International consensus is needed on a core outcome set to advance the evidence of best practice in cancer prehabilitation services and research

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Abstract

Prehabilitation aims to optimise patients' physical and psychological status before treatment. The types of outcomes measured to assess the impact of prehabilitation interventions vary across clinical research and service evaluation, limiting the ability to compare between studies and services and to pool data. An international workshop involving academic and clinical experts in cancer prehabilitation was convened in May 2022 at Sheffield Hallam University's Advanced Wellbeing Research Centre, England. The workshop substantiated calls for a core outcome set to advance knowledge and understanding of best practice in cancer prehabilitation and to develop national and international databases to assess outcomes at a population level.

Background

In 2020, there were an estimated 18.1 million new cancer cases globally; of those, 51% were cases in men and 49% were in women.[1] People undergoing treatment (including surgery, chemotherapy, and radiotherapy) for cancer may experience, or be at risk of, adverse effects, particularly those who are 'high-risk' (such as those who are deconditioned or experiencing frailty) or who do not possess sufficient physiological resilience to tolerate treatment well. For example, in England, approximately 45% of patients with cancer undergo surgical procedures[2] and, depending on the type of surgery, 10% to 56% of patients develop postoperative complications that delay discharge.[3] A range of factors contribute to the risk of complications including age, multiple comorbidities, frailty, poor aerobic fitness, and lifestyle factors such as physical inactivity, malnutrition, and smoking. Treatment-related complications inflate costs (longer hospital length of stay [LOS]), more medical interventions and increased readmissions), and vastly worsen patient experiences.[4] This is unsurprising given the physiological and psychological stress related to surgery[5] and the lack of physiological and psychological resilience in high-risk groups.[4] In the context of cancer care, prehabilitation is *"a process on the cancer continuum of care that occurs between the time of cancer diagnosis and the beginning of acute treatment and includes physical and psychological assessments that establish a baseline function level, identify impairments, and provide interventions that promote physical and psychological health to reduce the incidence and/or severity of future impairments"*.[6]

Over the last 5-10 years, the number of cancer prehabilitation studies and services has significantly increased. A search of the NCBI PubMed database for search terms "cancer prehabilitation" returned 17 items published in 2010 and 206 items published in 2020. Many of these studies have tested interventions aimed at modifying risk factors associated with poorer surgical outcomes in the preoperative period and, more recently, for patients undergoing non-surgical cancer treatments.[7-9]

The Macmillan Principles and Guidance for Prehabilitation within the Management and Support of People with Cancer report highlights the need to develop and consistently employ a range of

standardised screening, assessment, adherence, efficacy, experience, and outcome measures.[10] The most commonly reported outcomes in the prehabilitation literature relate to clinical (e.g., postoperative complications) and functional (e.g., aerobic capacity) endpoints.[11] However, the specific outcomes measured, the methods and tools used to capture them, and the timepoints at which they are captured vary across studies and services.[10, 12-14] Consequently, impact of prehabilitation for people with cancer is not well understood, and comparison between studies and services is limited.

Prospective RCTs of prehabilitation have been conducted, although most are small and selective, and the certainty of evidence varies across outcomes, cancer, and treatment types. Results from meta-analyses are promising with evidence that prehabilitation improves surrogate measures of fitness (e.g. functional capacity) but have shown inconsistency in patient-reported outcomes. Prehabilitation also has the potential to increase the range of treatment options available to patients who would not otherwise be suitable candidates.[6] A recent umbrella review of 55 systematic reviews of prehabilitation interventions, including nutrition, exercise, and psychological strategies, identified, with moderate certainty evidence, that prehabilitation improved functional recovery, and low certainty evidence suggested that prehabilitation supported reductions in complications, non-home discharge, and length of stay.[15] Included studies showed considerable heterogeneity in study outcomes, cautioning the strength of study findings. The prehabilitation community is yet to define the most appropriate outcomes to measure to demonstrate the impact of prehabilitation and this is perhaps a reflection of the relative infancy of the field. The outcomes also need to be relevant and important to a wide variety of stakeholders including patients and the public, health care professionals and others making commissioning/funding decisions about health care if the findings are to influence policy and practice.

