EUonQoL	Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe	Funded by the European Union

EUonQoL
Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe

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Contents

Abbreviations and Definitions

AE	Adverse events
QOL	Quality of Life
PRO	Patient reported outcomes
EORTC	European Organisation for Research and Treatment of Cancer
QLG	Quality of Life Group
WHO	World Health Organisation
ICF	International Classification of Functioning, Disability and Health
CAT	Computer Adaptive Testing
HRQOL	Health related quality of life
EU	European Union
EUonQoL-Kit	European Oncology Quality of Life toolkit
WP	Workpackage

General Information

This report provides detail on the results from work package 4 (WP4). This workpackage is part of an EU funded project “"EUonQoL-Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe” grant agreement n° 101096362). The overall project aims to develop, pilot and validate the European Oncology Quality of Life toolkit (EUonQoL-Kit), a patient co-researcher driven, unified system for the assessment of quality of life (QoL) based on the evaluations and preferences of cancer patients and survivors. The EUonQoL-Kit will be developed from the patient perspective, administered digitally, available in all 27 European Union (EU) and associated countries languages, applicable for use in future, periodic surveys to contribute to the EU’s mission on cancer and inform health policy. Workpackage 4’s aims are to develop the toolkit using mixed methods and then present the results of initial usability testing. This report describes the results of the usability study to support modifications to the toolkit prior to pilot testing in WP7. Table 1 below summarizes the different workpackages.

Table 1: Overview of the different workpackages

Workpackage (WP)	Workpackage Title
WP1	Ethics
WP2	Involvement of stakeholders and patients
WP3	Review of existing HRQoL databases, measures & item libraries
WP4	Development of the EUonQoL-Kit
WP5	Cross-cultural determinants of the QoL and linguistic and cultural adaptation of EUonQoL-Kit
WP6	Digital tools for data collection
WP7	EUonQoL-Kit Pilot Survey
WP8	Implementation
WP9	Dissemination
WP10	Project Management/Coordination

Study Summary

This report describes the usability study from WP4 and the initial development produced by WP4 as outlined in Deliverable report 4.1. The previous WP4 development work used mixed methods methodology to explore patient views and preferences through combining: 1) patient interviews, 2) Delphi survey for multiple stakeholders across seven centres in six countries (Table 2). The triangulated results led to selection of specific items to include within the toolkit. The quantitative and qualitative results were presented at a stakeholder consensus meeting organized by WP2 which included representation from co-researchers, and the executive committee (ExCo) and stakeholder board. The selected toolkit items, the digital IT infrastructure used to administer the questionnaire and supporting information were tested in the initial usability study. The results from this work will help finalize the draft of the EUonQoL-Kit for pilot testing in the following phases of the EUonQoL project.

Table 2: Participating Centres

COUNTRY	CENTRE NAME	ACRONYM
UK	Leeds Cancer Centre	LEEDS
IT	Fondazione IRCCS Instituto Nazionale Tumori-Milano	INT
FR	Institut Gustave Roussy,	GR
FR	Institut Curie	CURIE
NL	Netherlands Cancer Institute	NKI
DE	German Cancer Research Center	DKFZ
DK	Rigshopitalet, Copenhagen	RH
DK	Bispebjerg Hospital, Copenhagen	BH

Compliance

All aspects of the study were undertaken in accordance with the MRC Good Research Practice guidelines, Good Clinical Practice (GCP) guidelines, the Data Protection Act (2018), and the EU Clinical Trials Directive (although this study does not come under the scope of the directive).

Funder

The study is funded by an EU Horizons 2020 grant (EUonQoL - 101096362 - DLV-101096362).

Flow diagram of Overall Project

This flow diagram outlines the overall EUonQoL project. This protocol outlines procedures for workpackage 4 (WP4) – development of the EUonQoL-Kit (Figure 1).

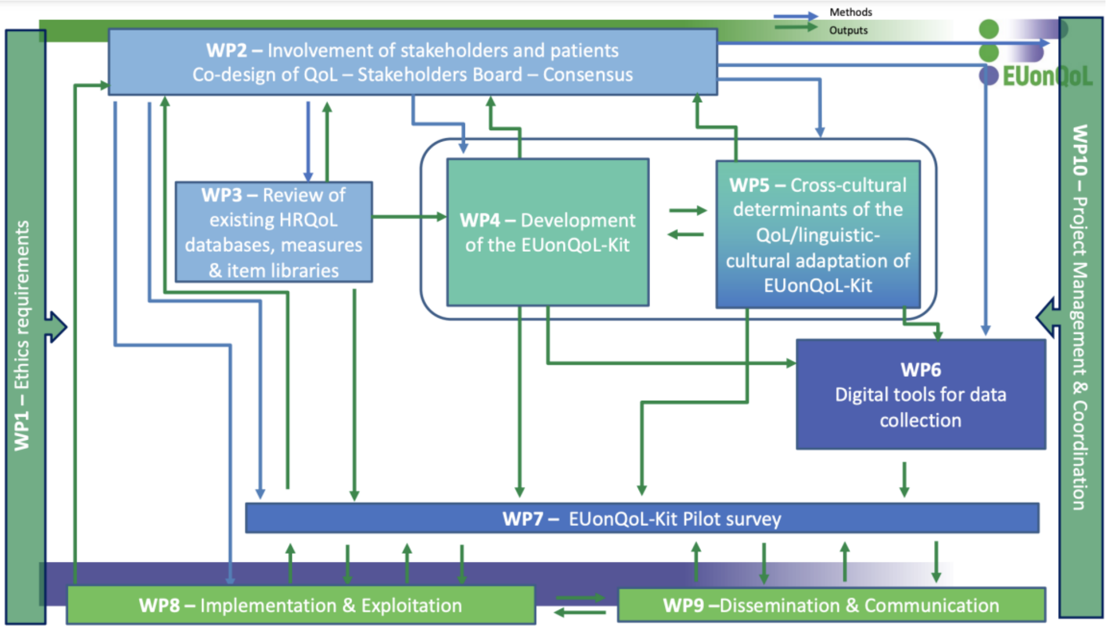

Figure 1. Flow of project.

Report Summary

Aim

The overall aim of this project is to develop a questionnaire toolkit called the EUonQoL-Kit intended to assess quality of life (QOL) across the whole cancer continuum of patients within Europe. The toolkit will assess QOL in three target groups of patients:

(A) receiving active treatment (curative and non-curative)
(B) cancer survivors for patients aged 18 years and older
(C) receiving palliative care

This stage of the project aims to develop a draft of the EUonQoL-Kit for pilot testing. This study uses co-design, working with patients and survivors as co-researchers (WP2) to explore patient views on the coverage of QOL items selected from the initial phases of WP4 in each part of the cancer continuum.

Method

The usability study was carried out in parallel across five countries (UK, The Netherlands, France, Germany and Italy). We tested a static version of the Toolkit using both the digital system and paper version to increase the reach of the work. We tested pre-developed (CAT) short forms; mild severity versions for survivors, and moderate for active and palliative patients.

A purposive sample of patients in target groups A, B and C, were invited to complete the initial versions of the questionnaire and provide feedback through a semi-structured interview. Interview data was analysed using a thematic framework analysis. Mean, median and range data on the questionnaire responses was collected, alongside feedback on various aspects of the questionnaire, including ordering of items, wording, overlapping and upsetting issues, and functionality of the system (if relevant). The preliminary usability results were presented at a second stakeholder meeting (12th December 2023) for further feedback. The final list of items for the toolkit will be reported in D4.3.

Results

Over the course of a three-week period (10/11/23 – 01/12/23), 53 patients were enrolled into the interview study across five countries (A=19; B=22; C=12). Qualitative and quantitative data were collected for Version 1 of the Toolkit (V1). Overall, Toolkit V1 was well received by participants, with general comments supportive of the development of the new questionnaire. With regards to the usability of the Toolkits, results highlighted that Toolkit V1 was too long, specifically with too many overlapping or repetitive items. Language issues were also prevalent with several items having problematic translations or phrasing. The overall usability of the App was somewhat mixed, largely due to the limitations of the digital platform leading to formatting errors which participants found to be frustrating and confusing.

Discussion

Overall, Toolkit V1 was well received. Findings suggest the key area for improvement was reducing the total number of items included, changing the time frame/temporality for some items, modifications to wording for some translations, and improving parts of the IT interface. Results of the usability study will be used to refine the Toolkit, with the final list of items included in version 2.0 to be tested within WP7 pilot study. The results of the items included in Toolkit V2 are to be presented in D4.3.

1. Introduction

This report follows on from report D4.1 - Patients priorities and preferences. In report D4.1, we described the rationale for this project and the initial development phase of the development of the EUonQOL toolkit. The aim of this initial work was to develop a draft of QOL domains and subdomains to include in the toolkit and involved an iterative process carried out in parallel across six countries (UK, The Netherlands, France, Denmark, Germany and Italy). Existing QoL frameworks were combined and used to structure the content of patient interviews and a Delphi survey of patients and health care professionals, which explored patient views and preferences. The summarised domains and subdomains explored are summarised in Figure 2.

