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Published in:
BMJ Open

DOI:
10.1136/bmjopen-2023-075752

Publication date:
2024

License:
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Document Version:
Final published version

BMJ Open

Investigating experiences of people with advanced breast or lung cancer in their natural context: protocol for an experience sampling study

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To cite: Geeraerts J, Pivodic L, De Nooijer K, *et al*. Investigating experiences of people with advanced breast or lung cancer in their natural context: protocol for an experience sampling study. *BMJ Open* 2024;**14**:e075752. doi:10.1136/bmjopen-2023-075752

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-075752).

Received 17 May 2023
Accepted 02 February 2024

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ABSTRACT

Introduction People with advanced cancer can experience a wide range of multidimensional symptoms or concerns, but little is known about when and how these fluctuate in daily life. Experience sampling methods (ESMs) involve repeated self-reports in people's natural contexts aimed at uncovering everyday life experiences. ESM has limited recall bias and good ecological validity but might be burdensome to patients. This study aims to pretest and evaluate the feasibility and clinical utility of a validated ESM and use it to explore everyday experiences of people living with advanced breast or lung cancer.

Methods and analysis In step 1, we will optimise our ESM method by pretesting it through usability interviews and a pilot ESM study. In step 2, we will evaluate and use the ESM method through an observational ESM study to investigate the daily experiences of people with advanced breast or lung cancer. Step 2 also includes interviews with healthcare professionals to determine the clinical utility of ESM in oncology. Participants will complete a digital questionnaire ten times per day, measuring momentary experiences in the physical, psychological, social, spiritual-existential domains and context. Multilevel regression models will analyse fluctuations and temporal relations among measured experiences and context. Analyses also include evaluation of compliance and participation rates. We will apply content analysis to the usability interviews and follow-up interviews of the pilot ESM study.

Ethics and dissemination We obtained approval from the ethics committees of the University Hospitals of Brussels (BUN: 1432023000043) and Ghent (ONZ-2023-0136). Results will be published in open-access, peer-reviewed journals and presented at conferences. If ESM appears feasible in this population, it could offer new insights into the daily experiences and help optimise support for people with advanced cancer.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ People with advanced breast or lung cancer and healthcare professionals contributed significantly to the development of the method used in the study. Moreover, patients will continue to contribute to the method, as this study aims to extensively pretest the method among patients before employment in an observational experience sampling method study.
⇒ This study makes sure to include the often under-represented group of people over the age of 70, by including an equal amount of people aged younger and older than 70 years old.
⇒ High frequency sampling allows the detailed exploration of the levels of variability of patient experienced symptoms, problems, and well-being throughout and across days.
⇒ Findings in this sample might not be generalisable to a broader oncology population.
⇒ Frequent daily assessments could cause patient burden and missing data, which this study aims to investigate.

INTRODUCTION

This study aims to uncover the potential of experience sampling methods (ESMs) for understanding symptoms and problems experienced by patients with advanced cancer. Increased efficacy of cancer treatments has led to a rising global population of people living with advanced cancer.[1 2] Despite effective strategies to reduce side effects of treatments, many people with advanced cancer experience an array of physical symptoms such as pain, fatigue or dyspnoea,[3 4] but also psychosocial[5] and spiritual or existential concerns.[6 7] However, as most available instruments (eg, patient-reported outcome measures or PROMs) assess these problems and concerns retrospectively over the previous days or week,[8] there is currently limited temporal fine-grained understanding of how these symptoms or concerns occur and fluctuate in the context of daily life. Gaining knowledge on the everyday experiences of patients with cancer is vital for improving patient-centred care, as it offers a comprehensive view of patients' daily lives and could lead to treatment optimisation (eg, due to higher sensitivity in detecting

adverse effects)[9] and identification of possible intervention targets.

To address this gap, one promising solution is offered by ESMs, also known as ecological momentary assessment (EMA).[10] ESM involves repeatedly gathering self-report data from participants in their daily lives, often using mobile technologies such as smartphones. ESM offers several advantages over 'traditional' measures of symptoms and concerns that rely on recall over a given preceding period.[11 12] First, ESM offers the ability to study fine-grained temporal variability of experiences by measuring the same concept multiple times per day, for several consecutive days.[13] Second, ESM limits recall biases as items are presented in the moment, not requiring the individual to recall or aggregate information over larger periods of time.[14] Third, ESM improves ecological validity by measuring experiences in natural contexts[14] and considering contextual factors such as current activities or social company. These advantages make ESM particularly useful for studying people's daily experiences and a unique addition to the so-called internet of medical things, as it can supplement current passive monitoring strategies in telemedicine with data on real-time patient-experienced symptoms, concerns and well-being.[15] Moreover, these advantages have helped

