysis, to facilitate enhance rigour, reflexivity within the research team and trustworthiness. Anonymised transcripts will be stored on the University OneDrive, separate to participant details.

Work-package 2: Co-creation of implementation package

Implementation of a complex intervention requires behaviour change from the diverse stakeholders. Involving end-users and recipients of care in intervention development improves effectiveness of design and aids dissemination.[45,46] *Co-creation of tailored implementation resources to address the knowledge to action gap* will be a key output from our project. A similar co-creation approach has been adopted in other NIHR funded research concerning the complex intervention of school toothbrushing programmes.[47] Bespoke training and support in design and delivery of workshops will be provided by Gemma Wheeler, co-designer and project manager at NIHR HealthTech Research Centre for Paediatrics and Child Health. Her support will optimise active contribution from our diverse stakeholders.

An implementation package will be designed in a series of workshops guided by the co-creation impact compass for healthcare researchers, an evidence-based collection of activities to aid co-creation design processes and maximise active stakeholder engagement (Figure 2).[48] The workshop series has been designed to gain insight from the interaction of all stakeholders in an introductory session for stakeholder mapping and discussion of work-package 1 findings, and in a plenary session for feedback on the prototype resource package. Remaining workshops will be separated into two groups to reduce

hierarchical influence: parent-CYP dyads as care recipients, and HCPs, commissioners, and equipment manufacturers, as target professionals.

Workshops will be conducted face-to-face to maximise engagement with a hybrid (virtual) component to reduce geographical restriction.

It is not yet known what format the implementation package will take or precisely what it will include, as this will be co-created. The planned package will include resources pertaining to: service design, equipment type (low-level laser vs Light Emitting Diode), equipment purchase, cross-infection, training, standard operating procedures, and outcome measurement and documentation.

Work-package 3: Testing of implementation package

The implementation package will be evaluated at three children's cancer centres at different stages of implementation through a mixed-methods approach. In the context of this study the implementation package in itself is the intervention, not the photobiomodulation treatment, which is an evidence-based treatment recommended in multiple clinical practice guidelines.

Study design: Mixed-methods consisting of lightning reports, quantitative patient-reported outcome measures and qualitative focus groups. Quantitative data allows exploration of *use of knowledge* and *outcome evaluation*. Qualitative focus groups and biweekly lightning reports provide experiential data regarding use of the implementation package, and perceived *use of knowledge*. However, they are subject to hindsight, social desirability bias and group think. A mixed-methods approach following the triangulation convergence model is therefore planned, where qualitative findings will be compared to quantitative findings to aid interpretation and improve validity.[49]

Ethical approval and consent: Ethical approval will be sought from the NHS REC, with support from the University of Leeds as sponsor, and research offices at each site confirming capability and capacity. Additional participant sites will be added as amendments as required.

Data collection and analysis:

i) Lightning reports

The Stanford Lightning Report Method is a validated type of rapid assessment procedure to evaluate implementation and *use of knowledge*.[50,51] They utilise a Plus/Delta/Insight debriefing capturing what is working (Plus), what needs to change (Delta) and participant ideas, experiences and recommendations (Insight).

Following initial face-to-face site set up, clinical leads in local implementation and healthcare professionals involved in its delivery will be invited to fortnightly online meetings for the first three months of implementation. These will be conducted virtually for accessibility, with initial and final meetings held face-to-face to aid engagement. A lightning report will be produced after each meeting and shared with the stakeholders involved.[50] This provides real-time data on the use of the implementation package and elicits modification to fit with local context to support photobiomodulation implementation. Feedback will be given in line with evidence-based best practice to optimise effectiveness.[52]

ii) Quantitative data

A lead clinician within each children's cancer centre will oversee collection of treatment and patient data for *outcome evaluation* as part of a locally registered service evaluation.[51] Anonymous clinical variables to be collected include: proportion of CYP eligible for treatment who have received PBM and

data collected as part of photobiomodulation treatment – treatment refusals, clinician reported World Health Organisation Mucositis grading and patient reported Children's International Mucositis Evaluation Scale (ChIMES).[53]. This enables *outcome evaluation* from a patient and provider construct and provides feasibility data on completion of these outcome measures as part of standard NHS care. This anonymous data will be analysed at the level of the centre.

