



BMJ Open Proactive and systematic multidimensional needs assessment in patients with advanced cancer approaching palliative care: a study protocol

Denise Pergolizzi ¹, Iris Crespo,² Albert Balaguer,^{1,3} Cristina Monforte-Royo,⁴ Alberto Alonso-Babarro,⁵ Maria Arantzamendi,⁶ Alazne Belar,⁶ Carlos Centeno,^{6,7} Blanca Goni-Fuste,⁴ Joaquim Julià-Torras,⁸ Marina Martinez,⁶ Dolors Mateo-Ortega,⁹ Luis May,¹⁰ Deborah Moreno-Alonso,¹¹ Maria Nabal Vicuña,¹² Antonio Noguera,^{6,7} Antonio Pascual,¹³ Encarnacion Perez-Bret,¹⁴ Javier Rocafort,¹⁴ Andrea Rodríguez-Prat ,¹⁵ Dulce Rodriguez,¹⁶ Carme Sala,⁹ Judith Serna,¹⁷ Josep Porta-Sales^{4,18}

To cite: Pergolizzi D, Crespo I, Balaguer A, *et al*. Proactive and systematic multidimensional needs assessment in patients with advanced cancer approaching palliative care: a study protocol. *BMJ Open* 2020;**10**:e034413. doi:10.1136/bmjopen-2019-034413

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-034413>).

Received 18 September 2019
Accepted 09 January 2020



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Cristina Monforte-Royo; cmfonorte@uic.es

ABSTRACT

Introduction The benefits of palliative care rely on how healthcare professionals assess patients' needs in the initial encounter/s; crucial to the design of a personalised therapeutic plan. However, there is currently no evidence-based guideline to perform this needs assessment. We aim to design and evaluate a proactive and systematic method for the needs assessment using quality guidelines for developing complex interventions. This will involve patients, their relatives and healthcare professionals in all phases of the study and its communication to offer clinical practice a reliable approach to address the palliative needs of patients.

Methods and analysis To design and assess the feasibility of an evidence-based, proactive and systematic Multidimensional needs Assessment in Palliative care (MAP) as a semistructured clinical interview guide for initial palliative care encounter/s in patients with advanced cancer. This is a two-phase multisite project conducted over 36 months between May 2019 and May 2022. Phase I includes a systematic review, discussions with stakeholders and Delphi consensus. The evidence gathered from phase I will be the basis for the initial versions of the MAP, then submitted to Delphi consensus to develop a preliminary guide of the MAP for the training of clinicians in the feasibility phase. Phase II is a mixed-methods multicenter feasibility study that will assess the MAP's acceptability, participation, practicality, adaptation and implementation. A nested qualitative study will purposively sample a subset of participants to add preliminary clues about the benefits and barriers of the MAP. The evidence gathered from phase II will build a MAP user guide and educational programme for use in clinical practice.

Ethics and dissemination Ethical approval for this study has been granted by the university research ethics committee where the study will be carried out (approval reference MED-2018-10). Dissemination will be informed

Strengths and limitations of this study

- This study intends to use guidance from the development of complex interventions, employing stages for informed development and subsequent implementation of a needs assessment in the first encounter of palliative care, to establish a valid and reliable method for the evaluation of patients.
- Data will be collected from patients, relatives and professionals throughout to ensure representative integration of all stakeholders invested in palliative care outcomes.
- Both qualitative and quantitative methods are used to inform theory and describe feasibility for use in actual palliative care clinical practice.
- A feasibility trial will evaluate the needs assessment in clinical practice using mixed methods as well as report a process evaluation to inform both refinement for future clinical trial and palliative care research of benefits and challenges involved.
- The study is limited to being carried out throughout regions of Spain, which may not generalise to other clinical contexts and/or professional culture, as does only recruiting patient with advanced cancer and their families, which limits generalisability to other palliative populations.

by the results obtained and communication will occur throughout.

INTRODUCTION

Palliative care (PC) was originally conceived to address the suffering of those dying from advanced disease such as cancer,^{1 2} but has evolved to providing early PC from diagnosis



of advanced cancer, and through the trajectory including bereavement.³⁻⁵ It is estimated that 69%–82% of cancer deaths would benefit from PC,⁶ which can improve quality of life,⁷ patient⁸ and caregiver distress⁹ and even survival.¹⁰ As a result, there have been multiple calls for the integration of PC into standard oncology care to achieve best outcomes.¹¹⁻¹⁴ With this greater demand for PC to improve cancer care throughout the disease trajectory, it is crucial to ensure clinical practice is prepared to understand and address the palliative needs of patients with cancer and their families.

