Health Research Authority

FULL/LONG TITLE OF THE STUDY

Mapping and Identifying Quality and Inequality in Prehabilitation for Cancer Surgery: Evidence for Improvement

Work packages 2 and 3: mapping questionnaire and case studies

SHORT STUDY TITLE / ACRONYM

PARITY

PROTOCOL VERSION NUMBER AND DATE

Version 1.3, 22/01/2024

RESEARCH REFERENCE NUMBERS

IRAS Number:	318939
SPONSORS Number:	N/A
FUNDERS Number:	NIHR134282

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature:
.....

Date:
..31./.03..... /.2023.....

Name: (please print): Dr Cliff Shelton
.....

LIST of CONTENTS

KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title	Mapping and Identifying Quality and Inequality in Prehabilitation for Cancer Surgery: Evidence for Improvement
Internal ref. no. (or short title)	PARITY
Study Design	Observational Qualitative Study
Study Participants	Healthcare professionals (HCP) providing Prehabilitation in cancer care including physiotherapists, dieticians, oncologists, anaesthetists, psychologists, surgeons, Cancer Specialist nurse and allied professionals such as ward nurses, receptionist etc. Patients with a cancer diagnosis who are referred to the Prehabilitation services for screening assessment Carers of patients who are/were referred to the Prehabilitation services for screening assessment.
Planned Size of Sample (if applicable)	**Mapping Questionnaire** Minimum 100 questionnaires **Case study** 10 Healthcare professionals per site (10x 8 = 80 HCPs) 10 Patients diagnosed with cancer and referred to Prehabilitation before cancer surgery (10 x8 =80 patients) 5 carers (5 x8= 40 carers)
Follow up duration (if applicable)	n/a
Planned Study Period	18 Months
Research Question/Aim(s)	1) What Prehabilitation services are available prior to cancer surgery in the UK 2) What are the best practices in Prehabilitation prior to cancer surgery

	3) How can the delivery of Prehabilitation prior to cancer surgery be improved?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute of Health Research Health and Social Care Delivery Research	£783,561.59

ROLE OF STUDY SPONSOR AND FUNDER

This study is sponsored by Lancaster University. The sponsor has no role or control in in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

This study is funded by the National Institute for Health Research. The funder has no influence over trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The research team will send reports regarding the progress of the trial to the funder at agreed intervals.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

PARITY Patient and Public Involvement (PPI) Group –

The PARITY PPI group is formed in October 2023 and includes seven members of the public with lived experience of cancer either as a patient or a carer of a patient. The role of the PARITY PPI group is to support the PARITY research team throughout the study from inception to reporting of the research outcomes.

PARITY PPI Lead (Andrea Partridge) – Miss Partridge is currently employed as a named PPI lead on the PARITY project whose main role is to be a patient advocate throughout the study, lead the communications with the PPI group, support the research team with translating the academically written work into lay language.

PROTOCOL CONTRIBUTORS

Cliff Shelton, Principal Investigator – Case Study project lead

Andrew Smith, Co-Investigator – Service Mapping project Lead

Lisa Ashmore, Co-Investigator

Jo Rycroft-Malone, Co-Investigator

Christopher Gaffney – Co-Investigator

Yasemin Hirst, Research Fellow

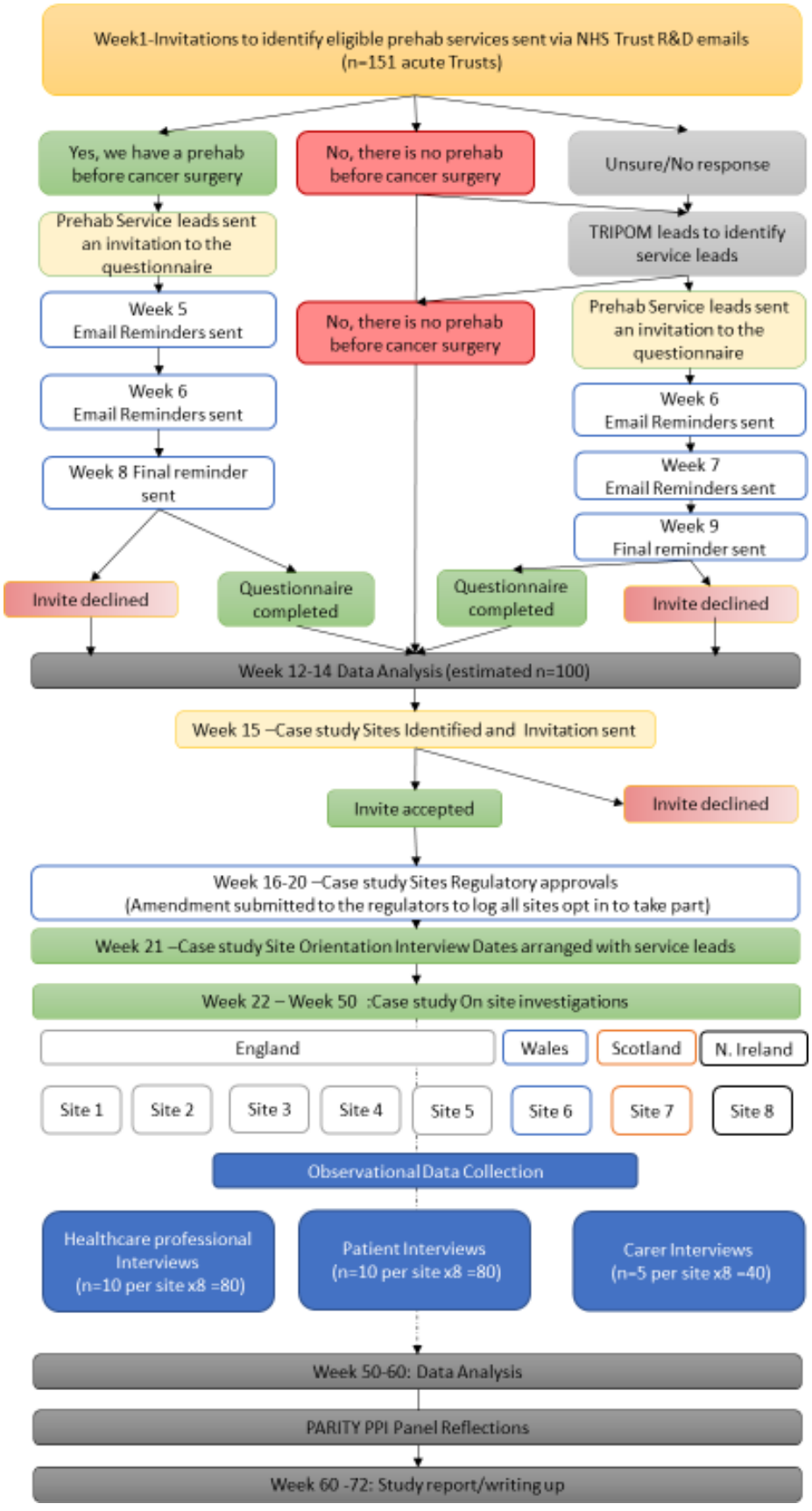
Laura Wareing, Senior Research Associate

