Full Title:
Inclusive prehabilitation (I-Prehab) to address inequity in cancer outcomes: mixed-methods evaluation research to enhance access, acceptance and adherence.

Short Title:
NIHR I-Prehab project

Version 5.0

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General Information:
This protocol describes the NIHR I-Prehab project, which has four sequential work packages,

Work package 1: systematic review
Work package 2: case study research
Work package 3: coproduction of I-Prehab
Work package 4: feasibility trial

It provides information about the study methods and procedures. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary.

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Table of Contents

Glossary of abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
NIHR	National Institute for Health Research
HRA	Health Research Authority
HSDR	Health and Social Care Delivery Research
ICF	Informed Consent Form
ISF	Investigator Site File
NHS	National Health Service
PI	Principal Investigator
PIS	Participant Information Sheet
R&D	Research and Development
REC	Research Ethics Committee
SSG	Study Steering Group

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol.

NIHR Amendment No.	NIHR Protocol version no.	Date issued	Summary of changes made since previous version
Not applicable	1.0	N/A	First version
1	2.0		1. Funder reference on page 5 corrected to read NIHR151668. 2. 'Currently pending' added to the Research Ethics Approval Plan on page 9. 3. The funding acknowledgement on page 27 revised to read, 'This study is funded by the NIHR Health and Social Care Delivery Research Programme (HSDR NIHR161558). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.' The 'Funded by NIHR' logo has been added to the footer of each page.
2	3.0		Research Ethics Approval Plan, page 10, amended from 'currently pending' to 'a favourable opinion given by London - Surrey Borders NHS Research Ethics Committee on 26th September 2023.'
3	4.0		Change to CI. Permission to Proceed with WP3. Permission to recruit from community for WP3. Request for approval of study documents for WP3: Participant information sheet, Consent form, recruitment flier, Demographic forms, workshop plan, Prioritisation topic guide Stakeholder coproduction workshop to be submitted at separate amendment
4	4.0		Change to Recruitment Posters. No change to protocol.
5	5.0		Protocol updated with new CI. The protocol revised to ask cancer care workers to 'reflect on' the I-Prehab education, rather than using 'think aloud'.

			The study outcomes have been amended to include the Health Education Improvement Wales HEIW evaluation. To avoid repetition the I-Prehab outcomes have been amended. Knowledge questionnaire revised from scoring correct answers to a 6-point Likert scale, ranging from 1 representing 'Strongly Agree,' to 6 representing 'Strongly Disagree.' The progression criteria have been revised to align with the objectives

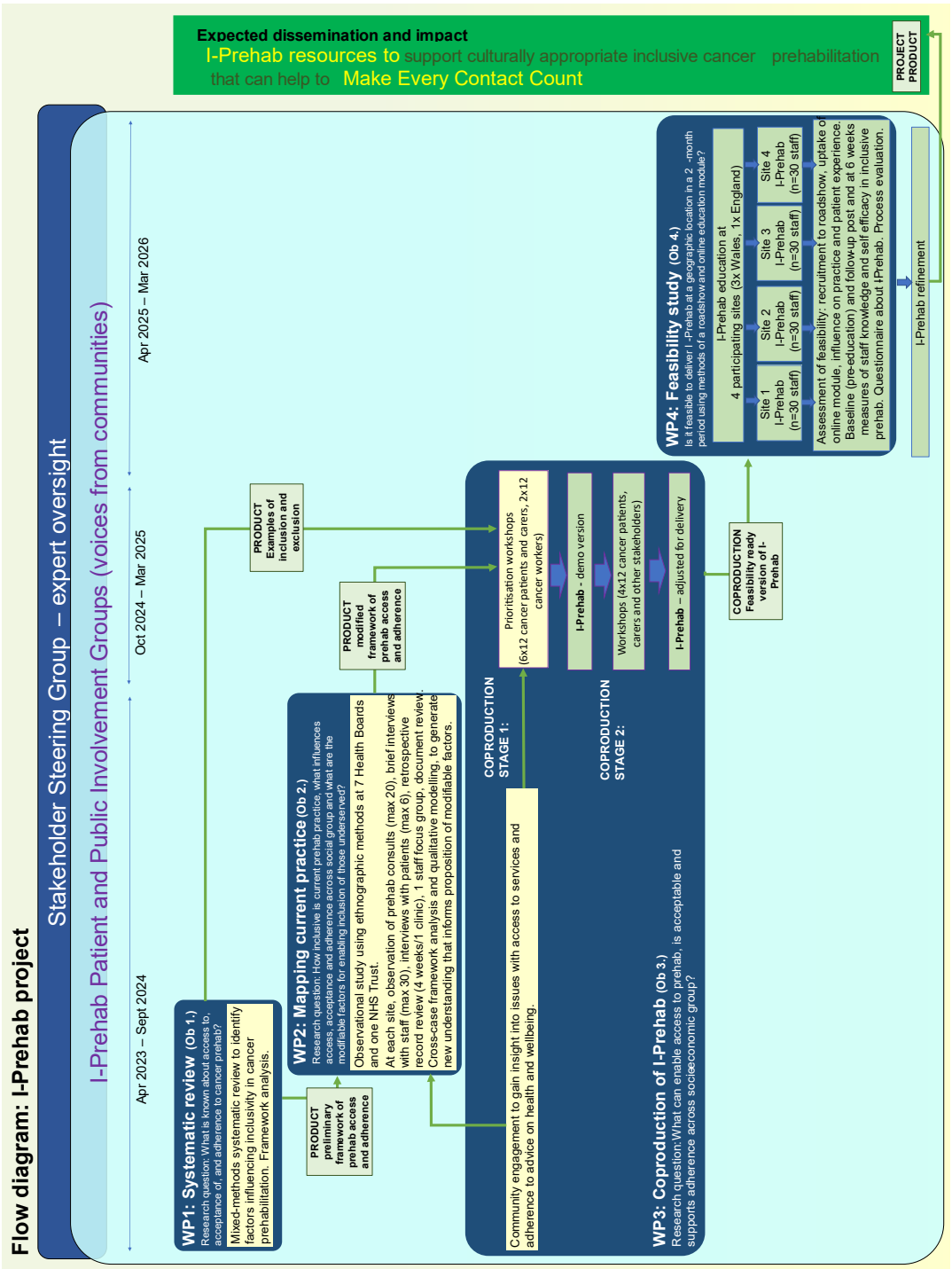
2 Synopsis

Short title	NIHR I-Prehab project
Acronym	I-Prehab
Funder and ref.	NIHR, HSDR NIHR151668
Study design	Four sequential interrelated work packages using mixed-methods to develop and test I-Prehab
Study participants	**Patients** with upper gastrointestinal, bowel, lung, prostate, or breast cancer **Cancer care staff**
Planned sample size	Work package two (WP2): Up to 160 patients and their carers and up to 160 cancer care staff Work package three (WP3): 96 patients and carers, 48 cancer care staff and other stakeholders Work package four (WP4): 120 cancer care staff and 24 patients
Planned number of sites	WP2. 8 : in Wales WP3. 12 community groups WP4. 4 : three in Wales and one in England
Inclusion criteria	**Patient participants** Adult (≥18 years old) Confirmed diagnosis of upper gastrointestinal, bowel, lung, prostate or breast cancer Pre or in treatment Able to provide informed consent **Staff participants** Professional or support staff Experience of the treatment and care of patients with cancer Able to provide informed consent
Exclusion criteria	**Patient participants** More than three months from the end of cancer treatment Unable to give informed consent (e.g. lack of capacity to consent)
Planned study period	01/04/2023 to 31/03/ 2026
Primary objective	To better understand access to, acceptance of and adherence to cancer prehab across socioeconomic groups to devise I-Prehab. I-Prehab will include an education toolkit for cancer workers enabling them to support inclusive prehabilitation. (A cancer worker is a person in paid employment who meets people with cancer in their job role)
Secondary objectives	Objective 1 (Ob 1.) Conduct a mixed-methods systematic literature review to investigate what is known about access to, acceptance of, and adherence to cancer prehab. Objective 2 (Ob 2.) Conduct case study research to explore multiple stakeholder perspectives of access to, acceptance of, and adherence to cancer prehab offered in Wales. Objective 3 (Ob 3.) Coproduce I-Prehab with core components and adjustments that facilitate engagement of people from socially deprived communities and ethnic minorities in prehabilitation.

	Objective 4 (Ob 4.) Evaluate the feasibility of delivering I-Prehab through education of cancer workers across primary and secondary care and to investigate impact on both cancer worker knowledge and confidence in delivering inclusive prehab and patient experience.
Impact	We will use I-Prehab to raise awareness of culturally appropriate prehab, thus enhance inclusivity in cancer prehab. We currently, March 2023, envisage delivering a 'roadshow' that may become part of the educational role of allied health professionals in the future, where an oncology allied health professional gives a short presentation on ways to encourage patients to engage with prehab, shows video stories of patients with different sociodemographic profiles engaging in prehab and promotes the I-Prehab online education. Our patient and public partners will work with us across the course of the project on our impact plan, which will include a public engagement event, press release and public-facing infographic, animation and videos for sharing on social media platforms, at public seminars and a public summit.

3 Study summary & schema

3.1 Study schema



3.2 Plain English Summary of Research

Background
Prehabilitation (prehab) prepares people for cancer treatment and helps them during treatment to eat well and to be physically active and emotionally resilient. Prehab can lead to fewer treatment complications and better cancer outcomes, including longer life. It can also produce service cost savings. If prehab services are to be inclusive for all, changes are required to improve access and to support participation. We need a better understanding of how people find out about and use prehab services (access) and whether and why they follow prehab guidance (adherence). Everyone should receive the same quality of person-centred care in the NHS.