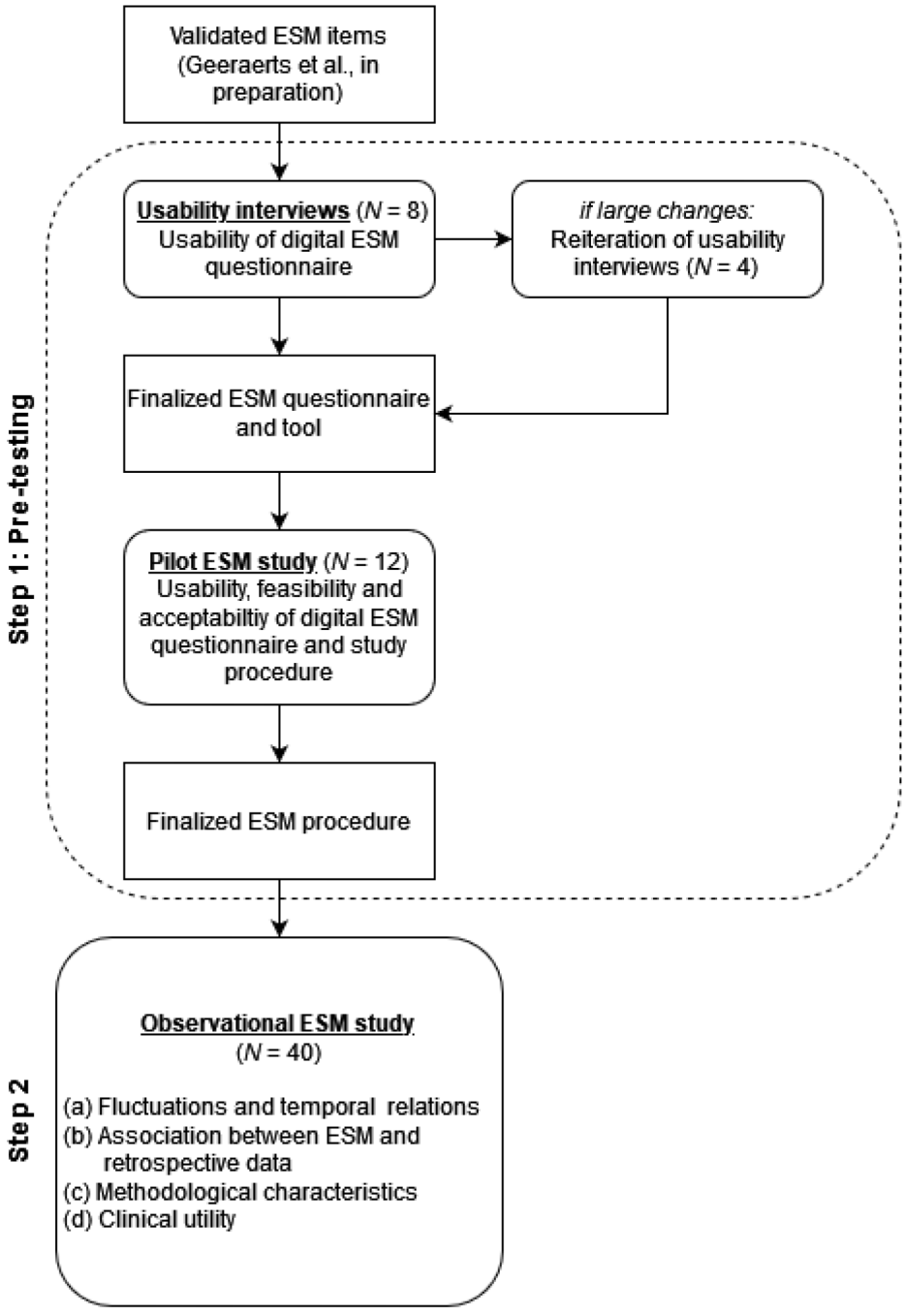

Figure 1 Relationship between study aims, research steps and methods. ESM, experience sampling method.

to establish ESM in mental health and psychosomatic research, as it provides a valid way to disentangle the multiple different determinants of psychopathology or psychosomatic symptoms and develop workable and personalised treatment targets.[13 16] We expect that ESM could provide the same opportunities in the context of oncology, for instance, for the treatment or management of fatigue or other physical or psychological symptoms.

Recent literature reviews found only a limited number of studies that used ESM to study experiences of people with cancer.[17 18] One review[18] found only three ESM studies exclusively focused on advanced cancer and were limited in certain methodological considerations, such as not including contextual items to account for the individual's current context.[19–21] Optimal study conditions remain unclear from this limited body of work.[18] This highlights the need for more methodological development and testing, especially for people at an already increased risk for symptom burden, such as people with advanced cancer (ie, stage IV).[18 22 23] As ESM is a novel method to be developed and evaluated in people with advanced cancer, the publication of this protocol strives to inform and inspire other researchers on the development of ESM questionnaires and study designs.

In this study, we aim to test the feasibility and clinical utility of an ESM questionnaire for people with advanced cancer. In previous work,[24] we have developed and validated a questionnaire to assess daily experiences across physical, psychological, social and spiritual-existential domains, as well as the context in which they occur among patients with advanced cancer (ie, stage IV breast or stage III or IV lung cancer). The questionnaire will be administered digitally through a mobile application designed for ESM measurements (ie, m-Path[25]). In this study, we will pretest the digital ESM questionnaire, adapt and optimise it, and subsequently conduct an observational ESM study in people living with stage IV breast cancer or stage III or IV lung cancer.