Andrea Partridge, Patient and Public Involvement Lead

PARITY PPI panel

KEY WORDS: Service mapping, inequalities, Prehabilitation, case-study, questionnaire, cancer surgery

STUDY FLOW CHART



STUDY PROTOCOL

Mapping and Identifying Quality and Inequality in Prehabilitation for Cancer Surgery: Evidence for Improvement

1 BACKGROUND

Prehabilitation has been defined as 'the practice of enhancing a patient's functional capacity before surgery, with the aim of improving postoperative outcomes' (Banugo and Amoako 2017). Typically, physical, behavioural and psychological interventions are used to enhance the patient's functional capacity prior to starting treatment. Cancer treatment often comprises recurrent major impacts, for example surgery in combination with chemotherapy (Banugo and Amoako 2017, Loughney et al 2016). Whilst prehabilitation has theoretical benefits in this setting, its evidence base in cancer care is variable. A 2016 systematic review in the context of neoadjuvant chemotherapy and surgery concluded that there is insufficient research "to draw reliable conclusions about the efficacy of such an intervention, the optimal characteristics of the intervention, or the impact on clinical or patient reported outcomes" (Loughney et al 2016). More recent reviews in settings of pancreatic cancer surgery and bowel resection are still drawing similar equivocal conclusions (Teo et al 2020, Bundred et al 2020).

Despite uncertain evidence, many healthcare providers offer prehabilitation programmes in the context of cancer care, most of which involve preparation for surgery. Though some are implemented on a regional basis, many are small-scale and limited to a particular service (Wynder-Blyth et al 2017). Whilst these interventions may be welcomed by those who receive them (Ferreira et al 2018), this localised approach creates the conditions for variation between regions, organisations, and diagnoses, thereby creating inequalities. Furthermore, patient preferences on the mode of delivery have been found to vary (Durrand etal 2019), and little is known about what patients want from prehabilitation, and how this relates to the aims of those who design, commission and deliver services (Beck et al 2020).

This project aims to provide robust evidence to address the inconsistent and inequitable provision of Prehabilitation prior to cancer surgery. This will be achieved by working with patients, carers and healthcare professionals to develop outcome measures against which Prehabilitation can be measured, mapping and characterising existing services, and identifying case studies of good practice (e.g.,Crowe et al 2011), in order to provide guidance for future service implementation. This is a vital step in moving towards the equitable provision of high-quality prehabilitation, and answers the call made by the NIHR, Royal College of Anaesthetists and Macmillan to "gather examples of how local areas have had Prehabilitation commissioned as part of the cancer pathway" (2019). Furthermore, this project aligns with the strategic aims of the Centre for Perioperative Care, and addresses two questions identified in the James Lind Alliance priority setting partnership on anaesthesia and perioperative care: "how can preoperative exercise or fitness training, including physiotherapy, improve outcomes after surgery?", and "what outcomes should we use to measure the 'success'of anaesthesia and perioperative care?" (Boney et al 2015). The idea for this study was discussed with the National Institute of Academic Anaesthesia Patient, Carer and Public Involvement and Engagement (PCPIE) group, who confirmed that in their experience, the provision for prehabilitation varies markedly between services and healthcare providers. Inequalities, for example based on ethnicity, socioeconomic and geographical factors, result in poorer outcomes following cancer care for

people from underserved and minority backgrounds (Wiese et al 2019). Introducing Prehabilitation into this landscape has the potential to exacerbate inequalities rather than narrow them, through disparities in access to infrastructures, technologies, and social and financial capital (e.g., Giles and Cummins 2019). An

PARITY Protocol (NIHR134282) v1.05 example of this was shared by a member of the PCPIE group, who noted that though his local hospital provides a gymnasium for prehabilitation, the need for patients to travel to this facility compounds inequalities based on access to transport, funds, and time off work. The PCPIE group considered that addressing inequalities should be a key facet of this study and suggested that those patients who did not participate in prehabilitation must nevertheless be represented. COVID-19 presents numerous challenges to the delivery of prehabilitation and may yet further exacerbate inequalities due to disparities in access to telemedicine and the closure of municipal exercise facilities (Bambra et al 2020, Silver et al 2021). Furthermore, the cessation and recommencement of elective surgery in response to 'surges' of COVID-19 can make scheduling unpredictable (Glasbey et al 2021). The effect of COVID-19 was identified as a key issue by the PCPIE group, who noted that service changes implemented in response to the pandemic may disrupt the delivery of care. This project will aim to describe the ways prehabilitation has adapted to the pandemic, including how health inequalities are addressed. Prehabilitation is based on specific goals, ideals, and medicalised understandings of healthcare behaviours. For example, one purported benefit is that patients may 'better understand' their surgery, implying ignorance with the potential to assign blame. Part of this study will be to examine the values underpinning programmes and the assumptions underpinning design.

