Rehabilitation outcomes for people with lung cancer (UNITE): protocol for the development of a core outcome set

Lara Edbrooke 1,2, Catherine L Granger 1,3, Jill J Francis 1,4, Tom John 5,6, Nasreen Kaadan 7, Emma Halloran 8, Bronwen Connolly 9, Linda Denehy 1,2

ABSTRACT

Introduction With treatment-related improvements in survival, rehabilitation is essential to improve function and health-related quality of life and manage the high symptom burden associated with lung cancer. Despite this, significant heterogeneity exists in the outcomes and instruments used to evaluate lung cancer rehabilitation programme impact. This study aims to develop a core set of clinically relevant lung cancer rehabilitation outcomes for use in clinical practice.

Methods and analysis An international Delphi consensus study involving consumer, healthcare professional and researcher stakeholders to determine which outcomes to include and how to measure these. Stage 1 (preliminary): mixed methods to develop the potential list of outcomes (1) overview of systematic reviews of lung cancer exercise interventions and (2) focus groups and individual interviews with people with lung cancer. Stage 2: outcomes were grouped according to the International Classification of Functioning, Disability and Health domains. Stage 3: to determine priority outcomes for core outcome set (COS) inclusion participants will rate each outcome’s importance (one-nine-point Likert scale) over two-three survey rounds. Stage 4: following review by the steering committee, a consensus meeting will be held if agreement on the COS has not been reached. Stage 5: recommendations will be made regarding a single instrument for measuring each COS outcome by reviewing existing resources where consensus has already been reached. Where resources do not exist the quality and feasibility of potential measurement instruments will be appraised, and the Delphi consensus survey and meeting process outlined in stages 3–4 will be repeated.

This protocol adheres to the COS-Standardised Protocol statement and will be conducted and reported according to the COS-Standards for Development recommendations and the COS-Standards for Reporting.

Ethics and dissemination Ethics approval (20/9/22, University of Melbourne ID 2022-24839-32231-3). Dissemination in peer-reviewed journals and conference presentations.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A large degree of heterogeneity exists in outcomes used to measure the effects of lung cancer rehabilitation programmes in clinical practice and research.

WHAT THIS STUDY ADDS

⇒ Consumer, healthcare professionals and researcher stakeholder groups will be involved to determine a core (minimum) set of outcomes for use in lung cancer rehabilitation clinical practice.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Use of a core set of outcomes has the potential to reduce burden on patients and healthcare providers, associated with collection of less relevant outcomes. A core outcome set may reduce research waste by allowing greater synthesis of evidence and allowing data harmonisation across future trials.

INTRODUCTION

Lung cancer is a devastating disease with high patient and caregiver burden. Almost 30,000 Australians were living with lung cancer in 2015, with 13,000 new cases diagnosed in 2020. Most people are diagnosed once the disease has already spread and many receive non-surgical treatments. Promisingly, detection and treatment advances have led to 5-year survival increases from 9.5% to 18.6% (1991–2016).1

People with lung cancer experience high symptom burden and progressive functional decline (including reduced physical activity and muscle wasting).2-6 These impairments, along with demanding treatment regimens, contribute to reduced health-related quality of life (HRQoL) and mood disturbance. Additionally, almost 50% of people with lung cancer have a comorbid underlying chronic respiratory disease, such as chronic obstructive pulmonary disease (COPD).6 Factors such as these significantly impact behaviours related to well-being: participation in activities of daily living, social, and family roles and the sequelae can persist for years.7 To counteract impairments, rehabilitation is essential.10-11
Rehabilitation is defined by the WHO as ‘a set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with their environment’. Guidelines recommend pulmonary rehabilitation for people with chronic respiratory diseases, commonly COPD, with level 1 evidence of effectiveness across multiple outcomes, including exercise capacity, peripheral muscle strength, symptoms and HRQoL. Commonly measured outcomes and instruments used to evaluate pulmonary rehabilitation include exercise capacity (6 min walk test, incremental shuttle walk test), lower limb strength (sit-to-stand tests), dyspnoea (Modified Medical Research Council or Borg Dyspnoea Scales) and HRQoL (St George’s Respiratory Questionnaire, the Chronic Respiratory Disease questionnaire). High-quality evidence from meta-analyses demonstrates rehabilitation effectiveness to improve outcomes for patients with cancer, predominantly in breast, colorectal, prostate and haematological populations. While there is high-quality evidence to support the effectiveness of lung cancer rehabilitation, predominantly in the surgical population, there is limited agreement in the scientific literature or in clinical practice regarding how to consistently measure outcomes to assess and monitor rehabilitation effectiveness. For example, in a previous systematic review by the study authors, 21 different measures used to assess physical activity in patients with lung cancer were identified. This increases patient burden and reduces comparability between research findings. Greater consensus is required regarding assessment of outcomes to evaluate and monitor rehabilitation and inform clinical practice guidelines. Developing a core set of outcomes reduces burden on patients and healthcare providers associated with the collection of less-relevant outcomes, reduces research waste by allowing greater synthesis of evidence, and allows data harmonisation across future trials.

