ABSTRACT

Introduction Literature suggests couple-based interventions that target quality of life and communication can lead to positive outcomes for patients with cancer and their partners. Nevertheless, to date, an intervention to address the needs of Latino families coping with advanced cancer has not been developed. Meta-analytic evidence suggests that culturally adapted evidenced-based intervention targeting a specific cultural group is four times more effective. Our goal is to culturally adapt a novel psychosocial intervention protocol entitled ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA). We hypothesized that combining two evidence-based interventions and adapting them, we will sustain a sense of meaning and improving communication as patients approach the end of life among the patient-caregiver dyad.

Methods and analysis To culturally adapt CASA, we will follow an innovative hybrid research framework that combines elements of an efficacy model and best practices from the ecological validity model, adaptation process model and intervention mapping. As a first step, we adapt a novel psychosocial intervention protocol entitled ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA). The initial CASA protocol integrates two empirically based interventions, meaning-centred psychotherapy and couple communication skills training. This is an exploratory and pre-pilot study, and it is not necessary for a size calculation. However, based on recommendations for exploratory studies of this nature, a priori size of 114 is selected. We will receive CASA protocol feedback (phase 1b: refine) by conducting 114 questionnaires and 15 semistructured interviews with patients with advanced cancer and their caregivers. The primary outcomes of this study will be identifying the foundational information needed to further develop the CASA (phase 1a: proof-of-concept and phase 1b: pilot study).

Ethics and dissemination The Institutional Review Board of Ponce Research Institute approved the study protocol #1907017527A002. Results will be disseminated through peer-reviewed publications.

INTRODUCTION

Patients with advanced cancer and informal caregivers

As the number of cancer diagnoses increases, informal caregivers (often family members) play an essential role in providing care throughout the cancer trajectory.1 2 Significant numbers of patients with advanced cancer and their families emphasise the need for increased attention to end-of-life care.3 Caregivers often assume the role without the necessary skills to help them address complex needs of a patient with cancer.4 8 Consequently, they can experience a substantial caregiving burden that negatively impacts family function (ie, communication, conflict and cohesion) and the patients' physical, emotional and social well-being.6 9–12

Impact of cancer on family caregiver's well-being

A substantial body of research has examined how caregiving processes are linked to the emotional health of family caregivers.13 Researchers continue to investigate how poor mental functioning in family caregiving among Latinx may affect patients’ outcomes; however, it is equally important to attend to the well-being of family caregivers. A consistent pattern of unmet need,14 15 and impact on mental functioning have been identified in recent years.16 Findings indicate that Latinx-caregivers ethnicity is associated with higher levels of clinically significant depression,16
and more caregiving demands are associated with higher levels of caregivers’ feelings of burden and psychological distress.\(^\text{17}\) Compounding this problem, Latinx contextual and cultural influences on caregivers present an unmet need for emotional support,\(^\text{19}\) especially when Latinx individuals are less likely to have adequate access to culturally congruent psychosocial interventions.\(^\text{19–30}\) Latinx cancer research had identified the psychosocial need of Latinx caregivers and described the importance of including psychosocial content related to communication and spirituality.\(^\text{31–33}\)

**Contribution of caregivers to patient’s well-being**

The contribution of family caregivers to their patient’s well-being has been evident, and several indirect partner effects are also apparent in the literature. Specifically, for Latinx, both patients and caregivers had significant direct and indirect actor effects (through family conflict) of perceived stress on depression and anxiety. Caregivers’ stress was predictive of patients’ depression and anxiety through survivors’ increased perceptions of family conflict.\(^\text{34}\) A culturally centred intervention for Latinx patients should include a family-centred (partners and other family members) approach to determine the content and goals of care preferred in Latinx families coping with cancer.\(^\text{35–37}\)