2 RATIONALE

This research is needed now because: 1) prehabilitation prior to cancer surgery across the UK is not available in all centres, and where it is available its implementation is highly variable; 2) there is a knowledge gap regarding what constitutes quality in prehabilitation; and 3) health inequalities in the UK have widened in recent years, and there is a risk that prehabilitation may further contribute to this problem.

There is clear evidence of a 'postcode lottery' of prehabilitation services prior to cancer surgery in the UK. Some centres do not offer any type of prehabilitation, others offer services only to specific patients, and others make Prehabilitation available on a universal basis (Carter et al 2019, Transforming Cancer Care Prehabilitation Short Life Working Group 2020). In centres where prehabilitation is available, it is uncertain whether a targeted or universal approach is more appropriate; where prehabilitation is implemented widely it is likely that it is being employed far beyond its evidence base. Whilst there is little evidence that prehabilitation causes harm (Michael et al 2021), a universal approach may represent a burden for patients without benefit or divert resources away from more effective interventions. As outlined in the literature review above, although there is a growing understanding of the benefits of some elements of prehabilitation, there is a dearth of understanding regarding service delivery in context. This problem is compounded by the limited capacity of prehabilitation services to audit or evaluate their programmes (Carter et al 2019). As a consequence, the effectiveness and impacts of the approaches currently implemented will continue to be unknown unless research is conducted to establish what services are available and identify best

practices. The UK has experienced rising health inequalities in the last decade (Marmot et al 2020). These have been further exacerbated by the ongoing COVID-19 pandemic (e.g., McKee et al 2021), which has thrown into sharp relief the influence of ethnicity, employment and housing on health. As a complex intervention that requires time, motivation and engagement, prehabilitation has the potential to be more accessible to some patients than others, even if it is offered to all. During the COVID-19 pandemic, services have been rapidly reorganised, for example moving in-person delivery online (e.g. Raman et al 2021). This creates the potential to further exacerbate inequality based on technological literacy and access to facilities such as broadband internet and a quiet environment in which to engage with online content. As the COVID-19 pandemic has entered an endemic phase, it is likely that prehabilitation services will never return to their prior form. There is therefore a pressing need both to assess how prehabilitation services can best address both new and established health inequalities.

3 THEORETICAL FRAMEWORK

The Promoting Action on Research Implementation in Health Services (PARIHS) will be the overarching study framework, guiding data collection, analysis, and synthesis (Rycroft-Malone et al 2002, Kitson et al 2008). This framework is relevant to this study because it provides an explanation of how and why innovations, services, and practises are implemented (or not) in practice. Specifically, it focuses on how implementation is facilitated in real-world contexts, which is a central concern of this study.

4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

The proposed study objectives are twofold. First, the research team will carry out a mapping questionnaire that will be completed by prehabilitation service leads and providers, which will be used to provide an evaluation of prehabilitation services (outcome of decision-making tool appended in this application) The mapping questionnaire will be used to produce a map and descriptive compendium of the prehabilitation services that are currently available in the UK for patients awaiting cancer surgery, according to geography, funding, commissioning and delivery. The mapping questionnaire will be used to identify current service offering and standards, which will be used to select suitable sites to carry out case studies. The case studies will aim to understand how various models of prehabilitation work in practice, to achieve the aims and objectives and uphold the values deemed important to stakeholders. Through these objectives we will address the following research questions:

1. What prehabilitation services are available prior to cancer surgery?
    a. What do they consist of?
    b. How are they commissioned and delivered?
    c. Who benefits from them and how?
    d. What values and assumptions underpin their design?

2. What are the best practices in prehabilitation prior to cancer surgery?
    a. How is a quality service delivered?
    b. How are inequalities best addressed?
    c. How have services adapted to the COVID-19 pandemic?
3. How can the delivery of prehabilitation prior to cancer surgery be improved?
    a. What measures should be used to classify and measure services?
    b. What are the important components of best practice principles?

4.2 Outcome

The primary outcome of this study is to generate rich descriptions and explanations of the ways in which prehabilitation services are designed, managed and delivered in the UK, investigate mitigators of health inequalities in service design, and develop a better understanding of the factors associated with the variation in the implementation of Prehabilitation before cancer surgery across the UK. Findings will be integrated with the PARIHS framework and used to develop actionable outputs including feeding into a set of best practice principles.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study Design

The study will be carried out using a mixed-method approach (quantitative + qualitative). First, a descriptive national service mapping questionnaire will be employed as part of a service evaluation to identify where prehabilitation before cancer surgery is provided, what, how and by whom it is delivered. The service mapping questionnaire will be used to identify suitable sites for the research phase of the project. The research phase of the study will employ a case study approach which will include qualitative observational data collection methods and one-to-one interviews with Healthcare professionals, Patients with cancer diagnosis and their carers.

Part 1 - Service Evaluation Mapping Questionnaire:

Prehabilitation programmes available to patients awaiting cancer surgery across the United Kingdom will be identified and mapped according to geographical location, organisational and funding arrangements, who provides the service what is included in the prehabilitation programme, how and when it is delivered, and to whom. This will include an appraisal of the three main elements of prehabilitation: physical activity, nutrition, and psychological support.

Questionnaire Design: The mapping questionnaire will be informed by the Template for Intervention Description and Replication (TIDIER) checklist inclusive of specific items on funding, setting, leadership, scope and item aiming to explore access to services such as travel, out of pocket expenses, digital literacy assessments, training, evaluation, etc (Heggie et al, 2020). The questionnaire will be predesigned and tested using cognitive interviews to make sure it can be easily completed all those who are invited to take part in the survey.

Procedure: Procedure: We will take a multi-pronged approach to collecting survey data. We will approach R&D departments to help us identify hospital trusts that meet the eligibility criteria using a screener questionnaire. Those that are eligible will be asked to include contact details of the relevant individuals in the service who will qualify to complete the questionnaire on behalf of the hospital trust. Once the screener questionnaire is submitted, we will send the main questionnaire to the nominated individuals for completion. Alternatively, the research team will make use of a network of stakeholders familiar with prehabilitation services (e.g. TRIPOM collaborators, Cancer Alliance staff) to identify services that meet the eligibility criteria. Stakeholders may share the survey with appropriate service staff or may complete some or all the survey on behalf of the service, providing they are familiar with the service. The participation of all who complete the survey will be voluntary.