More specifically, the pretesting phase of our ESM questionnaire (step 1) aims to optimise the ESM methods and study procedures among people with stage IV breast or stage III or IV lung cancer (figure 1). The observational ESM study (step 2) aims to examine (a) the fluctuations and temporal relationships between patient-experienced symptoms, concerns, and well-being, and the context in which they occur, (b) the relationship between responses on the ESM questionnaire and traditional retrospective PROMs, (c) the usability, feasibility and acceptability of this (digital) ESM questionnaire in people with stage IV breast or stage III or IV lung cancer and (d) its clinical utility in people with stage IV breast or stage III or IV lung cancer for healthcare professionals working in oncology.

METHODS

Study design

This study follows a two-step procedure (figure 1). In step 1 (addressing research aim 1), we will pretest and optimise our ESM method and procedure by evaluating barriers and facilitators related to its usability, feasibility and acceptability through usability interviews and a pilot ESM study. In step 2 (addressing research aim 2), we will conduct an observational ESM study and conduct interviews with clinicians on the clinical utility of ESM. This protocol is written in adherence to the Standard Protocol Items Recommendations for International Trials (SPIRIT) 2013 statement.[26]

Table 1 Inclusion and exclusion criteria for patients

Inclusion criteria All connected by 'AND'	(1) Being able to fluently speak and understand Dutch.
	(2) Being 18 years or older.
	(3) Having a confirmed diagnosis of stage III or IV lung cancer, or stage IV breast cancer.
	(4) Scoring 0, 1 or 2 on the Eastern Cooperative Oncology Group performance status.
Exclusion criteria All connected by 'OR'	(1) Have major communication difficulties or insufficient cognitive abilities to take part in a cognitive interview, as judged by the treating physician.
	(2) Have any psychiatric disorder that, in the opinion of the treating physician, makes participation in the study impossible.
	(3) Are unable to read digital ESM questions or hear interview questions due to uncorrectable vision or hearing problems.
	(4) Have participated in previous phases of this study.

ESM, experience sampling method.

Participants

Patients

The eligibility criteria for patients are provided in table 1. We will create four equally sized subgroups of participants based on primary tumour site and age. Primary tumour site groups will be breast or lung cancer, and age groups will be younger than 70 or older than or equal to 70.[27 28] The inclusion of older adults in this study is necessary to prevent under-representation of this group, as the mean age of participants in electronic symptom monitoring studies in oncology is typically lower than in the total cancer population,[18] potentially skewing research findings related to outcomes such as the burden by multiple assessments each day and self-efficacy of using the digital technology. Participants from previous phases of this research project will be excluded from participating in the current study.

Healthcare professionals

Healthcare professionals will be eligible for clinical utility interviews if they are the treating oncologist or oncopsychologist of a sample of consenting participants in the observational ESM study or if they are part of oncology nursing staff at the University Hospital of Brussels or Ghent.

Samples sizes

The usability interviews will be conducted with at least eight patients, and four additional patients will be interviewed if changes are made to the questionnaire based on the preceding usability interviews and are sufficiently large to require new testing. The pilot ESM study will be conducted with 12 patients. The observational ESM study will be conducted in 40 patients, equalling 2400 scheduled assessments across 6 days. Moreover, we aim to include eight oncologists, two oncopsychologists and two members of oncology nursing staff in clinical utility interviews. Based on previous studies,[18 29–31] these numbers seem appropriate to explore the method's usability, feasibility, acceptability and clinical utility.

Recruitment setting and timing

Recruitment for step 1 is expected to run from May 2023 to June 2023 for the usability interviews and from June 2023 to July 2023 for the pilot ESM study. Subsequently, step 2, the observational ESM study, will run with recruitment up to the end of 2023. Patients will be recruited at the oncology and radiotherapy departments of University Hospital Brussel, the oncology and pneumology departments of University Hospital Ghent, through peer support groups in Flanders and Brussels, and through snowball sampling. Reasons for non-participation will be documented if patients wish to state them.

Measurement instruments

An overview of measurement instruments is provided in table 2. All measures and interview guides to be used in this study are provided in online supplemental materials.

Digital ESM questionnaire for pilot and observational ESM studies

The digital ESM questionnaire was previously developed and validated in collaboration with people diagnosed with breast and lung cancer and a multidisciplinary group of healthcare professionals.[25] The questionnaire aims to assess symptoms, concerns and well-being and the context in which they occur in people with stage IV breast and stage III or stage IV lung cancer, as well as meta items pertaining to the experience of filling in the questionnaire (see figure 2 for an overview of the domains covered by the questionnaire and online supplemental material 1 for the full ESM questionnaire). The items included in the questionnaire were found relevant, appropriate and important by people with stage IV breast and stage III or stage IV lung cancer. More details of the questionnaire development are reported elsewhere.[25] The questionnaire contains a core item list which will be presented to all participants and a online supplemental item list from which participants can select items that are relevant to them specifically. Moreover, the first and last assessment of the day are, respectively, assessed using morning and evening versions of the questionnaire. The core morning questionnaire contains 30–34 items (including items on sleep quality), the core momentary questionnaire 29–33 items, and the core evening questionnaire 34–39 items (including items that reflect on experiences across the whole day). The exact questionnaire length depends on the responses on previous items (ie, conditional items). Response options differ per item and are given as '0–100' slider scales, yes-no and single-choice and multiple-choice questions. The ESM questionnaire will be administered using researcher-provided Motorola e20 devices through the m-Path app.[32 33] M-Path is an easy-to-use online platform that provides a 'flexible framework for implementing smartphone-based EMA and intervention in both research and clinical practice'.[33]

Baseline questionnaire for usability interviews

The 16-item baseline questionnaire of the usability interviews assesses sociodemographic characteristics (including patients' age, social network, work status, education level and religious beliefs), treatment trajectory, cognitive functioning and smartphone use (online supplemental material 2). Cognitive functioning will be briefly assessed through the validated European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) subscale,[34] whereas questions on smartphone use will be based on items from previous studies on this topic[35 36] (eg, 'How confident do you feel using a smartphone?', using a 5-point Likert scale).

