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Development of a Core Screening, Assessment and Outcome Set for Cancer Prehabilitation: An International Delphi Consensus Study Protocol

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Strengths and limitations

- This study addresses screening and assessment in addition to outcomes, offering a comprehensive standardisation framework applicable across all cancer types and treatments.
- This protocol adheres to established methodological standards and is prospectively registered on the COMET database, in alignment with best practice in core outcome set development.
- The study intends to internationally recruit diverse groups of healthcare professionals, researchers, policy makers and patient representatives.
- Patient and public involvement is embedded throughout the study design and conduct via patient research partners.
- Patient recruitment is primarily UK-based due to ethical and logistical constraints, which may limit the international representativeness of patient perspectives and should be considered when interpreting the final core set.

ABSTRACT

Introduction

A core screening, assessment and outcome set is needed in cancer prehabilitation to standardise what is measured in both research and services. Currently, there is significant variation in measures used, which limits comparability between studies and evidence synthesis. Standardising measures will improve the quality, comparability and impact of research by reducing heterogeneity between studies, minimising reporting bias, improving trial efficiency, enabling data synthesis into large datasets, supporting international collaboration and data sharing, and accelerating the implementation of best practices.

Methods and Analysis

An international Delphi consensus process will be conducted involving patients, healthcare professionals, and researchers to identify screening, assessment and outcomes, and their corresponding measurement instruments, to be included in a core set. The study consists of three phases: (1) A scoping review to identify screening, assessment and outcomes and associated measurement instruments currently used in cancer prehabilitation. (2) At least two-rounds of a modified Delphi survey to prioritise the identified screening, assessment and outcomes using a 1 to 9 Likert scale. Consensus will be defined across stakeholder groups using pre-specified thresholds. A consensus meeting will be held if agreement is not reached. (3) Measurement instruments corresponding to each retained screening, assessment and outcome will be assessed for quality for measurement properties and feasibility. Further Delphi

rounds will be conducted to reach consensus on the most appropriate measurement instrument for each core screening, assessment and outcomes.

Ethics and Dissemination

The study has ethical approval (Ref: 25/NW/0159). Findings will be disseminated through peer-reviewed publications, conference presentations, stakeholder networks, and made publicly available via the COMET database.

INTRODUCTION

Background

Cancer is one of the leading causes of morbidity and mortality worldwide, and the number of new cases is expected to double by 2070 due to ageing populations and advances in early detection and treatment.[1,2] As demand for cancer treatment rises, there is growing interest in cancer prehabilitation as a strategy to improve outcomes across the cancer care continuum.[3,4]

Cancer prehabilitation is delivered between cancer diagnosis and treatment and aims to optimise patients' physical and psychological function, nutritional status, enhance resilience to treatment, and support long-term health.[3,5] Prehabilitation has demonstrated effectiveness across a range of cancers, disease stages and treatments,[6–17] and may reduce healthcare burden by shortening hospital stays and reducing readmission rates.[18–20]

There is strong support amongst international stakeholders that prehabilitation is a valuable component of cancer care.[3,21] However, uncertainties exist in the evidence base, partly due to heterogeneity in service design and outcome reporting.[22–25] Without standardisation, it is difficult to synthesise evidence, compare programmes, or identify which components of prehabilitation deliver the greatest benefit.[25,26] This can slow the transition into best practice and policy uptake.[27]

The development of standardised measures can promote consistency across trials and services, improve research quality, reduce patient burden, and strengthen the evidence base.[28] To date, core outcome sets relevant to cancer prehabilitation have been limited, largely confined to specific cancers and treatments.[29,30] Furthermore, no attempt at standardisation addresses screening or assessment essential for identifying patient needs, tailoring interventions, or monitoring intervention effects.

The study aims to develop a core screening, assessment and outcome set for cancer prehabilitation that is applicable across all cancer types and treatments. The study objectives are:

- Conduct a scoping review to identify screening, assessment and outcomes as well as their associated measurement instruments currently used in cancer prehabilitation.
- Conduct a Delphi consensus process to prioritise the identified screening, assessment and outcomes and reach agreement on a core set.
- Conduct further Delphi rounds to agree on the most appropriate measurement instrument for each core screening, assessment and outcome.