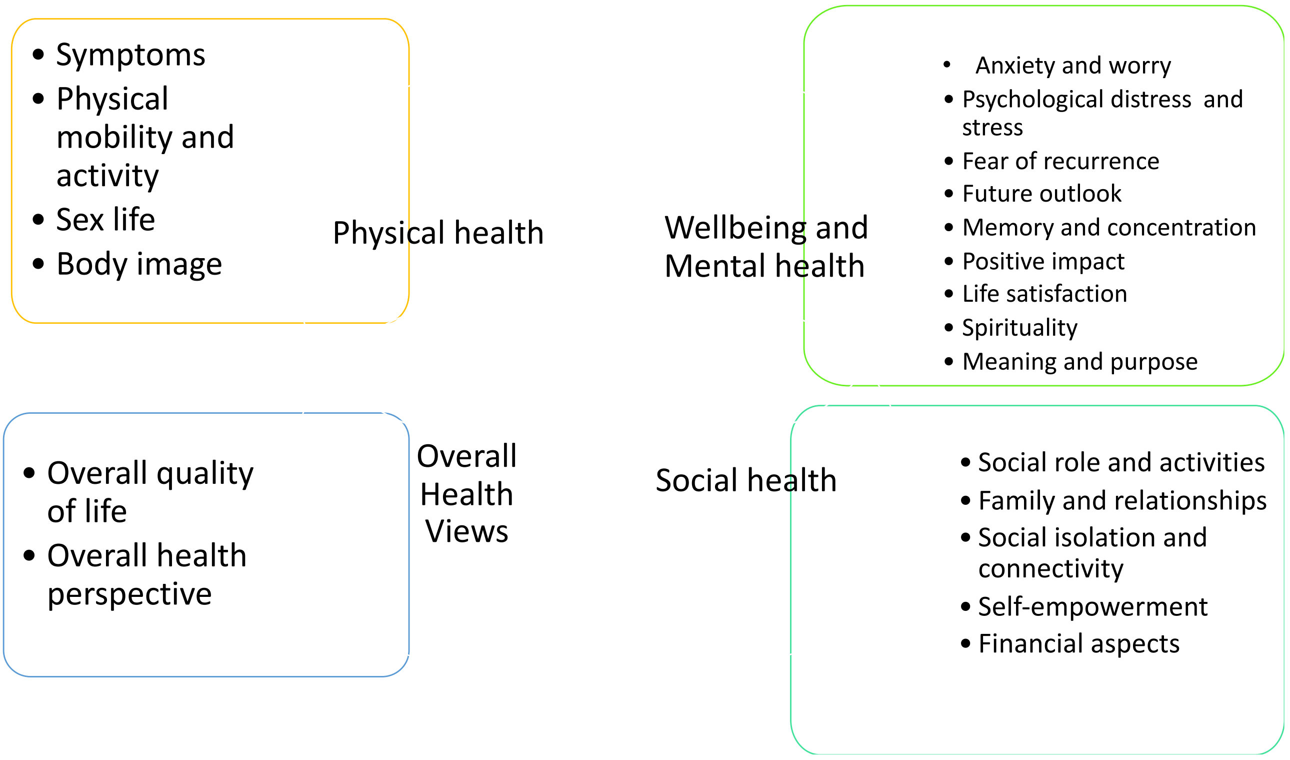

Figure 2. Initial framework.

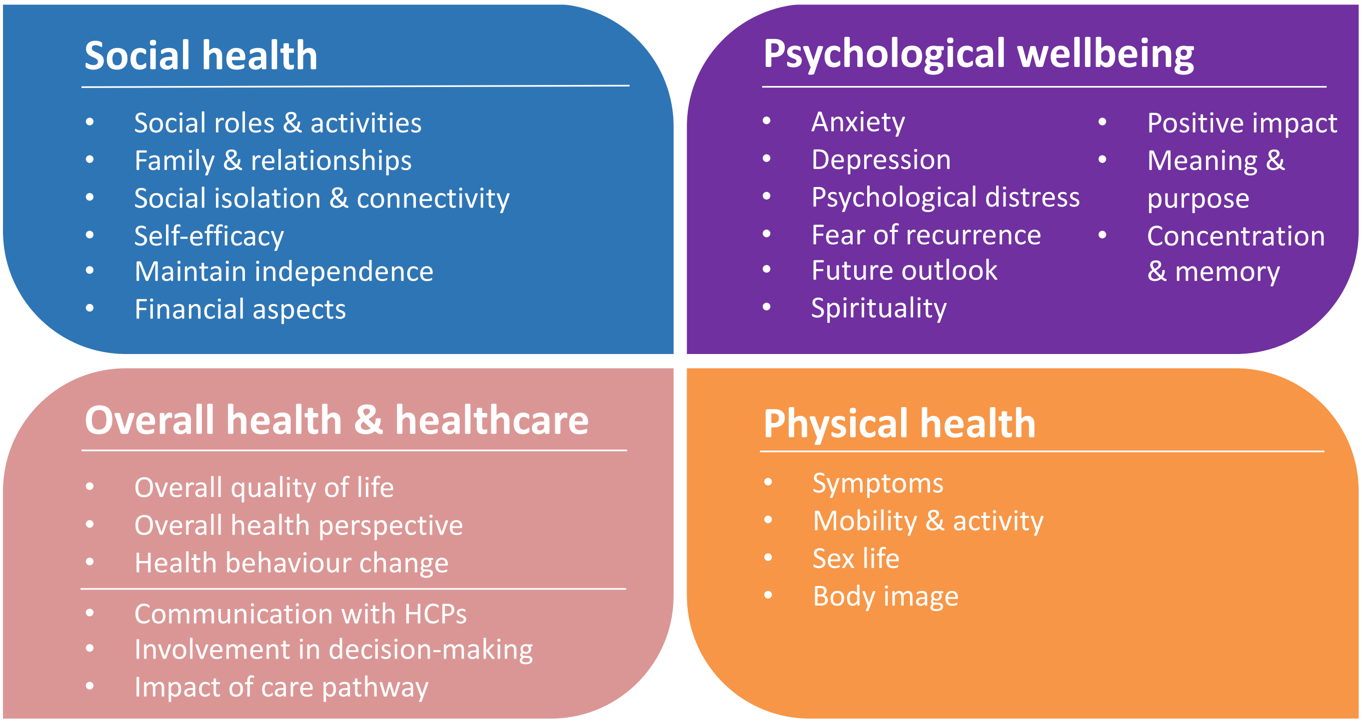

Figure 3: Updated Framework after Interviews and Delphi

The updated domains and subdomains following the Interviews and the Delphi survey are shown in Figure 3. In addition to the original 4 domains: social health, physical health, psychological health and wellbeing and overall health, the additional domain of 'Healthcare' was included after it was identified as important to include following the initial round of the Delphi and initial interviews. The results of the complete interviews and Delphi survey (rounds 1-3) were then combined with the results from two systematic reviews (WP3; report 3.1) using a process of triangulation. The combined results were presented at a stakeholder consensus meeting on 11th October 2023 for consensus voting using nominal technique to decide on the subdomains for inclusion. Following on from this meeting, using a further process of triangulation, all results were combined, prioritising patient and stakeholder views, supported by co-researchers, to decide on the subdomains for inclusion. The final initial draft toolkit mapped the list of domains and subdomains onto 60 CAT items, 24 items from the EORTC item library and 1 novel item and was approved by the ExCo and co-researchers.

This report describes the usability study, which aimed to test the selected items in the three target groups of adult patients ((A) receiving active treatment (curative and non-curative); (B) cancer survivors; (C) receiving palliative care) prior to wider testing. The aim of the usability study was to establish any issues with the questionnaire, including within the content of the questions and the functionality of the IT system, through a process of completing the questionnaire and providing feedback through a semi-structured interview. Sample sizes between 24 and 50 for similar studies (pilot and feasibility) have been recommended range (1, 2). This report describes the qualitative results from these interviews and the summarised results from the questionnaire content by target group.

2. Methodology

Definition of the target patient population

The aim of the final toolkit is to evaluate QOL effectively and comprehensively for patients across the cancer continuum ranging from survivors to active treatment patients to palliative care patients. Due to different definitions of palliative care in different countries there may be some overlap and variability when allocating patients to the pre-defined treatment groups. The definitions outlined do not encompass the entirety of the cancer patient population, but they were designed to validate the tool and to be able to distinguish between three different patient populations with relative precision.

As agreed with the EUonQoL executive, the target population groups are defined throughout all stages of this study as:

A. Active Treatment:

  I. Curative treatment - undergoing or recently completed curative treatment for early-stage cancers.
  Examples:
  - Early stage 1-2 breast cancer during or up to 3 months following radiotherapy, surgery or systemic treatments

  II. Non-curative treatment for advanced/metastatic cancers, including disease controlling/life prolonging tumour-directed treatment (e.g. patients with metastatic disease receiving chemotherapy, immunotherapy or targeted agents)

Examples:
- Metastatic breast cancer on 1st line palliative chemotherapy;
- Lung cancer on immunotherapy

B. Survivors: At least one year off active treatment (but can be on long-term adjuvant hormonotherapy) and being disease-free without evidence of active cancer. We will aim to recruit survivors >5 years.

Examples:
- ER/PR+ breast cancer treated with surgery, adjuvant radiotherapy and on 10 years of hormonal treatment.

C. Palliative care: Patients with advanced cancers who meet at least one of the following criteria:

I. Patients with projected prognosis <12 months with a Performance Status (PS)/Karnofsky (KPS) <=70 or ECOG <=2.
II. Patients referred to a specialist palliative care team for symptom control.
III. Patients may be receiving non-curative treatment purely for symptom control (including palliative radiotherapy and/or systemic treatment).

Examples:
- Patients with castrate-resistant prostate cancer, progressed through systemic treatment options referred for radiotherapy for bone pain.
- Metastatic breast cancer patient on 5th line systemic treatment.