Table 2 Measured outcomes with their respective scales or instruments and number of items for all study phases

Study phase	Measured outcomes (scale/instrument)	No of items
Usability interviews		
Baseline questionnaire	► Sociodemographic characteristics ► Treatment trajectory ► Cognitive functioning (EORTC QLQ-C30 subscale[34]) ► Smartphone use[35 36]	16
Think aloud procedure	► Experienced difficulties with method* ► Questionnaire completion times	/
Usability assessment	► Usability of ESM method (adapted System Usability Scale[37]) ► Reasons for difficulties encountered (interview probing)*	17
Pilot ESM study		
Baseline session	► Sociodemographic characteristics ► Treatment trajectory ► Cognitive functioning (EORTC QLQ-C30 subscale[34]) ► Smartphone use[35 36] ► Attitude towards participation in scientific studies ► Levels of anxiety and depression (HADS[39]) ► Activities of daily living (Barthel-Index-SF[40]) ► Instrumental activities of daily living (Lawton IADL[41]) ► Coping style (Brief-COPE[42])	71
ESM period	► Symptoms, concerns and well-being[25] ► Context[25] ► Experience of filling in questionnaire[25] ► Questionnaire completion times	29–39 items†
Follow-up session	► Quality of life (EORTC QLQ-C30[34]) ► Subjective well-being (ACSA[43]) ► Acceptability: Experience of taking part in the study[45] ► Careless responding[45–47] ► Usability of ESM method (adapted System Usability Scale[37]) ► Reasons for difficulties encountered (interview probing)*	76
Observational ESM study		
Baseline session	► Sociodemographic characteristics ► Treatment trajectory ► Cognitive functioning (EORTC QLQ-C30 subscale) ► Smartphone use[35 36] ► Attitude towards participation in scientific studies ► Levels of anxiety and depression (HADS[39]) ► Activities of daily living (Barthel-Index-SF[40]) ► Lawton IADL[41] ► Coping style (Brief-COPE[42])	71
ESM period	► Symptoms, concerns and well-being[25] ► Context[25] ► Experience of filling in questionnaire[25]	29–39 items†

Continued

Table 2 Continued

Study phase	Measured outcomes (scale/instrument)	No of items
Follow-up session	► Quality of life (EORTC QLQ-C30[34]) ► Subjective well-being (ACSA[43]) ► Acceptability: Experience of taking part in the study[45] ► Reasons for difficulties encountered (interview probing)* Careless responding[45–47]	59
Clinical utility interviews‡	► Experience with monitoring tools and computer technology[48]* ► Reflections on ESM data visualisations[48]* ► Reflections on the purpose of ESM in oncology[48]*	28 (interview questions)

*Qualitative data (non-marked outcomes indicate quantitative data).
†Depending on responses and timing of assessment.
‡Conducted with healthcare professionals.
ACSA, Amnestic Comparative Self-Assessment; Barthel-Index-SF, Short version of Barthel Index; Brief-COPE, Brief Coping Orientation to Problems Experienced; EORTC QLQ-C30, European Organisation for Research and Treatment ofCancer Quality of Life Questionnaire Core 30; ESM, Experience Sampling Methods; HADS, Hospital Anxiety and Depression Scale.

Adapted System Usability Scale for usability interviews

An adapted 17-item version of the System Usability Scale[37] (SUS) will be administered during the usability interviews (online supplemental material 3). The SUS is a widely used reliable scale to efficiently collect users' ratings of a product's usability.[37 38] We changed the wording of the original SUS to pertain to the usability of the 'digital questionnaire' and 'smartphone'. Moreover, we added items related to the instructions, response options, app layout, questionnaire length and the frequency of assessments to better inform us which aspects of the methodology could be optimised (eg, 'I thought the response options of the digital questionnaire