Data Analysis: The data will be analysed descriptively primarily focusing on the availability of the services and reported nominally as well as using proportions.

Part 2 - Research Case Studies:

Case studies will involve interviews and extensive in-person visits to the participating services, according to the following methods:

Procedures

Site Selection- Eight services from across the United Kingdom will be selected for in-depth analysis as case studies. These will be instrumental in nature (Crowe et al 2011), aiming to represent 'typical' examples of the various service models identified in the mapping questionnaire. By undertaking multiple case studies, different models for prehabilitation will be compared and contrasted. We have opted to include eight services because we anticipate this to be both practical and able to provide sufficient opportunity for capturing variation whilst not compromising depth of analysis.

Orientation -initial data collection will aim primarily to orient the researchers to the service. This will involve integrating the findings of the mapping questionnaire with sources such as literature (e.g., guidelines, patient leaflets and service level agreements), demographic and statistical information, and interviews with those responsible for service coordination and management. This will help to guide the data collection phase of the case studies by ascertaining the local funding, management and governance arrangements, how and where prehabilitation is provided, to whom, and what decision-making processes are involved in enrolling patients in a particular service.

Observations- An observation data collection form has been developed to be used based on the PARIHS framework capturing additional data which may not be collected through one-to-one interviews with the service providers. These will be used by the study team to allow observations based on the framework to be collected and recorded effectively.

One-to-one interviews- The patient and carer-based interview guides have been developed to understand what has been offered to the patients, their understanding of Prehabilitation, factors associated with engagement with Prehabilitation and general patient experience between diagnosis and surgery. In contrast, the healthcare professional interview guides will be informed by PARISH focusing on

- The level and nature of any evidence used in the design or delivery of prehabilitation practice (e.g., studies, service evaluations, and the experiences and opinions of individuals involved).
- The context and environment in which prehabilitation occurs (e.g., organisational structure and funding arrangements, and social factors such as cultural norms and organisational ethos)

- The method or way in which the process is facilitated (e.g., mode of delivery, schedule and content of prehabilitation).

Based on our previous work (e.g., Shelton et al 2018, Shelton 2019) we expect to recruit 10 staff members, 10 patients, and five carers per site to take part in one-to-one interviews. Our sampling approach will incorporate outreach and support measures to ensure that seldom-heard people are supported to participate, for example by working with translators to explain the research. Furthermore, we will draw on our prior experience of including people without mental capacity in studies of practice to ensure that the experiences of people with cognitive impairment and learning disability (who have a higher risk of perioperative complications) and their carers are represented in the data (Shelton 2019). Participant information will be designed in collaboration with our PPI panel and made available in various accessible formats (e.g., large type, audio, translated) to suit the needs of potential participants.

Data Analysis: an inductive thematic analysis of the data from all eight case studies will draw together best practices (Braun and Clarke 2006), with a particular focus on the features of a high-quality service, from the perspectives of patients, carers and professionals, and how services and clinicians address (or do not address) inequalities. We will adopt an interpretative approach, aiming to understand contexts and processes as perceived from different perspectives in order to identify and understand both individual and shared meanings. Because patient and carer perspectives and the factors that influence inequality in prehabilitation are central to this project, Andrea Partridge will participate in this analysis as a co-investigator, in liaison with the PPI panel.

6 STUDY SETTING

Service Mapping Questionnaire: The service mapping questionnaire will be delivered through Qualtrics Survey and Data Collection tool and will be primarily carried out online. If the participants request paper-based questionnaire, these will be posted for completion with freepost return envelopes.

Case-Study: The case study observations and interviews will take place at the NHS Acute Hospital Trusts that are selected and agreed to be a part of the PARITY. These sites will be selected based on the outcomes of the service mapping questionnaire across the UK.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

7.1.1.1 Mapping Questionnaire Inclusion Criteria:

Prehabilitation programmes meeting the following criteria will be eligible for inclusion in the mapping study:

- Intervention designed to enhance a patient's functional and / or psychological capacity
- Delivered following a cancer diagnosis and prior to cancer surgery.
- Part of the funded usual care pathway for patients in the trust / health board and offered, referred to, or signposted by the NHS cancer care team.
- May be for all cancer types and operations or specific cancers or operations
- May be offered universally (all patients), targeted (high risk patients) or specialist (for those with complex needs).
- May be delivered in hospital, community, or online settings, including by a commissioned non-NHS provider (including third sector, commercial and local authorities)

7.1.1.2 Case Study Inclusion Criteria:

Healthcare Staff:

- Involvement with the prehabilitation services available to patients awaiting cancer surgery at a case study institution.
- Involved in the commissioning, funding, coordination, management and / or delivery of prehabilitation prior to cancer surgery.
- Willing to participate in interviews and / or observations.

Patients:

- Age over 18
- Under the care of a case study institution.
- Awaiting surgery for treatment of any cancer diagnosis
- EITHER - Referred to a prehabilitation programme prior to cancer surgery as part of their NHS care AND/ OR – Referred to pre-operative clinic prior to cancer surgery as part of their NHS care
- Willing to participate in interviews and / or observations.

Carers:

- Age over 18
- Nominated by a patient involved in the study.
- The primary carer (paid or unpaid) of any patient involved in the study.
- Close family members (spouse, parent or child) of any patient involved in the study.
- Willing to participate in interviews and / or observations.

7.1.2 Exclusion criteria

7.1.2.1 Mapping Questionnaire Exclusion Criteria:

Acute hospital trusts will be screened out from the questionnaire distribution if they do not meet the inclusion criteria as described in section 7.1.1.1. This screening process will be carried out via R&D departments.

7.1.2.2 Case Study Exclusion Criteria:

Participants will be excluded from one-to-one interviews and observational data collection if they do not meet the inclusion criteria as stated in section 7.1.1.2.