Scope

The COS will apply to:

1. Patients: ≥18 years old with any type of cancer receiving treatment with curative intent.
2. Interventions: A unimodal intervention consisting of exercise, nutrition or cognitive/psychological training, or a multi-modal intervention that combines exercise, nutrition, or cognitive/psychological training with or without other interventions, which is undertaken for at least seven days prior to treatment to optimise a patient's pre-treatment condition and improve post-treatment outcomes.[31]
3. Setting: the core screening, assessment and outcome set is intended for use in research and services to evaluate the prehabilitation effects at an individual or programme level.
4. Timing: prehabilitation interventions delivered prior to any form of anti-cancer treatment. The periods during treatment and post-treatment (rehabilitation) are outside the scope of this core screening, assessment and outcome set.

Definitions

This study defines the following terms in alignment with guidance from The Principles and Guidance for Prehabilitation within the Management and Support of People with Cancer [32] and Core Outcome Measures in Effectiveness trials (COMET) Initiative.[28]

- Screening is the initial identification of people with cancer who may benefit from prehabilitation and determine the need for more detailed assessment.
- Assessment is the systematic and objective determination of an individual's prehabilitation needs across exercise, nutrition and psychological wellbeing, supporting the tailoring of interventions and allowing repeated assessments to monitor effectiveness over time.
- Outcome is a specific aspect of health or wellbeing that is measured or observed to capture the effect of interventions or the state of a health condition.

METHODS

This study protocol adheres to the 13-item Core Outcome Set-STAndardised Protocol (COS-STAP) statement,[33] and the Core Outcome Set-STAndards for Development (COS-STAD) recommendations.[34] The study has been prospectively registered on the COMET database (https://www.comet-initiative.org/Studies/Details/3098).[28]

Patient and public involvement

Patient research partners, recruited through Yorkshire Cancer Research (UK), are members of the study steering committee and were involved in the design and conduct

of the study. Their contributions include supporting patient recruitment and retention, advising on patient-facing study materials, and ensuring that the patient needs and priorities are reflected throughout the consensus process.

In addition, a wider group of patients will be recruited to participate directly in the Delphi consensus process. Following completion of the study, a lay summary of the findings will be made available and shared with patient participants.

Stakeholders

The project steering committee comprises the National Cancer Prehabilitation Collaborative, a multidisciplinary group of healthcare professionals and clinical researchers from nine institutions across the UK, alongside international collaborators from Australia, Canada and the Netherlands. Key partners include the Global (P)rehabilitation Initiative, and the Dutch Fit4Surgery Foundation.

Steering committee members are internationally recognised for their leadership in cancer prehabilitation research and implementation and maintain active engagement with global stakeholders. This network will support diverse and inclusive participation in the Delphi process, which is fundamental for the validity, credibility and potential uptake of the final core set.

In addition to the steering committee, a wider group healthcare professionals and researchers will be recruited to participate in the Delphi process.

Information sources

A scoping review was conducted to identify candidate screening, assessment and outcome measures used in cancer prehabilitation studies to inform the Round 1 Delphi survey for this core set. The review followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews (PRISMA-ScR) guidelines[35] and was prospectively registered on the Open Science Framework.[36]

Searches were performed in PubMed, PsychINFO, Web of Science, and CINAHL using a librarian-assisted strategy developed in accordance with the Peer Review of Electronic Search Strategy guidelines.[37] Terms included combinations of (cancer or oncol*) AND (prehab* OR pre-hab* OR prerehab* OR pre-rehab*) AND ((preop* OR pre-op* or pretreatment OR pre-treatment) W3 (exercise OR physical OR training OR psycho* OR nutrition* OR trimodal OR tri-modal OR multimodal OR multi-modal)) in title or abstract fields. The full search strategy is provided in supplementary materials.

Eligible studies included:

- Population (P): Adult patients (≥18 years old) with cancer (any types) who participate in prehabilitation prior to cancer treatment (surgical and non-surgical) with curative intent.

- Concept (C): Screening, assessment and outcomes reported in cancer prehabilitation. This includes measures used to identify patients who may benefit from prehabilitation (screening), evaluate baseline needs and progress (assessment), and determine the effects of prehabilitation (outcomes).
- Context (C): Prehabilitation interventions delivered prior to cancer treatment (surgical or non-surgical), which may be unimodal (exercise, nutrition, or psychological/cognitive training) or multimodal (combining two or more of these components), undertaken for at least seven days prior to treatment to optimise pre-treatment condition and improve post-treatment outcomes.[38]

Randomised controlled trials, non-randomised intervention studies, service evaluations and service delivery reports were included with no date restrictions.

The exclusion criteria were:

- Narrative reviews, editorials, systematic reviews, meta-analyses, scoping reviews, pooled or secondary analyses, study protocols, conference papers, and consensus guidelines.
- Qualitative-only studies.
- Literature published in a language other than English.
- Interventions involving only pharmacological management.