The WHO defines the success of PC to improve quality of life ‘by means of early identification and impeccable assessment’.¹⁵ An assessment of needs at the initial palliative encounter is therefore paramount, yet there are no guidelines or evidence-based standards for this critical aspect of care. Without evidence to guide PC practice, healthcare providers often defer to anecdotal or professional experience,¹⁶ which ultimately undermines equitable and comprehensive patient care.^{17 18} Clearly, a better approach to the comprehensive assessment of PC needs is urgently required, using evidence-based methods that are supported by standards of high-quality cancer care.^{17 19}

Evidence suggests providers lack consensus on the multiple dimensions that appropriately assess PC needs according to patient and family member perspectives. According to the WHO, minimum goals of PC include assessment of physical, psychosocial and spiritual problems.¹⁵ Meanwhile, a review of PC literature showed 62% of studies in the field limited their focus to physical or psychosocial symptoms.²⁰ Given that unmet needs are associated with increased healthcare costs²¹ and increased distress, which can reduce survival,^{7 22} the goals of PC should be to ensure that all possible dimensions are assessed in an efficient way.

Current research also overwhelmingly shows that assessments are based on tools,²³ that are neither personalised nor implemented for practice. Tools focus on merely identifying needs, but cannot permit the patient or family to express and explore issues with provider, nor replace a meaningful initial encounter that builds the therapeutic alliance.²⁴ Self-report tools place the burden on the patient, but the patient cannot always communicate what their care priorities are without empathic feedback.²⁵ What is needed is evidence for a feasible and efficient (being thorough in an acceptable amount of time) semi-structured clinical interview guide for the comprehensive needs assessment that providers can implement in practice.

A further issue is with the quality of evidence in service of clinical guidelines for PC. In 2009, the topic of PC was covered by <1% of cancer research.²⁰ The level of research evidence has been deemed as low-quality evidence in various aspects of PC.^{26 27} And two systematic reviews highlighted that palliative research is overwhelmed with surveys and descriptive studies.^{20 27} Thus, the field is

stunted by the lack of analytical studies that can inform practice guidelines.

The current protocol seeks to overcome the abovementioned limitations and challenges, aiming to develop and test the feasibility of an evidence-based proactive multidimensional efficient needs assessment in the initial encounter/s with PC. The goal is to design comprehensive and individualised care plans that will ensure equity in healthcare. We seek to guide and to advance clinical practice and therefore call this approach ‘MAP: proactive and systematic Multidimensional needs Assessment in Palliative care’. In addition, the knowledge gathered from the research programme will be the basis for an educational programme on needs assessment in PC that will be offered to the PC oncology community. This study will lay the groundwork for a future randomised controlled trial (RCT).

Objective

This multicenter study aims to design and implement a complex intervention that will proactively and systematically assess the multidimensional needs of patients with advanced cancer and their families when first assessed by a PC team.

Study setting

Nine different centres will participate and recruit patients. Five are public health university hospitals, two concerted-public health university hospitals, one private university hospital and a concerted-public health long-term hospital.

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were not involved in the design of the complex intervention; however, patients and their relatives will be involved throughout both phases to inform the development and feasibility of the MAP. The nature of the MAP is to explore and address the needs of patients, thus patient feedback is likewise included to assess the burden of the MAP, rating its acceptability and that it is not time-consuming, during phase II. Plans to communicate project goals and findings are aimed at engaging the public with the study objectives and preliminary results through a website along with a twitter account with specific hashtag designed to communicate progress throughout the development of MAP.

METHODS AND ANALYSIS

The study is guided by an established framework for developing complex interventions,²⁸ and is divided into two phases (figure 1): phase I will gather evidence to inform the design of the proactive and systematic MAP. Phase II will test the feasibility and acceptability of the MAP in a mixed-methods prospective cohort study. The

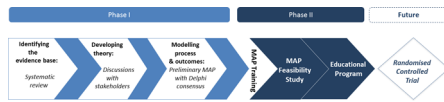


Figure 1 Study design phases of development and evaluation of the MAP toward a future intervention to be tested in a RCT. MAP, Multidimensional needs Assessment in Palliative care; RCT, randomised controlled trial.

study will be conducted over 36 months from May 2019 to May 2022.

Phase I—gather evidence to inform the design of the proactive and systematic MAP

Objectives

To define, develop and reach consensus on the design of the MAP in three stages:

1. Stage 1—identifying the evidence base.
2. Stage 2—developing theory.
3. Stage 3—modelling process and outcomes.

Stage 1: identifying the evidence base

Objective: To perform an integrative systematic review of the methods used in the PC literature for the assessment of needs and whether they correspond to all multidimensional needs reported by patients.

Procedure: An integrative systematic review of the literature began in May 2019 according to the requirements of the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols guidelines.²⁹ Details are submitted as a protocol in PROSPERO (International prospective register of systematic reviews). Following data extraction from the full-text stage, and an integrative method of analysis by the team,³⁰ a semistructured interview guide will be developed for Stage 2. This integrative review uses a data reduction method, clustering original articles according to a developed coding scheme that

summarises similarities or patterns between data derived from different methodologies (ie, quantitative, qualitative, mixed methods). Because the goal is to use this method to look for similarities according to the needs reported and assessed in the literature, the analysis will inform the interview guide with open-ended questions that probe the broad areas of need (eg, specific physical or psychological symptoms) found to be relevant from the review. The aim will be to explore the key issues that appear in the literature, to allow participants to define how these needs relate to their perceived needs and develop an understanding of their care priorities in an open discussion.