Items within the Toolkit

The number of items tested within each version of the Toolkit varied by target group depending on the domains included:

Active Treatment (Group A) – 75 items
Survivors (Group B) – 67 items
Palliative Care (Group C) – 79 items

The majority of items included in the Toolkit are selected from the EORTC Item Library and EORTC CAT item bank. These are validated items from existing questionnaires. Following on from the initial WP4 development work, it was decided to include a greater number of items rather than fewer items from the CAT item bank where CAT was available to cover a particular subdomain for the static version of the Toolkit (e.g. pain, role/physical/social function, constipation). This was in order to gain feedback from the usability process as to which items performed better than others and where there was redundancy. Therefore, the number of items selected for each subdomain was high at this testing stage, with one of the aims of the usability study being to select the best items for the static version to avoid patient burden at the pilot testing phase (WP7).

Within the Toolkit we created five new items following on from the initial WP4 development work. One new item was developed regarding support from work: ‘Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?’. Four new items were modified from the CCEQ questionnaire [3] within the Healthcare domain; Two in the Communication subdomain: ‘My decisions about care and treatment have been respected by my professional(s)’; and ‘I have been given the opportunity to discuss my treatment plan with my professional(s)’; and two in the Impact of care pathway subdomain: ‘My medical appointments have interfered with my work / household activities’ and ‘My medical appointments have caused problems for my family / carer’.

For the majority of items, the response scale consisted of 4-likert scale response categories: 1: not at all, 2: a little, 3: quite a bit and 4: very much. For all items there was an option to not complete (‘prefer not to answer’) and for some items, a ‘not applicable’ option was also included. The Overall QOL and Overall health response categories range from 1-7. The Healthcare domain response categories were: 4-likert scale response categories: 1: not at all, 2: a little, 3: quite a bit and 4: very much, or a 5-likert scale response 1: Poor, 2: Fair, 3: Good, 4: Very good and 5: Excellent.

The majority of items have a one week recall period however a few items have a four-week recall, including items on sexual activity. Other items include the item stem: ‘Since the diagnosis and treatment of your cancer’.

Eligibility criteria for participants

Patient were considered eligible for the study if they were:

- Age 18+, from the target groups defined above: A: Active treatment; B: Survivors; C: Palliative.
- Able and willing to give informed consent.
- Able to read and understand local language.
- Not exhibiting overt psychopathology or serious cognitive dysfunction, which would impede their being able to take part in the study.

Usability Study Design

Patients from each cancer group in five different countries took part; UK, The Netherlands, France, Germany and Italy. Interviews were planned in Denmark but were not able to be completed in the timeframe due to staff sickness. Participants were identified and approached by the clinical team and given an information sheet detailing their potential involvement as well as further study information. Participants provided written or verbal informed consent prior to participating in the interview. The interview study took place face to face, on the telephone or online depending on the preference of the patient. Participants completed a socio-demographic and brief medical information form at the start of the study. Additional clinical information was collected by the researcher after obtaining consent. The interview procedures were standardised across the countries and target groups according to a pre-defined and agreed upon interview guide (Appendix 7.1).

Patients completed their target groups' version of the questionnaire, either digital or paper version, and provided feedback on the content through a cognitive interview. Cognitive interviews use a think-aloud approach. The interview was audio recorded for reference. It was not possible to test the CAT version of the questionnaire due to delays in IT set up only the short form (static) versions.

Verbal probing focused on exploration of items and prompting around the question content, the additional text and the functionality of the digital system (if relevant). For example:

- Do the questions accurately reflect all of the quality of life issues they experience (disease and treatment related)? What are those additional symptoms or issues that are missing?
- How do patients interpret and understand the questions?
- How do patients understand the response categories?
- How do patients find readability of the supporting text (i.e. consent page, description of the study)?
- How do patients find the usability of the IT system? Is the visual layout easy to navigate?

After completion of the items, the interviewer asked the patient to report the thought and judgment process they used to answer the questions. The verbal probing started with general views about completion of the questionnaire e.g. level of difficulty, followed by other specific areas including:

- i) the appropriate wording of questions (particularly for cultural literacy),
- ii) interpretation and comprehension of questions,
- iii) comprehensibility of the response scale,
- iv) difficulty of choosing a response
- v) responses to the recall period
- vi) order of the questions

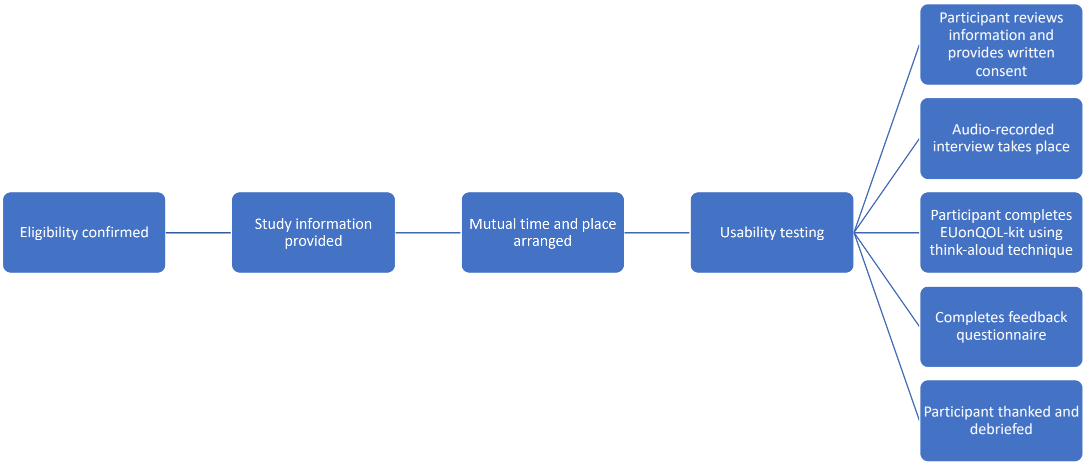

Figure 4: Flow chart for procedures: Usability study (UK).

Sample size

Our aim was to include at least 5-7 patients per target group, with an overall sample size between 24 to 50 patients, and to include patients across six countries, balancing cancer centre, age grouping, gender, and tumour type. The original sample matrix included Denmark (Table 3), however, due to staffing issues in this centre we were only able to recruit in five countries; Leeds, UK; Paris, France; Heidelberg, Germany; Amsterdam, Netherlands; and Milan, Italy. Within this sample, we aimed for 5-7 patients to review the paper version and 5-7 patients will review the online version. We continued the interviews until saturation of themes was reached, reported back to the WP4 team during weekly online research meetings where interview results were feedback.

Table 3. Purposive sampling strategy for the Usability testing.

Centre	**A) Active treatment**		**B) Survivors**	**C) Palliative care**	**Total**
	Curative	**Non-curative**			
LEEDS (UK)	2	2	2	0	6
INT (IT)	2	2	2	2	8
CURIE (FR)	0	3	0	3	6
GR (FR)	0	0	2	0	2
DKFZ (DE)	0	0	6	6	12
RH (DK)*	3	2	5	5	15
NKI (NL)	5	0	5	0	10
Total	**12**	**9**	**22**	**16**	**59**

* Unable to recruit due to staff sickness

Usability Study Analysis

Usability and acceptability will be assessed through descriptive statistics of questionnaire responses from the first draft of the EUonQoL-kit, and qualitative analysis using a thematic content analysis technique of patient cognitive interviews. Broad decision rules for inclusion and exclusion criteria of items, based on EORTC module development guidelines, were considered to highlight potential items which may be preferable for inclusion/exclusion from the list:

1. Range > 2 points (need to have 3 different response categories selected for all items)
2. No floor or ceiling effect: responses in categories 3&4 or 1&2 **>10%**
3. No significant concerns expressed by patients (e.g. item is upsetting, ambiguous, overlapping)
4. Consistency across languages/cultures
5. Compliance: at least 95% response to the item
6. Missing issues: need to have at least ***10%*** of patients mentioning a new issue

3. Results

Demographics

The recruitment of patients to the Usability study was conducted in six centres, across five countries, including UK, Italy, France, the Netherlands, and Germany. In total, 53 adult participants were enrolled into the study Table 4.

Table 4. Usability recruitment matrix.

Centre	A) Active treatment		B) Survivors	C) Palliative care	Total
	Curative	Non-curative			
LEEDS (UK)	4	6	1	1	12
INT (IT)	2	4	4	3	13
CURIE (FR)	0	2	0	4	6
GR (FR)	0	0	5		5
DKFZ (DE)	0	0	7	4	11
RH (DK)	0	0	0	0	0
NKI (NL)	1	0	5	0	6
Total	11	8	22	12	53

Table 5 provides a breakdown of the sample against the key sociodemographic and clinical variables.

Table 5. Demographic and clinical characteristics of the sample.