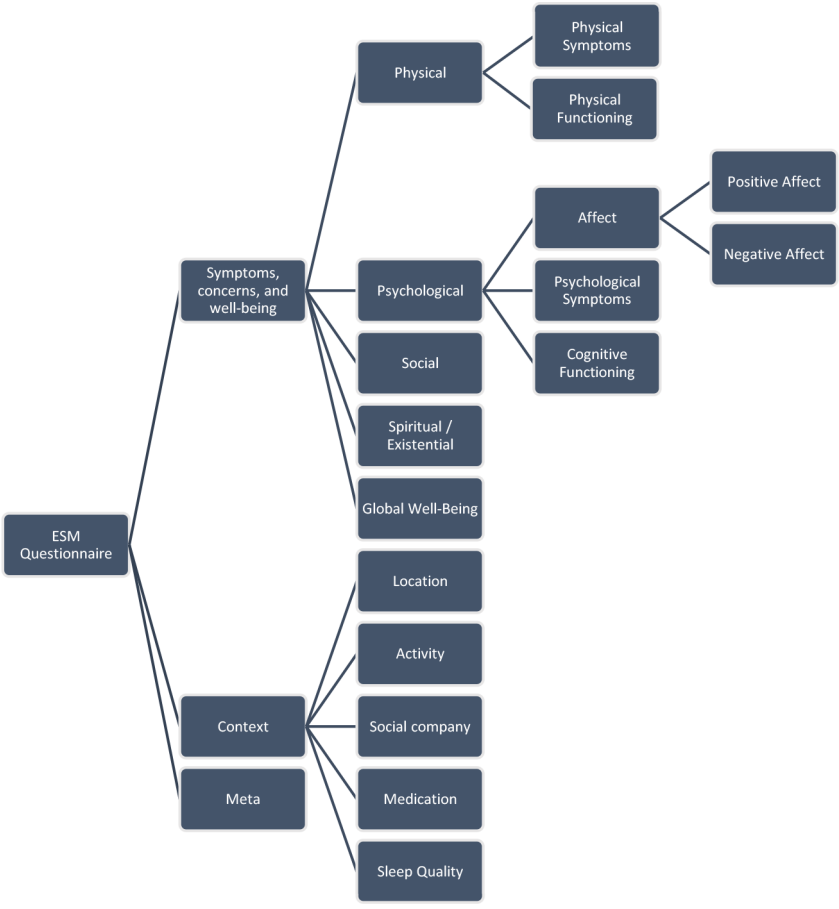

Figure 2 Overview of domains and subdomains covered by our ESM questionnaire. ESM, experience sampling method.

were clear.'). The adapted SUS uses a 5-point Likert scale.

Baseline questionnaire for pilot and observational ESM study

The pilot and observational ESM studies will employ an extended version of the baseline questionnaire for the usability interviews (see 'Adapted System Usability Scale for usability interviews' section), containing 71 items, of which 12 will be completed by the interviewer and other items will be completed by the patient (online supplemental material 4). In addition to the items of the baseline questionnaire, this questionnaire contains items on the individual's socioeconomic status, attitude towards participation in scientific studies, levels of anxiety and depression (Hospital Anxiety and Depression Scale,[39] 14 items), activities of daily living (shortened version of Barthel-Index,[40] 5 items) and instrumental activities of daily living (Lawton IADL,[41] 7 items) and coping style (Brief-COPE,[42] 28 items).

Follow-up questionnaire for pilot and observational ESM study

The pilot and observational studies will use a 59-item follow-up questionnaire battery containing the EORTC QLQ-C30 (30 items) to measure quality of life,[34] the Amnestic Comparative Self-Assessment (7 items) to measure subjective well-being,[43] a questionnaire to assess the experience of taking part in the study as an indicator of acceptability (19 items, including the following concepts of the Theoretical Framework of Acceptability: affective attitude, burden, opportunity cost, perceived effectiveness, self-efficacy and ethicality[44]) and careless responding (ie, not paying sufficient attention while responding; 3 items; online supplemental materials 5 and 6). The latter questionnaire was largely based on previous ESM studies in other disciplines.[45–47] The pilot study will include a 17-item adapted version of the SUS similar to the one for the usability interviews, pertaining to the usability of the ESM questionnaire and the study procedure.

Clinical utility interviews for observational ESM study

The interview guides to assess the clinical utility of ESM in oncology among healthcare professionals include 28 questions on previous experiences with monitoring tools and computer technology, reflections on visualisations of patients' responses to the ESM assessments, and reflections on the purpose of ESM for different stakeholders within oncology (online supplemental material 7). The interview guides are based on a survey study that assessed the perspectives of practitioners and researchers on the utility of ESM in mental healthcare.[48]

Study procedures

Eligible participants will be referred by research assistants/data collectors and medical staff at the medical oncology, radiotherapy or pneumology departments of the participating hospitals. If the patient agrees to be contacted by a researcher or contacts the researcher, the researcher will provide them with all study details at the patient's next hospital visit or over the phone. If the patient agrees to participate, the researcher will schedule the interview or baseline session at the patient's preferred place and time. If preferred by the patient, a close person can be present during the interview. To participate, patients identified through peer support groups will need to initiate contact with the researcher themselves. Written informed consent will be collected before or at the start of the initial research session.

Step 1: pretesting (usability interviews)

At the start of the session, the patient will complete a baseline questionnaire with the researcher reading the questions out loud (interview guide in online supplemental material 8). Next, the patient will be provided with a smartphone device and briefly instructed on how to open and use the m-Path application.[32] The patient will be asked to fill in a digital ESM questionnaire on the provided smartphone device, while thinking out loud. The patient will be asked whether something is not clear if the researcher observes difficulties with responding.

After completing the digital questionnaire, we will conduct a brief semistructured interview concerning the usability of the digital questionnaire. Where possible, we will ask the patient to provide more information on why a particular quality of the digital ESM questionnaire or the smartphone device is deemed more difficult to work with.