Aim
We will work with patients, carers, cancer workers, and cancer service managers to make (coproduce) and evaluate I-Prehab. I-Prehab will be a toolkit to support cancer workers to raise awareness of and encourage participation in prehab services for cancer patients. It will be designed to overcome access barriers and provide tools to support adherence, particularly for those from socially deprived and ethnic minority communities. We will study patients receiving treatment for upper gastrointestinal, bowel, lung, prostate, or breast cancer.

Design and Methods
The research will be in 4 stages, planned and delivered in partnership with representatives of socially deprived and ethnic minority communities:

Stage 1. A review of relevant published research to find out what is known about culturally appropriate support for physical activity, nutrition, and emotional resilience.

Stage 2. Investigate, in detail, the current prehab practices in all eight NHS organisations treating cancer in Wales.

Stage 3. Conduct workshops with people affected by cancer and service providers to use the findings of stages 1 and 2 to co-produce I-Prehab.

Stage 4. Test whether it is possible to deliver I-Prehab. This will include checking whether cancer workers will complete I-Prehab education and then use I-Prehab, whether they find I-Prehab useful and finding out about patients' experiences of I-Prehab.

Patient and Public Involvement representatives agree with clinician team members. There is significant potential for patient health benefit through improved access to prehab by people from socially deprived and ethnic minorities communities. Three patient and public members wished to be co-applicants for the research to lead and coordinate public involvement activities. They will join the I-Prehab research team and will contribute to data analysis, design of methods, patient facing documents, impact plan and effective sharing of the outcomes to maximise dissemination.

Dissemination
We will work with our partner organisations to distribute I-Prehab across Wales and the rest of the UK. We will share the research findings with healthcare professionals, hospital managers and people affected by cancer through NHS training, charities such as Macmillan Cancer Support, the press, social media, conferences, public meetings, and in scientific and professional journals.

4 Research Ethics Approval Plan

The delivery of work packages WP2, WP3 and WP4 includes research that requires a favourable opinion from an NHS Research Ethics Committee (REC). However, preliminary analysis of WP2 data is necessary to decide the content of the WP3 prioritisation workshops and until WP3, the details of I-Prehab and its implementation plans will remain uncertain. Therefore, REC approval has been sought for WP2 only and a favourable opinion given by London - Surrey Borders NHS Research Ethics Committee on 26th September 2023. REC approval for WP3 and WP4 will be sought when the details of IPrehab have been sufficiently clarified. Ideally, this later approval will be considered by the same REC and the project will be guided by the REC in determining whether this should be done via a new REC application or major amendment.

5 Background and rationale

Prehab, aims to optimise cancer treatment outcomes through support for physical activity, nutrition and emotional resilience, and can reduce morbidity and mortality[1] with associated healthcare cost and bed savings[2]. People who are physically active, well-nourished and emotionally resilient experience less treatment toxicity, fewer treatment complications and live longer[1, 3-5]. People from some minority ethnic groups and socioeconomically deprived communities are underserved in prehab services[1]. If prehab is to be inclusive, adjustments are needed to enable access, facilitate acceptance and support adherence [6].

Cancer outcomes are poor in the UK compared to similar European countries[7]. Although survival has improved, health inequity persists with avoidable differences in cancer treatment outcome across socioeconomic and demographic groups[8, 9]. The UK and devolved governments' policies recognise the need to reduce this inequity[10, 11]. Reducing health inequity is a key element of the 10-year cancer plan within the NHS Long Term Plan[12].

People from socially deprived communities, including some ethnic minority groups, are at higher risk of poor cancer treatment outcomes. Deprivation and minority ethnicity are interlinked[13]. Based on the Index of Multiple Deprivation (IMD), 22% of the Welsh population live in the most deprived areas of the UK and social deprivation is associated with poor survival [14] and risk factors for poor cancer outcome, namely late disease stage at diagnosis [15], behaviour with health risks such poor nutrition, inactivity and smoking[16]. The Wales Cancer Patient Experience Survey (2016) reports that 89% of patients rate their care as excellent or good [17] but that people from ethnic minorities have poorer experience in nearly all aspects of care[18, 19]. The needs of people with cancer from ethnic minorities are underserved and should be better understood[20]. The Quality Statement for Cancer Wales highlights the need for equity and person centred care with prehab a key part of the cancer pathway[10].

By focusing on prehab in cancer care, we seek to identify inequality in accessing services, and analyse reasons underlying variation in cancer outcomes. This new knowledge will help service providers meet their statutory requirements and policy directives to reduce variation in cancer outcomes thus improving the quality of cancer care.

5.1 The existing literature that supports the protocol

Cancer rehabilitation is a multidisciplinary approach to optimise physical activity and nutrition along with emotional support, to enhance function, reduce disability and improve emotional well-being[21]. Prehab is part of the cancer rehabilitation pathway[22]. In gastrointestinal (GI)[23] and lung cancers[24], it can improve surgical[23, 24] and non-surgical treatment outcomes[25, 26] and reduce

inequity in outcome[1]. Social groups with higher educational level have higher referral rates to rehabilitation services[27]. Ethnic minorities and patients with psychiatric comorbidities underutilise community-level cancer rehabilitation services[28]. There is also variability in awareness of prehab and knowledge of its evidence base across professional groups[29]. Most local initiatives have not been evaluated.

Cancer is now the second most common cause of disability globally[30] and is a top priority for action by governments worldwide, including in Wales[10]. Survivors of cancer report more activity limitations and poorer general health than the general population[31]. In the UK 31% of people living with and beyond cancer are inactive[32]. Barriers to physical activity are, cancer-related side effects (e.g. fatigue), fear of movement, low motivation, inaccessible services and facilities[33] and a high level of emotional distress including anxiety and depression[34]. Malnutrition is common, particularly in patients with upper GI, colorectal, and lung cancers[35, 36], which affect a disproportionately large number of people in disadvantaged communities, and is associated with infection and poor outcomes[35]. People with low mood, anxiety or depression are at higher risk of poor cancer treatment outcome[37]. We need a better understanding of the association between social deprivation, and both poor cancer treatment outcomes and low access to rehabilitation[38].

5.2 The need for the research

The James Lind Alliance Top 10 priorities for research about living with and beyond cancer include: *How can the short-term, long-term and late effects of cancer treatments be (a) prevented, and/or (b) best treated/ managed?[39]*

A growing body of evidence demonstrates that prehab before and during cancer treatment improves morbidity and mortality[2, 4, 5]. Availability of and patient engagement with prehab is variable[29]. NHS Wales data (presented at local meetings [40]) demonstrates that access rates range from 20% to 70% where there is availability. There is a need to understand access to prehab in the context of people's lives and life experiences.

This research arose from recognition by the Wales Therapies Leads (AHP Cancer Cymru) that engagement with prehab needs to improve. Therapies teams across NHS Wales want evidence to underpin a foundation level prehab education offer to all NHS and community staff involved in cancer care. This needs to have a practical focus, helping staff know how to help people access and engage with prehab. The vision of AHP Cancer Cymru is for education in culturally appropriate prehab to be part of Making Every Contact Count[1] – everyone in the cancer workforce needs to feel confident and competent to talk about physical activity, eating well and emotional strength. This research has been coproduced with patients and is part of the NIHR Cancer and Nutrition Collaboration's workstream activity.

The purpose of our research is to map existing prehab practice and learn from the best examples of inclusivity. In parallel, we will engage community groups in dialogue about obstacles and enablers of service access. We will use our new understanding of factors influencing access, acceptability and adherence to inform a coproduction process that generates 'Inclusive Prehab' (I-Prehab). I-Prehab will be online education and other resources, which help cancer workers know how to enhance the inclusivity of prehab. Our project is underpinned by the assumption that strategies to facilitate access will improve the health and wellbeing of people at higher risk of poor outcomes from cancer treatment.

Solutions to problems in healthcare require robust evaluation. We will evaluate I-Prehab for impact on cancer worker knowledge and confidence in improving access, acceptance and adherence to prehab. We will also evaluate the transferability of I-Prehab within and beyond Wales. The research is important because we will use our findings to inform recommendations for inclusive personalised

prehab (I-Prehab) to prevent avoidable adverse effects of cancer treatment, and support good quality of life and good treatment response, thus helping service providers meet their statutory requirements and policy directives to reduce variation in cancer outcomes.

6 The research question

What is the current prehab offer to patients with upper GI, colorectal, lung, prostate, or breast cancer and what modifiable factors affect access to, acceptance of and adherence to prehab in people from socially deprived communities at higher risk of poor treatment outcomes?

7 Aim and objectives

Our aim is to develop a theoretically informed understanding of access to, acceptance of and adherence to prehab to inform the coproduction of a socially and culturally sensitive complex intervention and test it in a feasibility study.

Objectives

Objective 1 (Ob 1.) To conduct a mixed-methods systematic literature review to investigate what is known about access to, acceptance of, and adherence to cancer prehab.

Objective 2 (Ob 2.) To conduct case study research to explore multiple stakeholder perspectives of access to, acceptance of, and adherence to cancer prehab offered in Wales.

Objective 3 (Ob 3.) To coproduce I-Prehab with core components and adjustments to facilitate engagement of people from socially deprived communities in prehab.

Objective 4 (Ob 4.) To evaluate the feasibility of delivering I-Prehab through education of cancer workers across primary and secondary care and to investigate impact on both cancer worker knowledge and confidence in delivering inclusive prehab and patient experience of I-Prehab.

8 Project plan/methods

The research will be conducted within Velindre University NHS Trust, all seven Health Boards across Wales that deliver cancer treatments to the Welsh population and one NHS Trust delivering cancer treatment to people in Sussex, England.