Stage 2: developing theory

Objective: To engage discussions with key stakeholders (individual semistructured interviews with patients and their relatives, a nominal group with healthcare professionals) to develop knowledge and build a framework of how to proactively and systematically assess the needs of patients in PC.

Eligibility criteria

Eligibility criteria for all participants, as well as pertaining specifically to the patients, relatives and professionals, are summarised in [table 1](#).

Sample size

Semistructured interviews with patients and relatives

PC teams from participating centres will offer consecutive patients participation in the study, who will be asked if they have a family member interested in participating. Individual in-depth interviews will be carried out with 10–12 patients with cancer and 10–12 relatives, separately. The number of participants is estimated based on recommendations in the qualitative literature to focus not on

	Inclusion	Exclusion
All participants	Age ≥18 Speak and understand Spanish or Catalan Cognitive capacity to communicate clearly Freely accept participation in the study and sign informed consent	Age <18
Patients	Advanced illness Receiving PC ECOG status 0–3 Inpatient or outpatient Without cognitive failure	Patients receiving PC at home ≥5 fails on Pfeiffer questionnaire ⁵²
Relatives	Caregiver responsible for patient Present at initial visit of patient from PC Familiar with diagnosis and prognosis of patient	
Professionals	PC doctors or nurses with an active role in the assessment of the patient in PC	

ECOG, Eastern Cooperative Oncology Group; PC, palliative care.

number of participants but the adequacy of information obtained from interviews.³¹ Thus, this sample size reflects a range that is recommended as adequate to achieve data saturation; that is, the point where themes from any further participant would be redundant.^{32 33}

Nominal group with healthcare professionals

In November 2018, in the context of a workshop we formed a work group with PC expert clinicians and researchers from 12 institutions throughout Spain (Barcelona, Girona, Lleida, Madrid, Pamplona and Tarragona). The nominal group will be constituted of, among others, these PC experts from various disciplines: nurses, physicians, psychologists and social workers. All experts who participate will have (1) more than 5 years of experience in PC and/or (2) be hospital service chiefs of PC. The group size of 12 is consistent with the literature using the nominal technique (for review see McMillan *et al*³⁴), and is sufficient in this context given it exceeds recommendations of only seven per group.³⁵

Procedure

Researchers trained in qualitative methods will lead the interviews and nominal groups. To maintain objectivity, these researchers will not be involved in patient care nor study design. Furthermore, the participants will be encouraged to comment on any aspect relevant to them, acknowledging there are no right or wrong responses expected from the interviewer. Finally, results will be analysed by a team including researchers not involved in data collection to avoid possible bias.

Individual semistructured interviews

Two researchers will lead individual interviews using a semistructured interview guide focusing on multidimensional needs of patients receiving PC. Opinions will be explored through a guided discussion about the needs assessment they experienced and what ways they felt satisfied or would make recommendations for improvement.

Nominal group

Face-to-face discussions will occur after the following four stages of the nominal group: (1) generating ideas, (2) discussion, (3) summary and conclusions and (4) ranking or individual prioritisation.³⁴

Data analysis

The semistructured interviews will be audio-recorded and transcribed verbatim. Thematic analysis of the data will be performed.^{36 37} Scores based on rankings from the nominal group will be recorded into Microsoft Office Excel (version 16.31) spreadsheets. We will calculate the sum of the scores for each idea and frequency of votes to create a list of priorities in order of highest frequency.

Stage 3: modelling process and outcomes

Objective: To draft the MAP as a semistructured clinical interview guide for PC practice and evaluate the

relevance of the preliminary version according to experts in PC.

Procedure: By means of the information from the semistructured interviews and nominal group with patients, relatives, PC professionals, a preliminary version of the MAP will be developed. The focus of development of the MAP will be to create a semistructured interview guide for clinical practice, which will provide a systematic way to ensure inquiry into the necessary topics that are most relevant for the patient.

To develop the interview guide that those in the field of PC would use in clinical practice, we will seek consensus from a larger group of 30 to 40 national experts about the contents of the MAP using the Delphi technique.³⁸ Participants in the Delphi process will be selected by means of intentional sampling from participating centres with at least one of the following criteria: health professionals with clinical experience in the field of PC, and/or researchers with knowledge and/or experience related to the patients' assessment in PC. In order to achieve a high-quality Delphi process, a heterogeneous group of experts will be recruited, selected from across various geographical regions and from different professional fields. Potential participants will be contacted by email and informed about the aims of the study, the tasks involved and the estimated necessary time commitment. The experts who agree to participate will provide responses through sequential online questionnaires completed individually and anonymously until consensus is reached. The key strengths of this approach are the anonymity of participants, structuring of the information flow and provision of regular feedback coordinated by the research team. The questionnaire will be formed by using statements that breakdown each of the topics and questions that comprise this preliminary version of the MAP.