7.2 Sampling

Observations of prehabilitation practice will target all stages of decision-making and patient contact. This may include, for example, multidisciplinary team meetings where decisions are made about whether to offer prehabilitation to patients, physical activity sessions, and ‘surgery schools’. Observations will be 'overt', where the researcher clearly identifies themselves and their role to all who are being observed; patients, carers, and all staff involved in any healthcare process observed will be invited to consent to the observation in advance of the observation period.

7.2.1 Size of sample

Mapping Questionnaire:

As not all NHS Trusts offer access to prehabilitation (Carter et al 2019), we anticipate survey returns from 50-60% of the ~150 acute hospital trusts in England, ~5 health boards in Scotland, 4 in Wales and 3 in Northern Ireland. In total, we anticipate responses from 100 organisations and believe that the multiple recruitment methods, incentivisation and reimbursement of time described above will ensure that this is achievable.

Case Study Interviews:

Depending on the proportion of patients recruited into prehabilitation services, we anticipate observing between five and eight patient journeys (out of 10 patients recruited) per site and interviews with 10 Healthcare professionals per site (10x 8 = 80 HCPs)

7.2.2 Sampling technique

Case study sites will be sampled using a purposive approach aiming to target ‘maximum variation’, based on the service models identified in the classification system and map developed in the mapping questionnaire. We will situate at least one case study each in Wales, Scotland, and Northern Ireland. If It the COVID-19 pandemic will still be a concern at the time of the study, we will identify alternative

sites for each service type, to mitigate the disruption that may be caused by local surges of COVID-19 interfering with planned cancer surgery, or restrictions in access for visiting researchers.

7.3 Recruitment

Service Evaluation Mapping Questionnaire Recruitment: We will send an invitation and a screener questionnaire to all NHS Trusts and Hospitals Research and Development (R&D) departments across the United Kingdom via email. The screener questionnaire will include the inclusion criteria which will be used to identify if the trust includes sites where prehabilitation is delivered. The R&D departments will be asked to respond to the eligibility with a categorical item (Yes/No/Unsure). If they answer "YES", then they will be prompted to provide the contact details of individuals from the Prehabilitation before cancer surgery departments at each hospital for the main questionnaire to be distributed. If they answer "No", this will be recorded as no, and their site will be recorded as "not eligible". The main questionnaire and service evaluation information sheet then will be sent via an email invitation to the relevant individuals. The questionnaire will include optional and mandatory questions allowing key questions to be collected. We will send bi-weekly reminders to the individuals to improve the response rate and offer our support in the completion of the questionnaire if required. We will receive support from an anaesthetist educational collaboration called TRIPOM (Trainees in Peri Operative Medicine) to identify potential NHS Trusts that might still provide prehabilitation but may not have been identified by the R&D departments using our screener questionnaire.

Case Study Health Care professional recruitment: Health care professionals who are eligible to take part in the one-to-one interviews will be identified during the development of the orientation forms which will include details about the service on the day of the observation agreed between the research team and the study site. This will then ensure time and capacity for interviews are pre-planned and discussed with the providers, and information sheets and consent forms are distributed timely.

Case Study Patient and carer recruitment: Recruitment of patients and carers will take place prior to prehabilitation (identified by their usual clinical team on referral to prehabilitation), and also prior to surgery (identified by their usual clinical team on referral to pre-operative assessment clinic), so that those who do not receive prehabilitation may nevertheless have the opportunity to participate. We will then give the information sheet and the consent form to the patients and carers to consider before taking part. They will be given an option to take the forms home if they wish to consider the invitation in detail and contact the research team if they wish to take part. If they agree to take part, they will be asked to choose the mode of the interview which will be offered as face to face, by telephone or through Microsoft teams (without video recording).

7.3.1 Sample identification

Mapping Questionnaire:

Participants will be identified via the NHS Trust Hospital Research and Development Department leads We will send an email to R&D departments using their generic contact address. In order to avoid

disincentivising participation at a time of unprecedented clinical demand, completion of the survey is costed as an NHS research cost in the SOECAT.

Case Study:

Posters and leaflets will be placed at the case study site receptions on the days when observations will take place prompting those who are eligible and interested to take part in the interview as well as allowing people who do not wish to be observed to be excluded from overt observations. Consent will be received from all the individuals who may have been included in direct observations during clinics and other activities.

Patients and carers who are also eligible to take part in the one-to-one interviews will be identified by their clinical team based on the eligibility criteria defined in section 7.1.1.2.

For healthcare professionals and for the mapping questionnaire, we will also use Clinical Research Networks and existing networks to enhance participation through social media and study-specific website engagement. NHS staff participation in interviews is costed as an NHS research cost in the SOECAT to avoid disincentivising participation.

7.3.2 Consent

Mapping Questionnaire

An online informed consent will be requested from the Prehabilitation service providers at NHS Trusts and Hospitals Research and Development (R&D) departments who receive a screener questionnaire via email. The screener questionnaire will include the inclusion criteria which will be used to identify if the trust includes sites where prehabilitation is delivered. The R&D departments will be asked to respond to the eligibility with a binary item (Yes/No). If they answer “YES”, then they will be prompted to provide the contact details of individuals from the Prehabilitation before cancer surgery departments at each hospital for the main questionnaire to be distributed. The main questionnaire and study information sheet then will be sent via an email invitation to the relevant individuals. The consent form will be placed after the information sheet in the online survey, and they will need to opt in to the study to complete the questionnaire. The questionnaire will include optional and mandatory questions allowing key questions to be collected.

They will also be given the opportunity to request paper documents if they wish to complete paper consent and the questionnaire. The questionnaire will include details about their service and their name therefore, we will need informed consent to retain this information while their consent clearly states that we will only use anonymised data in dissemination and publication of the results. They will be given the opportunity to ask questions to the research team at any time during their completion of the questionnaire. For this reason, we will use Qualtrics “save and return later” option allowing participants to complete their questions when it is convenient.