Demographics	N	%
Gender		
Female	32	60
Male	21	40
Age	N	%
18-39	4	8
40-59	8	15
> 60	41	77
Target Group	N	%
A – Active Treatment	19	36
B – Survivors	22	42
C – Palliative care	12	23
Country	N	%
UK	12	23
Italy	13	25
France - Gustave Roussy	5	9
France - Institute Curie	6	11
Netherlands	6	11
Germany	11	21
Denmark	0	0
Total	53	100
Employment	N	%
Full-time	14	26
Part-time	3	6
Unemployed	0	0.0
Homemaker	0	0.0
Student	0	0.0
Retired	29	55
Disabled	3	6
Other:	3	6
Missing	1	2
Education	N	%
None/ primary school only	14	26
High school	14	26
College or University	18	34
Missing	7	13
Partner Status	N	%

Single	3	6
Married/living with partner	32	60
Partner not living together	3	6
Separated/Divorced	1	2
Widowed	13	25
Missing	1	2
Toolkit version	N	%
Pen and paper	26	49
Digital app	27	51
Clinical Characteristics		
Disease location	N	%
Breast cancer	11	21
Colorectal cancer	11	21
Prostate cancer	5	9
Lymphoma	3	6
Gynaecological cancer	2	4
Head and neck cancer	1	2
Lung cancer	9	17
Melanoma	1	2
Other:	10	19

The sociodemographic background of the participants included is outlined in Table 5. The sample consisted of both males and females, with female participants accounting for 60% of the total sample. Patients of various ages, including those in a younger range (18-39), middle age (40-59) and an older range (60+), were represented. The majority of the sample were aged 60 or over (77%). The sample was also inclusive of patients across the cancer continuum, for example, it included those on active treatment, survivors, and those receiving palliative care. The recruitment targets for Active Treatment and Survivors were met, however for the Palliative group this was slightly lower than targeted.

Country

Multiple languages and European cultures were captured within the diverse sample, with six international sites recruiting participants for this study. Italy contributed the highest number of participants to the study, accounting for 25% of the sample. With the exception of one site (Denmark), where no participants were recruited due to staffing issues recruitment rates across the remaining counties ranged from between 9-23%.

Employment/ Education

The majority of the sample were retired (55%). The employment rate (full or part-time) of participants was 32%, of those 26% were in full-time employment. 6% were unable to work due to cancer related disability. Overall, the education level of the sample was split relatively evenly across the three groups, those that continued their studies beyond high school, for example college or university, accounted for the largest group (34%). Education data was missing for 13% of the sample.

Toolkit delivery

The mode of delivery for the Toolkit was equally split between those that completed via pen and paper and those that completed via the Digital app (49% vs 51%).

Clinical characteristics

With regards to the clinical characteristics of the sample, a wide range of cancers were included. Breast and colorectal cancer were the most commonly included (21%) and lung cancer was the third most common disease site (17%). The 'Other' category accounted for 19% of the sample and included multiple different cancers including rare cancers; for example, kidney, cholangiocarcinoma (and leukaemia), oral cavity squamous cell carcinoma, neuroendocrine tumour, oropharyngeal cancer and peritoneal carcinoma.

Physical Health Domain

The physical health domain consisted of four sub-domain Mobility and Activity, Symptoms, Sex life and Body image. The Symptom sub-domain included nine symptom related issues such as, pain, fatigue, insomnia, appetite, nausea/vomiting, constipation, dyspnoea, symptom burden and symptom side effects.

Quantitative

The overall means, range, response rate, counts of 'prefer not to answer' and 'not applicable' for the items within the Physical Health domain are presented in Table 6. Data are presented at a sub-domain and item level.

Table 6. Quantitative summary of the Physical Health domain.

Items	N	Mean	MAX	MIN	Range	Response rate %	Prefer not to answer	N/A
Mobility & Activity								
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	53	2.00	4	1	3	100	0	0
Do you have any trouble taking a long walk?	22	1.86	3	1	2	100	1	1
Do you need help caring for your feet (e.g. cutting your toenails)?	22	1.58	4	1	3	100	1	3
Do you have any trouble carrying a heavy bag upstairs?	53	2.14	4	1	3	99	1	1
Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	22	2.35	4	1	3	100	1	1
Do you have any trouble taking a short walk outside of the house?	31	1.54	4	1	3	100	0	0
Do you need help undressing?	31	1.03	4	1	3	100	0	0
Do you have any trouble walking for 30 min.?	31	1.79	4	1	3	100	0	0
Pain								
Did pain interfere with your daily activities?	53	1.58	4	1	3	100	1	0
Have you had pain?	53	1.78	4	1	3	100	0	0
Has pain interfered with your social activities?	53	1.48	4	1	3	100	0	1
Has pain made it difficult for you to do the jobs that you usually do around the house?	22	1.41	3	1	2	100	0	1
Have you had severe pain?	31	1.59	4	1	3	99	0	0
Lack of energy								
Were you tired?	53	2.18	4	1	3	100	0	0
Have you felt weak?	53	1.98	4	1	3	100	1	0
Have you felt exhausted?	53	1.79	4	1	3	100	0	0
Have you become easily tired?	22	1.85	4	1	3	100	0	0
Have you lacked energy?	22	1.94	3	1	2	100	0	0
Have you required frequent or long periods of rest?	31	2.14	4	1	3	99	0	0
Have you had a feeling of overwhelming and prolonged lack of energy?	31	1.78	4	1	3	96	0	0
Sleeping problems								
Have you had trouble sleeping?	53	2.06	4	1	3	100	0	0
Have you had trouble getting a good night's sleep?	53	1.96	4	1	3	100	0	0
Have you had trouble staying asleep?	22	2.58	4	1	3	100	0	0
Have you woken up for long periods during the night?	31	1.78	4	1	3	99	0	0

Appetite								
Have you forced yourself to eat?	12	1.75	4	1	3	100	0	0
Have you lacked appetite?	12	2.15	4	1	3	100	0	0
Have you lacked interest in eating?	12	1.52	3	1	2	100	0	0
Nausea								
Have you felt nauseated?	31	1.54	4	1	3	99	0	0
Have you vomited?	31	1.24	3	1	2	99	0	0
Has nausea or vomiting been a problem for you?	31	1.25	4	1	3	99	0	0
Has nausea or vomiting interfered with your physical activities like taking a walk?	31	1.20	4	1	3	99	0	1
Constipation								
Have you been constipated?	12	1.35	4	1	3	100	1	0
Have you had stools that were too hard to pass?	12	1.25	4	1	3	100	0	0
Have your stools been so hard that they were painful to pass?	12	1.15	4	1	3	100	0	0
Breathing problems								
Were you short of breath?	53	1.43	4	1	3	100	0	0
Did you have severe shortness of breath?	12	1.02	3	1	2	100	0	0
Were you short of breath when walking more than 100 m (100 yds)?	12	1.20	3	1	2	100	0	0
Were you short of breath when walking less than 100 m (100 yds)?	12	1.10	3	1	2	100	0	0
Symptom worries								
Have you been watching yourself closely for any new symptoms?	53	2.19	4	1	3	100	0	0
How much has your disease been a burden to you?	53	2.54	4	1	3	100	0	0
Symptom side effects								
To what extent have you been troubled with side-effects from your treatment?	53	2.12	4	1	3	100	1	5
Body Image								
Have you been dissatisfied with your physical appearance?	22	2.03	4	1	3	100	0	0
Sex Life								
Has the disease or treatment affected your sex life (for the worse)?	41	2.98	4	1	3	98	0	10

The N of each item varied, as this was dependent on whether the item was included in one, two or all three of the Toolkits related to the three different target populations. The range of responses were found to consistent across each of sub-domains with a full range of responses selected. The sub-domain ‘breathing problems’ was the exception to this, where three of the four items had a range of two. The response rate for the physical health domain was high, with each item reporting a response rate of above 95%. In general, items that ask about sex or sex related question often have a lower response rate, however the inclusion of N/A within the response scale of the Toolkits saw the compliance for this item remained high and in line with the rest of the physical health domain.

As part of the Usability testing, an additional response option was added to the Toolkit. This response option was 'prefer not to answer' and was included to highlight any problematic items within the Toolkits and to allow participants completing using the online version the same flexibility not to complete an item if they chose to as would be possible with the paper version. Within the Physical Health domain, the results for the 'Mobility and activity' subdomain highlighted potential issues with the items presented. This was then explored further in the qualitative data which suggested the participant did not know how to answer these questions due to the lack of a specified recall period for this subdomain. A 'Not Applicable' response option was included for all items within the digital version, however included only for specific items in the paper version. The item relating to sexual activity was most commonly responded as 'N/A' (n=10). When exploring the qualitative data, it was clear that the reason the item was N/A for many was related to aging. Symptom side effects item was marked as N/A for five participants, this was linked to the survivor group no longer experiencing treatment related side-effects. In the paper version the N/A' response was not available for this item, however these results from the digital version of the Toolkit suggested this should be added to the questionnaire for the survivors. Further to this, the item 'Do you need help caring for your feet…' was reported as N/A for three participants as they felt that they did not know how to respond.

Qualitative

The next section describes the qualitative summary of the interview data collected during the Usability study. Data is presented as an overview of the feedback provided across the three Toolkits and summarised at a sub-domain level
Table 7.