For each statement, each participant has to rate their agreement on a five-point scale (5=strongly agree to 1=strongly disagree). Space is also provided for participants to make comments and/or suggest an alternative. We will carry out a number of rounds until a consensus is reached (approximately 2–3). In the first round, each concept must achieve a rating of ≥ 4 , which according to established methods,³⁴ must reach a consensus of 80% to be accepted and included in the second round for rerating of items. The first round also serves to determine if any changes to wording of statements are required for re-evaluation. In the second round, each participant receives only the statements that reached consensus, along with personalised information regarding their previous rating for each statement and the comments provided by others for reference. If all statements do not achieve 80% agreement, this step is repeated in a third round for further and final consensus on what statements will be included in the version of the MAP that professionals will receive training on for feasibility testing in the next phase.

Table 2 Intervention eligibility criteria

Inclusion	Exclusion
Advanced cancer ¹³	
Age ≥18 years	Age <18 years
ECOG performance status 0–3	
Inpatients or outpatients	Home care patients
No cognitive failure	≥5 fails on Pfeiffer's questionnaire ⁵²
Referred to PC	

ECOG, Eastern Cooperative Oncology Group; PC, palliative care.

Data analysis

Data will be analysed by two members of the research team. Questionnaire responses will be entered into spreadsheets and will be calculated using the algorithm proposed by Tastle & Wierman.³⁹ This calculation provides the weighted targeted agreement for each statement, meaning statements rated as '4' (ie, 'agree') and above are assigned higher weights and summarised as a percentage that are dispersed within that range of responses for each statement.

Once the MAP preliminary semistructured clinical interview guide is developed, the coordinators from each participating clinical centre, as well as the teams of PC professionals that will participate in the next phase of implementation of the MAP, will receive the appropriate training to homogenise its practice.

Phase II: a mixed-methods prospective cohort study

Objectives

To implement a multicenter complex intervention testing the feasibility of the newly designed MAP among PC patients, their families and healthcare professionals.

Eligibility criteria

Eligibility criteria are defined in table 2. Consecutive participants will be offered participation. All participants will have the study explained to them and we will obtain both verbal and written informed consent. Patients with advanced cancer are as defined by the American Society of Clinical Oncology: distant metastases, late-stage disease, cancer that is life limiting and/or with prognosis of 6 to 24 months.¹³ Because we are interested in the initial encounter/s, we will not include home care patients,

whom often have had prior contact with PC teams during previous hospital visits.

A nested qualitative study will be carried out, in which data-rich participants will be purposively sampled for interviews, to add preliminary clues about the benefits and barriers perceived by patients with advanced cancer who have been assessed with the MAP, one relative of the patient and PC health professionals in charge of conducting the MAP (table 3). All will be informed of the study to obtain verbal and written consent prior to participation.

Intervention

This is a mixed-methods phase II multicenter cohort study on the use of the MAP in patients with advanced cancer. It is conceived as an implementation feasibility study to be carried out in the initial clinical encounter/s with a specialised PC team.

Quantitative procedures

PC teams will implement the MAP defined and agreed on from development in phase I. The MAP may be integrated with standard oncological care or where PC is a main attending service. The PC team members conducting the MAP will introduce themselves as per usual, and will explain the nature of the procedure and its goals. Patients who give their consent to assess the feasibility of the MAP will be referred to a clinical encounter using the MAP (note that the final time assigned to the encounter will be decided as part of the consensus process of phase I). Some critically ill or frail patients could require to split the time into two evaluations. Patients who do not give consent receive the usual assessment of PC.

Sample size

It is an accepted standard in the literature that feasibility studies, as trial runs, do not require power calculations.^{40 41} A sample size between 24 and 50 has been recommended.^{42–44} We will plan to recruit 34–35 eligible consecutive patients per center (total of 9 centers). This will provide a total sample size of 312 patients, and a 15% attrition rate based on the research teams' experience, which estimates a final sample of approximately 265 patients to exceed recommended sample sizes.

Table 3 Participant selection for the nested qualitative component of the intervention

Patients	Purposively sampled from the feasibility trial considering different sociodemographic characteristics, health status, family support, etc, in order to achieve maximum variability.
Relatives	The palliative healthcare professional will identify the relative who has been present during the MAP to participate.
PC health professionals	Members of the PC services involved in carrying out the MAP will participate in focus groups.

MAP, Multidimensional needs Assessment in Palliative care; PC, palliative care.