Covidence (www.covidence.org) was used to manage the scoping review. Two independent reviewers screened all titles and abstracts for inclusion. Literature that met the eligibility criteria then underwent full-text review. Extracted data included screening, assessment and outcome variables, measurement instruments, and time points were summarised descriptively using a pre-design data charting form (Excel, Microsoft 2010, Redmond WA) developed by the research team. Outcomes were categorised according to the conceptual framework of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) as biomarkers, patient-reported, clinician-reported, observer-reported, and performance outcomes.[39] A comprehensive list of measures was generated and reviewed by the steering committee independently and during a workshop. Overlapping or duplicate measures were combined or refined through discussion, and the final list of candidate measures was agreed for Delphi inclusion. Full screening, assessment and outcomes, measurement instruments and lay descriptions are provided in the Supplementary Materials.

Consensus process

The consensus process will be conducted in two stages, as illustrated in Figure 1:

- Stage 1: Establishing consensus on which screening, assessment, and outcome should be included in the core set.

- Stage 2: Establishing consensus on a measurement instrument for each core screening, assessment and outcome.

A modified Delphi process similar to previous studies will be used, involving three separate stakeholder groups:[40,41]

- Patients who are receiving or have received cancer treatment with curative intent following prehabilitation.
- Healthcare professionals actively involved in the cancer prehabilitation pathway.
- Researchers involved in the design, implementation, and analysis of cancer prehabilitation interventions.

[**Figure 1:** Flow diagram of the consensus process.]

A pragmatic, multi-channel recruitment strategy will be employed, recognising that no agreement exists on the optimal sample size for core outcome set development.[28] The aim is to achieve broad representation across cancer types, clinical specialities and international settings (Table 1). The study aims to recruit a minimum of 50 participants per stakeholder group. This is consistent with sample sizes in previous core outcome set development studies and is sufficient for sensitivity analysis.[42,43]

For healthcare professionals and researchers, the primary recruitment target is to achieve proportional representation across countries. This is based on findings from the scoping review and a recently published bibliometric analysis, which identified the UK, USA, Canada, Australia and the Netherlands as the most research-active countries.[44] Targets will also aim to include a broad range of cancer types and clinical specialities.

Primary recruitment of patients will take place within the UK across three sites due to ethical and logistical constraints associated with international recruitment. Recruitment will aim for equal representation by sex and broad inclusion of cancer types, and efforts will be made to include diversity in age, ethnicity, and socioeconomic background. While primary patient recruitment is UK-based, international patients with experience of cancer prehabilitation may also participate, provided their involvement complies with existing ethical approvals. This approach limits the international representativeness of patient perspectives, and findings will be interpreted with this consideration in mind.

Table 1: Recruitment and representation targets for the Delphi process.

Stakeholder group	Recruitment target
Healthcare professionals and researchers	• Top 5 countries (75%): UK, Canada, Netherlands, USA, Australia. • Other countries (15%): including Spain, France, Germany, Italy, Denmark, Sweden, China, Japan, Switzerland, Ireland, Belgium and Poland. • Cancer specialities: Colorectal, lung, oesophageal and esophagogastric junction, gastric, prostate, breast and bladder. • Treatment specialities: Surgery, chemotherapy and radiotherapy. • Clinical specialities: Physicians, anaesthetists, surgeons, nurses, occupational therapists, physiotherapists, exercise specialists, dietitians and psychologists.
Patients	• Sex: Women (50%) and men (50%). • Cancer types: Colorectal, lung and Upper GI. • Treatment types: Surgery, chemotherapy and radiotherapy.

Participants will be recruited through the following channels:

- Steering committee members will distribute invitations through their clinical, academic and patient networks.
- Authors of published cancer prehabilitation studies identified via the scoping review will be invited.
- Attendees of the 2023 cancer prehabilitation symposium held at the Advanced Wellbeing Research Centre (Sheffield Hallam University, UK) will be invited.[27]
- Members of professional networks including, iPOETTS (the International Prehabilitation and Perioperative Exercise Testing and Training Society), EBPOM (Evidence-based Perioperative Medicine), the Global (P)rehabilitation Initiative, and the Dutch Fit4Surgery Foundation will be invited to participate.
- Delegates of the World Congress of Prehabilitation and Perioperative Medicine (2024 Melbourne, Australia and 2025 Vancouver, Canada) will be invited.
- Patients who have accessed prehabilitation services in Sheffield (Active Together), Manchester (Prehab 4 Cancer) and Southampton (Southampton Perioperative Medicine and Prehabilitation Service) will be invited to participate.