Table 7. Qualitative summary of the Physical Health domain (green shading = item included for target population)

	Sub-Domain	A	B	C	QUALITATIVE SUMMARY
	Pain				
Q22	Did pain interfere with your daily activities?	🟩	🟩	🟩	General – “hard to answer because of co-morbidities”. Overlapping - Pain questions repetitive. Conditional to if experienced Pain. Formatting - Q12 should come first. Recall period - Make clear 'in the past week'. Language - 'Severe' item not understood (x1)
Q12	Have you had pain?	🟩	🟩	🟩	
Q758	Has pain interfered with your social activities?	🟩	🟩	🟩	
Q750	Has pain made it difficult for you to do the jobs that you usually do around the house?		🟩		
Q759	Have you had severe pain?	🟩		🟩	
	Lack of energy				
Q21	Were you tired?	🟩	🟩	🟩	General - Age related? Need more info at start of questionnaire e.g. is it specific to cancer. Overlapping - repetitive items. Recall period - Make clear 'in past week'. Language - 'Weak' & 'Exhausted' sometimes perceived as psychological. Some items too vague.
Q15	Have you felt weak?	🟩	🟩	🟩	
Q502	Have you felt exhausted?	🟩	🟩	🟩	
Q737	Have you become easily tired?		🟩		
Q159	Have you lacked energy?		🟩		
Q743	Have you required frequent or long periods of rest?	🟩		🟩	
Q740	Have you had a feeling of overwhelming and prolonged lack of energy?	🟩		🟩	
	Sleep issues				
Q14	Have you had trouble sleeping?	🟩	🟩	🟩	General - Q14 key item. Overlapping - repetitive, not necessary to ask all. Language - Q788 + Q790 problematic in understanding the item.
Q789	Have you had trouble getting a good night's sleep?	🟩	🟩	🟩	
Q788	Have you had trouble staying asleep?		🟩		
Q790	Have you woken up for long periods during the night?	🟩		🟩	
	Appetite				
Q303	Have you forced yourself to eat?			🟩	No comments
Q16	Have you lacked appetite?			🟩	

Q783	Have you lacked interest in eating?			🟩	
	Nausea + Vomiting				
Q17	Have you felt nauseated?	🟩		🟩	General - Conditional, not necessary to ask all items. Overlapping - All items repetitive. Mixed feedback on which items to include out of Q17, Q18 & Q35.
Q18	Have you vomited?	🟩		🟩	
Q767	Has nausea or vomiting been a problem for you?	🟩		🟩	
Q768	Has nausea or vomiting interfered with your physical activities like taking a walk?	🟩		🟩	
	Constipated				
Q19	Have you been constipated?			🟩	Missing diarrhoea
Q825	Have you had stools that were too hard to pass?			🟩	
Q826	Have your stools been so hard that they were painful to pass?			🟩	
	Shortness of breath				
Q11	Were you short of breath?	🟩	🟩	🟩	Overlapping - Not necessary to ask all.
Q804	Did you have severe shortness of breath?			🟩	
Q807	Were you short of breath when walking more than 100 m (100 yds)?			🟩	
Q817	Were you short of breath when walking less than 100 m (100 yds)?			🟩	
	Symptom worries				
Q556	How much has your disease been a burden to you?	🟩	🟩	🟩	General - Very important to ask. Add N/A for Q556. Linked to Anxiety/worry. Language - German - Q46 wording 'Burden' physical or psychological?
Q46	Have you been watching yourself closely for any new symptoms?	🟩	🟩	🟩	
	Symptom side effects				
Q168	To what extent have you been troubled with side-effects from your treatment?	🟩	🟩	🟩	General - Not relevant to Group B Recall period - Hard to answer 'in the past week. Response scale – Difficulty answering for one participant (GER), too few options.
	Mobility & Activity				
Q4	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	🟩	🟩	🟩	Items too general - no reference to whether its referring to cancer related experience. Age related. Overlapping - Carrying bags and Walking. To be reduced/combined. Group B has issues with redundancy.
Q5	Do you have any trouble taking a long walk?		🟩		
Q628	Do you need help caring for your feet (e.g. cutting your toenails)?		🟩		

Q641	Do you have any trouble carrying a heavy bag upstairs?	🟩	🟩	🟩	Language - Ambiguous e.g. what is 'long' – with patients preferring more specific descriptors e.g. 30mins.
Q644	Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?		🟩		
Q6	Do you have any trouble taking a short walk outside of the house?	🟩		🟩	
Q647	Do you need help undressing?	🟩		🟩	
Q631	Do you have any trouble walking for 30 min.?	🟩		🟩	
	Sex life				
Q467	Has the disease or treatment affected your sex life (for the worse)?	🟩	🟩		General - No issues asking this question. N/A important, most cases was Age related. Recall period - past week is too short. Could be 4 weeks or since diagnosis or no recall period.
	Body Image				
Q981	Have you been dissatisfied with your physical appearance?		🟩		Language – One reported issue interpreting 'physical appearance' (GER). Requires participants to be self-critical.

Physical Health Domain Themes

A key theme emerging from the qualitative data was the issue of overlapping and/or repetitive items within certain sub-domains of Physical Health. This was a common theme amongst the items within the Symptom sub-domain. More items were included at this stage of the process for each subdomain from the CAT options available to provide feedback and detail on the best items to include in the final version for pilot testing (see detail from Report D4.1). Participants identified Pain, Lack of energy, Sleeping problems and Nausea as including overlapping items and suggested that they be reduced. Further examination of the data highlighted that in the palliative care Toolkit, symptoms relating to Appetite, Constipation and Shortness of breath also included repetitive items that should be removed. Overlap was also identified in the Mobility and activity sub-domain whereby participants felt items were repetitive, for example, duplication of items asking about 'heavy bags' and 'walking'.

A second theme that emerged from the data was related to language issues. This included instances where the item wording was challenging to comprehend, or there were issues with the included translations. Minor comprehension related issues were found for some items within the Pain, Sleep and Body image subdomains, with participants not always understanding what the items were asking. Lack of specificity within the items was found for Mobility and activity and Lack of energy. Minor translational issues were identified within the Symptom worries and Side effects sub-domains in German and Dutch.

The recall period of the items was also raised as a concern for some items. The recall period for the Mobility and activity and Pain domains were often highlighted. This may be due to the fact that these sub-domains were presented first, and participants were unsure of how to respond, particularly for the Mobility and activity questions as these do not include a recall period (as per EORTC QLQ-C30). Symptom side effects and Sex life questions were also identified as being difficult to answer in the proposed recall period of 'During the past week' and instead should include a wider range, for example 'During the past 4 weeks'.

Psychological Health and Wellbeing Domain

The psychological health domain consisted of five sub-domains and included Anxiety and worry, Fear of recurrence, Future outlook, Spirituality and Concentration and memory.

Quantitative

The overall means, range, response rate, counts of 'prefer not to answer' and 'not applicable' for the items within the Psychological Health and Wellbeing domain are presented in Table 8. Data are presented at a sub-domain and item level.

Table 8. Quantitative summary of the Psychological Health and Wellbeing domain.

Items	N	Mean	MAX	MIN	Range	Response rate %	Prefer not to answer	N/A
Anxiety and worry								
Did you feel tense?	31	1.73	4	1	3	99	0	0
Have you felt vulnerable?	53	1.67	4	1	3	99	0	0
Have you felt that nothing could cheer you up?	31	1.19	4	1	3	99	1	0
Have you felt miserable?	53	1.52	4	1	3	100	0	0
Did you feel depressed?	53	1.54	4	1	3	100	0	0
Did you worry?	22	2.49	4	1	3	100	0	0
Have you felt sad?	22	1.90	4	1	3	100	0	0
Fear of recurrence								
Have you worried about recurrence of your disease?	22	2.76	4	1	3	100	0	0
Have you been afraid of tumor progression?	19	2.03	4	1	3	100	0	0
Future outlook								
Have you worried about your health in the future?	53	2.39	4	1	3	100	0	0
Because of your experience with cancer, have you had to limit your life plans or goals?	53	2.39	4	1	3	100	0	1
Spirituality								
I have felt at peace with myself	53	2.40	4	1	3	96	1	1
Concentration & Memory								
Have you had difficulty remembering things?	53	1.54	4	1	3	100	0	0
Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	53	1.72	4	1	3	100	1	0
Have you been forgetful?	22	1.68	3	1	2	100	0	0
Have you had difficulty remembering what someone just told you?	31	1.29	4	1	3	99	0	0
Have you had difficulty maintaining concentration even when doing something important?	53	1.70	4	1	3	100	0	0

Overall, there was a strong performance of the items across the psychological sub-domains, including high response rates and a wide range of responses given by participants. There were no concerns over participants skipping items using the ‘prefer not to answer’ response option, nor were there excessive use of the ‘not applicable’ response within this domain.

Qualitative

The next section describes the qualitative summary of the interview data collected during the Usability study. Data is presented as an overview of the feedback provided across the three Toolkits and summarised at a sub-domain level Table 9.

Table 9. Qualitative summary of the Psychological Health and Wellbeing domain (green shading = item included for target population)

	Sub-Domain	A	B	C	QUALITATIVE SUMMARY
	Anxiety and worry				
Q24	Did you feel tense?	🟩		🟩	General - Comments around items not being specific to cancer. Overlapping - Q655, 665, 27,25 669. Repetitive and overlapping items. Language - Interpretation of items were sometimes seen as physical Q24, Q655. Translation German Q665, Dutch Q669.
Q655	Have you felt vulnerable?	🟩	🟩	🟩	
Q660	Have you felt that nothing could cheer you up?	🟩		🟩	
Q665	Have you felt miserable?	🟩	🟩	🟩	
Q27	Did you feel depressed?	🟩	🟩	🟩	
Q25	Did you worry?		🟩		
Q669	Have you felt sad?		🟩		
	Fear of recurrence				
Q364	Have you worried about recurrence of your disease?		🟩		General - important to ask these items. Recall period - Participants suggested the recall period of 'past week' might be too short. Language – 'Progression' might be difficult to comprehend for those with lower literacy levels. Translation issue in German Q364.
Q587	Have you been afraid of tumor progression?	🟩			
	Future outlook				
Q41	Have you worried about your health in the future?	🟩	🟩	🟩	General - Participants suggested the answers may be related more to Age. Overlapping - Select one item to ask as there is overlap. Recall period - difficult to answer as within 'past week' Response scale - could be widened for these types of items.
Q988	Because of your experience with cancer, have you had to limit your life plans or goals?	🟩	🟩	🟩	
	Spirituality				
Q596	I have felt at peace with myself	🟩	🟩	🟩	General - somewhat mixed feedback with participants reporting the question was unclear, difficult to answer and one found it to be upsetting which could

		🟩	🟩	🟩	related to the translation in German. Positive wording was confusing for some.
	Concentration & Memory				
Q28	Have you had difficulty remembering things?	🟩	🟩	🟩	General - very relevant sub-domain for some. Many raised issues around memory issues being related to age rather than cancer. This was a strong theme. Overlapping - many found this sub-domain to include repetitive and redundant items.
Q23	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	🟩	🟩	🟩	
Q692	Have you been forgetful?		🟩		
Q695	Have you had difficulty remembering what someone just told you?	🟩		🟩	
Q703	Have you had difficulty maintaining concentration even when doing something important?	🟩	🟩	🟩	

Psychological Health and Wellbeing Domain Themes

Within the Psychological Health and Wellbeing domain, several of the sub-domains were identified as including overlapping and/or repetitive items. Specifically, participants highlighted this for items within the Anxiety and worry, Future outlook and Concentration and memory sub-domains. These were identified by the participants and could therefore be considered for removal in the next phase of the project.