Lastly, the patient will complete the same digital ESM questionnaire from the beginning of the session again, but this time without thinking out loud. The last assessment of the digital ESM questionnaire will provide estimates on how much time it takes to fill in the questionnaire. The entire session is expected to take between 30 and 40 min.

Step 1: pretesting (pilot ESM study)

The pilot ESM study procedure contains a baseline session, a 6-day ESM period and a follow-up session (figure 3).

Baseline session

At baseline, the researcher or research assistant will ask the patient to complete the baseline questionnaire. The researcher will train the patient in using the digital ESM questionnaire on the provided smartphone device and afterwards ask to unlock the phone, open the digital ESM questionnaire, and fill in the questionnaire, to check if the training was sufficient. Afterwards, the researcher will ask if the patient wants to choose additional items from the supplementary ESM list, with a focus on constructs that are meaningful to them and have potential impact on their daily life, to expand and personalise the core questionnaire for the ESM period. If present, the patient's close person may help in looking for supplementary items.

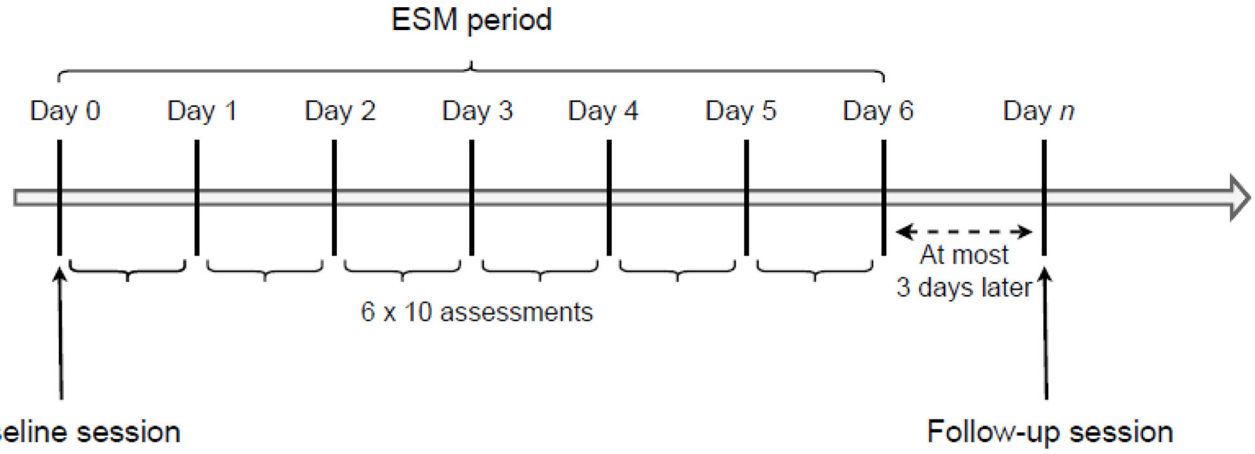

Figure 3 Overview of ESM study procedure. ESM, experience sampling method.

The researcher will provide an informational page with instructions to take home and will schedule a follow-up session with the patient, preferably 1 week after the baseline session. The entire baseline session is expected to take 30–40 min.

ESM period

Starting on the same day directly after the baseline session, participants will receive up to ten prompts for ESM assessments, depending on the time of day when the baseline session was completed (figure 3). A total of 60 ESM assessments will be scheduled over 6 days, meaning 10 prompts per day. Such an ESM schedule was shown to adequately balance the resolution required to assess variability of target constructs and assessment burden for vulnerable participants.[30 49] Participants will be prompted to complete the ESM questionnaire at semirandom times through a sound alert ('beep'), scheduled to start at least 1 hour after waking and at most 1 hour before going to bed (determined individually, before the ESM period). A minimum time of 30 min will be scheduled between consecutive assessments. After the first full day of assessments, the researcher or research assistant will phone the patient to check whether they have any questions or are experiencing technical difficulties. Throughout the 6-day ESM period, the researchers will be available by telephone and email to help patients with possible problems.

Follow-up session

In the follow-up session, postmeasurements will be conducted. The follow-up questionnaire will preferably be conducted within 1 day or at most 3 days after ESM period completion. After completing the questionnaire, the researcher will invite the patient to participate in the semistructured interview following a questionnaire to evaluate the patient's experiences of using the ESM tool during the study period. At the end of the session, the researcher will provide the patient with a paper version of a visual summary of the patient's ESM data and will send a digital PDF version via email. The audio of this session will be recorded with the patient's consent. The follow-up session is estimated to take 50 min.

Step 2: observational ESM study

ESM study

The data collection procedure for the observational ESM study will be analogous to the pilot ESM study but with a shortened follow-up questionnaire. Lessons learnt during the pilot study may result in changes to participant instructions and other aspects of the methods.

In the baseline session of the observational ESM study, patients will be given the option to have their responses to the ESM assessments shared with healthcare professionals to explore the clinical utility of ESM assessment. As patients willing to share their data run the risk of getting recognised by the healthcare professionals, we will ask those patients to provide additional informed consent. If a patient declines to share their data with healthcare professionals, the data will not be used in the testing of clinical utility, but will still be included in the ESM study where pseudonymisation is ensured.