The COMET (Core Outcome Measures in Effectiveness Trials) initiative supports investigators in developing and applying agreed standardised sets of outcomes, known as a “core outcome set”

(COS). COS is defined as "An agreed, standardised set of outcomes that should be measured and reported, as a minimum, in all clinical research in specific areas of health or health care".[16] A search of the COMET Initiative database for prehabilitation COS studies returned only two study protocols; one specific to intra-abdominal cancer (study ongoing)[17] and another focused on colorectal surgery (study complete - pending publication).[18] Although the results of these studies will be helpful, some measures may not be applicable to studies and services that include a broad range of cancer types and treatment options. A standard set of outcome measures that should be reported, as a minimum, across all cancer prehabilitation research studies and service delivery (including all types of cancer treatment) will enable researchers and healthcare professionals to compare and contrast different delivery models and combine datasets with a view to assessing the impact of prehabilitation interventions and services on cancer outcomes at a population level.

International cancer prehabilitation outcomes workshop

On the 27th of May 2022, an international workshop was convened at Sheffield Hallam University's Advanced Wellbeing Research Centre in Sheffield, England. The workshop invitation was distributed through the workshop organising committees prehabilitation networks. Academic and clinical experts in cancer prehabilitation attended in-person or virtually from across the United Kingdom, Australia, Canada, and Italy. The workshop explored current practice as well as future directions and opportunities for outcome data collection in prehabilitation research and service evaluation. The purpose of the workshop was to discuss and pursue consensus on a core outcome data set for prehabilitation trials and services to enhance the quality and comparability of prehabilitation studies in cancer. To inform discussion on the day, delegates were asked to provide the outcomes they are currently capturing in their research or service evaluations. This information was collated and presented back to the group on the day. Additionally, cancer prehabilitation groups from each country were invited to present current practice and research pertaining to core outcomes in prehabilitation. The day ended with a roundtable discussion about current state-of-the-art outcome

data capture in prehabilitation, current gaps and inconsistencies and next steps toward a core outcome set for prehabilitation research and service evaluation.

Summary of current outcomes being captured by prehabilitation groups attending the workshop

Ten prehabilitation groups provided information about the reporting characteristics and outcomes being captured in their research and service evaluation. Data were grouped into five domains: baseline characteristics, medical history and screening, objective (physical or physiological) measures, self-report (psychological and behavioural) measures, and medical record data (Table 1). There was inconsistency across groups in the outcomes being captured and the frequency with which they are assessed. Where there was consistency in the type of outcome being captured, the tools and tests used to capture them varied. For example, aerobic capacity was measured by all ten groups. However, one was using cardiopulmonary exercise testing (CPET), two were using the 6-minute walk test (6MWT), and seven were using both CPET and 6MWT. Where CPETs were being conducted, this was not routine across participants and depended on whether clinical teams were using it to assess suitability for surgery.

Variability in self-report measures was even more apparent, partially driven by choice between questionnaires which capture the same or very similar outcomes. For example, self-reported physical activity was assessed by eight groups using five different questionnaires (exercise vital signs, CHAMPS physical activity questionnaire, Active Lives Survey, Godin Leisure-Time Exercise Questionnaire (GLTEQ) and the International Physical Activity Questionnaire (IPAQ)). Fatigue was measured using either the Functional Assessment of Chronic Illness Therapy – Fatigue scale (FACIT-Fatigue) or the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) fatigue sub-scale, quality of life was assessed using the European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L), the EORTC QLQ-C30 or the 12-Item Short Form Survey (SF12), and anxiety and depression was measured using the Patient Health Questionnaire-9 (PHQ-9), General Anxiety Disorder-7 (GAD-7), Hospital Anxiety and Depression Scale (HADS) and the