9 Design

The design is four discrete but interrelated work packages (WPs) (see Figure 1.). Mixed-methods (including systematic review, qualitative interviews, observation, focus groups, secondary analysis of survey data, and questionnaires) will be used across the interdependent packages. We will synthesise findings to answer our research question.

Our proposed work packages are consistent with the pragmatic guide for quality intervention development, 6SQuID[41]. The project will deliver five of the six crucial steps i) defining and understanding a problem, access and adherence to prehab, ii) identifying modifiable factors with greatest scope for change and benefit by collating empirical data and conducting a qualitative

modelling process, iii) deciding on active ingredients for change, iv) clarifying delivery options for bringing about change and, v) testing and adapting the intervention. (Step vi will be a follow-on study to test for effectiveness).

9.1 Theoretical/conceptual framework

The study will adopt an ontological and epistemological position of a reality known through interpretation. Our methodology and methods will be underpinned and informed by the assumptions of social constructionism. We will assume that knowledge and understanding of the world is through our own view (construction) of reality. Our proposed mixed-methods research will collate multiple forms of observable information about the complex problem of prehab access, acceptance and adherence, using systematic methods to inform an interpretation. As researchers in a practice discipline our values include emphasis on utility, which leads us to seek understanding of what can be modified/changed by clinicians and managers of health services for improved health equity. In this project, our particular concern is understanding access to and uptake of cancer prehab services to then address disparities through an initiative we will call I-Prehab. We will assume that inclusion is dependent on an interactional process involving negotiation in a context of competing values.

Access to healthcare

According to the World Health Organisation's Constitution, "…the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition"[42]. Access to healthcare can be defined as "the opportunity to identify healthcare needs, to seek health services, to reach, to obtain or use health services and to actually have the need for services fulfilled''[43]. Levesque et al. (2013)[43] synthesised conceptualisations of access proposing access is a process with five dimensions of accessibility (Approachability; Acceptability; Availability and accommodation; Affordability; Appropriateness) and five corresponding abilities of populations (Ability to perceive; Ability to seek; Ability to reach; Ability to pay; Ability to engage). We will use this framework to operationalise access for our project.

A tension exists between horizontal and vertical dimensions of equity in access. The NHS has traditionally focused on horizontal access, an equal service for all. In recent years there has been an increasing emphasis on vertical access, unequal access for equal health outcomes [44]. However, this puts emphasis on the importance of healthcare for achieving health equity when unequal distribution of health outcomes reflects social determinants of health in the population [45]. Levesque et al.'s (2013) framework is socioecological enabling attention to social, service organisation and person-centred factors influencing access.

Adherence to healthcare

Access is the first step in adherence, with adherence having a pattern across time. We will adopt the WHO definition of adherence; "the extent to which a person's behaviour - taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider [46].' It is understood as the interplay of five sets of factors, i) social/economic factors, ii) provider-patient/health care system factors, iii) condition-related factors, iv) therapy-related factors, v) patient-related factors, thus it is a socioecological model consistent with our selected conceptualisation of access.

9.2 Framework for data collection and analysis

We will draw on our earlier cancer research about physical activity, nutritional care, and supported self-management to adapt the WHO framework of adherence for our study problem, for example placing emphasis on evoking positive emotion [47]. We will further develop the framework to include a

time dimension with access, as conceptualised by Levesque, the start-point and disengagement with prehab the end point. We will use the framework to guide data collection and to manage our analysis.

10 Work package One (Ob 1.): mixed-methods systematic review

Our scoping review has found cancer treatment and survival outcomes are poorer among people from socio-economically deprived communities and minority ethnic groups [2,3,4]. While layered with complexity, contributing factors include disparities in cancer awareness [5], screening programme engagement [6-8] and timely presentation with symptoms indicative of cancer [9]. Furthermore, Danish studies have found that socially deprived patients receive less cancer rehabilitation [48, 49]. Multimodal cancer prehab can help and support physical and psychological health and improve survival outcomes [12-14]. It is therefore important to identify and understand barriers to, and facilitators of, prehab.

Aim

This systemic review will find out what is known about culturally sensitive support for physical activity, nutrition, and emotional resilience before and during cancer treatment.

Review Question

What do we know about access, acceptance and adherence to cancer prehab, particularly among socially deprived and minority ethnic groups?

Review objectives

1. To identify cancer patients' understandings of, views on, and the need for prehab.
2. To identify the enablers and barriers that impact on access to, acceptance of and adherence to cancer prehab.
3. To develop a conceptual model of access and adherence to cancer prehab among socially deprived and minority ethnic groups.

Design

Methodology and methods will be informed by the Joanna Briggs Institute methodology for mixed methods systematic reviews (MMSR) [50]. A protocol is registered on PROSPERO (registration number CRD42023403776).

Searches

Searches will be performed in Medline; Cumulative Index to Nursing and Allied Health Literature (CINAHL); Applied Social Sciences Index and Abstracts (ASSIA); PsycInfo, EMBASE, Physiotherapy Evidence Database (PEDRo), ProQuest Medical Library, Cochrane Library, and Web of Science. Search terms and strategies will be developed in collaboration with a specialist librarian using medical subject headings and key words relating to cancer, prehab, inequity, inequality, socioeconomic deprivation, ethnic groups, and health services accessibility, and adapted for different databases. Only research published in peer-reviewed journals in English will be included. Time limit will be January 2017 to current, as Macmillan Cancer Support published a prehab evidence and insight review and defined prehab in 2017. Reference lists of papers retrieved for full review will be searched. For grey literature, we will search Open Grey, Grey Literature Report, Pro quest Dissertations and Theses Global.

Types of study to be included: Quantitative, qualitative, and mixed methods studies.

Exclusions: Commentaries, conference abstracts, editorials, not published in the English language. Studies involving children, adolescents, and end-of-life care.

Participants: Adults age 18 and over with a cancer diagnosis.

Intervention: Cancer prehab (support for physical activity, nutrition or emotional resilience)

Data extraction

Using Covidence software, two reviewers will independently screen titles and abstracts of retrieved papers against pre-determined eligibility criteria. Full text papers will be retrieved for all titles and abstracts meeting the inclusion criteria and for papers where there is uncertainty. Two reviewers will independently screen full text papers for inclusion, disagreement will be resolved in discussion with a third reviewer. The study selection process will be reported using a PRISMA flow chart. A bespoke data extraction sheet based on published guidelines and using the Cochrane Evaluation of Practice and Care Group's template[51] will be developed and piloted. Included papers will be quality assessed by two reviewers independently using the mixed methods appraisal tool [52]. Publications will not be excluded on the basis of quality. The quality assessment will be used to comment on confidence in the findings.

Analysis and synthesis

Heterogeneity in study methodology and methods is anticipated. Data extracted from quantitative, qualitative, and mixed methods studies will be synthesised using JBI's convergent integrated approach. The quantitative data will firstly be converted by two independent researchers into 'qualitized data.' This will involve transforming quantitative data into textual narrative in a way that tells the story of results from the included quantitative studies whilst responding to the review questions. The extracted qualitative data will be analysed by two researchers independently using methods of thematic analysis [53]. The findings will be displayed in a summary table and synthesised in a narrative. A conceptual model of access and adherence will be devised. This will provide the foundation for propositions that structure data collection and analysis in WPs 2-4.

11 Work package Two (Ob 2.): case study research

An observational **mapping study** of prehab practice within all eight NHS cancer treatment providers across Wales. Our data collection will be informed by what we learn from our systematic review about cancer prehab and health inequity. The case will be prehab across Wales and its boundary will be people pre or during treatment for upper GI, colorectal, prostate, breast or lung cancer. We will learn from examples of prehab to develop theory that is transferable to other contexts. We expect our research to be useful and relevant across the NHS.

The research questions to be addressed are,

1. What proportions of patients awaiting cancer treatment are offered and take up prehab?
2. What are the sociodemographic characteristics of patients offered prehab and what proportion are in groups at higher risk of poor treatment outcome and thus most likely to benefit?
3. What is the pathway to prehab?
4. What prehab is offered, and how is it offered and followed up?
5. What are the barriers and enablers of prehab as perceived by patients, by their family carers and by health professionals?
6. What are the patterns of clinical practices and service delivery that affect prehab?
7. What are the commonalities and differences in access to prehab between social groups with differing risk profiles for poor cancer treatment outcome? How are they influenced by local context? What are the intersects (common factors) across social groups?

Objectives

Obs 2.1. Map current prehab practices across Wales

Obs 2.2. Evaluate the inclusivity of current prehab practices in Wales

Obs 2.3. Devise an empirically based model of access and adherence to cancer prehab

Obs 2.4. Develop a theoretical understanding of access and adherence to cancer prehab that can inform practical action for improved inclusivity

Study design and methodology

The mapping research will be a longitudinal mixed-methods case study design using an inductive methodology. It will use multiple sources of evidence derived from observations from clinical consultations, brief interviews with health professionals in the clinical setting, interviews with patients and carers about prehab, focus groups with cancer teams, clinical measures, secondary analysis of existing survey data, and a retrospective medical record review (see Figure 2.). A case study approach has been chosen as it is a versatile approach that can capture information about the how and why of a complex situation [54]. We consider prehab to be complex with its three component parts (physical activity, support for eating well and support for emotional resilience), and case study to be a way of tracing events, decisions and changes across a period of time. Our empirical work will investigate prehab practice in different locations (eight nested cases). Whilst case study research describes cases in detail, it enables learning from the particular to develop theoretical understanding that can inform practical action and that is transferable to different contexts.