A snowball sampling approach will be employed, with all participants encouraged to share the invitation within their professional and patient networks to broaden reach and representation. Stakeholders will first be asked to register their interest in participating, enabling the collection of demographic data to support monitoring of diversity and

guide targeted recruitment. It also ensures all participants begin the Delphi process at the same time. Demographic variables are listed in the Supplementary Materials.

Stage 1: What to measure

The Delphi survey will be written in English and primarily administered electronically using an online platform (Qualtrics, Utah, USA, 2025). To minimise patient exclusion, alternative methods, such as paper copies or researcher-assisted completion, will be offered to patients who are recruited from the three UK sites. Due to practical constraints, the same level of support cannot be provided for patients participating from outside the UK sites, and the survey will not be available in languages other than English.

Participants will complete a minimum of two Delphi rounds. In each round, participants will rate the importance of each measure using a 9-point Likert scale, consistent with the GRADE approach (Table 2).[28]

Table 2: Scoring criteria for screening, assessment, and outcome importance based on the GRADE approach.

Rating	Descriptor
1 to 3	Not important
4 to 6	Important but not critical
7 to 9	Critically important

In Round 1, participants may suggest additional screening, assessment and outcomes. The steering committee will review any items proposed by two or more participants. If the suggestion is deemed relevant by the steering committee and within the scope of the core set, it will be included in Round 2.[28] Round 1 will remain open for a minimum of two weeks. Participants who complete Round 1 will be invited to Round 2, which will commence approximately two weeks after Round 1 closes.

The aim of Round 2 is to refine and prioritise screening, assessment and outcomes considered critically important. In line with best practice, participants will receive structured feedback from Round 1.[28] This will include a summary of the score distribution showing the proportion of participants rating each measure as not at all important (1–3), important but not critical (4–6), and critically important (7–9) for each stakeholder group, accompanied by histograms and the participants previous round score. This feedback will be embedded within the Round 2 survey and presented alongside each measure to support reflection and re-rating, and convergence toward consensus.

Attrition between rounds will be monitored. If retention falls below 70%, the Delphi process will be terminated due to concerns regarding methodological rigour. Strategies to minimise attrition include extending the survey window, avoiding holiday periods, recruiting known experts, sending personalised reminders with progress updates, and listing participants as collaborative authors in future publications. Attrition bias will be assessed by comparing average ratings between participants who complete only Round 1 and those who complete both rounds, stratified by stakeholder group.[45]

For items that do not reach consensus, the committee will consider whether a third Delphi round is warranted, based on stakeholder-specific feedback. If a third round is conducted, the list of measures within the survey will be refined and only screening, assessment and outcomes rated critically important (7 to 9) by 60% or more participants within each stakeholder group will be retained. All other items will be omitted from the Delphi process. This 60% threshold is distinct from the predefined consensus criterion (≥70% rating 7–9) used to determine final inclusion in the core set and is applied solely to streamline subsequent rounds by focusing on measures with broad perceived relevance across groups, while reducing participant burden.[46]

If clear consensus is not achieved following the predefined Delphi rounds, a consensus meeting will be held online. (Microsoft teams, version 25212.2204.3869.2204) at the discretion of the steering committee to support progression of the consensus process. In the absence of standardised guidance on consensus meeting conduct, procedures will be agreed a priori by the steering committee.[28]

A purposive sample of at least 10% of participants from each stakeholder group who complete all Delphi rounds and express interest in attending will be randomly selected to participate. Anonymised Delphi results will be presented to facilitate structured discussion. Following discussion, anonymous structured voting will be undertaken. A domain will be included in the final core set if ≥70% of meeting participants vote in favour. The final core screening, assessment and outcome set will inform Stage 2, which will focus on the selection and evaluation of appropriate measurement tools for these core domains.

Stage 2 – How to measure

Following the agreement of the core screening, assessment and outcome set, the process of determining a measurement instrument for each core item will follow the methodology outlined in the COSMIN/COMET guidelines.[47,48] First, measurement instruments identified through the scoping review are mapped to the core measures reaching consensus in Stage 1 and reviewed by the steering committee.

Measurement instruments will be evaluated for both measurement properties and feasibility aspects. Key measurement properties will be assessed, including content validity (as a minimum requirement) and internal consistency, where applicable.[49]

Feasibility considerations will include respondent burden, time required for completion, required equipment or training, licensing costs, and suitability for use across research and clinical service settings. Evidence relating to measurement properties feasibility will be presented to participants as summary instrument cards within the Delphi survey and considered concurrently during the prioritisation process.