iii) Qualitative focus groups

Focus groups are planned at six months to evaluate *sustainment of knowledge use* and experiences of the implementation package. Focus groups can encourage participation from individuals who may not feel confident to participate in an individual interview and can draw on the shared experiences of the healthcare team.[54] Separate focus groups will be conducted for each participant site. Focus groups will be conducted both as a multi-disciplinary team and as separate professional groups at different sites to evaluate hierarchical influence. They will be conducted face-to-face where possible (with a virtual format available where needed), audio recorded and transcribed. Focus group participants will be remunerated for their time and contribution. The RE-AIM framework will form the basis of topic guide development and qualitative analysis, as is common in evaluating implementation and related interventions.[34] Qualitative methods are otherwise as described in work-package 1 and will be informed on the research experiences.

6. STUDY SETTING

Work-package 1: Qualitative interviews of stakeholders in photobiomodulation implementation.

Qualitative interviews will take place at Leeds Teaching Hospitals Trust, Candlelighters Children's Cancer Charity family support centre (The Square) or online by Zoom. This flexibility in approach has proven useful in previous qualitative research we have conducted in this population.

Work-package 2: Co-creation of implementation package

Co-creation workshops will be conducted face-to-face with a hybrid component to maximise participation across wider geographical regions. These will occur on University of Leeds premises.

Work-package 3: Testing of implementation package

Following initial face-to-face site set up, clinical leads in local implementation and healthcare professionals involved in its delivery will be invited to fortnightly online meetings for the first three months of implementation. These will be conducted virtually for accessibility, with initial and final meetings held face-to-face to aid engagement.

A focus group will be conducted with up to eight healthcare professionals from each participant site up to six months after initial implementation to evaluate maintenance. This will be conducted face to face at the participant site where possible, or online by Zoom if this is more practicable.

7. SAMPLE AND RECRUITMENT

7.1 Sampling

7.1.1 Sampling Methods

Work-package 1: Qualitative interviews with stakeholders in photobiomodulation implementation.

Diverse stakeholders in photobiomodulation implementation will be recruited purposively from different geographic areas. Snowball sampling will be utilised to enhance recruitment. Potential participants will be at different levels of implementation e.g., NHS commissioners, HCPs, CYP and their parents. For CYP: participants will be recruited by maximum variation to ensure diversity in experience of photobiomodulation and mucositis, range of cancer diagnoses and age and gender.

This list is not exhaustive, and my iterative sampling approach will evolve as analysis progresses and theoretically important categories are generated. Participants will be identified through networks in which I have existing links and contacts: the Children's Cancer & Leukaemia Group (CCLG), Candlelighters children's cancer charity, our national photobiomodulation network and, for CYP, direct clinical care.

For HCPs, we will map principal treatment centres to different implementation stages in relation to the Rogers Adoption Curve (early adopters, early majority, late majority, "laggards"),[55] and purposively sample diverse professional roles from centres at different implementation stages, in different geographical locations. This will enable exploration of key barriers and facilitators encountered during early adoption, the behaviours and views that sustain majority participation and reluctance to adopt or roll-out PBM in a service. Demographic data will be collected for context.

Recruitment will be adapted as findings develop, but from our previous survey research and networks we anticipate recruitment of 20 HCPs and 5 CYP/parent dyads (n=10). Sample size is guided by the number of principal treatment centres (n=20), but theoretical depth (and generalisability) will be encouraged by taking enough time to do justice to the qualitative methods, participant voices and high-quality data for analysis.