Case Study Interview Consent – (Patients, Carers, Translators, Consultee and Healthcare professionals)

Patients and carers who are eligible to take part in case study interviews will be identified by the prehabilitation clinic lead at each hospital that agrees to be a part of the study and will be contacted by a member of the research team. The study will be described, and a participant information sheet (co-designed with patient and public involvement) will be provided (available in standard or large text, for those with visual impairment). If required, the researchers will read through the information sheet with the patient. Any questions will be answered. After the information sheet has been read and questions answered an assessment of the mental capacity to consent will be made. If the patient has mental capacity, they will be invited to sign a consent form. Subsequently, consent will be confirmed verbally before any research contact (interviews, observation,). Patients with cancer may be considered a vulnerable group, and in addition to the accessibility measures described above, they will be offered the presence of an advocate (relative, carer or healthcare worker, as chosen by the patient) to help them make their decision. They will be allowed sufficient time (by their own definition) to decide whether to sign the consent form. It will be made explicit that the study is observational, and participation does not affect the treatment they will receive in any way.

We will aim to recruit patients and carers face-to-face at the hospitals, however, if this is not possible, an invitation will be posted by the hospital team including the study participant information sheet, consent form and prepaid freepost envelope.

Staff Participants: All staff working in the prehabilitation services of each case study institution will be made aware of the study by email and by a brief presentation at departmental meetings. Staff participants will be identified according to their usual professional roles. Key informants (those with particular knowledge of the workings of the service) and staff involved in the delivery of prehabilitation to patients awaiting cancer surgery will be approached by the researchers. They will be provided with a participant information sheet and offered the opportunity to ask questions. They will be invited to sign a consent form. Consent will be confirmed verbally before each research contact (interviews, observations).

Case Study Observations - (Patients, Carers, Consultees and Healthcare professionals)

Direct observations: We will have a direct observation information sheet and consent forms for patients, consultees, carers and healthcare professionals that we might observe during consultations or Prehabilitation sessions. Using the case study orientation form, we will predefine which health care professional, prehab session, time of the day, and where and when the observations will take place. This will help us identify which healthcare professionals will be present on those dates, which prehab sessions can be observed and the potential prehab characteristics e.g., cancer type, and prehab type will be recorded. As the number of direct observations will be pre-planned, we will request consent from all the individuals who will be part of these observations.

For indirect ‘overt’ observations, posters and leaflets will be hung in the waiting room area notifying the health care professionals and the patients who will be observed on those dates. The posters will include the researcher's name, contact details and how to be excluded from observations if they do not wish to be included.

Assessment of capacity

Whenever patients and carers are invited to participate in the study, a capacity assessment will be made by the researchers (who have received training in this), and individuals without capacity will be included in the study only if their consultee deems that they would wish to participate and the patient does not object to participation, as per the Mental Capacity Act (2005) in England and Wales, and the Mental Capacity Act (2016) in Northern Ireland. In Scotland, we will consult a guardian, welfare attorney, or the individual's nearest adult relative and seek consent for participation, as per the Adults with Incapacity (Scotland) Act (2000). As this is a peri-operative study, the capacity of patient participants will vary predictably over the course of the study, due to the administration of anaesthetic drugs or the occurrence of postoperative confusion, for example. The patient consent form will therefore acknowledge this and will incorporate a statement regarding ongoing consent to observation during predicted losses of capacity.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The study follows the British Psychological Association Code of Ethics and Conduct (2021) and is designed considering the key principles based on respect, competence, responsibility and integrity.

Respect: Participation in this research is voluntary and the research team will not collect data without informed consent. The participants' privacy and confidentiality will be maintained through the study and dissemination of the results by excluding any identifiable information from the direct quotations using SAFE researcher guidelines for anonymisation of identifiable data. Participants have the option to withdraw without any reason before, during and after the study and can request their data to be deleted permanently.

Furthermore, in order to maximise inclusivity and maintain our focus on reducing health inequalities, the observational data collection will be open to all including those who lack the capacity to give informed consent. A proportion of patients with cancer have cognitive impairment, and it is important to be able to include these patients in our study because this is a potential cause of health inequality. Where patients lack the capacity for consent, we will aim to include their carers in the study to represent those who are unable to provide consent for themselves.

Patients who prefer to communicate in a language other than English (including sign language) will be assisted in the consent process by a healthcare translator, funded by the study. This will include the production of a translated consent form and participant information sheet. The translator will then attend subsequent research contacts with the patient in order to translate for them. Large text versions of information sheets and consent forms will be made available and can be read out loud by the researcher if needed. We will identify the reasonable adjustments required for interviews during the orientation interviews with the service leads.

Welsh language versions of the consent forms and participant information sheets will be produced. Though none of the research team are fluent in Welsh, a translator will be available (via telephone) when required.

For healthcare professionals, it is possible that the process of observation is affecting their ability to carry out clinical work. If any such instances arise, observation will be halted.

Competence: The PARITY researcher team will obtain NHS research passports, risk assessments and DBS checks to ensure they are able to carry out research in NHS settings.

The research team has extensive experience carrying out both qualitative and quantitative research in cancer, health and focusing on underserved populations. Prior to this study, the team have carried out three workshops with people with lived experience of cancer and with healthcare professionals which informed the design of the questionnaire and the interview schedules. The research team will also receive training to improve their communication skills further for discussions for difficult conversations and also for rapid ethnographic research.

The research team will receive regular supervisory meetings with the wider research team for reflection and open dialogues about the research process, the unintended negative impact of carrying out research in healthcare settings and working with patients who have been diagnosed with cancer. Thinking about cancer and carrying out research in these settings can be stressful, therefore, the PPI lead Andrea Partridge and the PPI panel will also be made available to the researchers to discuss these potential challenges (if any).

Responsibility: The participant information sheet states that the research team does not have clinical expertise therefore, they are not to provide any clinical support and answer medical queries during interviews. However, the information sheet includes details of the Macmillan helpline if patients want to support their care. If the research team has interactions of this nature with the patients and the carers, the queries will be kindly declined and signposted to where they can get support for relevant information.