**Latinx patients and caregiver dyadic**

Latinx have a higher intensity (ie, hours per week and help with activities of daily living) of caregiving than non-Latinx whites and Asians.\(^\text{38}\) Our preliminary data show that 86% of Latinx patients with advanced cancer reported low family function, and those with low family cohesiveness had higher depression and anxiety levels. Several studies show that low family function negatively impacts the cancer illness trajectory (ie, adherence, depression, poor prognostic and stress).\(^\text{39–41}\) Patients with advanced cancer and their families experience significant distress in four domains: physical, psychological, social, and spiritual.\(^\text{42–44}\) These domains are often summarised by the term ‘quality of life (QOL)’. QOL, spirituality and reduction of distress are essential goals of cancer care.\(^\text{45}\) A meta-analysis and systematic review found that Latinx patients with cancer show worse distress, depression and overall health-related quality of life (HRQOL) than other minority patients and whites.\(^\text{46}\) Similarly, Latinx patients report higher levels of burden, depression and physical health problems than patients of other ethnicities.\(^\text{47, 48}\) Therefore, addressing family issues is crucial in the adjustment and well-being of Latinx with advanced cancer and their informal caregivers.

**Cultural adaptation of evidence-based practice**

Cultural adaptations of interventions for ethnic minority groups are feasible and acceptable.\(^\text{49–52}\) Meta-analytic evidence suggests that culturally adapted interventions targeting a specific cultural group (eg, Puerto Ricans as part of the Latinx community) are four times more effective than those provided to various cultural backgrounds, and twice as effective as English interventions if conducted in the participants’ native language (if other than English).\(^\text{49–52}\) The literature suggests that behavioural interventions must be culturally adapted for cultural groups by following the phases of information gathering, preliminary design, preliminary testing and final trial to reduce health disparities.\(^\text{52}\)

**The conceptual framework**

Our conceptual framework, grounded in theory, developed by Dr. Breitbart, aims to target specific psychospiritual needs of patients with advanced cancer.\(^\text{53}\) Its primary goal is to help patients enhance a sense of meaning, peace and purpose as they approach end of life. The intervention focuses on assisting patients in identifying sources of meaning in their lives despite their diagnosis. In addition to its effectiveness with non-Latino whites, Dr. Costas-Muñiz demonstrated the acceptability and feasibility of meaning-centred psychotherapy (MCP) for Latinx patients with advanced cancer.\(^\text{31, 32}\) Preliminary findings suggested that Latinx with advanced cancer identified family and communication issues as crucial in adjusting to their cancer diagnosis and well-being.\(^\text{31, 32}\) Further, we identified evidence of communication skill training that indicated that communication skills for couples improve family communication dynamics, especially among Latinx families,\(^\text{54}\) and there are data on the effectiveness of couple communication skills training (CCST) in Caucasian couples; however, literature is absent about effectiveness in Latinx coping with advanced cancer.\(^\text{56}\) These findings indicate the need to explore the integration of CCST (components) for patients dealing with advanced cancer to an MCP.

**OBJECTIVES**

The purpose of this study is to culturally adapt and integrate (1) MCP and (2) CCST a novel psychosocial intervention protocol entitled ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA). The CASA intervention aims to improve the QOL and spiritual well-being of patients with advanced cancer and their informal caregivers. This paper describes the conceptual framework used for the cultural adaptation process, initial phases and future plans.

**METHODS AND ANALYSIS**

This significant milestone for forward movement lead to the initial CASA protocol integration of two empirically based interventions, MCP and CCST, with the goals of (1) helping patients and caregivers sustain or enhance a sense of meaning and (2) improving communication to improve health-related outcomes. We hypothesised that helping patients and caregivers sustain a sense of meaning and improving communication as patients approach the end of life among the patient–caregiver dyad will
improve spirituality and communication and, in turn, improve QOL. This is an exploratory study and prepilot study, and its treatment components including (MCP and CCST) will be adapting and forward movement by the findings and grounding in theory. For the pilot phase, we will easily translate and adapt the intervention for Latinx sample living in the USA by conducting a pilot study in Puerto Rico and New York; see phase IIb: pilot study.