Work-package 2: Co-creation of the implementation package

Stakeholders in work-package 2 are not considered research participants in themselves, as is typical for co-creation and research involvement. However, similar networks as described in work-package 1 will be engaged. We will invite stakeholders to a co-design group a diverse range of cancer care commissioners, HCPs (dentists, dental nurses and therapists, doctors, nurses), patients and parents, equipment manufacturer representatives, and healthcare researchers. Up to 20 stakeholders will be involved, including at least five parents and CYP dyads, and at least one member of each named professional group across different geographical locations. Stakeholders will be engaged as described in work-package 1 participant recruitment. This will be modified as needed considering work-package 1 recruitment experiences.

Work-package 3: Testing of the implementation package

Three children's cancer will be purposively sampled to ensure: different photobiomodulation implementation stages in relation to the Rogers Adoption Curve (early majority, late majority, laggards),[55] different geographical areas, different number of eligible cases and, presence or absence of specialist Paediatric Dental teams (as this has been reported as an implementation facilitator in our previous research).[13] Additionally, sampling will aim for diversity in the children's cancer setting, and may include Principal Treatment Centres, Paediatric Oncology Shared Care Units (POSCUs) and other cancer treatment settings such as specialist radiation or stem cell services. This will allow testing of the

implementation package in different contexts to evaluate external validity and transferability through the Knowledge to Action lens. A sample of three sites has been chosen to allow sufficient variation in outer and inner settings in KTA, within the confines of the number of eligible pre-implementation treatment centres.

Potential participant sites are likely to change over time, with continued adoption of photobiomodulation. At the time of application, Alder Hey Children's Hospital (where specialist paediatric dentistry services are present) are at the point of pre-implementation, with interest in adoption expressed through our national network. Southampton Children's Hospital (where specialist paediatric dentistry services are absent) are at the stage of beginning implementation and have requested resources and support through our national photobiomodulation network. Additionally, Great Ormond Street and The Christie Proton Beam Centre have been approached to take part. The CCLG is a network inclusive of all U.K. principal treatment centres and, alongside our national photobiomodulation network, supports recruitment.

7.1.2 Sample Size

Work-package 1: Qualitative interviews with stakeholders in photobiomodulation implementation. 30 Participants.

Recruitment will be adapted as findings develop, but from our previous survey research and networks we anticipate recruitment of 20 HCPs and 5 CYP/parent dyads (n=10). Sample size is guided by the number of principal treatment centres (n=20), but theoretical depth (and generalisability) will be encouraged by taking enough time to do justice to the qualitative methods, participant voices and high-quality data for analysis.

Work-package 2: Co-creation of the implementation package

Up to 20 stakeholders will be involved in workshops, including at least five parents and CYP dyads, and at least one member of each named professional group across different geographical locations. These stakeholders will be involved. As is typical for co-creation workshops, the stakeholders involved in workshops are not considered research participants in and of themselves, but partners in the research process in a research involvement capacity. These stakeholders are therefore not included in recruitment targets.

Work-package 3: Testing of the implementation package. 3 Children's Cancer Centres, 8 healthcare professionals at each centre. 24 Participants.

Three children's cancer centres will be purposively sampled to ensure: different photobiomodulation implementation stages in relation to the Rogers Adoption Curve (early majority, late majority, laggards),[55] different geographical areas, cancer treatments delivered, different number of eligible cases and, presence or absence of specialist Paediatric Dental teams (as this has been reported as an implementation facilitator in our previous research).[13] A sample of three sites has been chosen to allow sufficient variation in outer and inner settings in KTA, within the confines of the number of eligible pre-implementation centres. At each site, one lead clinician will lead the testing of the implementation package and be involved in fortnightly lightning reports. Up to seven further healthcare professionals at each site will be recruited to a focus group to explore implementation experiences at six months.

7.2 Sampling Criteria

7.2.1 Inclusion Criteria

Work-packages 1 & 2: Qualitative interviews with stakeholders in photobiomodulation implementation & co-creation of the implementation package

a) Children and young people (CYP)

Children and young people with experience of cancer treatment or haematopoietic stem cell transplant (between 6-17 years of age inclusive)

b) Parents

Individual with parental responsibility for patients meeting inclusion criteria above

c) Healthcare professionals (HCPs)

Staff members directly involved in management of patients receiving treatment for cancer including: doctors, nurses, dentists, dental nurses, play therapists

d) Wider stakeholders in photobiomodulation

Individuals who act as stakeholders in photobiomodulation treatment (e.g., industry representatives, charity representatives) and its implementation in NHS services (e.g., commissioners).