Integrity: The study team and the documents follow the published NHIR grant protocol (Mapping and Identifying Quality and Inequality in Prehabilitation for Cancer Surgery: Evidence for Improvement - NIHR Funding and Awards) to ensure transparency throughout the research study. We will also use the Standards for reporting qualitative research (SRQR) to improve the transparency of all aspects of the qualitative case studies included in this project (O'Brien et al. 2014).

8.1 Assessment and management of risk

There are no physical risks to the participants as a result of their participation in this study. However, there may be indirect psychological harm as a result of discussions about care provided, cancer diagnosis and outcomes soon after the diagnosis and before cancer treatment. To mitigate this, the interview guides have been carefully designed and discussed with patient representatives to minimise the risk of negative feelings and thoughts arising as an outcome of the study participation. During the interviews, we also included statements in between sections asking the participants if they wish to continue or not which is encouraged to make sure they feel that they are valued. We followed the Cancer Research UK guidelines for carrying out patient interviews and used our previous experience in health research to develop in direct and carefully designed questions. Participants can withdraw from the study anytime without giving any reason and this will also not affect their clinical care.

If inappropriate clinical practice or potential error that may lead to patient harm is identified, researchers will be permitted to challenge or highlight this during observations of clinical practice (with an appropriate documentation made in the observation fieldnotes). This may also be reported using

local guidelines and those outlined in the NHS Code of Practice for Confidentiality, if appropriate for the safeguarding of patient safety and following discussion with the site principal investigator and/or chief investigator and appropriate documentation. Likewise, inappropriate clinical practice identified in interviews or documentary sources may be reported according to legal and governance requirements and guidelines. If good practice is identified that has the capacity to save lives and/or improve outcomes, we will seek to publish this quickly as a rapid report to make the information widely.

Individuals or institutions may be concerned that the data may compromise their privacy or reflect poorly on their reputation. Data will therefore be anonymised during the process of transcription and pseudonyms will be used for the people and institutions described in the study in any publications and presentations arising from this work. Nevertheless, it is possible that people with existing knowledge (e.g., colleagues) may recognise the individuals represented in the data despite anonymisation - and this will be specifically mentioned in the consent process available.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a Research Ethics Service NHS REC for the study protocol, informed consent forms and other relevant documents e.g., advertisements. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at the site.

As it is planned to conduct case studies in all four nations of the UK, and the case studies may involve individuals without mental capacity, approvals will be required from a Scottish REC, in addition to a REC based in England, Wales or Northern Ireland. An application for Scottish REC approval will be made once the study has been approved by a REC based in England, Wales or Northern Ireland

All correspondence with the RECs will be retained and shared with the sponsors. Annual REC reports will be completed by the Chief Investigator. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Research sites will be based in England, Wales, Scotland, and Northern Ireland. As the study is taking place within the NHS and falls within the UK Policy Framework for Health and Social Care Research remit, we will be applying the Health Research Authority (HRA) and Health Care Research Wales (HCRW) regulatory approval, as well as NHSREC. As this will take place in Scotland and Ireland, we will also obtain the equivalent in each country.

We will seek support from the Clinical Research Network or National equivalents as this is a multi-centre trial and will designate a local principal investigator at each site. The study will be sponsored by Lancaster University. After the mapping questionnaire is completed, each case study site will be

identified and invited to the study. If they agree each site will be added via an amendment to the appropriate regulatory body and the study sponsor will be notified.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of the amendment to the REC for consideration. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. Amendments will also be notified to the HRA. The amendment will be submitted in IRAS Identity Gateway to HRA, which will determine whether the amendment requires notification to English sites or may be implemented immediately (subject to REC approval where necessary). The research team in consultation with the funder will be responsible for the decision to amend the protocol. The research team in consultation with the sponsor will be responsible for deciding whether an amendment is substantial or non-substantial, considering HRA guidance. The amendment history will be tracked using version numbers to identify the most recent protocol version.

8.3 Peer review

The funder obtained external peer review comments from several independent expert reviewers. Revisions were made to the design, and these were reviewed by an external independent committee convened by the funder.

8.4 Patient & Public Involvement

This project has been developed with the involvement of a formal patient and public involvement panel, the Patient, Carer and Public Involvement and Engagement (PCPIE) Group of the National Institute of Academic Anaesthesia Health Services Research Centre, and our PPI co-applicant, Andrea Partridge. Andrea works as the service user involvement coordinator for the Corporate Cancer Team at Lancashire Teaching Hospitals NHS Foundation Trust, and also has lived experience of cancer care. The PCPIE Group was involved at an early stage of the development of this work and were presented with a summary of the project idea. They were asked to comment on the idea and potential approach from their perspectives as patients, carers and members of the public, and some members also commented based on their experience in other PPI roles, for example when visiting departments of anaesthesia as part of an accreditation process led by the Royal College of Anaesthetists. This provided invaluable insights from members of the public who had seen first-hand the diversity of services offered by the NHS. The PCPIE group confirmed the need for this study including that in the experience of the group, prehabilitation services are indeed diverse. Furthermore, they provided some examples of inequalities in prehabilitation that members of the group had encountered.

All the materials that are patient and public facing were shared with the PARITY Patient and Public Involvement group during the protocol and development of the study materials. The feedback and changes were applied accordingly to improve understanding and ease of completion of the documents.

We will engage with the PARITY PPI group throughout the mapping questionnaire and the case studies to be reflective of the study process, discuss, reflect and address potential challenges engaging with a patient population which has recently received a cancer diagnosis and waiting for surgery from the researcher's point of view in order to ensure that patient's needs, values and expectations are met and cared by the research team. Once data is collected and analysed, the PPI panel will also be invited to evaluate the study outcomes to ensure that the results are reflecting the data that was collected from the participants.

8.5 Protocol compliance

- Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

In order to ensure that there are no protocol deviations, the study team will meet regularly and after each site visit to discuss issues encountered, how they were resolved and if they pose any deviations from the protocol. If there have to be changes to the protocol that needs to be addressed this will be reported to the study sponsors at Lancaster University to facilitate a study amendment to be submitted for NHS REC approval.

