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 María Arantzamendi,6 Alazne Belar,6 Carlos Centeno,6,7 Blanca Goni-Fuste,8 Joaquin Julià-Torras,8 Marina Martinez,6 Dolors Mateo-Ortega,9 Luis May,10 Deborah Moreno-Alonso,11 María Nabal Vicuña,12 Antonio Noguera,6,7 Antonio Pascual,13 Dulce Rodriguez,16 Carme Sala,9 Judith Serna,17 Josep Porta-Sales4,18

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 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, but has evolved to providing early PC from diagnosis.
of advanced cancer, and through the trajectory including bereavement.\textsuperscript{3-5} It is estimated that 69\%–82\% of cancer deaths would benefit from PC,\textsuperscript{6} which can improve quality of life,\textsuperscript{7} patient\textsuperscript{8} and caregiver distress\textsuperscript{9} and even survival.\textsuperscript{10} As a result, there have been multiple calls for the integration of PC into standard oncology care to achieve best outcomes.\textsuperscript{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’.\textsuperscript{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,\textsuperscript{16} which ultimately undermines equitable and comprehensive patient care.\textsuperscript{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.\textsuperscript{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.\textsuperscript{15} Meanwhile, a review of PC literature showed 62\% of studies in the field limited their focus to physical or psychosocial symptoms.\textsuperscript{20} Given that unmet needs are associated with increased healthcare costs\textsuperscript{21} and increased distress, which can reduce survival,\textsuperscript{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,\textsuperscript{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.\textsuperscript{24} Self-report tools place the burden on the patient, but the patient cannot always communicate what their care priorities are without empathic feedback.\textsuperscript{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.\textsuperscript{20} The level of research evidence has been deemed as low-quality evidence in various aspects of PC.\textsuperscript{26,27} And two systematic reviews highlighted that palliative research is overwhelmed with surveys and descriptive studies.\textsuperscript{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 multi-dimensional 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,\textsuperscript{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.

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. 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, 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

<table>
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<th>Table 1 Study population criteria for phase I, stage 2</th>
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<td><strong>Inclusion</strong></td>
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<tr>
<td>Relatives</td>
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<tr>
<td>Professionals</td>
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ECOG, Eastern Cooperative Oncology Group; PC, palliative care.
number of participants but the adequacy of information obtained from interviews. 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.

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), and is sufficient in this context given it exceeds recommendations of only seven per group.

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.

Data analysis
The semistructured interviews will be audio-recorded and transcribed verbatim. Thematic analysis of the data will be performed. 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. 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, 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

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
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<tbody>
<tr>
<td>Advanced cancer</td>
<td>Age ≥18 years</td>
</tr>
<tr>
<td>Age ≥18 years</td>
<td>Age &lt;18 years</td>
</tr>
<tr>
<td>ECOG performance status 0–3</td>
<td>Home care patients</td>
</tr>
<tr>
<td>Inpatients or outpatients</td>
<td>≥5 fails on Pfeiffer’s questionnaire</td>
</tr>
<tr>
<td>No cognitive failure</td>
<td>Referred to PC</td>
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</table>
| 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. 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. 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. A sample size between 24 and 50 has been recommended. 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

<table>
<thead>
<tr>
<th>Patients</th>
<th>Purposively sampled from the feasibility trial considering different sociodemographic characteristics, health status, family support, etc, in order to achieve maximum variability.</th>
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</thead>
<tbody>
<tr>
<td>Relatives</td>
<td>The palliative healthcare professional will identify the relative who has been present during the MAP to participate.</td>
</tr>
<tr>
<td>PC health professionals</td>
<td>Members of the PC services involved in carrying out the MAP will participate in focus groups.</td>
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MAP, Multidimensional needs Assessment in Palliative care; PC, palliative care.
Table 4  Quantitative outcomes and analyses to assess the feasibility of the MAP intervention

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

*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 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, we will perform a process evaluation using the Reach, Efficacy, Adoption, Implementation, Maintenance (REAIM) model (table 5). 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’, 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. Given existing evidence alongside evidence collected from stakeholders, we anticipate the content of the MAP will adhere to other consensuses of best methods for a needs assessment in PC. This will include assessing multiple symptoms from multiple domains, and allowing for open-ended questions that practitioners can flexibly adjust to each patient’s needs within a feasible and practical time frame. We will implement the

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<th>Table 5</th>
<th>Process evaluation definition, outcomes and analyses</th>
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<td>Acronym</td>
<td>Focus</td>
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<td>E</td>
<td>Efficacy</td>
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<td>Adoption</td>
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<td>Implementation</td>
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<td>M</td>
<td>Maintenance</td>
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*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 semi-structured 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
6Clinica Universidad de Navarra, Pamplona, Spain
7Instituto de Cultura y Sociedad, Universidad de Navarra, IdiSNA, Pamplona, Spain
8Institut Català d’Oncologia L’Hospitalet, L’Hospitalet, Spain
9Hospital Universitari Arnau de Vilanova, Lleida, Spain
10Hospital Universitari Arnau de Vilanova, Lleida, Spain
11Instituto de Cultura y Sociedad, Universidad de Navarra, IdiSNA, Pamplona, Spain
12Palliative Care Supportive Team, Hospital Universitari Arnau de Vilanova, Lleida, Spain
13Department of Humanities, School of Humanities, Universitat Internacional de Catalunya, Barcelona, Spain
14Hospital Universitari Sant Joan de Reus, Reus, Spain
15Hospital Universitari Vall d’Hebron, Barcelona, Spain
16Institut 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-D, LM, DM-A, MN, 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.

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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.

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