This list is not exhaustive, and an iterative sampling approach will evolve as analysis progresses and theoretically important categories are generated.

Work-package 3: Testing of the implementation package

a) Children's Cancer Centres

- Children's cancer centres delivering chemotherapy, radiotherapy (or proton beam therapy), and/or stem cell transplant treatments. This may include centres delivering treatments for haemoglobinopathies as well as cancers. Clinician leads will be approached purposively based on: different photobiomodulation implementation stages in relation to the Rogers Adoption Curve (early majority, late majority, laggards), different geographical areas, different number of eligible cases, cancer treatments delivered and, presence or absence of specialist Paediatric Dental teams (as reported as an implementation facilitator in our previous research).

b) Healthcare professionals

- Staff members directly involved in management of patients receiving treatment for cancer including: doctors, nurses, dentists, dental nurses, play therapists

7.2.2 Exclusion Criteria

- Children and young people outside of the specified age range

- Parents and healthcare professionals lacking capacity to consent

7.3 Recruitment

7.3.1 Sample Identification

Work-packages 1 & 2: Qualitative interviews with stakeholders in photobiomodulation implementation & co-creation of the implementation package

Children and families

For children and young people treated at Leeds Teaching Hospitals Trust (LTHT) and their parents, where identification and recruitment of participants occurs through LTHT this will be conducted only by members of the direct clinical team. Two members of the research team (Bob Phillips - BP & Claudia Heggie - CH) act in both capacities as members of the direct clinical team and the research team. Other members of the direct clinical team, delivering photobiomodulation, will make potential participants aware of the research and can direct them to contact the research team. Potential participants will be made aware that any photobiomodulation treatment they may receive will not be influenced by participation in the study.

Children and young people and their parents may also be recruited by Candlelighters children's cancer charity, through their established network of families with experience of cancer treatment. This will support diversity of recruitment in regard to geographical location across Yorkshire. Relevant approvals from the charity through their organisation will be sought. Study information will be circulated through this network, with contact being initiated by potential participants direct to the research team by email.

Members of the research team will also circulate recruitment posters by their academic social media accounts (e.g. X, LinkedIn, Facebook) and known networks (e.g., Children's Cancer and Leukaemia Group). However, potential participants will be required to contact the research team directly.

This combined approach of direct recruitment through clinical care, and through charity partners, has proved successful in previous research in this area (IRAS 316813).

Work-package 3: Testing of the implementation package

The Children's Cancer and Leukaemia Group is a network inclusive of all U.K. principal treatment centres. Additionally, the research team has an existing established national working group of lead clinicians with an interest in photobiomodulation, including clinicians at POSCUs and other cancer treatment sites. These networks will be utilised to support recruitment, with study information shared through these groups. Existing professional relationships and contacts as well as snowball sampling will also be utilised. Where snowball sampling is utilised, existing participants will email potential participants and copy in the research team.

Potential participant sites are likely to change over time, with continued adoption of photobiomodulation. Sites will be added to the ethics application as amendments at the time of recruitment.

7.3.2 Consent

Work-packages 1 & 3: All qualitative, focus groups and lightning reports

Potential participants will be approached and provided with age-appropriate participation sheets (attached to this application). Participants will have an appropriate amount of time to consider whether they wish to take part and to ask any further questions. Our patient and public involvement groups felt that 24 hours would be a sufficient time period to consider participation in a low risk study, and that often participants may not require this length of time.

At the time of qualitative interviews, participants will complete written consent forms (people with parental responsibility, staff, young people aged 16 years old or over or those deemed capable of consenting for themselves) and assent forms for children less than 16 years of age where appropriate. These are attached to this ethics application. These will be completed on paper for face-to-face interviews. For virtual interviews, documents will be sent by e-mail to be returned to the research team prior to interview.