If clear consensus on a suitable measurement instrument is not achieved through the Delphi rounds, a consensus meeting may be convened to support decision-making. The meeting will present anonymised Delphi results along with measurement properties and feasibility information to facilitate structured discussion. This will be followed by anonymous structured voting. A measurement instrument will be selected if ≥70% of meeting participants vote in favour for inclusion.

Based on the Delphi findings and, where required, consensus meeting outcomes, the steering committee will attach a measurement instrument to each core screening, assessment and outcome where sufficient evidence and stakeholder agreement exist. Where no suitable instrument is identified, the committee will highlight evidence gaps and recommend further research.

Consensus definition

Consensus criteria will be applied consistently to determine whether screening, assessment and outcomes, and their measurement instruments should be included in or excluded from the core set (Table 3).

Table 3: Consensus classification for screening, assessment and outcome domains and measurement instruments.

Consensus classification	Description	Definition
Consensus in	Agreement that the measure/instrument should be included in the core set.	≥70% of participants rate the measure 7–9 (critically important), and <15% rate it 1–3 (not important).
Consensus out	Agreement that the measure/instrument should not be included in the core set.	≥70% of participants rate the measure 1–3 (not important), and <15% rate it 7–9 (critically important).
No consensus	Uncertainty regarding the importance of the measure/instrument.	Any other distribution of ratings.
Recommended inclusion[†]	Strong support for a measurement instrument,	≥60% of participants rate the measure 7–9 (critically

	where consensus in was not reached.	important), and <15% rate it 1–3 (not important).

[†] Applied only to measurement instruments in Stage Two.

Consensus thresholds will be applied to each stakeholder group separately. This per-group approach ensures that the views of patients, healthcare professionals, and researchers are considered independently and equitably, acknowledging the potential for differing perspectives on measure priorities.[28] A measure will only be classified as 'consensus in' or 'consensus out' if the threshold is met within each stakeholder group. Measures that meet the criteria in only one or two groups will be classified as 'no consensus' and considered further by the steering committee and, if necessary, at the consensus meeting.

Where no measurement instrument achieves consensus in, the threshold for recommended inclusion may be applied.[40] Instruments meeting this criterion will be reviewed by the steering committee and may be considered for inclusion where strong support exists and supporting evidence indicates feasibility and measurement quality.

ANALYSIS

All Delphi response data will be analysed in SPSS (version 29, IBM Corp., Armonk, NY, USA). For each measure in each round, the proportion of participants rating the measure as not important (1 to 3), important but not critical (4 to 6), or critically important (7 to 9) will be calculated, stratified by stakeholder group.

Partial responses within a round will be included in the analysis for the measures completed. However, participants must rate at least 80% of measures in a given round to be included in the overall analysis of that round.

DISSEMINATION

Findings from this study will be disseminated through multiple channels to maximise reach. The scoping review will be published in a peer-review journal. The final core screening, assessment and outcome set will be published in a peer-reviewed journal, via the study website (https://www.shu.ac.uk/advanced-wellbeing-research-centre/projects/defining-key-outcomes-in-cancer-prehabilitation) and presented at relevant scientific conferences. It will also be shared through the steering committees' professional networks and social media platforms to reach a broad international audience.

To support early adoption of the core screening, assessment and outcome set in future research, the research team will contact key funders of cancer prehabilitation trials and principal investigators of planned and ongoing studies identified through prospective

registries (e.g. ClinicalTrials.gov). Researchers will be informed about the core screening, assessment and outcome set and encouraged to incorporate it into upcoming studies.

Finally, the research team will consider contacting relevant journals to suggest an editorial or commentary to further highlight the importance and application of the core screening, assessment and outcome set in cancer prehabilitation research.

DECLARATIONS

Ethics approval and consent to participate

Ethical approval for this study was obtained prospectively from NHS Health Research Authority Greater Manchester South Research Ethics Committee (Ref: 25/NW/0159). All participants will be provided with a plain language summary of the study, outlining its purpose, procedures, and their rights as participants. Informed consent will be presented at the start of the first Delphi survey. Participants will be required to confirm their consent before gaining access to the survey.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

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Authors contribution

RC, AM, and LH were involved in securing funding for the study. All authors contributed to the study design. TP drafted the protocol manuscript. All authors reviewed the initial version of the manuscript and approved the final version.

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