Major Depression Inventory. Nutritional status was assessed by seven of the groups and three different tools were used (Patient-Generated Subjective Global Assessment (PG-SGA), modified PG-SGA (mPG-SGA), Malnutrition Universal Screening Tool (MUST) and Canadian Nutrition Screening Tool). Most groups were using length of stay, readmissions, and mortality, but there was inconsistency in how these outcomes were defined. For example, readmissions were classified in several ways, including being an unplanned inpatient for less than three days/more than three days, 30-day all-cause readmission, and 90-day all-cause readmission.

Table 1 around here

Key priorities

There was general consensus on the constructs that should be measured in prehabilitation research and evaluation amongst the ten prehabilitation groups who provided information. Despite alignment on the general areas of evaluation (e.g., physical and psychological health, quality of life, hospital-related outcomes), these constructs have large variability in how they are measured. The international stakeholders agreed that developing a core outcome set is a priority to advance our knowledge and understanding of best practice in cancer prehabilitation. An umbrella review of systematic reviews also emphasised the need for a core outcome set in this area to develop a robust evidence base[15] and a recent international Delphi study rated defining prehabilitation core outcome measures as a top ten research priority.[19] Achieving consistency of outcome reporting across research studies and services will require international consensus and clear guidance. A natural next step would be to develop national and international databases to compare and contrast the impact of different interventions and to assess outcomes at a population level and authors here are committed to working internationally to deliver this.

Additional priorities were highlighted during the workshop. First, the diversity of cancer prehabilitation interventions was acknowledged and the need to clearly describe the intervention in line with accepted frameworks (e.g. the Template for Intervention Description and Replication checklist (TIDieR)[20] and the Consensus on Exercise Reporting Template (CERT)[21]) was emphasised. Second, once consensus is reached on *what* core prehabilitation outcomes to measure, additional work is needed to clearly define those measures and *how* and *when* to utilise them. Third, the need to utilise and adopt new information technology systems to link routinely collected primary and secondary care data with research and service evaluation data is vital to save time and resource and demonstrate impact. Importantly, outcomes should be relevant to a wide variety of stakeholders, including patients and the public, health care professionals and others making commissioning decisions about health care if the findings are to influence policy and practice. For example, a patient might be most interested in the potential impact of prehabilitation on postoperative recovery or quality of life whilst a commissioner might want to know the cost savings associated with implementing a prehabilitation programme. It is acknowledged that not all cancer prehabilitation stakeholders were present at the workshop (including patients, commissioners, and oncologists). Similarly, we acknowledge that not all groups working in prehabilitation were represented and so it is possible that some perspectives have not been captured. Therefore, the COS consensus process should endeavour to include a variety of stakeholders to represent different perspectives.

In conclusion, cancer prehabilitation has demonstrated its initial and intuitive value with evidence from small-scale intervention studies. To fully understand the impact that can be made on clinical endpoints through a multimodal support programme prior to treatment, robustly designed, large-scale studies that utilise consistent outcomes and tools are essential so that data can be pooled to increase the confidence in the estimates of effect and ultimately advance clinical practice.

Authors' contributions

Anna M Myers: Conceptualisation, Methodology, Formal analysis, Investigation, Writing - Original Draft; Rachael C Barlow, Gabriele Baldini, Anna M Campbell, Franco Carli, Esther J Carr, Tom Collyer, Gerard Danjoux, June F Davis, Linda Denehy, James Durrand, Chelsia Gillis, Diana M Greenfield, Stuart P Griffiths, Mike Grocott, Liam Humphreys, Sandy Jack, Carol Keen, Denny Z H Levett, Zoe Merchant, John Moore, Susan Moug, William Ricketts, Daniel Santa Mina, John M Saxton, Clare E Shaw, Garry A Tew, Michael Thelwell, Malcolm A West: Writing - Review & Editing; Robert J Copeland: Conceptualisation, Methodology, Writing - Review & Editing.