Issues with the included translations were identified across three of the sub-domains, of which, the German translations seemed to be problematic for Q665 in Anxiety and worry, in Q364 in Fear of recurrence and Q596 in Spirituality. Item Q669 in the Anxiety sub-domain was also challenging to comprehend in Dutch.

The recall period of ‘past week’ was found to be somewhat challenging for some participants who felt that this was not long enough to either capture the issue well or not long enough to be able to answer the question in a meaningful way. This issue was raised in the Fear of recurrence and Future outlook sub-domains.

The Spirituality item was perceived to be upsetting by one participant from Germany and is thought to be as a result of the translation used. This is to be examined further in the next phase of the study to ensure the item is not upsetting those completing the questionnaire. Whilst the items in the psychological domain can be considered or viewed as potentially upsetting, participants were willing to answer and did not raise major concerns around this issue.

Social Health Domain

The Social health domain comprised of four sub-domains, Social role and activities, Family and relationships, Maintaining independence and Financial aspects. The summarised results from each subdomain are presented within this section and included both the quantitative and qualitative results of the study. The individual items for each sub-domain are presented.

Quantitative

The overall means, range, response rate, counts of ‘prefer not to answer’ and ‘not applicable’ for the items within the Social Health domain are presented in Table 10. Data are presented at a sub-domain and item level.

Table 10. Quantitative summary of the Social Health domain.

Items - English	N	Mean	MAX	MIN	Range	Response rate %	Prefer not to answer	N/A
Social role & Activities								
Have you been limited in doing light housework (e.g. dusting or making the bed)?	31	1.49	4	1	3	99	0	0
Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?	22	1.53	4	1	3	97	1	1
Were you limited in doing either your work or other daily activities?	53	1.70	4	1	3	100	0	0
Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	31	2.00	4	1	3	97	1	1
Were you limited in pursuing your hobbies or other leisure time activities?	53	1.82	4	1	3	100	0	1
Family and Relationships								
As a result of your physical condition or medical treatment, have you preferred to spend time alone?	22	1.93	3	1	2	100	0	0
As a result of your physical condition or medical treatment have you been less able to see your family or friends?	31	1.80	4	1	3	99	0	0
As a result of your physical condition or medical treatment, have you spent less time with your family or friends?	53	1.66	4	1	3	100	0	0

As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?	53	1.47	4	1	3	100	2	2
As a result of your physical condition or medical treatment, have you found it hard to make contact with people?	53	1.53	4	1	3	100	1	1
Has your physical condition or medical treatment interfered with your family life?	53	1.58	4	1	3	100	2	1
Has your physical condition or medical treatment interfered with your social activities?	53	2.00	4	1	3	100	2	2
Has your physical condition or medical treatment interfered with your relationships with your family or friends?	31	1.42	4	1	3	99	0	0
Have you worried about your ability to have children?	41	1.67	4	1	3	96	1	23
Maintain independence								
Have you worried that you are a burden to other people	53	1.85	4	1	3	99	0	0
Have you worried about becoming dependent on others?	53	2.06	4	1	3	100	1	1
Financial aspects								
Has your physical condition or medical treatment caused you financial difficulties?	53	1.32	4	1	3	100	0	0
Has your physical condition or medical treatment caused you financial difficulties leading to changes in your lifestyle?	53	1.21	4	1	3	99	0	1
As a result of your physical condition or medical treatment, have you had less money to spend on yourself (e.g., for buying yourself something that you would like to have but don't necessarily need)?	53	1.48	4	1	3	99	1	1
As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?	31	1.04	4	1	3	98	0	0
Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	41	1.32	4	1	3	98	1	13
Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	53	1.59	4	0	4	94	1	26

This domain elicited strong ranges and response rates. Several patients selected “prefer not to answer” for items in the Family and Relationships subdomain. The qualitative data shows that many participants found these items difficult to answer due to the selected recall period for the questions.

The ‘not applicable response’ was also selected in response to several items in the Social domain, including on items relating to fertility and finance/work as expected, with the results affected by the large percentage of participants (55%) who are retired and/or over the age of 60 (77%).

Qualitative

Qualitative data is presented below as an overview of the feedback provided across the three Toolkits and summarised at a sub-domain level Table 11.

Table 11. Qualitative summary of the Social Health domain (green shading = item included for target population)

	Sub-Domain	A	B	C	QUALITATIVE SUMMARY
	Social role & Activities				
Q673	Have you been limited in doing light housework (e.g. dusting or making the bed)?	🟩		🟩	General - Housework N/A to some. Recall period - Make 'in the past week clearer. Participants often didn’t respond to this recall period. Or consider extending. Language - Difficulty understanding Q674 'recreational' & 'physically demanding' (Dutch). German translation issues Q679.
Q674	Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?		🟩		
Q7	Were you limited in doing either your work or other daily activities?	🟩	🟩	🟩	
Q679	Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	🟩		🟩	
Q10	Were you limited in pursuing your hobbies or other leisure time activities?	🟩	🟩	🟩	
	Family and Relationships				
Q714	As a result of your physical condition or medical treatment, have you preferred to spend time alone?		🟩		General - Q29 was perceived as good. Q714 could be difficult for those living alone. Q719 was ‘Prefer not to answer’ by 2 due to recall period difficulties. Q155 - N/A for most due to Age. Overlapping - Lots of items for this topic, could ask fewer. Repetitive. Recall period - difficulties answering, 'in past week'. Language - Issues having both 'Family' & 'Friends' in the same item. Made it
Q715	As a result of your physical condition or medical treatment have you been less able to see your family or friends?	🟩		🟩	
Q718	As a result of your physical condition or medical treatment, have you spent less time with your family or friends?	🟩	🟩	🟩	
Q719	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?	🟩	🟩	🟩	
Q720	As a result of your physical condition or medical treatment, have you found it hard to make contact with people?	🟩	🟩	🟩	

Q29	Has your physical condition or medical treatment interfered with your family life?	🟩	🟩	🟩	difficult to answer for some. Take 'As a result of…' out the item and add above.
Q30	Has your physical condition or medical treatment interfered with your social activities?	🟩	🟩	🟩	
Q721	Has your physical condition or medical treatment interfered with your relationships with your family or friends?	🟩		🟩	
Q155	Have you worried about your ability to have children?		🟩		
	Maintain independence				
Q294	Have you worried that you are a burden to other people	🟩	🟩	🟩	General - Important issue. Could be made more specific. One participant preferred Q294 over Q209. Language - Q294 (Dutch) translation clashes with recall period.
Q209	Have you worried about becoming dependent on others?	🟩	🟩	🟩	
	Financial aspects				
Q31	Has your physical condition or medical treatment caused you financial difficulties?	🟩	🟩	🟩	General - important domain, Q31 good as its General but also people liked the more specific items too. Overlapping - Q848 & Q850 overlap with Q77. Recall period - More specific items harder to answer in past week (Q1011, 850 & NEW. Mixed recall periods in the same domain. Language - Item stems are too long, they make the questions harder to answer. NEW item – potential issues with if this is physical or emotional support, mixed recall period as asked with past week section. Participants also felt it was a good question to ask. Q848 'Prefer not to answer' because it was viewed as a vulnerable line of questioning.
Q848	Has your physical condition or medical treatment caused you financial difficulties leading to changes in your lifestyle?	🟩	🟩	🟩	
Q849	As a result of your physical condition or medical treatment, have you had less money to spend on yourself (e.g., for buying yourself something that you would like to have but don't necessarily need)?	🟩	🟩	🟩	
Q850	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?	🟩		🟩	
Q1011	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	🟩	🟩		
New	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	🟩	🟩	🟩	

Social Domain Themes

General comments around the included sub-domains and items with the Social Health domain were positive, with participants recognising the importance of asking these questions particularly those relating to maintaining independence, financial difficulties, and employment.

Overlapping items were highlighted in two of the sub-domains. The family and relationships subdomain included up to eight items on the usability questionnaire. As a result, several participants found some of the items to be repetitive. For example, participants felt that Q715, Q718, Q719, and Q720 were overlapping and all addressed the idea of personal isolation. This same pattern emerged in relation to the financial subdomain; participants found several of the six items to contain overlapping content including Q848, Q850, and Q77.