Table 4 Quantitative outcomes and analyses to assess the feasibility of the MAP intervention

Outcomes	Definition	Measurement	Criteria	Analysis
Acceptability	Patient's opinions of the appropriateness of the MAP	Likert scale (0 completely inappropriate; 3 extremely appropriate).	≥75% patients score ≥2*	Participants with rating ≥2 coded as '1'; else '0'. = $(\sum '1'/N) * 100$
Participation	Proportion of eligible patients with cancer who are assessed following the MAP	Number of patients who completed assessment via the MAP divided by the total number recruited and consented	≥75% of eligible patients are assessed	Eligibility rate: # eligible (I); # consented (C) = (I/C) *100
Practicality	Time for execution	Time elapsed in minutes	≥75% of the MAP completed in the agreed on time from phase I	=Total min to complete MAP/ finalised agreed on time in minutes
Adaptation	Clinician's perceived acceptability for clinical utility	Likert scale (0 completely useless; 3 highly useful)	≥75% clinicians score ≥2	Participants with rating ≥2 coded as '1'; else '0'. = $(\sum '1'/N) * 100$
Implementation	The success of execution	Researchers will check a standardised template of the encounter ⁹ for completeness	≥80% of the dimensions of the MAP are covered in the clinical encounters	=Completion score from template *100; must be ≥80%

*Patient and relative's acceptability will be reported (relative's score will be considered as a secondary outcome). MAP, Multidimensional needs Assessment in Palliative care.

Outcomes

Outcomes to assess feasibility are explained in table 4. These outcomes were chosen to explore feasibility as recommended by the literature.⁴⁵

Statistical analysis

Analyses are outlined in table 4. Descriptive statistical analyses done for feasibility data will be compared with feasibility criteria values (eg, ≥75%) and reported as success or failure to meet criteria proposed. A subanalysis will provide a centre-by-centre comparison, with Analysis of variance (ANOVA) performed per criterion value between centres to determine statistically significant differences. Bonferroni post-hoc comparisons between centres will be carried out if an overall significant difference is observed.

Qualitative procedures

Participants who have participated in the quantitative portion of the feasibility study will be informed about the specific objectives of the qualitative interviews. Participants' attitudes towards participation in this additional phase of data collection will be queried.

Individual semistructured interviews will be carried out with patients and relatives separately. An interview guide will be developed aligning with the feasibility criteria to explore acceptability, perceived benefits and concerns and adaptation in the form of reactions to the content and process of the MAP. During the interview, the participants will be encouraged to comment on any aspect relevant to him. Interviews will be conducted by experts in qualitative research in three settings; three types of hospitals (public, private, concerted) in separate autonomous regions. The patient interviews will be conducted with 24–48 hours after

having finished the MAP; and the relative interview as soon as possible after having conducted the patient interview to avoid data contamination through patient–family conversations. Interviews will be audio-recorded and transcribed verbatim.

PC health professionals' perspectives will be gathered through focus groups that will be conducted in participating settings by an expert in qualitative research. In total three focus groups will be carried out. Participants will be anonymised by assigning them a code. Focus groups will explore strengths and weaknesses of the MAP, with reference to both their view on patients' and relatives' reactions, and their own role within the study including the MAP deliberation and integration within available resources (practicality) and setting context (adaptation). Focus groups will be audio-recorded and transcribed verbatim.

Sample size

Qualitative interviews

Patients. Data will be collected until saturation is reached. Sample size is estimated to be approximately 15–20 patients, a documented sample size range that allows us to explore as many possible themes that arise as possible.⁴⁶

Relatives. Data will be collected until saturation is reached. Sample size is again estimated to be approximately 15–20 relatives (one for each patient).

Healthcare professionals. As PC services usually consist of a limited number of health professionals, we expect that there will not be need to sample, as the whole sample will participate. Data will be collected until saturation is reached. In cases where there is a team that has many health professionals, different health professionals will be

purposefully selected up to a maximum of 10 participants in each setting.

Analysis. Thematic analysis^{36 37} of transcribed individual interviews and focus groups data will be conducted. To ensure the validity and reliability of the results, the data will be analysed independently by a qualitative expert familiar with the context of the data collection centre and another researcher. During data analysis, a consensus process between the researchers at the separate sites will devise a coding framework to review and guide the analysis of data and direct the thematic presentation of findings. Two workshops will be conducted during the analysis process to enhance adequate analysis process between researchers. The draft of the results will be shared across with the PC professionals involved on the MAP for their inputs and to ensure external validity. A 2-day workshop will be conducted with all the partners to reach a final agreement on the analysis results themes and culminate in the final reports.

Timeline

Data collection for the mixed-methods cohort study will occur over 26 months, from March 2020 through May 2021. The design of MAP will occur over months 1–10, training of professionals will occur between months 8 and 10, alongside recruitment from months 8 to 16, followed by data analysis and preparation of manuscripts from months 16 to 26.