Theoretical/conceptual framework

We will use the WHO adherence framework, adapted by using what we learn from our systematic review, to structure our data collection and analysis. We will assume adherence is a process with access to prehab as the start point, variability in acceptance (uptake and persistence) across time, and disengagement with adherence to prehab advice or transition to rehabilitation post treatment at the end point. At this stage we propose our framework will have the five dimensions of the WHO framework (see 9.1 above), each with three component parts; access, acceptance, and cessation of/sustained adherence. Our concern with inequality with access to prehab will predominate, with Levesque et al.'s (2013)[43] dimensions of access added to the framework to focus attention on this concept during data collection and analysis.

Prehab

Prehab is a complex intervention for adults with cancer who are awaiting surgical or non-surgical cancer treatment [1]. It comprises of assessment by a multidisciplinary team (MDT), typically a nurse, dietitian, and physiotherapist, who then offer tailored advice on physical activity, eating well, and emotional resilience. It is patient-centric and proactive. Therapies teams within each of the eight NHS cancer treatment provider organisations in Wales deliver a prehab service, although there is wide variability in what is currently offered. The service is offered pre-treatment with on-going support through treatment dependent on clinical judgement informed by the initial MDT assessment. Where appropriate, patients are signposted to relevant local community services that can enable follow-through with the prehab advice, such as a Maggie's Centre physical activity group.

Methods

This work package is an investigation of access to, acceptance of and adherence to prehab to understand how, when and why patients engage (or otherwise) with the offer of prehab.

Target Population

The target population is patients with a confirmed primary or recurrent diagnosis of lung, colorectal, upper GI, prostate, or breast cancer who are offered prehab. Health care professionals who are involved in the treatment and care of people with cancer and with experience of a prehab service will also be invited to be study participants.

Inclusion/Exclusion Criteria

Patients will be eligible for participation if they are adults (18 years or older) with a diagnosis of lung, colorectal, upper GI, prostate, or breast cancer, experience of prehab, scheduled to receive active or palliative cancer treatment, not at end of life, and willing to participate (any language with support of an interpreter/family interpreter). Cancer workers will be eligible for participation if they have a job role involving contact with adults (18 years or older) with a diagnosis of lung, colorectal, upper GI, prostate or breast cancer.

Data sources

Eight nested cases will be studied in detail; one prehab service within each NHS cancer service provider organisation in Wales. Each eligible service will offer prehab to patients with one or more of five cancers (lung, colorectal, upper GI, prostate, or breast). The nested cases will be selected for maximum variation in population and patient-provider/health system factors known to affect access and adherence, for example surgical and non-surgical cancer treatments and groups with varying indices of socioeconomic deprivation.

Data will be gathered in the same ways for each nested case study:

- A retrospective patient medical record review (n=8 services).
- Observation of the prehab offer (maximum 20 patients).
- Interviews with patients and their carers following the prehab consultation (n=6).
- Measure of General, Nutrition and Exercise Self-efficacy (Appendix 1.) post patient interview (n= 6)
- Hospital Anxiety and Depression Scale (HADS) (Appendix 2.) post patient interview (n= 6)
- Brief 5-minute interviews with cancer workers during the multidisciplinary prehab clinic session to clarify reasons for decisions and actions (one per patient)
- Focus group with cancer workers (one per nested case study).
- Demographics (age, postcode to assess Index of Multiple Deprivation, main source of income, and employment) collated at the end of the patient interview and medical history (cancer diagnosis and stage, co-morbidity) extracted from clinical records of interviewed patients with their consent.
- Secondary analysis of Wales Cancer Patient Experience Survey data.

Sampling

For each of the eight selected prehab services, all eligible referrals will be invited to take part in the research until recruitment targets have been met. In this way we will maximise opportunity for inclusion in our study of any patient receiving the prehab service. A screening log will be kept at the site so that potential participants will receive only one approach.

Data Collection

Clinical note review

The review will collate data from all referrals to eight prehab services over a 4-week period. An administrator at each site will be trained by a researcher in the use of a data extraction tool. Data collected will include demographics, cancer site and stage, planned cancer treatment, comorbidities, prehab assessments of physical activity, dietary intake, and emotional wellbeing (to include measures, if recorded, such as nutritional screening), recorded prehab interventions and any follow-up. Anonymised data will be recorded and shared with the research team for entry into a database, data cleaning and analysis. The findings of this retrospective medical record review will be used to assess the representativeness of the observed and interviewed samples.

Observations

The researcher will undertake observations using ethnographic methods [55]. The researcher will observe (shadow) the staff members conducting the initial patient prehab assessment. Detailed field notes will be made. We are interested in learning how conversations about prehab are started, how information about health risks is communicated and how interactions motivate and support self-efficacy in engaging with prehab. In our earlier work, we found that how health behaviour advice to reduce cancer risk was approached and communicated by health professionals shaped perceptions

of healthcare and future medical help-seeking behaviour for symptoms of lung cancer among people from socioeconomically deprived communities [56].

We have sought and will continue to seek advice from our patient and public representatives on appropriate incentives and representation for gaining trust of potential participants, for example, they advise to help people see the relevance study information seeks 'people living in the west end of Rhyl' (not from 'an area of deprivation') and explains the study is about difference in people's experience. We will apply our expertise within the study team for recruitment/engagement of socioeconomically deprived groups and ethnic minority groups, and we will work with our patient and public representatives to promote equity of participation in this study. This will help us to gain insight into the nature of prehab offered to all patients accessing the service. The target for recruitment to interview is 6 per site (2 people from ethnic minority groups, two people from socially deprived communities, and two people from affluent communities) in 8 sites (48 interviews). We will continue observations until the recruitment target has been achieved, or until 20 patients have been observed (8 nested cases x 20 observations max = 160 observations max). We will ask clinical staff to identify eligible patients using a screening checklist. During the pandemic we have successfully piloted the feasibility of joining a virtual prehab consultation, as an observer.

Verbal consent will be sought by the researcher prior to observation and written (wet ink on hard copy or agreement to statements and typed signature on an electronic form) or audio-recorded consent will be obtained after the observation. Patients will be offered time to consider their decision. They will be asked by the researcher if their contact details only can be recorded on the study demographic questionnaire, to enable follow-up of their decision. Taking retrospective consent will ensure the patient has had sufficient time to understand the nature of the study and they are aware of what type of research they are agreeing to. Taking consent using one of a range of methods will facilitate inclusion. It will increase the likelihood of equity in opportunity to participate and diversity within the recruited sample. Taking retrospective consent is an approach we have used, with ethical approval, in two previous studies to include people who lack capacity or have dementia [57]. During the consent process we will seek data on ethnicity using census categories. We will use postcode to categorise by Index of Multiple Deprivation. We will use this categorised data to purposively sample for interview.

Follow up Interviews

Patients who have agreed to observation of their prehab consultation will be given the option of also attending interview at a time and in a place convenient to them, which may be following the consent process on the day of the observation. They will confirm their choice in exercising this option on the signed Patient Consent Form or an audio-recorded statement of agreement at the time of initial consent. Confirmation of this consent will be sought immediately prior to interview. The researcher will work closely with the clinical team. Any issues arising at interview with treatment and care, will, with participant consent, be discussed with clinical team members. Interviews will be audio recorded. The interview will investigate the pathway to prehab, perceptions of prehab and intent to adhere to the prehab advice given. Patient participants can invite a carer to be present during their observation and interview. Written informed consent or audio-recorded consent will be taken before the interview from carers who wish to take part in the observation and/or interview. From our earlier work with people approaching the end of life and people with cognitive impairment, we anticipate 50% of people who agree to observation will agree to interview (maximum 10 per case). We will use a sampling frame to select 6 patients (2 people from ethnic minority groups, two people from socially deprived communities (the two most deprived quintiles of deprivation), and two people from affluent communities) in each of the 8 nested cases (48 interviews).

Measures

Interviewed patients will be invited to complete measures of General Self-efficacy to include Nutrition Self-efficacy and Exercise Self-efficacy scale (see Appendix 1) and anxiety/depression using the Hospital Anxiety and Depression Scale (HADS, see Appendix 2) post interview, along with a

demographic questionnaire, to enable the study samples to be compared with each other and with other cancer patient samples. This data will enable evaluation of the transferability of findings.

Observation and follow up interviews: clinical team members
Informed consent from clinical team members will be sought prior to observations and/or interviews. Brief interviews of 3-5 minutes duration will be audio recorded and conducted in the course of everyday clinical practice to capture the perspective of the clinician soon after assessment or a prehab intervention. The purpose of the interview will be to explore decision making in the specific case, what is considered supportive and what facilitates acceptance of and adherence to recommendations for physical activity, diet and building emotional resilience.

Focus groups
Focus groups (one per nested case) with cancer workers will explore perceptions of who accesses and adheres to prehab and will explore contextual issues to include the interface of prehab with other services. Participant information sheets will be made available to interested staff at least one week before each face-to-face focus group and informed consent will be taken by the researchers (either the focus group facilitator or moderator) at the start of each meeting. Discussion will be audio-recorded.

Secondary analysis (to run in parallel to WP1 but results synthesised with findings of WP2)
Cancer Patient Experience Surveys (CPES) are national surveys that aim to provide NHS commissioners and managers with patient perspective data about their cancer care[17]. Existing Wales CPES[17] data (N=7342) will be analysed to understand the experiences of patients on aspects of care that may be modifiable by prehab. Permission has been granted to download data as an SPSS file from UK Data Service. We will characterise our CPES population by ethnicity and IMD quintile and compare responses on items that relate to pre-treatment and recovery. Estimates will be accompanied by 95% confidence intervals. As the Welsh survey had a low participation from ethnic minorities, we will supplement analyses with responses to the much larger English surveys (waves 5 to 8). If subgroups allow, variation in patients' responses by patient and health board level factors will be investigated using univariate logistic regression. This will provide an overview of patient experience by socio-economic status and ethnic group in which to situate our findings about access, acceptance, and adherence to prehab.