Work-package 2: Co-creation workshops

No written consent will be collected in co-creation workshops in work-package 2. Ongoing evaluation of consent to participate in the workshops will be monitored by researchers delivering the workshops, being sensitive to signs of withdrawal of consent. Information regarding the aims of the workshops will be shared at the time of invitation to workshops. Consent to participate is implied by attendance at workshops.

Work-package 3: Quantitative outcome data

In work-package 3, anonymous clinical variables will be collected from patient records of all children receiving photobiomodulation during the 3 month implementation period at each individual cancer centre. This will include: proportion of CYP eligible for treatment who have received PBM and data collected as part of photobiomodulation treatment – age, cancer diagnosis, chemotherapy agent, treatment refusals, clinician reported World Health Organisation Mucositis grading, and patient reported Children's International Mucositis Evaluation Scale (ChIMES). Access to patient identifiable information will only be by members of the direct healthcare team in the relevant cancer centre.

This enables outcome evaluation from a patient and provider construct and provides feasibility data on completion of these outcome measures as part of standard NHS care. This anonymous data will be analysed at the level of the children's cancer centre by lead clinicians recruited to this research. The children receiving photobiomodulation are doing so as part of their standard NHS care, they are not research participants in themselves. Our patient and public contributors felt that collection of this non-identifiable data by members of the direct healthcare team for the purpose of this locally registered service evaluation was acceptable.

7.3.3 Reimbursement and payment of participants

Vouchers have been costed into the research grant to allow recognition of the time and expertise of participants at all stages. These amounts have been determined based on INVOLVE guidance.

WORK-PACKAGE 1: Qualitative interviews

As a recognition of their contribution to the study, participants in qualitative interviews in work-package 1 will be offered a £25 gift voucher. This will be as a thank you for their time and contribution, anticipated to be 60 minutes per participant. 30 participants x £25 vouchers = £750.

Travel and parking has been costed in for reimbursement of participants travelling to qualitative interviews. Maximum of 20 healthcare professionals and 5 parent/CYP dyads. Costed at average 20 mile round trip at 45p per mile (£9) + £5 parking = £14. £14 x 25 = £350

WORK-PACKAGE 2: Co-creation workshops

As a recognition of their contribution to the study, participants in co-creation workshops in work-package 2 will be offered a £50 gift voucher. This will be as a thank you for their time and contribution, anticipated to be 2-3 hours per workshop. A maximum of 20 participants will be recruited to each of the 4 workshops, resulting in 80 total workshop participants. 80 participants x £50 vouchers = £4000.

Travel and parking reimbursement for participants travelling to co-creation workshops. Costed at average 20 mile round tip at 45p per mile (£9) + £5 parking = £14. Four workshops with maximum 20 participants and Gemma Wheeler co-creation expert, with an average of 16 separate groups for travel when accounting for CYP/parent dyads. £14 x 16 groups x 4 workshops = £896

Funds have been costed in for provision of refreshments at co-creation workshops for up to 20 participants at 4 planned workshops costed at £6 per head (total £480)

WORK-PACKAGE 3: Healthcare professional focus groups

As a recognition of their contribution to the study, participants in qualitative focus groups in work-package 3 will be offered a £25 gift voucher. This will be as a thank you for their time and contribution, anticipated to be 30-60 minutes per participant.

It is anticipated that a maximum of 8 healthcare professionals would be recruited for each of the 3 participant sites equating to 24 participants. 24 participants x £25 vouchers = £750.

8. ETHICAL AND REGULATORY COMPLIANCE

8.1 Assessment and management of risk

Participants may become upset if a topic arises that is sensitive in nature. It will be outlined to participants before the focus group or interview that they can stop the interview at any time and decline to answer any questions if they wish.

A full distress protocol has been designed to be followed during interviews (enclosed with this ethics application), which was developed for our previous qualitative interviews in this area. This is anticipated as low risk, as the topic in question is of low sensitivity.