The unifying theoretical framework of the culturally adapted evidence-based practice, ecological validity model (EVM), developed by Dr. Guillermo Bernal, the cultural adaptation process model (CAPM), and intervention mapping, provide viable approaches to treating ethnic minorities and culturally diverse groups. According to EVM, to adapt an intervention for a new cultural group, seven dimensions need to be addressed: language, context, persons, metaphors, concepts, goals and methods. CAPM is a complementary process model to EVM and prescribes four phases for the adaptation process: formative, adaptation iterations, intervention and measurement adaptation. Cancer contextual model of HRQOL (eg, spiritual well-being, depression, anxiety, hopelessness, functional assessment of cancer therapy, family relationship index, burden, fatalism, religiosity, distress and patient’s needs-semistructured interview) are outlined to specify individual, cultural and contextual influences (ie, dyadic relationships and communication with partners) as essential determinants of QOL. Drawing from social cognitive (ie, CCST) and existential theory (ie, meaning-centred therapy), the ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA) intervention is designed to increase the spiritual well-being and self-efficacy in communication between patients with advanced cancer and their informal caregivers.

To identify the foundational information necessary to culturally adapt and integrate MCP and CCST to adapt de CASA intervention for Latinx patients and their informal caregivers, we will use a four-phase approach guided by the ORBIT model to the cultural adaptation process: (1a) define, (1b) refine, (2a) proof-of-concept, (2b) pilot, (3) efficacy trial and (4) effectiveness research. The ORBIT model for behavioural treatment development model provides a progressive, clinically relevant approach to increasing the number of evidence-based behavioural treatments available to prevent and treat chronic diseases. The ORBIT model includes a flexible and iterative progressive process, prespecified clinically significant milestones for forward movement, and return to an earlier phase for refinement in the event of suboptimal results; see figure 1.

**Phase Ia: define intervention components**
The selection of intervention components was defined by the cultural expert (NTB) and a group of mentors (EMC, MJS, RCM, GB and LP) after careful review of the intervention’s selected components. The rationale for selecting the MCP and CCST approaches, out of numerous other psychotherapeutic approaches, is that research indicated that communication skills for couples improves family communication dynamics, especially among Latinx families and are there prior data of the effectiveness of MCP as well as Latinx prior indications of need for meaning making such as the literature around spirituality. Specifically, there is only one intervention in the adaptation process for Latinx dealing with advanced cancer, the individual MCP. We decided to optimise and further the development of the adapted MCP for Latinx by incorporating the patient’s reported needs in training for communication skills and the inclusion of other family members. By using the CCST approach, we enhanced the MCP session by adding taught coping skills (eg, how to communicate and listen) as well as how to increase their self-efficacy (ie, confidence) for sharing through behavioural practice, goal setting and monitoring progress. The CCST approach was adapted for non-spousal patients’ caregivers by eliminating spousal terms (eg, taking care of your partner–spouse) and changing it to general caregiving terms (eg, taking care of your significant other). Overview table 1 presents the MCP and CCST components that will be cultural and linguistic adapted and integrated for the CASA adapted protocol.

The cultural and linguistic adaptation seven dimensions need to be addressed: language, context, persons, metaphors, concepts, goals and methods. Table 2 presents how we addressed seven dimension (1) language: translate the CCST into Spanish and eliminating spousal terms, (2) person: assessing other possible ends of life themes (ie, different ends of life themes), (3) goals: access the integration of communication skills training and MCP goals, (4) metaphors: we will include culturally consonants stories by adapting the communication skills training and meaning-centred components, (5) concepts: integration of culturally consonants MCP concepts and important end-of-life care topics, (6) methods: use of visual aids and simple definitions.

![Figure 1](image-url)  
Summary of the ORBIT model, applying for the development of the Caregivers-Patients Support to Latinx coping advanced-cancer for forward movement and a return to an earlier phase for refinement in event of other findings.
to describe the content and (7) context: integration of Latino family (caregivers–patients) values, traditions and uniqueness in communication and meaning.