Data Analysis

Quantitative data will be entered into SPSS for Windows and presented using descriptive statistics. Field notes of observation and near verbatim comment will be written up into word files and all audio recordings of interviews and focus groups will be transcribed verbatim by a professional transcription company. Computer software, NVIVO, will be used to assist the management of qualitative data. A qualitative modelling process will compare within and between nested cases enabling the derivation of overarching themes. The interpretive cross-case comparison will be informed by Wolcott's (1994)[58] framework for qualitative data analysis and conform to Miles and Huberman (1994)[59] 'mixed strategy for cross-case analysis. We will conduct preliminary analysis of data collected at each site to inform data collection at the next. Thus, our understanding will evolve whilst data collection is on-going. We will investigate barriers to prehab, referral practices, perceived importance and outcomes to discover the what, when, where and with whom of current practices that enable access and participation and conversely exclude. We will identify what works well, learning from current practices (positive deviance). Following data collection, we will conduct an in-depth thematic analysis. Themes and the relationships between them will form the basis of our inferences, refinement of our conceptual model of access and adherence, and a substantive theory of access to, acceptance of and adherence to cancer prehab. Our emerging findings will be discussed within the research team and with our community leads. The debate will inform our analysis and synthesis. Hence, the theory constructed from the data analysis and interpretation will be a creative product but developed through a structured approach and with involvement of communities. Team members have a strong track-

record of collecting and analysing qualitative and survey data within clinical settings[47, 57, 60-63]. The proposed analytic approach has previously been used by our group to devise conceptual models and generate theories [60, 64, 65] that have informed the development and refinement of complex interventions adopted in clinical practice. The theoretical understanding developed, along with the quantitative description of the cases, will provide the foundation for an Inclusive Prehab (I-Prehab) toolkit, as explained in WPs 3&4.

12 Work package Three (Ob 3.): coproduction of I-Prehab

WP3, will be a **coproduction process** using what is learned from WPs1&2 to develop I-Prehab. We will work with our clinical partners, AHP Cancer Cymru, and with stakeholders, to include a diverse group of people affected by cancer. We will use a person-centred approach[66] to identify transferable and modifiable factors influencing access to and engagement with prehab that cut across disadvantaged social groups and can therefore impact health inequity. Generating a complex intervention is an iterative process that brings evidence, theory and expert opinion together. We will achieve this in two stages, prioritisation workshops and prototype coproduction workshops.

We will use method and process proven in our previous translational studies that include working with community representatives [61, 67]. Different people, each with their own knowledge, techniques and experiences, will work together in dialectical process [68].

Question
What can enable access to prehab, is acceptable and supports adherence across socioeconomic groups?

Objectives
Obs 3.1. Hold two stakeholder prioritisation workshops informed by our WP1&2 research
Obs 3.2. Produce a prototype I-Prehab system of enablement to include a digital learning resource for cancer workers
Obs 3.3. Refine the prototype for delivery after running two coproduction workshops

We will draw on our learning from WP1 and WP2 to create a prehab offer, with recommended adjustments (tailored support) for engagement of patient groups at risk of poor outcome, that can be delivered by all cancer workers across Wales, as part of Making Every Contact Count [69]. This will include consideration of adaptation or modification of existing resources produced by organisations such as Cancer Research UK and Macmillan Cancer Support during the coproduction process. While we envisage that there will be an educational product from the project, there will likely also be other products to include new understanding of obstacles to and enablers of prehab that will inform, yet unknown, solutions. We will use the analytic approach to intervention development adopted for our previous studies [57, 67, 70, 71]. We will use the data driven conceptual model and hypotheses relating to prehab access, acceptance and adherence (WP2) to generate maps of concepts and relationships showing how access to prehab may be changed/improved. Together they will be a system of modifiable factors for enablement of prehab access, acceptance and adherence that will be presented at the prioritisation workshops.

Community voices
Our strategy for inclusion in coproduction is to work flexibly with community leaders and ethnic specific cultural networks. Our plan for seeking to hear and understand multiple voices is for community leaders but also local authority service leads, such as head teachers and libraries, to broker access to conversations in a culturally sensitive way. We envisage talking with people at everyday groups not just gatekeepers. For example, in our previous and on-going research about men with prostate cancer a community leader has enabled one of our team to talk with Somali men at

a Domino Club. Using a similar approach, we have talked with Asian women during coffee mornings held at primary schools. Our PPI Team members support this approach. They advise meeting people at local enjoyed everyday events where they are most likely to feel comfortable talking about health and well-being. Leaders within each of our community groups and cultural networks will facilitate discussion within the group leading to the community's view on obstacles and access to, acceptance of, and adherence to lifestyle interventions. Working with community leaders will enable us to engage meaningfully but also safely with people who may lack trust in or be resistant to services. We already have three groups within socially deprived communities and three groups from ethnic minority communities offering to support the project (four comprising solely cancer patients and two a wider community). Their contribution so far has included raising our awareness of a need for cultural humility by asking patients 'what do I need to know to provide you with best care?' and asking our community groups 'what sort of support they require.' We envisage methods of engagement and dialogue will differ across group. The community leader will liaise with a nominated member of the research team. Community leaders or members who volunteer to take part in the coproduction process will be able to attend training provided by Co-production and Involvement Network for Wales Ltd., if they wish. If they are willing to co-lead a workshop we will manage attendance at the training and will also provide one-to-one preparation for using our planned methods. An appropriate means of thanking the community for their time contributing to the project will be agreed. From our previous work we know this will differ across community and will likely include, food at meetings prepared by local businesses, shopping vouchers, travel expenses, and agreement to present to the community on health topics in local venues.

Consultancy

Soh Yon, Research Product Designer, London, has expertise in coproduction with diverse communities, for example on the Global Health Innovation Project, funded by the Royal Marsden Partnership Cancer Alliance. She has experience of brainstorming solutions with communities using creative methods, for example sharing through drawing. She is willing to run three workshops and contribute to the analysis and development of I-Prehab.

Toral Shah, Nutritionist, has expertise in South Asian diet and lifestyle when living with cancer. This expertise includes support in selection of appropriate foods and working with barriers to both change and language used to communicate information and advice.

Gray and Savage Design Ltd. (https://savageandgray.co.uk/) professional animator also experienced in video story production, who we have worked with before, will develop culturally sensitive resources, that can be embedded in the online education, I-Prehab.

Prioritisation workshops

We will run 10 iterative workshops of 90 minutes duration with groups of up to 12 people, initially from each community group and then with inclusion of clinical and other stakeholders (This may change as our understanding evolves through the coproduction process with our community groups). The purpose will be to prioritise the content and what needs to happen e.g. format and mode of delivery, for I-Prehab to be inclusive.

Workshops will be run by a community leader working in partnership with a researcher. The identified modifiable factors theorised to enable prehab will be shared. The collective opinion of each community group on obstacles and enablers to cancer prehab will also be shared. Modifiable factors will be discussed at the workshops in light of likely competing community views on access. A consensus process will be used when working with study expert advisers and in the workshops. A modified nominal group technique will be used to agree priorities for content of cancer worker education. The group of experts will be invited independently and in private to evaluate the potential components of a system for enablement of prehab. Their ideas and opinions will then be collated and shared, as anonymous views, with all group members. Each member will then vote on the components they consider most valuable. In this way, diverse views can be taken into account.

Following the workshop, participants will be asked to complete a short questionnaire inviting additional feedback. This will be offered as an opportunity to complete a paper-based or on-line questionnaire, or to discuss the questions one-to-one with a researcher who will document comment, suggestions, opinion and advice.

Following the prioritisation exercise supporting resources for the envisaged enablement system will be drafted or produced in a mock-up, to include web animation, videos, and I-Prehab online education for cancer workers.

Prototype coproduction workshops

The inclusive prehab prototype will be modified using coproduction methods developed by the team in earlier studies [61, 71]. This will be a consultation process with patients, carers and experts in cancer care and representatives from our community groups. These participatory workshops (n=4) will include key stakeholders, including representatives of relevant organisations such as Macmillan Cancer Support, education commissioners from Health Education and Improvement Wales, and NHS cancer therapies managers. They will take place approx. eight weeks following the prioritisation workshops. The researcher will work collaboratively with the groups of study experts (comprising both professionals and public) to modify the prototype to meet stakeholder needs, thus optimising I-Prehab ready for implementation. In this way, we will collate workable solutions, likely based on intervention principles for different socially deprived groups, that will inform refinement of the I-Prehab delivery plan to be tested in WP4.

We will offer both on-line and face-to-face coproduction workshops to maximise participation from the public and professionals living in geographically distant locations and with different access needs. Zoom provides flexible space that enables people to take breaks as they need to and minimises travel time. However, we anticipate those from socioeconomically deprived communities may prefer face-to-face and may not have the necessary internet access, phone or computer, and/or literacy skills needed for online meetings. We will hold a final Summit bringing everyone together to comment on the I-Prehab prototype for supporting all cancer workers to become inclusive prehab champions.

The coproduction product

The product will be a full version of I-Prehab prepared for WP4 to include education in inclusive prehab, an online learning module called I-Prehab. At this stage we anticipate it will include culturally adjusted ways to communicate messages such as ‘maintain muscle’ and ‘move as much as you can’ and will support people to practice cultural humility in facing what they do not know about other people’s lives and values. It will raise awareness of normative perspectives and how these can unintentionally exclude. It will challenge the cancer workforce to think differently, taking a relational approach to care.