PROCESS EVALUATION

In addition to feasibility study outcomes, and given calls to combine evaluation of outcomes with an evaluation of intervention process,⁴⁷ we will perform a process evaluation using the Reach, Efficacy, Adoption, Implementation,

Maintenance (REAIM) model (table 5).⁴⁸ Outcomes will be incorporated back into the development of the intervention by explaining whether or what changes to the MAP may be needed for a feasible use in practice. The process data will be reported with trial outcomes to generate hypotheses and research questions to be addressed for the future RCT.

ETHICS AND DISSEMINATION

Findings from the feasibility study and process evaluation will be used to inform appropriate dissemination strategies. We will use an Evidence-based Model for the Transfer and exchange of Research Knowledge ‘EMTReK’,⁴⁹ which is specifically designed to support knowledge transfer and exchange given the challenges of working with vulnerable populations in PC research.

DISCUSSION

This project aims to offer clinicians a proactive and systematic method for a multidimensional needs assessment in the initial encounter/s, deemed acceptable by all its stakeholders. The development and evaluation of the MAP is guided by standards on how to build evidence towards long-term implementation of complex interventions.²⁸ Given existing evidence alongside evidence collected from stakeholders, we anticipate the content of the MAP will adhere to other consensus of best methods for a needs assessment in PC. This will include assessing multiple symptoms from multiple domains,⁵⁰ and allowing for open-ended questions that practitioners can flexibly adjust to each patient’s needs⁵¹ within a feasible and practical time frame. We will implement the

Table 5 Process evaluation definition, outcomes and analyses

Acronym	Focus	Definition	Measurement	Analysis
R	Reach	Participation	Consent rate defined as number of participants recruited/number of participants approached for participation	Analysis of variance on consent rate to determine differences between each centre*
E	Efficacy	Positive and Negative Reactions	Interview questions probing positive and negative responses to methods used from all stakeholders	Qualitative analysis according to themes of benefits or issues arising during intervention
A	Adoption	Different Settings’ ease of integration	Success rate defined as proportion=total number of patients who completed intervention/intended N	Analysis of variance on success rates by centre to determine if any significant regional differences across settings exist*
I	Implementation	Adherence to protocol	Professional responses in qualitative interviews probing if any aspects were unclear or difficult to implement the intervention	Qualitative sub-analysis for themes that arise according to question regarding difficulties in use of the MAP
M	Maintenance	Intervention sustained over time	Mean recruitment rates (N per month) across centres for each month	Analysis of variance on mean recruitment rate, analysing differences in recruitment rate over time*

*Bonferroni post-hoc analysis carried out if significance observed.
MAP, Multidimensional needs Assessment in Palliative care.

MAP in a small-scale study to examine feasibility that will allow us to evaluate and refine content towards evaluation in a future RCT. In turn, this project aims to provide structured teaching courses on a multidimensional needs assessment in PC in the near future.

We propose that development of the MAP will respond to an urgent need to investigate the most effective but time-efficient method to assess multidimensional needs of patients with cancer. The objective is to bring equity to cancer care. By providing an evidence-based semistructured clinical interview guide, all healthcare providers can systematically and efficiently meet the demand for PC across the cancer continuum. This will advance scientific discovery to define the approaches that best fit the needs of patients and families.

Author affiliations

- ¹School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Barcelona, Spain
- ²Department of Basic Sciences, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Barcelona, Spain
- ³Universitat Internacional de Catalunya, Hospital Universitari General de Catalunya, Barcelona, Spain
- ⁴Nursing Department, School of Medicine and Health Sciences, Universitat Internacional de Catalunya, Barcelona, Spain
- ⁵La Paz University Hospital, Madrid Autonomous University, Madrid, Spain
- ⁶Clínica Universidad de Navarra, Pamplona, Spain
- ⁷Instituto de Cultura y Sociedad, Universidad de Navarra, IdiSNA, Pamplona, Spain
- ⁸Institut Català d'Oncologia Badalona, Badalona, Spain
- ⁹Consorci Sanitari de Terrassa, Terrassa, Spain
- ¹⁰Hospital Universitari Arnau de Vilanova, Lleida, Spain
- ¹¹Institut Català d'Oncologia L'Hospitalet, L'Hospitalet, Spain
- ¹²Palliative Care Supportive Team, Hospital Universitari Arnau de Vilanova, Lleida, Spain
- ¹³Hospital Universitari Sant Pau, Barcelona, Spain
- ¹⁴Fundación Vianorte-Laguna, Madrid, Spain
- ¹⁵Department of Humanities, School of Humanities, Universitat Internacional de Catalunya, Barcelona, Spain
- ¹⁶Hospital Universitari Sant Joan de Reus, Reus, Spain
- ¹⁷Hospital Universitari Vall d'Hebron, Barcelona, Spain
- ¹⁸Institut Català d'Oncologia Girona, Girona, Spain

Contributors DP drafted the manuscript. IC provided critical review and revisions. ABa, CM-R and JP-S contributed the conception of study design as well as methodology and analysis alongside AA-B, MA, AB, CC, JJ, MM, DM-O, LM, DM-A, MNV, AN, AP, EP-B, JR, DR, CS, JP-S, DP, IC, BG-F and AR-P contributed intellectual content and development of the protocol. All authors reviewed and revised the manuscript before submission and approved its content.