Clinical utility interviews with treating oncologists and oncopsychologists

Treating oncologists and oncopsychologists of a purposive sample of consenting participants of the observational ESM study will be contacted to schedule a semistructured interview at a preferred location. Before the start of the interview, the researcher will ask the healthcare professional to provide written informed consent. The healthcare professional will receive the visual ESM summary of their patient and will be given time to visually explore it. If no patients agreed to have their data shared, all clinical utility interviews will be conducted using hypothetical data generated by the researchers to mimic real patient responses. The interview will be recorded with the participant's consent. The interview session is estimated to take 60 min.

Clinical utility interviews with nursing staff

Nursing staff members will be recruited through the research teams' professional networks. The interviews will follow a similar procedure as the oncologist and psychologists interviews, but patient names will not be disclosed to the staff being interviewed. The audio of this session will

be recorded with the participant's consent. The interview session is estimated to take 60 min.

Outcomes

Step 1: pretesting

During pretesting, outcomes for the usability interviews will include the readability, comprehensibility, ease-of-use of the ESM questionnaire in the smartphone application, reasons for difficulties encountered, time required to complete the ESM questionnaire, expected burden of multiple daily assessments for 6 days and ways to lessen this burden, and patient characteristics that may affect questionnaire completion time. These outcomes will inform optimisation of the ESM methodology and procedure for the pilot and observational ESM study.

Outcomes for the pilot ESM study will include the response-related characteristics of the ESM period indicative of its feasibility (ie, compliance rates, missing data patterns), patient experiences with the study method and procedure as an indication of acceptability, reasons for difficulties encountered, time required to complete the questionnaire, patient demographics, smartphone use, functional and cognitive state, anxiety and depression levels, activities of daily living, and coping style. These outcomes will identify factors to optimise the ESM methodology and procedure for the observational ESM study.

Step 2: observational ESM study

In the observational ESM study, outcomes will assess the relationship between ESM and retrospective patient-reported outcome data, levels of within-person and between-person variation in daily experiences, within-person and between-person temporal relationships between daily experiences (including contexts), response-related characteristics of the ESM period indicative of its feasibility (ie, compliance rates, missing data patterns), patient experiences with the study method and procedure as an indication of acceptability, reasons for difficulties encountered, the moderating role of baseline constructs (eg, IADL) on temporal relationships, patterns of missing data and their relationship with baseline patient characteristics, and visual summaries of individual patient ESM data.

The visual summaries of ESM data will be used for the outcomes of the clinical utility interviews, which will explore the perceptions of healthcare professionals on the concrete and potential clinical value of using ESM in oncology clinical practice and research.

Patient and public involvement

We reported public and patient involvement guided by the Guidance for Reporting Involvement of Patients and the Public 2 - Short Form (GRIPP2-SF) reporting checklist.[50] To improve the relevance of our study for the target population and clinical practice, we systematically developed and validated our ESM questionnaire in collaboration with 34 patients and 8 healthcare professionals through semistructured interviews.[25] Moreover, patient representatives at Ghent University Hospital discussed and provided feedback on the ESM questionnaire and procedure, which led to minor changes in wording of items and instructions. Overall, the patient involvement shaped our ESM questionnaire, and we experienced patients as engaged and open to share their views.

In this study, pretesting of our ESM questionnaire and procedure will provide opportunities for at least 20 patients to give feedback on their experiences with the study to ensure a user-friendly ESM method for participants in the observational ESM study and future studies.

DATA ANALYSES

We will use descriptive statistics to show the sample characteristics gathered at baseline and follow-up. Continuous variables will be reported through means and SD, while categorical variables will be reported through frequencies and percentages.

We will use R for all data analyses and visualisations, with the lme4 package for multilevel modelling. We will use NVivo V.20 software to transcribe all audiorecordings and to conduct content analyses. All content analyses will follow conventional content analysis using inductive category development as described by Hsieh and Shannon,[50] which chronologically includes familiarisation with data, coding of the text, labelling the codes, creating categories (with possible overarching categories) and reporting.

Step 1: pretesting (usability interviews)

We will summarise quantitative data on readability, comprehension, ease-of-use, expected burden gathered with the usability questionnaire using descriptive statistics (ie, means and SD).

Questionnaire completion times will be analysed descriptively. A median time above 3 min will indicate that a questionnaire is too long.

We will conduct content analysis on the interview transcripts to explore aspects that influence the usability of the ESM questionnaire,[51] such as difficulties or conveniences in the user experience or comprehension of the questionnaire and application.

Step 1: pretesting (pilot ESM study)

ESM data

We will use descriptive analyses to assess compliance (ie, number of completed assessments divided by the total number of scheduled assessments), attrition, momentary burden and questionnaire completion times. Multilevel linear regression models will be used to analyse compliance as a function of patient characteristics, time and levels of outcome variables and to explore temporal variation in responses on a within-person and between-person level.