Language related problems were identified across each of the sub-domains and included translational issues, comprehension issues and burdensome items. Translational issues impacted Social role and activities and Maintaining independence whereby participants reported difficulty understanding Q674 'recreational' & 'physically demanding' in Dutch, and Q679 in French. Participants also noted that the items in the Family and relationships and Financial domains were overly long and could have been clarified by separating the item stem from the prompt itself. Additionally, items that referenced family and friends were difficult to answer for two participants as they were alone.

Some participants found responding to the ‘During the past week’ recall period challenging for the items included in the Social Health domain, specifically for the items relating to finances. Items within this sub-domain had mixed recall periods including both ‘During the past week’ and ‘Since the diagnosis and treatment of your cancer:’ which some participants found confusing. It was also noted that Q850 asks directly about monthly tasks yet was included in the past week recall period (note that this item is part of the CAT item bank). The order and presentation of this sub-domain should be considered when developing Version 2 of the Toolkit to ensure that the recall period is clear to users.

Overall Health and Healthcare Domain

The final domain included in the conceptual framework is that of Overall Health and Healthcare. Overall Health is comprised of three sub-domains, Health behaviour change, Overall Quality of Life and Overall Health Perspective. The Healthcare domain consists of three sub-domains that assess patient experience related to the care they received: Communication with healthcare professionals, Involvement in decision making and Impact of care pathway.

Quantitative

The overall means, range, response rate, counts of 'prefer not to answer' and 'not applicable' for the items within the Overall Health and Healthcare domain are presented in Table 12. Data are presented at a sub-domain and item level.

Table 12. Quantitative summary of the Overall Health & Healthcare domain.

Items	N	Mean	MAX	MIN	Range	Response rate %	Prefer	N/A
Overall Health Domain								
Health behaviour change								
Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?	41	2.27	4	1	3	100	0	1
OVERALL QOL								
How would you rate your overall quality of life during the past week?	53	4.13	6	1	5	94	1	0
Overall health perspective								
How would you rate your overall health during the past week?	53	3.98	6	1	5	94	0	0
Healthcare Domain								
Communication with HCPs								
Have you been satisfied with your communication with your professional(s)?	53	3.47	4	1	3	100	0	0
Have your professional(s) spent enough time talking with you?	53	3.39	4	1	3	100	0	0
Have your professional(s) used language that you understand (avoided medical jargon, used clear terms)?	53	3.34	4	1	3	100	0	1

Have your professional(s) taken into account how you prefer to receive information?	53	3.18	4	1	3	100	2	2
Involvement in decision making								
Have you felt that you and your professional(s) had a shared understanding of your disease and treatment?	53	3.33	4	1	3	100	1	1
My decisions about care and treatment have been respected by my professional(s)	31	3.28	4	1	3	99	0	2
I have been given the opportunity to discuss my treatment plan with my professional(s)	31	3.23	4	1	3	99	1	0
Impact of care pathway								
Have you felt satisfied with the care you have received?	53	3.45	4	1	3	99	1	1
Have you felt satisfied with the information you have received (e.g. about the disease and its treatment)?	53	3.30	4	1	3	100	0	0
My medical appointments have interfered with my work / household activities	53	1.37	4	1	3	100	0	4
My medical appointments have caused problems for my family / carer	53	1.32	4	1	3	100	0	2
The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?	53	3.98	5	1	4	99	1	1

Within the Overall Health domain, participants selected a wide range of response options indicating strong performance of the items. The scale for overall health and overall quality of life sub-domains were 1-7, however no participants rated health or quality of life as being excellent (7). These items had slightly lower response rate than the others, however this was not of significant concern as the response rates were close to 95% (94%) and these items are widely validated as part of the EORTC QLQ-C30.

Impact of care pathway saw mixed performance of items, with regards to the mean scores; a likely result of the inclusion of both satisfaction questions, which scored very highly, versus inference questions that addressed the participant’s experience. Items relating to medical appointments saw slightly higher number of N/A responses due to the Survivorship group no longer having regular appointments.

Qualitative

Qualitative summary of the interview data collected during the Usability study. Data is presented as an overview of the feedback provided across the three Toolkits and summarised at a sub-domain level Table 13.

Table 13. Qualitative summary of the Overall Health & Healthcare domain (green shading = item included for target population)

	Sub-Domain	A	B	C	QUALITATIVE SUMMARY
	Health behaviour change				
Q1012	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?	🟩	🟩		General - Mixed feedback. Some say good to ask this question, others felt N/A because they already had positive lifestyle before diagnosis. Recall period - doesn't fit with the 'past week', should be longer. Result of an IT formatting issue.
	OVERALL QOL				
Q33	How would you rate your overall quality of life during the past week?	🟩	🟩	🟩	Overlapping - Similar to Q32. Recall period - one suggestion of changing to 'past 4 weeks'. Response scale - some issues with changing scales and lack of labelling was strange. Others had no issue with this.
	Overall health perspective				
Q32	How would you rate your overall health during the past week?	🟩	🟩	🟩	General - will capture variance across illness phases.
	WISP				
WISP	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?	🟩	🟩	🟩	The Write in Symptoms or Problems was not adequately assessed as the digital app was unable to accommodate this style of question. Overall feedback was that this type of question was important to include to allow participants to write in any missing issues they have.
	Communication with HCPs				

Q429	Have you been satisfied with your communication with your professional(s)?	🟩	🟩	🟩	Overlapping - Repetitive Q401 covered by Q429. Recall period - Issues with 'Most Recent' What does this refer too? Language - Issues with 'professionals' who are they. Q421 extremely problematic with regards to comprehension and the word Professionals (German). Response scale - could be extended to include more options. Several participants not satisfied with scale as the responses did not fit with the scale e.g. should include 'very satisfied'.
Q401	Have your professional(s) spent enough time talking with you?	🟩	🟩	🟩	
Q409	Have your professional(s) used language that you understand (avoided medical jargon, used clear terms)?	🟩	🟩	🟩	
Q421	Have your professional(s) taken into account how you prefer to receive information?	🟩	🟩	🟩	
	Involvement in decision making				
Q398	Have you felt that you and your professional(s) had a shared understanding of your disease and treatment?	🟩	🟩	🟩	Language - CCEQ 91 French translation issue. Q398 Prefer not to answer due to unclear wording. Response scale - Several participants not satisfied with scale as the responses did not fit with the scale e.g. should include 'very satisfied'.
CCEQ - mod	My decisions about care and treatment have been respected by my professional(s)	🟩		🟩	
CCEQ - mod	I have been given the opportunity to discuss my treatment plan with my professional(s)	🟩		🟩	
	Impact of care pathway				
Q386	Have you felt satisfied with the care you have received?	🟩	🟩	🟩	Language - Q884 problematic due to wording 'after treatment' N/A for group A and C. Too long and translation issues (Dutch). Recall period - Consider 'past 4 weeks'. Response scale - Several participants not satisfied with scale as the responses did not fit with the scale e.g. should include 'very satisfied'.
Q387	Have you felt satisfied with the information you have received (e.g. about the disease and its treatment)?	🟩	🟩	🟩	
CCEQ - mod	My medical appointments have interfered with my work / household activities	🟩	🟩	🟩	
CCEQ - mod	My medical appointments have caused problems for my family / carer	🟩	🟩	🟩	
Q884	The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?	🟩	🟩	🟩	

Overall Health and Healthcare Themes

Overall Health consisted of three sub-domains, Health behaviour change, Overall quality of life and Overall health perspective. Emerging themes related to overlap between Overall health and Overall quality of life as well as suggestions to consider extending the proposed recall periods. The overall levels of qualitative feedback for this domain were lower than in other domains, although useful suggestions were provided for consideration in the development of Toolkit V2. The Write in Symptoms and Problems item was not evaluated fully due to restrictions of the digital app not allowing this format of question at this development stage, however, general feedback from those completing on paper was that this item was important to include as it allows participants to include any issues they have that may be missing from the Toolkit.

The Healthcare Domain was categorised into Communication with healthcare professionals, Involvement in decision making and Impact of care pathway. This domain emerged during Stage 1 interviews, as reported in D4.1, and was included in Toolkit V1 to be further assessed in the Usability study. The emerging themes from the Usability study were related to comprehensibility, response scale and overlap between items. Language related issues included translational issues and item phrasing being unclear.

For the Communication sub-domain, participants found it difficult to determine which professionals the item referred to and also raised translation issues for this English word in German and Italian with translation from the English word ‘personnel’ being more appropriate in this context. Participants suggested that the definition of professionals must be explicitly defined either within the question or in the supporting test, to answer the question properly. In addition to this, the term ‘most recent experience’ raised concern as participants struggled to conceptualise what most recent meant. Q421 was highly problematic with regards to its comprehension, many participants failed to understand this item across multiple languages. Many participants evaluated the response scale as insufficient as it did not, in their view, capture what the items were asking, particularly for the satisfaction-based items.

For ‘Involvement in decision making’, Q398 was highlighted as having translation issues in French and for being conceptually difficult to understand for some. In the Impact of care pathway sub-domain, Q884 was a difficult item for active treatment and palliative care patients to answer due to its exclusionary phrasing of ‘After treatment’. This item also had translation issues in Dutch. Overall, the Healthcare Domain should be carefully reviewed during the development of Toolkit V2 to incorporate the feedback from the Usability study. Items with potentially difficult or challenging items will be highlighted to the translation team to facilitate the successful translation of items.