8.6 Data protection and patient confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act 2018 and General Data Protection Regulation.

Any PARITY documents in paper form will be kept in a locked cupboard in a locked office within a locked department in the Lancaster Medical School at Lancaster University main study location and only the chief investigator will have access to raw documents once these are collected and stored securely.

Any information the interviewees provide during interviews will be fully anonymised. We may use direct quotations from responses, but any names or identifiable data will be removed before these are shared.

The data collected for this study will be stored securely:

- The computer files will be encrypted and the computer itself password protected.
- We will be using encrypted voice recorders for recording interviews and the raw data will be transferred into Lancaster University PARITY study secure drive immediately after the interviews and the recordings will be deleted from the recorder.
- Direct quotations from interviews may be used, but participants name will not be attached to them.
- Any personal data will be confidential and will be kept separately from the processed and anonymised data.

At the end of the project's timeframe, all research data will be kept securely and accessible, according to Lancaster University's Research Data Management policy (a minimum of 10 years).

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR, participants have certain rights when personal data is collected about them. They will have the right to access any personal data held about them, to object to the processing of their personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit: https://www.lancaster.ac.uk/research/participate-in-research/data-protection-for-research-participants/

8.7 Indemnity

Lancaster University holds negligent harm insurance policies which apply to this study.

8.8 Access to the final study dataset

Access to the final dataset will be limited to the PARITY Research team. NHS research sites will not have access to the dataset. The study steering group and the reference group may receive summaries from the dataset such as quotations from participation and summary tables from the mapping questionnaire.

The information sheet and the consent form include an item that is requesting permission to use the anonymised datasets for secondary data analysis for appropriate and relevant research questions. The decision for secondary data analysis will be made by the Principal Investigator and the study team on a case-by-case basis allowing collaborators to propose and investigate potential research questions using the data collected in this project improving the value of data collected from patients, carers and healthcare professionals. Data-sharing agreements will be put in place to collaborate with researchers outside of the research team to carry out secondary data analysis of the anonymised datasets.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

At the end of the study, we aim to publish the results of the findings in peer-reviewed and open-access journals and present them at conferences. Extra care will be taken to ensure no participants are identifiable in any of the dissemination. The full study report will be published by the funding organisation, NIHR. We will use quotations from our studies from consenting participants excluding their real names from publications. They will be given pseudonyms. The final study report will be produced summarising the information we have learned and will also be hosted on the study website. The results will also inform the development of best practice guidelines as part of a nominal decision-making process carried out by the PARITY reference group. The protocol for the funded research project is available via NIHR website (Mapping and Identifying Quality and Inequality in Prehabilitation for Cancer Surgery: Evidence for Improvement - NIHR Funding and Awards)

Patient and public involvement Panel will help us develop suitable materials for lay readership and these will be made available to relevant patient and carers organisations.

9.2 Authorship eligibility guidelines and any intended use of professional writers

On completion of the study, the data will be analysed, and a Final Study Report prepared for the funder. This will be accessible free of charge via the funder's website. All study team members who make a substantive contribution to reading and writing the final report will be granted authorship on the final study report and peer-reviewed publications.

The funding body will be acknowledged within any study publications, and they have review and publication rights of the data from the study. It is possible for any participant to specifically request results from the CI and these would be provided after the Final Study Report has been peer-reviewed and published. The full study report including anonymised quotations will be made publicly available in the final study report which is due for submission at the end of the study. This will be available following external independent peer review and revisions on the funder's website.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

1. Mapping Questionnaire Advert (mail and post combined)
2. Mapping Questionnaire Information Sheet
3. Mapping Questionnaire Consent Form
4. Mapping Questionnaire
5. Mapping Questionnaire R&D screening survey
6. Case Study Interviews Patient Information Sheet
7. Case Study Interviews Carer Information Sheet
8. Case Study Interviews Consultee Information sheet
9. Case Study Interviews Healthcare Professional Information Sheet
10. Case Study Interviews Patient Consent Form
11. Case Study Interviews Carer Consent form
12. Case Study Interviews Consultee Consent form
13. Case Study Interviews Healthcare Professional Consent form
14. Case Study Interview Schedule for Patients
15. Case Study Interview Schedule for Carers
16. Case Study Interview Schedule for Health care professionals
17. Case Study Observation Data Collection form
18. Case Study Observation Information Sheet – Patients
19. Case Study Observation Information Sheet – Consultees
20. Case Study Observation Information Sheet – Health and care professionals
21. Case Study Observation Consent Form – Patient
22. Case Study Observation Consent Form – Carer
23. Case Study Observation Consent Form – Healthcare professional
24. Case Study Orientation Form
25. Insurance Form
26. Research passport- Yasemin Hirst
27. Research passport – Laura Wareing
28. Yasemin Hirst DBS certificate
29. Laura Wareing DBS certificate
30. Yasemin Hirst CV
31. Laura Wareing CV
32. Cliff Shelton CV
33. Andrew Smith CV
34. Decision Making Tool for Service Evaluation
35. Decision Making Tool for Observation Research
36. Easy-read Patient Information Sheet
37. Observation Poster

11.2 Appendix 2 – Gantt Chart

Table 2. Revised Gannt Chart for WP2 ad WP3																
	Mar 23	Apr-23	May23	Jun 23	Jul 23	Aug 23	Sept 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	Mar 24	Apr 24
Ethics Sponsorship																
Ethics submission and approval																
Research Passport																
Identification of contacts																
Mapping Questionnaire data Collection																
Site Selection																
Case Study Recruitment																
Case Study 1																
Case Study 2																
Case Study 3																
Case Study 4																
Case Study 5																
Case Study 6																
Case Study 7																
Case Study 8																
Data Analysis																
Write up																

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.3	22/01/2024	C Shelton	1) Updated mapping questionnaire procedure in section 5 to clarify that collaborators may complete some or all of the surveys. 2) Updated mapping questionnaire for clarity, and added the facility to record the role of the person who is completing the questionnaire.