Efforts are currently underway to develop a core outcome set (COS) in pulmonary rehabilitation for people with COPD, following a systematic review demonstrating high heterogeneity. While there will likely be commonalities in outcomes of importance for people with COPD or lung cancer, differences between the two diagnoses means a disease-specific approach, which includes a set of core outcomes and valid measurement instruments for people with lung cancer is also required. Differences may include symptom burden, for example, cancer-related fatigue, due to the disease and treatments, or the impact of stigma and prognosis for people with lung cancer. The aim of this study is to develop a core (minimum) set of clinically relevant lung cancer rehabilitation outcomes for use in clinical practice which are important to all stakeholders; patients and caregivers, healthcare professionals and clinician researchers.

METHODS AND ANALYSIS
This COS development study protocol adheres to the Core Outcome Set-STAndardised Protocol statement and will be conducted according to the Core Outcome Set-Standards for Development recommendations, reported according to the Core Outcome Set-Standards for Reporting (COS-STAR) and is prospectively registered on the Core Outcome Measures in Effectiveness Trials (COMET) database. Figure 1 summarises the methods that will be used to develop the COS.

COS scope
The study COS applies to:

1. Setting: the COS is intended for use in clinical practice; either to evaluate rehabilitation effects at an individual or programme level. The setting may be any clinical practice setting where lung cancer rehabilitation occurs (eg, outpatient hospital department, community health, private practice, local gymnasium).
2. Patients: ≥18 years with non-small and small cell lung cancer at any stage.
3. Interventions: exercise or physical activity rehabilitation interventions (supervised and/or unsupervised). Exercise or physical activity can be delivered either alone or combined with additional intervention which may include nutrition, education, behaviour change support, symptom management support or psychosocial support.
4. Timing: rehabilitation interventions delivered during and following any form of non-surgical management or following surgery (at any stage postacute hospital discharge). The periods prior to commencing medical treatment (prehabilitation) and postoperatively during the acute hospital admission, are outside the scope of this COS.

Patient and public involvement
The project steering committee comprises consumers (NK and EH) and researchers and clinicians with expertise in exercise oncology (LE, LD and CLG), medical oncology (TJ), COS development (BC and LD) and implementation science (JF). The steering committee was formed by the lead investigator (LE) and comprises the investigators who were involved in development of the study research questions and funding application and a new member with expertise in COS development. The steering committee members are employed by Australian (University of Melbourne, Peter MacCallum Cancer Centre, Lung Foundation Australia, Royal Melbourne Hospital) and UK (Queen’s University Belfast, Queen Mary University of London, Royal London Hospital) organisations. Consumers (patients and caregivers with a lived experience of lung cancer), healthcare professionals and clinical researchers working in lung cancer rehabilitation, regardless of the number of years of...
experience in the area, were invited to participate in the Delphi study in separate panels.