We will use examples of improving access and adherence for patients receiving treatment for the most common cancers in people from deprived communities, upper GI, colorectal, breast, prostate, and lung cancers [22]. We envisage delivering a ‘roadshow’ that may become part of the educational role of allied health professionals in the future, where an oncology allied health professional gives a short presentation on ways to encourage patients to engage with prehab, shows video stories of patients with different sociodemographic profiles engaging in prehab and promotes the I-Prehab online education.

Our PPI team members advise it ‘has to be a practical product,’ as ‘technical and academic language puts people off, even professionals.’ Our discussions so far indicate I-Prehab education will need to be patient-centred to include ‘tips on how to ask questions,’ and ‘steps in starting conversations.’ The approach needs to be one where the person does not feel shamed, embarrassed, punished. Communication about available resources needs to be in plain English, such as ‘here's where you can

get cheap fruit'. I-Prehab resources need to include a reference guide for cancer workers. Where resources do not exist, we will make an action plan for follow-on work from the project.

13 Work package Four (Ob 4.): feasibility of delivering I-Prehab

Feasibility of I-Prehab education study within three sites in Wales and one NHS trust in England (University Hospitals Sussex NHS foundation trust). Our English comparator will help us to assess transferability beyond Wales through analysis of I-Prehab delivery across sites. Brighton and Hove is in the upper 40% of the most deprived English authorities with 15 out of 165 neighbourhoods falling within the 10% most deprived areas and it is an asylum dispersal city[72]. We will evaluate the feasibility of educating cancer workers in primary and secondary care in using I-Prehab to improve inclusion. We will use examples of improving access and adherence for patients receiving treatment for the most common cancers in people from deprived communities, upper GI, colorectal, breast, prostate, and lung cancers [22]. We envisage delivering a 'roadshow' in each site (n=4) where an oncology allied health professional gives a short presentation on ways to encourage patients to engage with prehab, showing video stories of patients with different sociodemographic profiles engaging in prehab during treatment, and providing access to the I-Prehab online education.

Aims
The feasibility study will evaluate the recruitment, completion, acceptability and deliverability of the education roadshow and resources. It will evaluate the impact on knowledge and confidence (self-efficacy) of cancer workers to support inclusive prehab. The study will include calculation of implementation costs to aid future economic evaluation.

Research question
Is it feasible to deliver I-Prehab at a location within a 2-month period using a roadshow, on-line education and other relevant means of implementation identified during workpackage WP3?

Objectives
Obs 4.1. Evaluate recruitment to and completion of I-Prehab training
Obs 4.2. Assess acceptability and deliverability of I-Prehab
Obs 4.3. Complete economic evaluation of I-Prehab training for the cancer workforce

Inclusion criteria
Cancer workers. This may include those with specialised training in oncology, non-specialists and support workers, e.g oncology therapists, practice nurses, care navigators.

Sample size
Based on the primary outcome of feasibility (recruitment to and completion of I-Prehab education), a sample size of n=120, 30 cancer workers per site, is required. We have selected diverse sites, three in Wales and one in England, to explore deliverability in different socioeconomic and geographical contexts. We seek to learn about engagement with I-Prehab by staff, with a sample of 30 staff members per site enabling an estimate of the proportion of staff made aware of I-Prehab who engage in training and then go on to practice components of I-Prehab. We will evaluate feasibility using the parameters and progression criteria set out in Table 1. A Traffic light system will be used as progression criteria where RED indicates stop (not feasible), AMBER requires review (explore methods of increasing recruitment), or GREEN indicates go (feasible) (Table 1.) [73].

We will also seek preliminary evidence of a change in the knowledge and confidence (self-efficacy) of staff in supporting I-Prehab in different contexts. A review of existing pilot and feasibility studies found a median sample size of 30-36 [74]. Thus, we aim to recruit 30 participants per site to explore change in staff knowledge and confidence in practising I-Prehab at each site following I-Prehab education.

Methods

We will work with representatives at four geographically dispersed locations, AHP Cymru, to recruit 30 cancer workers per site who will be offered I-Prehab education. Following this recruitment, we will also count the number of participants who attend the Roadshow and those who complete the on-line education. We will calculate the completion and dropout rates

To assess the deliverability of the roadshows, a member of the research team will observe the roadshows to assess fidelity: how closely the training is delivered according to the planned protocol.

We will also analyse the representativeness and reach of I-Prehab delivery by describing the demographics (Age, sex, ethnicity) of cancer care workers who commence I-Prehab education, as well as professional backgrounds, geographic work location, and how they heard about I-Prehab education.

Health Education and Improvement Wales (HEIW), who will host the I-Prehab education package, have a standard evaluation that they use for all of their education delivery. The HEIW evaluation includes questions on change in knowledge, impact on practice, learning quality and suggested improvements (Table 13.1)

Table 13.1. Health Education and Improvement Wales (HEIW) evaluation

Area	Questions	
Knowledge change	Please rate your overall knowledge of the topic **before** you completed this learning (0 no knowledge to 10 expert knowledge) Having completed the learning on the topic, what is your overall knowledge **now**? (0 no knowledge to 10 expert knowledge)	
Impact on practice	What extent will this learning impact upon your practice? • Significant impact • Moderate impact • Slight impact • No impact	
	Please describe how this learning will change/alter your practice *Free text comments*	
Learning quality	How would you rate the quality of the **content** of this learning?	0 (poor) to 10 (excellent)
	How would you rate the quality of the **delivery** of this learning?	0 (poor) to 10 (excellent)
	How would you rate the quality of the **resources** in this learning?	0 (poor) to 10 (excellent)
	How would you rate the **overall quality** of this learning?	0 (poor) to 10 (excellent)
Suggested improvements	How would you suggest that the learning is improved? *Free text comments*	
Access	Did you experience any access, equality or diversity issues whilst completing this learning? Yes/No. If yes, please explain what these were. *Free text comments*	

Other CPD topics that would be useful	Are there any additional CPD topics that you would like HEIW to offer? *Free text comments*
Delivery mode (Online, Face to face)	Which of the following best describes how this learning was delivered? • Online • Face to face

Secondary outcome measures will be assessed using a pre-test/post-test design to measure self-efficacy [75]. We will administer a questionnaire prior to and immediately post education in I-Prehab (roadshow and online), and again 6 weeks later. The questionnaire will include the self-efficacy questionnaire (SE-12, see Appendix 3.) a valid and reliable measure of the clinical communication skills of health care professionals [76]. This includes 17 questions scored 1=very uncertain to 10= very certain and an open text box for additional comments.

Self-efficacy with respect to the provision of inclusive prehab, will be assessed with an additional bespoke questionnaire developed and scored on a Likert scale similar to the SE-12. Perceived knowledge and understanding of inclusive prehabilitation will be assessed with a bespoke questionnaire. Participants will rate their level of agreement with each statement using a 6-point Likert scale, ranging from 1 'Strongly Agree' to 6 'Strongly Disagree.'

Evaluation case studies

To further evaluate barriers to and facilitators of implementation of I-Prehab and acceptability, observations with a purposive sample of cancer workers who have completed I-Prehab will take place through 6 case studies at each site (total n=24). This will include interviews with cancer workers to help us understand the acceptability of the education and impact on interactions with patients. Informed consent from cancer workers will be sought prior to observations and/or interviews. The interviews will include an invitation to 'reflect on' the I-Prehab resources. We will study cancer worker accounts of support for physical activity, optimisation of nutritional intake and self-management of stress and distress. In this way, we will evaluate acceptability, and cancer worker perception of the impact of I-Prehab education on patient experience and adherence.

We will also interview 24 patients to understand their experiences of I-Prehab trained cancer workers (6 at each site including interactions with patients from socially deprived, ethnic minority communities and affluent communities). Potential patient participants will be referred to the research project by their local cancer workers and informed consent will be taken by the researcher. Methods will be the same as for WP2, written consent (wet ink on hard copy or agreement to statements and typed signature on an electronic form) or audio-recorded consent. Patients will be invited to attend an interview of up to one hour duration at a time and in a place convenient to them.

Patients will be eligible for participation if they are adults (18 years or older) with a diagnosis of lung, colorectal, upper GI, prostate, or breast cancer, experience of I-Prehab, scheduled to receive active or palliative cancer treatment, not at end of life, and willing to participate (any language with support of in interpreter/family interpreter).

Analysis

Descriptive statistics will be used to analyse recruitment, completion and the questionnaire data using SPSS. Feasibility parameters will be used to assess the success of the I-Prehab education study (see Table 13.2). Field notes of observation and near verbatim comment will be written up into word files and all audio recordings of interviews will be transcribed verbatim by a professional transcription company. Computer software, NVIVO, will be used to assist the management of qualitative data.

An embedded process evaluation will be analysis informed by Normalisation Process Theory (NPT)[78] to identify and understand key elements of delivery. NPT theory proposes coherence, cognitive participation, collective action and reflective monitoring are mechanisms that shape implementation. It enables identification of factors that promote and inhibit the routine incorporation of complex interventions into everyday practice and how it works. Observations, field notes and interview data will be analyzed according to NPT components: coherence (or sense-making); cognitive participation (or engagement); collective action (work done to enable the intervention to happen); and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention). Insights, patterns in the data and interactions between concepts will be identified. Our process evaluation will help to explain any between site differences and to further refine our I-Prehab access and adherence model. It will help us to know how I-Prehab can become embedded in practice and core components necessary for optimising its uptake and impact within the UK.