For children and young people, interviews will be conducted alongside their parent or carer, which will provide psychological and practical support. Interviewers will be responsive to signs of indirect withdrawal from children and follow parents' recommendations if they feel their child is becoming distressed.

Lead clinicians at the children’s cancer centres in work-package 3 will experience increased burden in regularly meeting for fortnightly lightning reports and in collecting local service evaluation data. This

burden is minimised by meeting virtually at a time to suit the lead clinician, and the collection of limited relevant data recorded as part of standard NHS care.

Interviews will be conducted within the Leeds Children's Hospital, Leeds Dental Institute or the Square (Candlelighters Family Support Centre) which are deemed a low risk environment for researchers. Two researchers will be present at each interview.

In the unlikely scenario that participants are rude or abusive to the research team, the researchers will leave the interview setting. The distress protocol (attached to this application) details considerations for the research team at all stages of the research study and actions to follow should a member of the research team become distressed.

Over the course of this study, it is possible that child participants may become unwell or die with cancer, which may be distressing for the research team. The principal researcher as a PhD student at the University of Leeds is supported by Student Support services, which complements the support available from the experienced wider research team and Candlelighters Children's Cancer Charity.

8.2 Research Ethics Committee (REC) and other regulatory review and reports

Prior to study commencement, a favourable opinion is being sought from NHS REC for study protocol, consent forms, participants information leaflets and advertisements.

Substantial amendments that require review by the NHS REC, including addition of sites in work-package 3, will not be implemented until such a review has been completed.

All correspondence with the REC will be retained. The Chief Investigator will produce annual reports as required and will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including reasons for premature termination. Within one year of study conclusion, the Chief Investigator will submit a final report with the results, including any publications and abstracts, to the REC.

Prior to any site enrolling patients into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

8.2.1 Amendments

For any study amendments, the Chief Investigator, in agreement with the sponsor, will submit information to the NHS REC (utilising the Amendment Tool) in order for them to issue approval for the amendment. The Chief Investigator will amend the protocol and decide with the sponsor whether the amendment in question is substantial or non-substantial. The Chief Investigator will then work with R&D departments at NHS sites, and the study deliver team, so that the necessary arrangements can be put in place to implement the amendment to at each site.

Addition of sites for work-package 3 will be completed as separate amendments. The study will not start at new sites until the required approvals and reviews as listed in the amendment tool are in place, and the participating site has confirmed readiness to start. A log of amendment history will be kept by the Chief Investigator, and protocol versions updated with each amendment.

8.3 Peer Review

This protocol was the project plan submitted to the NIHR Doctoral Research Fellowship recruitment round 9. Prior to submission, it underwent internal peer review within the University of Leeds (Sponsor Organisation). External peer review by the NIHR panel was then received at shortlisting and at interview stages, before the fellowship was awarded. No changes to the protocol were proposed by the NIHR.

The protocol has been reviewed within the research team, and my PhD supervisors (Prof Peter Day, Prof Carl Thompson, Prof Bob Phillips and the wider project advisory group.

Ethics application has been reviewed by the University of Leeds as Sponsor prior to submission to NHS REC.

8.4. Patient and Public Involvement

Children and young people (CYP) with cancer, and their parents, have been central to the design of this fellowship proposal. Candlelighters children's cancer charity have supported me in eliciting the voice of CYP and their families. They have previously provided £700 of matched funding, including staff, enabling access to their network of families, and a non-clinical area to host our Patient and Public Involvement (PPI) meetings. Our collaboration has included a public science fair stall and conversations with six families with experience of childhood cancer.

CYP and families at different stages of their cancer treatment have described their experiences of mucositis and identified important topics in this research area. Our families are of diverse ages, ethnicities, cancer treatment modality and severity, photobiomodulation experience and geographical location. We have gained views from parent and child dyads, as well as bereaved parents. CYP and their families identified oral mucositis as one of the "worst things" about their cancer treatment. One child described how they "ended up in intensive care" for pain relief and another had long standing food aversion following severe mucositis. One bereaved parent, Hayley, told us that her daughter Elsa's oral tissues were so swollen from mucositis that this stopped her radiotherapy mask from fitting and delayed her treatment. Hayley has agreed to be a named representative on the project advisory group, having seen the significant impact on Elsa's quality-of-life and the lack of treatments available.

