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

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10 **Keywords**

11 Prehabilitation, Rehabilitation, Cancer, Surgery, Core Outcome Set

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93 **Abstract**

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

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115 **Background**

116 In 2020, there were an estimated 18.1 million new cancer cases globally; of those, 51% were cases in
117 men and 49% were in women.¹ People undergoing treatment (including surgery, chemotherapy, and
118 radiotherapy) for cancer may experience, or be at risk of, adverse effects, particularly those who are
119 ‘high-risk’ (such as those who are deconditioned or experiencing frailty) or who do not possess
120 sufficient physiological resilience to tolerate treatment well. For example, in England, approximately
121 45% of patients with cancer undergo surgical procedures² and, depending on the type of surgery,
122 10% to 56% of patients develop postoperative complications that delay discharge.³ A range of
123 factors contribute to the risk of complications including age, multiple comorbidities, frailty, poor
124 aerobic fitness, and lifestyle factors such as physical inactivity, malnutrition, and smoking.
125 Treatment-related complications inflate costs (longer hospital length of stay [LOS]), more medical
126 interventions and increased readmissions), and vastly worsen patient experiences.⁴ This is
127 unsurprising given the physiological and psychological stress related to surgery⁵ and the lack of
128 physiological and psychological resilience in high-risk groups.⁴ In the context of cancer care,
129 prehabilitation is *“a process on the cancer continuum of care that occurs between the time of cancer
130 diagnosis and the beginning of acute treatment and includes physical and psychological assessments
131 that establish a baseline function level, identify impairments, and provide interventions that promote
132 physical and psychological health to reduce the incidence and/or severity of future impairments”*.⁶
133 Over the last 5-10 years, the number of cancer prehabilitation studies and services has significantly
134 increased. A search of the NCBI PubMed database for search terms “cancer prehabilitation”
135 returned 17 items published in 2010 and 206 items published in 2020. Many of these studies have
136 tested interventions aimed at modifying risk factors associated with poorer surgical outcomes in the
137 preoperative period and, more recently, for patients undergoing non-surgical cancer treatments.⁷⁻⁹
138 The Macmillan Principles and Guidance for Prehabilitation within the Management and Support of
139 People with Cancer report highlights the need to develop and consistently employ a range of

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

147 Prospective RCTs of prehabilitation have been conducted, although most are small and selective,
148 and the certainty of evidence varies across outcomes, cancer, and treatment types. Results from
149 meta-analyses are promising with evidence that prehabilitation improves surrogate measures of
150 fitness (e.g. functional capacity) but have shown inconsistency in patient-reported outcomes.

151 Prehabilitation also has the potential to increase the range of treatment options available to patients
152 who would not otherwise be suitable candidates.⁶ A recent umbrella review of 55 systematic reviews
153 of prehabilitation interventions, including nutrition, exercise, and psychological strategies, identified,
154 with moderate certainty evidence, that prehabilitation improved functional recovery, and low
155 certainty evidence suggested that prehabilitation supported reductions in complications, non-home
156 discharge, and length of stay.¹⁵ Included studies showed considerable heterogeneity in study
157 outcomes, cautioning the strength of study findings. The prehabilitation community is yet to define
158 the most appropriate outcomes to measure to demonstrate the impact of prehabilitation and this is
159 perhaps a reflection of the relative infancy of the field. The outcomes also need to be relevant and
160 important to a wide variety of stakeholders including patients and the public, health care
161 professionals and others making commissioning/funding decisions about health care if the findings
162 are to influence policy and practice.

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

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

176 **International cancer prehabilitation outcomes workshop**

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

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

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

193 Ten prehabilitation groups provided information about the reporting characteristics and outcomes
194 being captured in their research and service evaluation. Data were grouped into five domains:
195 baseline characteristics, medical history and screening, objective (physical or physiological)
196 measures, self-report (psychological and behavioural) measures, and medical record data (Table 1).

197 There was inconsistency across groups in the outcomes being captured and the frequency with
198 which they are assessed. Where there was consistency in the type of outcome being captured, the
199 tools and tests used to capture them varied. For example, aerobic capacity was measured by all ten
200 groups. However, one was using cardiopulmonary exercise testing (CPET), two were using the 6-
201 minute walk test (6MWT), and seven were using both CPET and 6MWT. Where CPETs were being
202 conducted, this was not routine across participants and depended on whether clinical teams were
203 using it to assess suitability for surgery.

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

215 Major Depression Inventory. Nutritional status was assessed by seven of the groups and three
216 different tools were used (Patient-Generated Subjective Global Assessment (PG-SGA), modified PG-
217 SGA (mPG-SGA), Malnutrition Universal Screening Tool (MUST) and Canadian Nutrition Screening
218 Tool). Most groups were using length of stay, readmissions, and mortality, but there was
219 inconsistency in how these outcomes were defined. For example, readmissions were classified in
220 several ways, including being an unplanned inpatient for less than three days/more than three days,
221 30-day all-cause readmission, and 90-day all-cause readmission.

222

223 *Table 1 around here*

224

225 **Key priorities**

226 There was general consensus on the constructs that should be measured in prehabilitation research
227 and evaluation amongst the ten prehabilitation groups who provided information. Despite alignment
228 on the general areas of evaluation (e.g., physical and psychological health, quality of life, hospital-
229 related outcomes), these constructs have large variability in how they are measured. The
230 international stakeholders agreed that developing a core outcome set is a priority to advance our
231 knowledge and understanding of best practice in cancer prehabilitation. An umbrella review of
232 systematic reviews also emphasised the need for a core outcome set in this area to develop a robust
233 evidence base¹⁵ and a recent international Delphi study rated defining prehabilitation core outcome
234 measures as a top ten research priority.¹⁹ Achieving consistency of outcome reporting across
235 research studies and services will require international consensus and clear guidance. A natural next
236 step would be to develop national and international databases to compare and contrast the impact
237 of different interventions and to assess outcomes at a population level and authors here are
238 committed to working internationally to deliver this.

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

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

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264 **Authors' contributions**

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278 licence to any Author Accepted Manuscript version arising from this submission.

279 **Declaration of interest**

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

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Table 1 Summary of reporting characteristics and outcome measures being captured by ten cancer prehabilitation groups 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 heart 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; DASIS – 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.