Table 13.2. Feasibility parameters and criteria for progression to a definitive trial

Feasibility parameter	**Method of measurement**	**Progression criteria**			
			Feasible (green)	Review (amber)	Not feasible (red)
Objective 4.1 a) Was it feasible to recruit to I-Prehab?	1a number of staff who started I-Prehab after attending the roadshow	1a % of staff who started I-Prehab after attending the roadshow	>50%	30-50%	<30%
b) Was completion of I-Prehab feasible?	1b completion of online I-Prehab module	1b % of staff completed I-Prehab education at 6 weeks	>50%	30-50%	<30%
Objective 4.2 a) Was the Intervention acceptable to the patients and staff?	- Interviews with I-Prehab trained staff and their patients - I-Prehab staff questionnaire - Observation of I-Prehab roadshows and consults	Process evaluation. Review of key themes by the Project Team	Themes identify minor concerns	Themes identify moderate concerns	Themes identify major concerns
b) Can outcomes be delivered	Completion of online I-Prehab questionnaires?	% of questionnaires completed pre-post I-Prehab	>50%	30-50%	30-50%
c) Difference in pre/post in staff scores?	Knowledge and understanding questionnaire	% of staff showing improvement	>50%	30-50%	<30%
	Confidence (self-efficacy SE-12)	% of staff showing improvement	>50%	30-50%	<30%

If the feasibility study gives positive results we will seek funding for a multicentre Phase II trial to test the effect on patients' access to, acceptance of and adherence to cancer prehab.

Implementation costs to aid future economic evaluation

We will calculate the delivery costs of I-Prehab including developing the online module, training costs, staff costs, printing and design costs and advertising costs. We will also assess the feasibility of future health economic evaluation (cost-effectiveness analysis) by considering the availability of published

unit costs and finance records and the viability of collecting healthcare resource use and quality of life data.

14 Site and Investigator selection

This study will be carried out at nine participating sites within the UK, 8 in Wales during WP2 and 3 in Wales plus 1 in England during WP4. Each site will be required to complete a registration form to confirm that they have adequate resources and experience to conduct the study.

Before a Site can begin recruitment, a Principal Investigator must be identified. The following documents must be in place and copies sent to the I-Prehab@cardiff.ac.uk study email account:

- A letter confirming capability and capacity from the site's R&D Department, following sharing of the local information pack
- A signed Study Agreement
- Current, signed Curriculum Vitae and GCP training certificate of the Principal Investigator (PI)
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all host care organisation PI and other personnel involved
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s) on host care organisation headed paper.

Upon receipt of all the above documents, the Study Researcher will send written confirmation to the Principal Investigator detailing that the centre is now ready to recruit participants into the study. This letter/email must be filed in the site's Study Site File. Along with the written confirmation, the site will receive a study pack holding all the documents required to recruit into the Study.

15 Informed consent

The participant's written informed consent or audio-recorded informed consent must be obtained using the study Informed Consent Form (ICF). At the request of the participant the ICF and the PIS will be made available in Welsh language. Participants will be asked to consent to use of data for the purposes of the study. Consent will be taken by the I-Prehab Researchers. Verbal consent will be sought by the researcher prior to observation and written or audio-recorded consent will be obtained after the observation. Participants will be offered time to consider their decision. They will be asked by the researcher if their contact details **only** can be recorded on the study demographic data sheet to enable follow up by the research team on the person's decision to participate or not. Please note, only when fully informed consent has been obtained from the participant and they have been enrolled into the study can they be considered a study participant and additional participant demographic and other data be collected.

Taking consent using one of a range of methods will facilitate inclusion. It will increase the likelihood of equity in opportunity to participate and diversity within the recruited sample.

Written consent
Written consent will be taken using either a hard copy consent form and wet ink signature or an online tick box survey with auto date and typed signature. Electronic copies of the hard copy consent form or online survey will be stored securely in accordance with Cardiff University policy and Sponsor requirements. Participants who prefer to consent using the online survey will be asked to give an email address in addition to other contact details and the electronic survey will be sent via email. Taking retrospective consent will ensure the patient has had sufficient time to understand the nature of the study and they are aware of what type of research they are agreeing to.

In the case of written consent (wet ink on hard copy or online survey), one copy of the ICF should be given to the participant but the original copy should be kept by the researcher. Participants who sign a hard copy will be given a paper copy to keep and participants who complete an online survey will be given an electronic copy to keep. A copy should be filed in the Study Master File (SMF) held at Cardiff University. A further copy should be kept with the patient participant's hospital notes (patient participants only).

The right of the participant to refuse to participate in the study without giving reasons must be respected. Similarly, the participant must remain free to withdraw at any time without giving reasons and without prejudicing his/her further treatment.

Audio-recorded consent
If the participant prefers, they will be given the option to provide verbal consent which will be audio-recorded at a time and place convenient to the participant and the researcher that is after the observation and precedes the interview. In these situations, the researcher will read through each consent statement on the approved ICF and the participant will be given time to consider each statement. Participants will be asked to provide their name at the start of the recording and will be given the option to either say 'I consent' or 'I do not consent' in response to each statement. The person taking consent will also confirm their name and details at the start of the recording. If a participant indicates that they do not consent to any non-optional statement on the ICF, then it will be assumed that they do not consent to taking part, observational data will be destroyed and the interview will not go ahead. Audio-recording method using an encrypted device, storage, and access will be the same as for the research interview data. An audio file containing the recording of the consent process will be provided to the participant and will be retained securely at Cardiff University for a period of 15 years following the end of the study.

16 Withdrawal & lost to follow-up

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The care of patient participants, or the person a carer participant cares for, will not be affected at any time by the participant declining to participate or withdrawing from the study.
The withdrawal of participant consent shall not affect the study activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on the informed consent given before its withdrawal.

17 Protocol/GCP non-compliance

The Principal Investigators should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice (GCP) to the CI as soon as they become aware of it. Non-compliances will be managed and reported to Sponsor, REC and participating sites by the I-Prehab researcher coordinator.

18 End of Study definition

The end of the study is defined as the date of final report submission to the funder.

19 Archiving

The SMF and SSF containing essential documents will be archived at an approved external storage facility for a minimum of 15 years on behalf of the Sponsor. The Principal Investigator is responsible for archival of the Investigator Site File (ISF) at site on approval from Sponsor. Essential documents pertaining to the study shall not be destroyed without permission from the Sponsor.

20 Regulatory Considerations

20.1 Ethical and governance approval

For project progression, a work package set out in this protocol will have a favourable opinion from an NHS Research Ethics Committee (REC) that is legally "recognised" by the United Kingdom Ethics Committee Authority for review and approval.

This study protocol will be submitted through the relevant permission system for global governance review Health Care Research Wales (HCRW).

Confirmation of capability and capacity to support the study work package will be obtained from the host care organisation who will consider local governance requirements and site feasibility. The Research Governance approval of the host care organisation must be obtained before recruitment of participants within that host care organisation.

Cancer is a sensitive topic of conversation, particularly for some communities. Similarly, health inequity can evoke strong emotions. Our team has track record in conducting and delivering projects about sensitive topics and in underserved groups of cancer patients and vulnerable people. Our intention is that no harm should result from participation in the research and we intend to respect the dignity, integrity, and personhood of the participants. To achieve this a person-centred approach will be interwoven throughout and we will adopt a process approach to consent. Formal applications for ethical approval will be submitted to the relevant Research Ethics Committee, to ensure our work conforms with the World Medical Association Declaration of Helsinki and the Guidelines for Good Clinical Practice.

20.2 Data Protection

The research team will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner at Cardiff University. The data controller for this study is the Sponsor, Cardiff University. The data processors are the School of Healthcare Sciences and the participating sites.

20.3 Study sponsorship

Cardiff University will act as Sponsor for study.

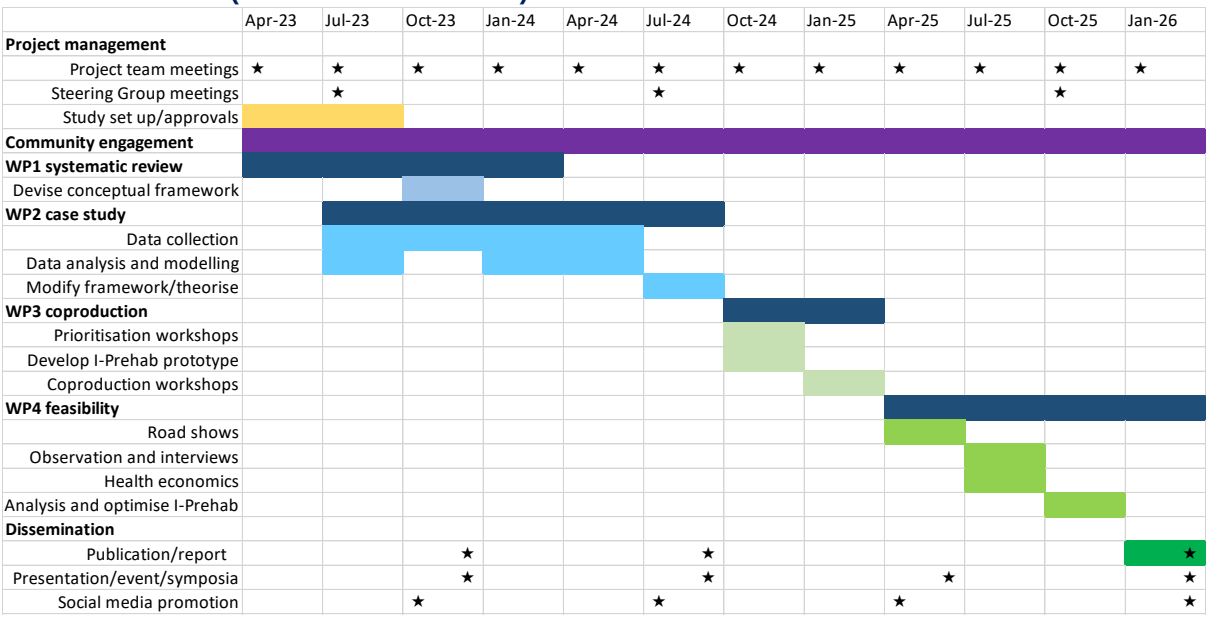
20.4 Funding

This study is funded by the NIHR Health and Social Care Delivery Research Programme (HSDR NIHR161558). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

21 Study management

The Sponsor has delegated the management of the study to the School of Healthcare Sciences.
The National Institute for Health Research (NIHR), Cancer and Nutrition Collaborative, Living With and Beyond Cancer subgroup is in support of the project and will offer guidance on project delivery, and dissemination. This group includes consultant dietitians, medical consultants, scientists and members of the public affected by cancer.