**Information sources**

**Stage 1 (preliminary work, completed): overview of reviews of lung cancer exercise interventions**

To generate the initial list of outcomes to be included for consideration in the COS an overview of systematic reviews of lung cancer exercise interventions was conducted in accordance with the Cochrane Handbook of Systematic Reviews of Interventions guidance. The overview was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-2020 guidelines and a protocol was published prospectively on the PROSPERO database (CRD42015001068 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD4201257038). Full details have been previously reported, in summary a comprehensive literature search was performed of the Cochrane Systematic Review Database, the Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library), Ovid SP MEDLINE, Ovid SP EMBASE, SPORTDiscus and CINAHL via EBSCO host and PEDro from inception until 18 May 2021 and updated on 21 February 2022. The search string was developed in consultation with content specialists and a research librarian using the medical subject headings (MeSH) dictionary in MEDLINE to identify key terms and was adapted for use in CINAHL, SPORTDiscus, PEDro, CENTRAL, EMBASE. The inclusion criteria for systematic reviews were as follows: Population—patients (≥18 years old) diagnosed with lung...
cancer; Intervention—any supervised or unsupervised exercise intervention delivered alone or in combination with any non-exercise interventions (eg, nutritional, symptom management, psychological support). Interventions could be delivered over any number of weeks or months, with no limits placed on the number of sessions per week or session duration; Comparator—usual care or no exercise intervention; Outcomes—at least one health-related outcome. Systematic reviews which included randomised controlled trials (RCTs) only, or reported these findings separately, were eligible for inclusion. Additionally, systematic reviews of RCTs with mixed-cancer types were included if >50% of participants had lung cancer and these findings were reported separately. The evidence was synthesised narratively according to intervention timing (pre, during and or post treatment). Information extracted regarding outcomes included details of primary and secondary outcomes and measurement instruments used. Where systematic review authors had completed Grading of Recommendations Assessment, Development and Evaluation (GRADE) quality assessments in a given patient population (eg, preoperative) these were reported. For systematic reviews and meta-analyses where GRADE was not reported for a patient population, two overview authors independently performed GRADE quality assessments, with any disagreements resolved by a third author.32

Stage 1 (preliminary work, completed): patient/carer focus groups/individual interviews
To ensure important outcomes from a patient and carer perspective were included in the Delphi study list of potential outcomes we undertook focus groups and semi-structured interviews with people with lung cancer and carers. The Consolidated Criteria for Reporting Qualitative Research guidelines informed the design, execution and reporting of the study.33 The International Classification of Functioning, Disability and Health (ICF) framework was used to group outcomes identified in the overview of reviews and inform question development.34 Focus groups and individual interviews were recorded, transcribed verbatim and coded using NVivo software to identify and generate a list of outcomes and also main themes, utilising Braun and Clarke’s phases of thematic analysis; data familiarisation, initial code generation, potential theme development, review of themes, theme definition/naming and report/manuscript production.35 36

Stage 2: establishing a potential outcome list (completed September 2022)
All outcomes identified in stage 1 (see online supplemental appendix A) were included in the survey and grouped in domains according to the ICF framework. This was performed by one researcher (LE) and duplicate outcomes were omitted. The list of potential outcomes, text explaining each outcome and ICF domain grouping were then independently reviewed and revised by additional members of the steering committee who were consumer advocates or who had previous experience in Delphi study methodologies (BC, LD, NK and EH). DelphiManager software, facilitates data management and enabled the use of electronic surveys, survey reminders and feedback between rounds to participants. The consumer panel was also given a hard copy survey option.