Funding This work was supported by Instituto de Salud Carlos III, Fondo Europeo de Desarrollo Regional (FEDER) grant number PI19/01901.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Full ethical approval for this study has been obtained from the university ethics committee leading the study (approval reference MED-2018-10). Data collection and analysis will be conducted following the ethical principles of research.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Denise Pergolizzi <http://orcid.org/0000-0002-8357-9462>
 Andrea Rodríguez-Prat <http://orcid.org/0000-0001-6382-243X>

REFERENCES

- 1 Clark D. From margins to centre: a review of the history of palliative care in cancer. *Lancet Oncol* 2007;8:430–8.
- 2 Saunders C. The evolution of palliative care. *J R Soc Med* 2001;94:430–2.
- 3 Jordan K, Aapro M, Kaasa S, *et al*. European Society for medical oncology (ESMO) position paper on supportive and palliative care. *Ann Oncol* 2018;29:36–43.
- 4 American Academy of Hospice and Palliative Medicine, Center to Advance Palliative Care, Hospice and Palliative Nurses Association. National consensus project for quality palliative care: clinical practice guidelines for quality palliative care, executive summary. *J Palliat Med* 2004;7:611–27.
- 5 Lynn J, Adamson DM. *Living well at the end of life: adapting health care to serious chronic illness in old age*. 6th edn. Santa Monica, CA: RAND, 2003.
- 6 Murtagh FEM, Bausewein C, Verne J, *et al*. How many people need palliative care? A study developing and comparing methods for population-based estimates. *Palliat Med* 2014;28:49–58.
- 7 Temel JS, Greer JA, Muzikansky A, *et al*. Early palliative care for patients with metastatic non-small-cell lung cancer. *N Engl J Med* 2010;363:733–42.
- 8 Kavalieratos D, Corbelli J, Zhang D, *et al*. Association between palliative care and patient and caregiver outcomes: a systematic review and meta-analysis. *JAMA - J Am Med Assoc* 2016;316:2104–14.
- 9 El-Jawahri A, Greer JA, Pirl WF, *et al*. Effects of early integrated palliative care on caregivers of patients with lung and gastrointestinal cancer: a randomized clinical trial. *Oncologist* 2017;22:1528–34.
- 10 Bakitas MA, Tosteson TD, Li Z, *et al*. Early versus delayed initiation of concurrent palliative oncology care: patient outcomes in the enable III randomized controlled trial. *J Clin Oncol* 2015;33:1438–45.
- 11 Bauman JR, Temel JS. The integration of early palliative care with oncology care: the time has come for a new tradition. *J Natl Compr Canc Netw* 2014;12:1763–71. quiz 1771.
- 12 Kaasa S, Loge JH, Aapro M, *et al*. Integration of oncology and palliative care: a Lancet oncology Commission. *Lancet Oncol* 2015;16:1–66.
- 13 Ferrell BR, Temel JS, Temin S, *et al*. Integration of palliative care into standard oncology care: ASCO clinical practice guideline update summary. *J Oncol Pract* 2017;13:119–21.
- 14 Smith TJ, Temin S, Alesi ER, *et al*. American Society of clinical oncology provisional clinical opinion: the integration of palliative care into standard oncology care. *J Clin Oncol* 2012;30:880–7.
- 15 World Health Organization. WHO definition of palliative care, 2016. Available: <http://www.who.int/Cancer/Palliative/Definition/En/#>
- 16 Krouse RS, Rosenfeld KE, Grant M, *et al*. Palliative care research: issues and opportunities. *Cancer Epidemiol Biomarkers Prev* 2004;13:337–9.
- 17 Bowles EJA, Tuzzio L, Wiese CJ, *et al*. Understanding high-quality cancer care: a summary of expert perspectives. *Cancer* 2008;112:934–42.
- 18 Snyder CF, Dy SM, Hendricks DE, *et al*. Asking the right questions: investigating needs assessments and health-related quality-of-life questionnaires for use in oncology clinical practice. *Support Care Cancer* 2007;15:1075–85.
- 19 Kaasa S, Caraceni A. Palliative cancer care research. *Palliat Med* 2010;24:259–60.
- 20 Hui D, Parsons HA, Damani S, *et al*. Quantity, design, and scope of the palliative oncology literature. *Oncologist* 2011;16:694–703.
- 21 Balboni T, Balboni M, Paulk ME, *et al*. Support of cancer patients' spiritual needs and associations with medical care costs at the end of life. *Cancer* 2011;117:5383–91.
- 22 Faller H, Bülzebruck H, Drings P, *et al*. Coping, distress, and survival among patients with lung cancer. *Arch Gen Psychiatry* 1999;56:756–62.
- 23 Aslakson RA, Dy SM, Wilson RF, *et al*. Patient- and Caregiver-Reported assessment tools for palliative care: summary of the 2017 agency for healthcare research and quality technical brief. *J Pain Symptom Manage* 2017;54:961–72.
- 24 Mack JW, Block SD, Nilsson M, *et al*. Measuring therapeutic alliance between oncologists and patients with advanced cancer: The human connection scale. *Cancer* 2009;115:3302–11.
- 25 Suchman AL. A model of Empathic communication in the medical interview. *JAMA* 1997;277:678.