Follow-up data

We will use descriptive analyses to summarise follow-up questionnaire data. Content analysis will be used to

explore difficulties with the ESM questionnaire or procedure.[51]

Step 2: observational ESM study

In addition to the analyses described for the pilot ESM study, we will employ vector autoregressive multilevel modelling to explore within-person and between-person temporal relationships among patient experiences, context and context appraisals.[52 53] Furthermore, we will examine the moderating role of baseline measures (eg, IADL, social network) on these temporal relationships.

To further analyse the data, we will calculate mean scores for each construct measured with a slider scale across 6 days for each participant. Pearson correlations will be used to investigate the relationship between the mean scores and similar constructs measured retrospectively in follow-up sessions.

We will conduct content analyses of the qualitative data obtained from the clinical utility interviews to identify themes that highlight the concrete and potential clinical value of ESM in oncology clinical practice and research.[51]

DATA MANAGEMENT PLAN

JG will transcribe all audiorecordings and destroy them immediately afterwards. We will assign identification codes to participants, ensuring pseudonymity and we will restrict access to the key file to a select few individuals (JG and LP). We will enter non-ESM questionnaire responses into Qualtrics and download the datasets. We will download the ESM data from secure m-Path servers. Only approved team members will have access to the databases. We will securely store data on the central network drive of the Vrije Universiteit Brussel SharePoint servers for 25 years after study completion. Following the publication of the main results of the observational ESM study, the respective data will be made available for non-commercial research purposes on a reasonable request made to the researchers.

SAFETY PROTOCOL

Previous ESM studies in similar populations suggest acceptability of the procedure,[17 18 53 54] and we, therefore, anticipate no serious adverse events. What may occur is mild psychological discomfort or distress due to questions about one's health and well-being and frequent assessments. Before giving informed consent, participants will be fully informed of potential risks and sources of psychological distress, such as reactivity to negative questions or irritation from repeated assessments. They may refuse to answer any question or ESM prompt. In case of adverse events, participants can contact the research team, several of whom have master's degrees in psychology. The researcher will provide contact information for psychological support at the participant's treating hospital, if appropriate.

LIMITATIONS

Due to the nature of the methodology, possible study limitations are to be expected. First, the ESM studies will only collect data over a limited time, and as such, it may not capture the full range of experiences and fluctuations that occur within individuals over a longer period of time. Moreover, the specific inclusion of patients with advanced breast or lung cancer limits the generalisability of findings towards people with other forms of cancer at different disease stages.

Second, selection bias may be apparent due to the self-selection of, for instance, patients who are more experienced and confident in using digital technology or those interested in research. As this may limit the generalisability of the results to the broader population of people with advanced breast or lung cancer, we will include experience with smartphone technology in the baseline questionnaire to describe this for our sample and check for possible associations with missing data and study experience. Moreover, to lower the participation threshold for people with less experience using smartphones, interested patients will be reassured that the system will be easy to use and will include clear instructions. Additionally, we will purposively include an equal number of people aged above and below 70. We will analyse reasons for non-participation to screen for possible selection bias.

Third, in addition to potentially causing selection bias, lower levels of digital literacy may introduce negative study experiences for patients or limit the study's feasibility, for instance, due to difficulties in working with the smartphone device or ESM application. To mitigate these risks, our study implements comprehensive training and clear instructions, maintains communication between researchers and participants regarding technical difficulties during the study, and registers participants' levels of smartphone experience.

Fourth, the ESM study requires patients to carry a researcher-provided smartphone with them. This could lead to people forgetting the phone or forgetting to charge the battery, leading to missing data. Therefore, participants will be reminded to charge the phone and always keep it with them. To ensure data completeness, the researcher (JG) will conduct a follow-up check after 1 day to confirm a smooth study procedure and experience.

ETHICS AND DISSEMINATION

The current protocol has received ethical approval by the ethics committees of the University Hospitals Brussels (BUN: 1432023000043) and Ghent (ONZ-2023-0136). The research will be conducted in accordance with the Declaration of Helsinki and applicable Belgian and European legislation.

We will pseudonymise all data, except visual ESM summaries presented to oncologists and oncopsychologists. We will not publish data that could lead to the identification of participants.

Written informed consent by participants will be required for participation in this study. We will make participants aware that participation is voluntary and that they may withdraw from the study at any time, without negative consequence for the study or their relationship with the research or treating team. We will provide no monetary incentives for participation in this study.

We will make available and publish all study documents and questionnaires as online supplemental data. Results from this study will be used to write several manuscripts to submit to open access peer-review journals and to present at national and international conferences and other forums for the dissemination of knowledge.

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Acknowledgements The authors would like to thank Lise Rosquin for her careful reading of the manuscript.

Contributors Conception and design of the work: LP, LVdB and JG. Ethics committee application: JG, LP, KDN, EN, GC, MDR and LVdB. Drafting of the article: JG, LP, KDN and LVdB. Critical revision of the manuscript: JG, LP, KDN, EN, GC, MDR and LVdB. All authors read and approved the final manuscript.

Funding This work is part of a wider study funded by the Research Foundation–Flanders (FWO), under grant agreement 'G0C8120N'. LP is a Senior Postdoctoral Fellow of the Research Foundation–Flanders. LVdB holds the Collen-Francqui Research Professor Chair 'Aging, dementia and palliative care' (2020–2023).

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.

Provenance and peer review Not commissioned; externally peer reviewed.

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