Consensus process and definitions: ‘what to measure’
Stage 3: prioritisation of outcomes through a Delphi survey Delphi study: round 1 (completed October–November 2022)
Eligible participants were sent an email with the plain language statement attached and a link to register to participate in the Delphi study. The study was advertised through social media platforms, including a link to the plain language statement and registration. During registration, participants were asked to provide their name, contact email (to allow contact for round 2 and reminders) and identify which stakeholder group they represent. To increase participation, respondents who completed all survey rounds were offered acknowledgement in the publication. Consumers were invited to participate using language from COMET plain language summaries. They were identified through advertising via a number of mechanisms (including consumer newsletters and social media platforms of organisations such as Lung Foundation Australia, Cancer Council Victoria, the Peter MacCallum Cancer Centre consumer registry and via the Twitter accounts of the project investigators). Exercise clinicians working with people with lung cancer were invited via professional associations, including, but not limited to, the Pulmonary Rehabilitation Network database (141 members, hosted by the Lung Foundation Australia), the Australian Physiotherapy Association, Cancer, Palliative Care and Lymphoedema special interest group (260 facebook group members) and steering committee member contacts. First and last authors of RCTs included in the preliminary work overview of reviews were invited to the clinical researcher group. Delphi study optimal panel size is undetermined.29 For generalisability as many participants as possible were recruited. A snowballing approach was used to identify additional participants.
Each participant was asked to rate the importance of each outcome on a Likert scale 1–3 (not important), 4–6, 7–9 (critically important) or ‘unable to rate’ and all outcomes were retained until round two. There was also an option for participants to provide feedback regarding an outcome in a free-text box. During round 1, participants were also able to suggest additional outcomes they felt were important to include in the COS for consideration in round 2 in a free-text box. If the same additional outcome was reported by at least two participants it was discussed with the steering committee. If deemed relevant and within the scope of the COS it was included in
round 2. Survey round 1 remained open for a minimum of 2 weeks, with personalised completion reminders sent weekly to participants who had yet to complete the survey.

**Delphi study: round 2 (completed in December 2022)**

Only round 1 participants were contacted for involvement in round 2, approximately 2–3 weeks following the completion of round 1. The aim of the round 2 survey was to reduce the number of outcomes that participants agree are critically important to include in the COS. To achieve this, the round 2 survey commenced with participants being provided with feedback from round 1 including a histogram showing the distribution of all participants’ responses (by stakeholder group) and their own response for each outcome’s importance rating. As per round 1, each participant was asked to rate the importance of each round 1 outcome, and any additional outcomes on the same Likert scale from 1 (not important) to 9 (critically important). Strategies to minimise attrition between rounds included keeping rounds open for longer than the planned 2–3 weeks if response rates were low, avoiding holidays and the first day of the month. Participants who responded to both survey rounds were randomly selected to participate in the consensus meeting. The format and structure of any consensus meeting was decided by the steering committee and conducted in line with current guidelines for consensus meeting conduct.

**Consensus process and definitions: ‘how to measure’ (yet to be commenced)**

Stage 5: Following finalisation of determining ‘what’ outcomes should be included in the lung cancer rehabilitation COS, the process of recommending which outcome measurement instruments to use will follow the steps outlined below:

1. Review of existing resources (eg, International Consortium for Health Outcomes Measurement standard sets, Patient-reported Outcomes Measurement Information System) and database searches for outcome measurement instruments in lung cancer where consensus has already been reached.
2. Where consensus has not been researched, database searches for systematic reviews or original articles of outcome measurement instruments will be performed. The PubMed patient-reported outcome measure (PROM) filter will be used when searching for PROMs.
3. Evaluate the quality and feasibility of each outcome measurement instrument. With quality pertaining to (1) the risk of bias of retrieved studies (rated using the COmments on cONsensus-based Standards for the selection of health status Measurement Instruments checklist) and (2) the measurement properties of the instrument in patients with cancer. Only instruments demonstrating content validity and internal consistency (if applicable) will be considered for inclusion.
4. Repeat stages 3 and 4 as outlined previously. Two Delphi survey rounds will be conducted to rank each outcome measurement instrument (for each COS outcome). For each outcome in the COS participants will be presented with a list of valid measurement instruments (listed in alphabetical order). Cards will be created for each instrument which will provide a summary of key instrument details which may impact the feasibility of implementation (eg, the number of questionnaire items, time required to complete, licensing costs, equipment or training required). Participants will rate each instrument using the same Likert scale used in the ‘what to measure’ stage. In round 1, participants will be able to suggest additional instruments. Inclusion of additional instruments in round 2 and no consensus had been reached the committee reviewed the responses from each stakeholder panel and considered whether a third Delphi survey round or a consensus meeting was likely to achieve consensus on any further outcomes for retention or removal from the COS. If it was determined that a consensus meeting was required, a minimum of 10% of participants from each stakeholder group who responded to both survey rounds were randomly selected to participate in the consensus meeting. The format and structure of any consensus meeting was decided by the steering committee and conducted in line with current guidelines for consensus meeting conduct.