Parents felt that children should have access to photobiomodulation. They felt that research to support wider implementation of photobiomodulation would benefit other CYP undergoing cancer treatment in the future. CYP want to be involved in research in this area and discussed how to manage potentially sensitive topics in qualitative interviews. They identified their limited experience of qualitative research methods, as most of their previous research participation has related to cancer treatment randomised controlled trials. CYP have provided clear insight into how to explain qualitative research to potential participants. Additionally, they have informed dissemination methods, advising preference for video. Parents have co-written the plain English summary for this application, which has been reviewed by Candlelighters.

To ensure the voice of CYP with cancer is central to this project, PPI involvement is costed throughout to remunerate contributors for time and expenses, following INVOLVE guidance. My fellowship is supported by Candlelighters, a charity dedicated to supporting families of children diagnosed with cancer within Yorkshire. Their family support team, headed up by Natalie Kisby, will support PPI

recruitment and activities, and dissemination (equivalent to a further £2,100 in matched funding). Haylee McGee is a bereaved parent who contributed to our preliminary PPI. She has agreed to join my project advisory group, alongside Natalie and a CYP representative, to provide input and lived experience.

A child and their family's life can be subject to significant change, particularly during cancer treatment. Insights from other research projects led by my supervisor Prof Phillips have highlighted a need for a responsive model of research involvement, sensitive to the life stage of CYP. Therefore, engagement is planned throughout, with different representatives likely to contribute at different time points and to different activities. Our PPI representatives have highlighted the importance of flexibility to reduce time burden, including use of email and video conferencing as alternatives to face-to-face meetings. Research involving CYP with cancer relies on the ability to contact families and Candlelighters' support has proven invaluable in engaging these families. We will recruit a core group of four dyads from Yorkshire with diverse backgrounds at each project stage, with additional scope to recruit representatives from other locations using local networks and charities. Following an initial training event to support representatives in their contribution, biannual meetings with eight PPI representatives are scheduled throughout the fellowship (Gantt chart). Initial PPI consultation has occurred prior to seeking ethical approvals to support finalisation of study protocol, topic guides and documents. Infographics will be created following PPI meetings to demonstrate impact on research design, these will be disseminated as the fellowship progresses. In addition to biannual meetings, consultation will occur with smaller PPI subgroups for: website content design, bespoke qualitative research training and analysis of interview transcripts, video co-creation and dissemination event planning.

8.5 Protocol Compliance

All protocol deviations and serious breaches of protocol will be reported to the sponsor (governance-ethics@leeds.ac.uk within 1 working day of the research team becoming aware.

A log of any deviations will be kept by the Chief Investigator in the electronic study files. The Chief Investigator will report any serious breaches of the protocol or the principals of Good Clinical Practice to the REC. A "serious breach" is defined as a breach which is likely to affect to a significant degree the safety or physical or mental integrity of the research participants, or the scientific value of the research.

8.6 Data Protection and Patient Confidentiality

Only members of the research team involved with data collection will have access to participants' personal data. Participants will directly contact the research team with their written consent forms and personal data will be collected at this point. Personal data such as email or home addresses will be deleted after the interview or focus group has taken place and vouchers have been sent. Participants will be asked if they would like to be contacted at a later date with the results of the study, by email, once the study is complete. If they agree, their email address will be retained, which will be stored separate from other documents.

FOR ALL QUALITATIVE INTERVIEWS (WORK-PACKAGES 1 & 3)

Each participant will be assigned a code number and group identifier (e.g., parent, child, doctor), and from that point, the analysis will take the place on the written text with no identifiable material in it. Demographic data will be assigned the code number so that it is non-identifiable, and it will be saved

on the University of Leeds OneDrive or Microsoft Teams/SharePoint. Anonymised transcripts (with the code number) will be password protected, stored, and saved on the University One Drive.