21.1 Timeline **(see Gantt Chart below)**



21.2 SSG (Study Steering Group)

The SSG will be chaired by Dr Stephen Wootton, Deputy Chair, NIHR Cancer and Nutrition Collaboration. The CI and SSG members will be required to work together within agreed Terms of Reference compliant with NIHR expectations. The SSG will meet at least three times across the course of the project. The SSG will be responsible for reviewing study progress against project milestones compliance oversight, and resolution of unexpected challenges.

21.3 PMG (Project Management Group)

The PMG is responsible for day-to-day management of the study and chaired by the CI. All co applicants and contract researchers will be members of the PMG meeting monthly. The core team, CI, administrator and researchers will meet weekly to review a detailed workplan and progression.

22 Quality Control and Assurance

Local PIs will be made aware of possible monitoring activity by Health and Care Research Wales (HCRW), NHS REC, or the Sponsor, Cardiff University, including audits and regulatory inspections, when they may be required to provide direct access to source data/documents. Participant consent for this will be obtained.

Findings generated from monitoring, audit or inspection activities will be shared with the Sponsor, CI, PI & local R&D.

23 Publication and dissemination

All publications and presentations relating to the study will be authorised by the SMG. A Publication Plan is included within the overall project plan and milestones document.

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25 Appendices

25.1 Appendix 1: Generalised, exercise and nutrition self-efficacy scales

GENERALIZED SELF-EFFICACY SCALE

GL assessment
the measure of potential

Name:.....

Date:..... **Record Number:**.....

	Not at all true	Barely true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in a bind, I can usually think of something to do.	1	2	3	4
10. No matter what comes my way, I'm usually able to handle it.	1	2	3	4

Nutrition Self-Efficacy and Physical Exercise Self-Efficacy Scale Description:
Response format is (1) very uncertain, (2) rather uncertain, (3) rather certain, and (4) very certain.

Table 1 *The Nutrition Self-Efficacy Scale*

"How certain are you that you could overcome the following barriers?"

I can manage to stick to healthful foods, ...

Item	
1	...even if I need a long time to develop the necessary routines.
2	...even if I have to try several times until it works.
3	...even if I have to rethink my entire way of nutrition.
4	...even if I do not receive a great deal of support from others when making my first attempts.
5	...even if I have to make a detailed plan.

Table 2 *The Physical Exercise Self-Efficacy Scale*

"How certain are you that you could overcome the following barriers?"

I can manage to carry out my exercise intentions, ...

Item	
1	...even when I have worries and problems.
2	...even if I feel depressed.
3	...even when I feel tense.
4	...even when I am tired.
5	...even when I am busy.

Schwartz R, Renna B. Health Specific Self-Efficacy Scales. Available at: http://userpage.fu-berlin.de/~health/healself.pdf Accessed 23.3.2023

25.2 Appendix 2: HADS

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

25.3 Appendix 3 – Self efficacy (SE-12)

Communication with the patient

The following questions concern selected communication skills regarding the conversation with the patient. Please answer every question, and only use the 'not relevant' box if the question asked does not apply to you in your daily work.

On a scale from 1-10, 1 = very uncertain 10 = very certain:

1	**How certain are you that you are able to successfully identify the issues the patient wishes to address during the conversation?**										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐
2	**How certain are you that you are able to successfully make an agenda/plan for the conversation with the patient?**										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐
3	**How certain are you that you are able to successfully urge the patient to expand on his or her problems/worries?**										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐
4	**How certain are you that you are able to successfully listen attentively without interrupting or changing of focus?**										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐
5	**How certain are you that you are able to successfully encourage the patient to express thoughts and feelings?**										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

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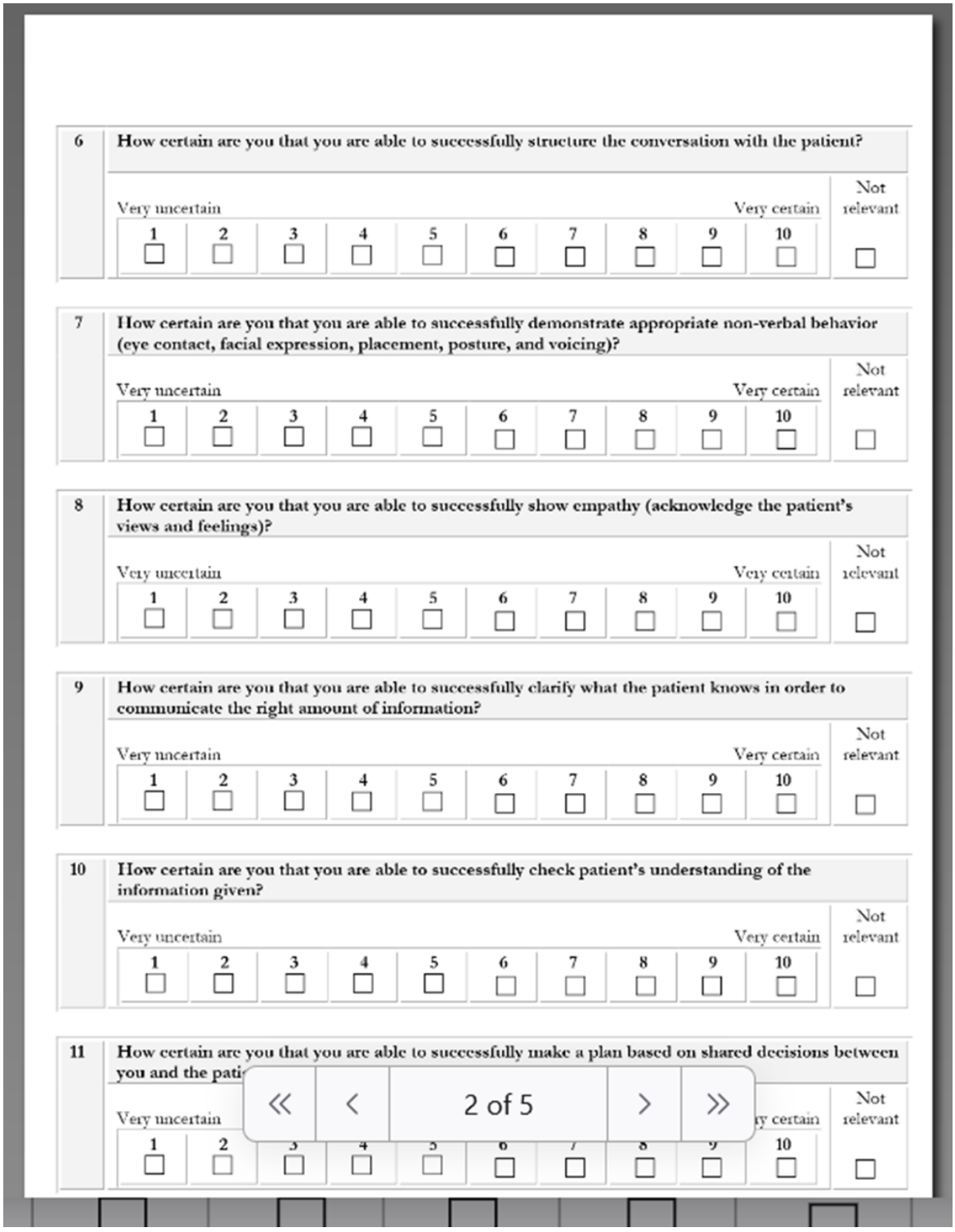

6 How certain are you that you are able to successfully structure the conversation with the patient?

Very uncertain									Very certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

7 How certain are you that you are able to successfully demonstrate appropriate non-verbal behavior (eye contact, facial expression, placement, posture, and voicing)?

Very uncertain									Very certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

8 How certain are you that you are able to successfully show empathy (acknowledge the patient's views and feelings)?

Very uncertain									Very certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

9 How certain are you that you are able to successfully clarify what the patient knows in order to communicate the right amount of information?

Very uncertain									Very certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

10 How certain are you that you are able to successfully check patient's understanding of the information given?

Very uncertain									Very certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

11 How certain are you that you are able to successfully make a plan based on shared decisions between you and the pati

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Very uncertain									ry certain	Not relevant
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

12	How certain are you that you are able to successfully close the conversation by assuring, that the patient's questions have been answered?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

In your daily work with patients/relatives

The next five questions concern specific conversation situations with patients/relatives. Please answer every question, and only use the 'not relevant' box if the question asked does not apply to you in your daily work.

13	How certain are you that you are able to successfully cope with emotional patients/relatives?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

14	How certain are you that you are able to successfully handle angry patients/relatives?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

15	How certain are you that you are able to successfully communicate difficult news to patients/relatives?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

16	How certain are you that you are able to successfully manage your time with patients/relatives?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

17	How certain are you that you are able to successfully involve the patients/relatives in the decisions being made?										
	Very uncertain									Very certain	Not relevant
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐	7 ☐	8 ☐	9 ☐	10 ☐	☐

If you have anything to add, or wish to elaborate any of your answers, please list below:

_____

_____

_____

_____

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Thank you for completing the questionnaire!