**Consensus definitions, following survey round 2**

‘Consensus achieved—outcome retained’: if $\geq 70\%$ of voting participants from each stakeholder group score an outcome 7–9 and $\leq 15\%$ of voting participants from each stakeholder group score an outcome 1–3.

‘Consensus achieved—outcome removed’: if 50% of voting participants from each stakeholder group score an outcome 7–9.

**Data analysis**

During registration, participants were assigned a study ID. Any data extracted for analysis will be deidentified. Survey data will be analysed quantitatively (absolute values and percentages) and qualitatively (listings of the comments and suggestions given by the members of each stakeholder group in round 1).

**Stage 4: final COS agreement (completed February 2023)**

The project steering committee performed an initial review of the Delphi study findings. The committee reviewed the number of outcomes that met the consensus definitions to be retained or removed from the COS as defined above. Consideration was given as to whether the number of outcomes meeting consensus was feasible to implement into clinical practice. For outcomes where
consensus definitions of instruments to retain or remove will follow stage 3 principles. As in stage 4, survey rounds may be followed by a consensus meeting involving all stakeholder groups if deemed necessary by the steering committee.

5. Make recommendations regarding one outcome measurement instrument for each COS outcome.

ETHICS AND DISSEMINATION
Ethics approval was obtained prospectively from The University of Melbourne, Australia (ID 2022-24839-32231-3, dated 20 September 2022). Participants were provided with a plain language statement regarding the study and for survey rounds participant consent was implied by completion of the survey. Prior to the consensus meetings, participants will be asked to provide verbal consent.

Study participants will be provided with a summary of study findings. Findings will be disseminated to the research community through publication in peer-reviewed journals, presentation at scientific conferences and via social media. We will communicate findings to consumers at forums in collaboration with our consumer partner organisation, The Lung Foundation Australia.

Author affiliations
1Department of Physiotherapy, The University of Melbourne, Melbourne, Victoria, Australia
2Department of Health Services Research, Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia
3Department of Physiotherapy, The Royal Melbourne Hospital, Melbourne, Victoria, Australia
4Melbourne School of Health Sciences, The University of Melbourne, Melbourne, Victoria, Australia
5Department of Medical Oncology, Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia
6The Sir Peter MacCallum Department of Oncology, The University of Melbourne, Melbourne, Victoria, Australia
7Consumer Representative, Sydney, New South Wales, Australia
8Lung Foundation Australia, Milton, Queensland, Australia
9Wellcome-Wolfson Institute for Experimental Medicine, Queen’s University Belfast, Belfast, UK

Twitter Lara Edbrooke @LaraEdbrooke

Acknowledgements The authors would like to thank Professor Paula Williamson who provided feedback on the initial version of the protocol manuscript.

Contributors All authors were involved in securing funding for the project. LE drafted the protocol manuscript and all authors reviewed the initial version and approved the final version.

Funding LE is supported by a Victorian Cancer Agency Early Career Research Fellowship (ECRF21003).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by University of Melbourne ID 2022-24839-32231-3. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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ORCID iDs
Lara Edbrooke http://orcid.org/0000-0002-4149-5578
Catherine L Granger http://orcid.org/0000-0001-6169-370X
Jill J Francis http://orcid.org/0000-0001-5784-8995
Tom John http://orcid.org/0000-0003-3399-5342
Bronwen Connelly http://orcid.org/0000-0002-5676-5497
Linda Deney http://orcid.org/0000-0002-2966-8436

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### Appendix A.