Toolkit Feedback

Several patients required minor assistance completing the questionnaire in the form of either practical, supportive, or understanding support. Practical support included reading the items aloud, this was for one patient from the palliative group and was particularly frail, or holding the tablet, supportive assistance included encouragement that they were completing it correctly and understanding support was provided to participants that perhaps did not understand the wording. The Toolkit was administered both digitally via an App or via paper and pen. There were several issues identified within the App which made it difficult to use. Problems included major formatting issues (wrong numbering system used, incorrect items appearing & inability to ‘skip items’); minor formatting issues such as font, font size, use of colour and general presentation of the information; functionality of the App not supporting free text response options for the WISP item.

4. Discussion

The results of the Usability study have provided a wealth of quantitative and qualitative data relating to Toolkit V1, that will be used to shape the development of Toolkit V2. It identified key areas of the Toolkit that require further modification and improvement, particularly to reduce the overlap and repetition of items, as well as address the language related issues highlighted during usability testing. The preliminary draft of Toolkit V2 is shown in Appendix 7.2. It also highlighted IT interface weaknesses that will need to be finetuned to administer the questionnaire correctly during the Pilot Study.

Overall, patients found the questionnaires easy to complete and no significant gaps in the content of the questionnaire were highlighted. Several patients required assistance completing the questionnaire in the form of either practical, supportive or understanding support. Although time taken to complete the questionnaire was recorded, however, does not provide a reliable or meaningful insight due to the fact participants were discussing and providing feedback on the items as they were completing and therefore this data is not presented, however, patients provided feedback on the length of the questionnaire in regards to the number of overlapping items. The questions which were most often answered as ‘Not applicable’ could be justified by gender or age-related factors such as fertility issues, sexual activity, work related, and financial (related to applying for insurance, mortgages). None of the items were recorded as upsetting, however, for many of the scaled items patients highlighted significant overlap when completing the static version of the questionnaire. The issue of overlapping items was relevant for all groups, particularly the palliative group who are more vulnerable and may have less energy, because the excessive number of items made the questionnaire more burdensome to complete. This is a challenge when converting a CAT scaled item to a static form and overall there needs to be a balance between improved statistical accuracy and patient burden when selecting items for pilot testing in WP7.

Another common theme from survivors was the recall period for items, for example, that the one-week recall period was not long enough. For non-CAT items, it is possible to review these and agree on a strategy to support patient comprehension and overall this concern can be addressed within the supporting text – for example, explaining that not having a particular issue at the current time is important information, even if it is not representative of their whole patient journey.

5. Conclusions

The Usability study has provided important qualitative and quantitative data from patients that will be used to refine the Toolkit. As a result, Toolkit V2 will be developed and presented in deliverable D4.3 and later tested in the WP7 Pilot study.

6. References

1. Julious S. Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat. 2005;4:287-91.
2. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J Clin Epidemiol. 2012;65:301-8.

3. Harley, C., Pini, S., Kenyon, L., Daffu-O'Reilly, A., & Velikova, G. (2016). Evaluating the experiences and support needs of people living with chronic cancer: development and initial validation of the Chronic Cancer Experiences Questionnaire (CCEQ). BMJ supportive & palliative care.

7. Appendix

7.1 Usability study - Interview debrief schedule

Toolkit - Debrief

1. How long did it take to complete the questionnaire?
2. Did the participant need anyone to help to complete the questionnaire?
2a. If Yes, report the following type(s) of assistance needed to complete the questionnaire (tick all that apply).
2i. Did the participants need PRACTICAL assistance
2ii. Did the participants need SUPPORTIVE assistance
2iii. Did the participants need assistance required for UNDERSTANDING
3. Were there questions that the participant found confusing or difficult to answer?
3a. Which questions were confusing or difficult to answer?
List any issues and relevant code /question number
4. Were the 'intensity' questions difficult to answer with the current response scale? E.g. Have you had severe pain?
4a. Which questions were difficult to answer?
5. Were there questions that the participant you found upsetting?
5a. List any issues and relevant code /question number
6. Questionnaire design
6a. Was the order of the questions acceptable?
6b. Was the appropriate wording used? (translations)
6c. Were the response scales confusing or difficult to select?
6d. Are the response scales for the 'Healthcare domain' items acceptable? E.g. is there preference between using a 4-point or 5-point scale? PREM items (very poor/ poor/ fair/ good/ excellent OR not at all / a little bit/ somewhat/quite a bit/very much)
6e. Were the included recall/time periods acceptable? E.g. in the past week, 4 weeks, since diagnosis.
6f. Were there any items that could be removed/ are not necessary?
7. How easy was it to use the system? (online version only)
8. How did you find the layout of the questionnaire (paper version only)?
9. Were there any changes you would make to the text in the questionnaire (e.g. wording of the consent, description of the study)? (Y/N)
10. Any other comments
10a. Missing issues?
11. Specific IT feedback
11a. Would you have been able to complete this questionnaire at home?
Areas to prompt discussion around:
i) Feedback on the Healthcare domain items e.g. patient preference of items
ii) Feedback on new item 'Have you received support from your employer e.g. arranging flexible working?'
iii) Feedback on the total number of items participants would be willing to answer. E.g. 50, 60 100.

7.2 Provisional Draft Toolkit V2 – All items

Code	All Items – English	N/A	Not at all	A little	Quite a bit	Very much
	We are interested in some things about you and your health. Please answer all of the questions yourself by SELECTING the number that best applies to you. There are no "right" or "wrong" answers.					
Q4	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?		1	2	3	4
Q5	Do you have any trouble taking a long walk?		1	2	3	4
Q641	Do you have any trouble carrying a heavy bag upstairs?		1	2	3	4
Q6	Do you have any trouble taking a short walk outside of the house?		1	2	3	4
Q631	Do you have any trouble walking for 30 min.?		1	2	3	4
	During the past week:					
Q7	Were you limited in doing either your work or other daily activities?		1	2	3	4
Q10	Were you limited in pursuing your hobbies or other leisure time activities?		1	2	3	4
Q12	Have you had pain?		1	2	3	4
Q758	Has pain interfered with your social activities?		1	2	3	4
Q21	Were you tired?		1	2	3	4
Q743	Have you required frequent or long periods of rest?		1	2	3	4
Q14	Have you had trouble sleeping?		1	2	3	4
Q16	Have you lacked appetite?		1	2	3	4
Q17	Have you felt nauseated?		1	2	3	4
Q19	Have you been constipated?		1	2	3	4
	Have you had diarrhoea?		1	2	3	4
Q807	Were you short of breath when walking more than 100 m (100 yds)?		1	2	3	4
Q665	Have you felt miserable?		1	2	3	4
Q27	Did you feel depressed?		1	2	3	4
Q25	Did you worry?		1	2	3	4
Q556	Have you been watching yourself closely for any new symptoms?		1	2	3	4
Q168	To what extent have you been troubled with side-effects from your treatment?		1	2	3	4
Q364	Have you worried about recurrence of your disease?		1	2	3	4
Q587	Have you been afraid of tumor progression?		1	2	3	4
Q41	Have you worried about your health in the future?		1	2	3	4
Q46	How much has your disease been a burden to you?		1	2	3	4
Q988	Because of your experience with cancer, have you had to limit your life plans or goals?		1	2	3	4

Q596	I have felt at peace with myself		1	2	3	4
Q703	Have you had difficulty maintaining concentration even when doing something important?		1	2	3	4
Q30	Has your physical condition or medical treatment interfered with your social activities?		1	2	3	4
Q721	Has your physical condition or medical treatment interfered with your relationships with your family or friends?		1	2	3	4
Q1004	Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?	N/A	1	2	3	4
Q981	Have you been dissatisfied with your physical appearance?		1	2	3	4

During the past 4 weeks:

Q467	Has the disease or treatment affected your sex life (for the worse)?	N/A	1	2	3	4
Q155	Have you worried about your ability to have children?	N/A	1	2	3	4
Q209	Have you worried about becoming dependent on others?		1	2	3	4

During the past week:

Q31	Has your physical condition or medical treatment caused you financial difficulties?		1	2	3	4
Q850	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?		1	2	3	4
Q1011	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	N/A	1	2	3	4
New	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	N/A	1	2	3	4
Q1012	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?		1	2	3	4

	For the following questions please circle the number between 1 and 7 that best applies to you.	Very poor						Excellent
Q33	How would you rate your overall quality of life during the past week?	1	2	3	4	5	6	7
Q32	How would you rate your overall health during the past week?	1	2	3	4	5	6	7

WISP	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?	No	Yes

Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these symptoms or problems during the past week:

During the past week, to what extent have you experienced:

Symptom/problem A:______________________ 1 2 3 4
Symptom/problem B:______________________ 1 2 3 4
Symptom/problem C:______________________ 1 2 3 4

We are interested in your MOST RECENT experience of the care you have received by the professional(s) (doctors, nurses and other caregivers) who have treated you.

CCEQ - mod	Have your medical appointments interfered with your work / household activities?	N/A	1	2	3	4	
CCEQ - mod	Have your medical appointments caused problems for my family / carer ?	N/A	1	2	3	4	
CCEQ - mod	Have you been given the opportunity to discuss your treatment plan with your professional(s) ?		1	2	3	4	
Q409	Have your professional(s) used language that you understand (avoided medical jargon, used clear terms)?		1	2	3	4	
Q429	Have you been satisfied with your communication with your professional(s)?		1	2	3	4	5
Q386	Have you felt satisfied with the care you have received?		1	2	3	4	5
NEW	Do you feel doctors, nurses and other caregivers involved in your care work together as a team?		1	2	3	4	
NEW	Having completed the questionnaire, what do you feel most impacts your QOL?	______________________ ______________________					

Please note that your answers will not appear in your medical record. If you experience symptoms or side-effects or are in need of help, please report them to your doctor or nurse specialist.