Collaborators

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Declaration of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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339 *Table 1 Summary of reporting characteristics and outcome measures being captured by ten cancer prehabilitation groups*
340 *across the United Kingdom, Australia, Canada and Italy.*

	Count (%)	Measurement method/tool where applicable
Baseline characteristics		
Age	10 (100%)	
Sex	10 (100%)	
Postcode	10 (100%)	
Ethnicity	7 (70%)	
Education	4 (40%)	
Marital status	2 (20%)	
Employment status	7 (70%)	
Medical history and screening		
General medical history	8 (80%)	
Cancer type	6 (60%)	
Surgery type	3 (30%)	
Cancer stage	3 (30%)	
Nutritional assessment/screening	7 (70%)	PG-SGA, mPG-SGA, MUST, Canadian nutrition screening tool
Objective (physical or physiological) measures		
Blood pressure	9 (90%)	
Resting heat rate	9 (90%)	
Height	10 (100%)	
Body mass	10 (100%)	
Waist girth	4 (40%)	
Hip girth	3 (30%)	
Waist-hip-ratio	3 (30%)	
Aerobic capacity	10 (100%)	CPET, 6MWT
Spirometry	4 (40%)	
Hand grip strength	9 (90%)	Hand grip dynamometer
Leg strength	7 (70%)	Sit to stand test
Accelerometry	1 (10%)	
Self-report (psychological and behavioural) measures		
Physical activity	8 (80%)	EVS, CHAMPS, Active Lives Survey, GLTEQ, IPAQ
Functional status	5 (50%)	DASI
Fatigue	5 (50%)	FACIT-Fatigue, EORTC QLQ-C30 sub-scale
Patient Activation	4 (40%)	PAM
Quality of life	10 (100%)	EQ-5D-5L, EORTC QLQ-C30, SF12
Health and disability	2 (20%)	WHODAS 2.0
Anxiety and depression	7 (70%)	PHQ-9, GAD-7, HADS, major depression inventory
Exercise self-efficacy	3 (30%)	Self-efficacy for exercise scale
Exercise motivation	1 (10%)	BREQ-3
Satisfaction with support	4 (40%)	Family and Friends test, bespoke patient satisfaction survey
Medical record data		
Length of stay	9 (90%)	
Treatment completion rates	5 (50%)	
Cancer recurrence - site and stage	5 (50%)	
Accident and emergency attendance	7 (70%)	

	Count (%)	Measurement method/tool where applicable
Hospital readmissions	8 (80%)	unplanned inpatient less than 3 days/more than three days, 30-day readmission, 90-day readmission
Surgical complications	2 (20%)	Clavien-Dindo
Mortality	8 (80%)	

PG-SGA – Patient-Generated Subjective Global Assessment; mPG-SGA – modified Patient-Generated Subjective Global Assessment; MUST - Malnutrition Universal Screening Tool; CPET - Cardiopulmonary exercise test; 6MWT – 6-minute walk test; EVS – exercise vital signs; CHAMPS – CHAMPS physical activity questionnaire; GLTEQ – Godin Leisure-Time Exercise Questionnaire; IPAQ – International Physical Activity Questionnaire; DASI – Duke Activity Status Index; FACIT – Functional Assessment of Chronic Illness Therapy; EORTC QLQ-C30 - European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; PAM – Patient Activation Measure; EQ-5D-5L – European Quality of Life-5 Dimensions-5 Levels; SF12 – 12-Item Short Form Survey; WHODAS 2.0 – World Health Organization Disability Assessment Schedule 2.0; PHQ-9 – Patient Health Questionnaire-9; GAD-7 – General Anxiety Disorder-7; HADS - Hospital Anxiety and Depression Scale; BREQ-3 – Behavioural Regulation in Exercise Questionnaire.

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