Table A1. Outcomes identified during the overview of reviews and consumer focus groups and interviews

<table>
<thead>
<tr>
<th>Outcome Name</th>
<th>Outcome Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities of daily living</td>
<td>The ability to carry out usual everyday activities including looking after yourself (e.g., bathing, dressing or feeding), or other activities (e.g., cooking, cleaning, managing finances, caring for others or shopping)</td>
</tr>
<tr>
<td>Appetite</td>
<td>The natural and recurring desire for food and drink</td>
</tr>
<tr>
<td>Balance</td>
<td>The ability to remain upright and steady</td>
</tr>
<tr>
<td>Balance confidence</td>
<td>The confidence that you can perform activities without losing balance (e.g., walking inside or outside the home, climbing stairs, standing on tip toes to reach for an object, bending to pick something up off the floor)</td>
</tr>
<tr>
<td>Body composition</td>
<td>The amount of fat, muscle and bone in your body</td>
</tr>
<tr>
<td>Breathlessness</td>
<td>How short of breath you are</td>
</tr>
<tr>
<td>Cognition</td>
<td>The ability to learn, think, remember things, problem solve, understand instructions, make decisions or pay attention</td>
</tr>
<tr>
<td>Emotional and Mental Wellbeing</td>
<td>Your mood - whether and how often you feel happy, calm, anxious, depressed, sad or angry - and your self esteem</td>
</tr>
<tr>
<td>Fatigue</td>
<td>An overwhelming, sustained feeling of exhaustion, mental or physical tiredness, having little energy for physical and mental work</td>
</tr>
<tr>
<td>Haematological status</td>
<td>Components of your blood (e.g., levels of inflammation, the amount of red or white blood cells)</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>How well you feel about life; how much your health is affecting your quality of life</td>
</tr>
<tr>
<td>Lung function</td>
<td>How well your lungs work to help you breath</td>
</tr>
<tr>
<td>Muscle oxygenation</td>
<td>Use of oxygen by your muscles when you exercise</td>
</tr>
<tr>
<td>Neurological symptoms</td>
<td>This may include numbness (reduced sensation of surfaces and their texture or quality) or weakness (loss of muscle strength) in your arms and/or legs</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nutrition status</td>
<td>Changes to your weight, food intake and/or taste</td>
</tr>
<tr>
<td>Pain</td>
<td>A sensation of unpleasant feeling indicating potential or actual damage to any part of your body</td>
</tr>
<tr>
<td>Peripheral skeletal muscle strength</td>
<td>The strength of the muscles in your arms and/or legs</td>
</tr>
<tr>
<td>How active you are (e.g., the number of steps you take a day, how long you are active for, how much time you spend sitting)</td>
<td></td>
</tr>
<tr>
<td>Physical activity levels</td>
<td>How active you are. Your ability to perform sports, occupations and daily activities</td>
</tr>
<tr>
<td>Physical fitness</td>
<td>How fit you are. Your ability to perform sports, occupations and daily activities</td>
</tr>
<tr>
<td>Physical function</td>
<td>Having the mobility and strength to perform activities required for day to day tasks (e.g., get out of bed, stand up from a chair, walking, or climbing stairs)</td>
</tr>
<tr>
<td>Resilience</td>
<td>The ability to cope with and recover quickly from difficult situations</td>
</tr>
<tr>
<td>Respiratory muscle strength</td>
<td>The strength of the muscles that help you to breathe in and out</td>
</tr>
<tr>
<td>Return to work or prior role</td>
<td>Returning to your previous job (full or part-time), changing to a different job, or doing the same thing you did before your lung cancer diagnosis</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Self-belief that you can manage your condition or symptoms or complete your rehabilitation program</td>
</tr>
<tr>
<td>Sleep and related symptoms</td>
<td>The quality of your sleep (e.g., how long you take to go to sleep, how many times you wake up at night, how much sleep you get)</td>
</tr>
<tr>
<td>Social roles, activities or relationships and support</td>
<td>Connecting with others and maintaining family, friendship and/or romantic relationships. The ability and desire to join in activities with others. The support you receive from family and/or friends.</td>
</tr>
<tr>
<td>Treatment response</td>
<td>Your response to medical treatments (e.g., chemotherapy, radiotherapy, immunotherapy, targeted therapies)</td>
</tr>
</tbody>
</table>