- 26 Ahluwalia SC, Chen C, Raaen L, *et al.* A systematic review in support of the National consensus project clinical practice guidelines for quality palliative care, fourth edition. *J Pain Symptom Manage* 2018;56:831–70.
- 27 Kaasa S, Hjermstad MJ, Loge JH. Methodological and structural challenges in palliative care research: how have we fared in the last decades? *Palliat Med* 2006;20:727–34.
- 28 Craig P, Dieoee P, Macintyre S, *et al.* Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. *Med Res Counc* 2019:1–39.
- 29 Moher D, Liberati A, Tetzlaff J, *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *J Clin Epidemiol* 2009;62:1006–12.
- 30 Whitemore R, Knaf K. The integrative review: updated methodology. *J Adv Nurs* 2005;52:546–53.
- 31 Bowen GA. Naturalistic inquiry and the saturation concept: a research note. *Qual Res* 2008;8:137–52.
- 32 Morse JM, Size DS. Determining sample size. *Qual Health Res* 2000;10:3–5.
- 33 Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res* 2016;26:1753–60.
- 34 McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. *Int J Clin Pharm* 2016;34:1–66.
- 35 McMillan SS, Kelly F, Sav A, *et al.* Using the nominal group technique: how to analyse across multiple groups. *Health Serv Outcomes Res Method* 2014;14:92–108.
- 36 Aronson J. A pragmatic view of thematic analysis. *Qual Rep* 1994;2:4–5.
- 37 Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *Int J Qual Methods* 2006;5:80–92.
- 38 Dalkey N. An experimental study of group opinion: the Delphi method. *Futures* 1969;1:408–26.
- 39 Tastle WJ, Wierman MJ. Using consensus to measure weighted targeted agreement. *Annu Conf North Am Fuzzy Inf Process Soc - NAFIPS* 2007:31–5.
- 40 Browne RH. On the use of a pilot sample for sample size determination. *Stat Med* 1995;14:1933–40.
- 41 Arain M, Campbell MJ, Cooper CL, *et al.* What is a pilot or feasibility study? *A Rev Curr Pract Editor policy BMC Med Res Methodol* 2010;10:1–7.
- 42 Hooper R. Justifying sample size for feasibility study. *Natl Inst Heal Res Res Des Serv London NETSCC Gloss* 2017:4–5.
- 43 Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307–12.
- 44 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat* 2005;4:287–91.
- 45 Bowen DJ, Kreuter M, Spring B, *et al.* How we design feasibility studies. *Am J Prev Med* 2009;36:452–7.
- 46 Guest G, Bunce A, Johnson L. How many interviews are enough?: an experiment with data saturation and variability. *Field methods* 2006;18:59–82.
- 47 Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: the new medical Research Council guidance. *BMJ* 2008;337:979–83.
- 48 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322–7.
- 49 Prihodova L, Guerin S, Tunney C, *et al.* Key components of knowledge transfer and exchange in health services research: findings from a systematic scoping review. *J Adv Nurs* 2019;75:313–26.
- 50 Garzón Rodríguez C, Martínez Losada E, Julia Torras J, *et al.* [Tools for palliative care physicians for the multidimensional assessment. The ICO tool kit project]. *Herramientas para la evaluación multidimensional de uso para médicos de Cuidados Paliativos: Proyecto ICO-tool kit. Med Paliativa* 2010;17:348–59.
- 51 Maté-Méndez J, González-Barboteo J, Calsina-Berna A, *et al.* The Institut Catal d'Oncologia model of palliative care: an integrated and comprehensive framework to address the essential needs of patients with advanced cancer. *J Palliat Care* 2013;29:237–43.
- 52 Martínez de la Iglesia J, Dueñas Herrero R, Carmen Onís Vilches M, *et al.* [Adaptation and validation in Spanish of the Pfeiffer Questionnaire (SPMSQ) to detect the existence of cognitive decline in persons 65 years and older]. Adaptación y validación al castellano del cuestionario de Pfeiffer (SPMSQ) para detectar la existencia de deterioro cognitivo en personas mayores e 65 años [Cross-cultural adaptation and validation of Pfeiffer's test (Short Portable Mental Status Questionnaire)]. *Med Clin* 2001;117:129–34.