A conversion document pertaining to the details of the code numbers will be held separately on the University of Leeds OneDrive. The OneDrive is suitable for storing data deemed confidential according to the University guidance.

All members of the research team will have access to the anonymised data (transcripts from work-packages 1&3, quantitative outcome data work-package 3). This will be password protected, stored and saved on the University OneDrive by invitation only.

Claudia Heggie, Kara Gray-Burrows & Amrit Chauhan will undertake transcript analysis supported by the research team. The anonymised transcripts will be accessible to the whole research team and research collaborators via the University of Leeds approved One Drive.

Once the study is over, we will keep the anonymised transcripts for up to five years or until publication, whichever is longer. This is to allow for write up and dissemination but also to support future research projects to be completed by the research team in this area. The expected study completion is September 2026.

QUANTITATIVE OUTCOME DATA (WORK-PACKAGE 3)

Data will be collected in work-package 3 as a locally registered service evaluation at each recruited children's cancer centre. This anonymised data will be analysed at the level of the centre.

Only healthcare professionals involved in patient care at the relevant children's cancer centre will have access to their data at the point of data collection. This will be anonymised at the point of collection. This will undergo separate local quality improvement permissions. Anonymised data will then be transferred to the research team by invitation only via University OneDrive.

Anonymised data will be kept for up to five years or until publication, whichever is longer. This is to allow for write up and dissemination but also to support future research projects to be completed by the research team in this area. The expected study completion is September 2026.

Claudia Heggie and Bob Phillips will collate anonymised data gained from lead clinicians in the children's cancer centres in work-package 3. This anonymised data will be accessible to the whole research team and research collaborators via the University of Leeds approved One Drive.

8.7 Indemnity

University of Leeds indemnity applies for meeting potential legal liability of the sponsor for harm to participants arising from the design and management of the research.

In the event of harm arising to participants in the conduct of the research, insurance and indemnity lies with the participating site. This will be NHS indemnity where interviews are conducted on NHS sites, University of Leeds indemnity for co-creation workshops on University campus, and Candlelighters public indemnity for any interviews taking place at their Family Support Centre.

8.8 Access to the final dataset

Only members of the research team involved with data collection will have access to participants' personal data, such as names and contact details for remuneration and demographic data. Participants will directly contact the research team with their written consent forms and personal data will be collected at this point. Personal data such as email or home addresses will be deleted after the interview

or focus group has taken place and vouchers have been sent. Participants will be asked if they would like to be contacted at a later date with the results of the study, by email, once the study is complete. If they agree, their email address will be retained, which will be stored separate from other documents.

All members of the research team will have access to the anonymised data (transcripts from work-packages 1&3, quantitative outcome data work-package 3). This will be password protected, stored and saved on the University OneDrive by invitation only.

For quantitative outcome data in work-package 3: only healthcare professionals involved in patient care at the relevant children's cancer centre will have access to their data at the point of data collection. This will be anonymised at the point of collection. This will undergo separate local quality improvement permissions. Anonymised data will then be transferred to the research team as previously described.

8.9 End of study

The study is planned for completion by October 2026. The end of the study is defined by completion of the last site visits for focus groups with healthcare professionals in work-package 3, as this is the last point of data collection. Analysis, completion of thesis and publication will occur beyond end of study.

9. DISSEMINATION POLICY

Participants will be invited to give their email addresses to the research team and indicate if they wish to be contacted directly with the study results. This will also help provide reassurance of their anonymity. This list will be kept secure on the University of Leeds secure drive (OneDrive) and will be password protected. It will be destroyed 24 months after the completion of the study (expected completion September 2026).

A dissemination event, hosted by Candlelighters children's cancer charity, has been costed into the research for 25 stakeholder attendees. This will be advertised through existing networks, social media and to participants with a view to be conducted in Summer 2026.

This project is part of the Chief Investigator's PhD studies. A thesis will be prepared and submitted to the University of Leeds. Three academic papers are planned as outputs of this project, in addition to two international conference presentations.

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