### Phase Ib: refine intervention components

With the CASA protocol, we develop an acceptability and feasibility questionnaire and semi-interview of the intervention. The recruitment and administration of the questionnaire (quantitative phase) and the semistructured interviews (qualitative phase) started in September 2020 and are ongoing until recruitment goals are met. Using the Ecological Validity Framework, the cultural expert (NTB) developed a questionnaire and semistructured interview to administer to patients and their informal caregivers. The questionnaire (quantitative phase) and the semistructured interviews (qualitative phase) were designed to gather information from patients and informal caregivers about integrating Latinx families and cultural values (ie, spirituality, familism and fatalism) to the CASA manual. The intervention targets include: patient and caregiver psychosocial needs, caregiving burden and family function (ie, communication, conflict and cohesion)\(^63\)\(^64\); see Table 1.

#### COVID-19 recruitment phase Ib

Due to social distancing measures during the COVID-19 pandemic, an updated recruitment plan was approved to facilitate ongoing activities and testing. This plan includes (1) using open-access media (ie, Facebook and Ponce Health Science University official webpages) to recruit

### Table 1 Caregivers-Patients Support to Latinx coping advanced-cancer

| Treatment goal                      | MCP components | CCST components | Cultural adaptation | Linguistic adaptation |
|-----------------------------------|----------------|-----------------|---------------------|-----------------------|
| Communication skill: speaker      | X              | X               | X                   | X                     |
| Communication skill: listen       |                | X               |                     | X                     |
| The will to meaning               |                | X               |                     | X                     |
| Freedom of will                   | X              |                |                     |                       |
| Life has meaning                  | X              |                |                     |                       |
| Homework: encountering life’s limitations | X         |                |                     |                       |
| Identity                           | X              |                |                     |                       |
| Experiential sources of meaning   | X              |                |                     |                       |
| Creative sources of meaning       | X              |                |                     |                       |
| Homework: share your legacy–tell your story and legacy project | X | | | |
| Homework: connecting with life    | X              |                |                     |                       |
| Four session                      |                | X              |                     |                       |
| Other to related to end-of-life care | X           |                |                     |                       |

CCST, couple communication skills training; MCP, meaning-centred psychotherapy.

### Table 2 Ecological validity model

| Adaptations |
|-------------|
| Language    | Culturally appropriate and culturally syntonic |
| Persons     | Role of similarities and differences |
| Goals       | Supportive of adaptive values of culture |
| Metaphors   | Culturally consonant sayings and stories |
| Concepts    | Concepts consonant with culture and context |
| Methods     | Strategies consonant with patients’ culture |
| Context     | Consideration of contextual factors |

CCST, couple communication skills training.
participants; (2) including possession of a smartphone, tablet or computer/laptop as an eligibility criterion; and (3) providing the option of conducting informed consent, questionnaire and semi-structured interview procedures during telehealth visits, ensuring they take place in a private location. Depending on the participant’s access, one of the following platforms will be used: VidyoConnect, Zoom, VSee or Doxy.me.

Sample quantitative phase Ib

Participants will be recruited through the Programa de Apoyo Psicosocial Integrado al Cuidado Oncológico (PAPSI—Integrated Psychosocial Support Program for Cancer Care), a psychosocial support programme integrated into oncology care at Ponce Health Sciences University. Patients with advanced cancer who completed PAPSI’s routine distress screening measure will be screened to assess whether they meet the following inclusion criteria: (1) diagnosed with stage III or IV solid tumours, (2) ≥21 years or older, (3) self-report being Latinx or Hispanic and (4) fluent in Spanish. With the patient’s permission, their informal caregiver will be invited to participate if they meet the following inclusion criteria: (1) informal caregiver of a patient recruited to the study and identified by the patient as the person he/she gets the most support, (2) ≥21 years or older, (3) self-report being Latinx or Hispanic and (4) fluent in Spanish.

One hundred and forty patients and their informal caregivers who meet the inclusion criteria will be recruited and participate in the process of informed consent when they agree to enrol in the study. A priori sample size of 114 is selected based on recommendations for exploratory studies of this nature.66–70 Following informed consent, participants will be assigned a subject number. The cultural expert (NTB) will administer the cross-sectional questionnaire (Table 3) to assess the acceptability of the goals, concepts of MCP and communication skills training, and the feasibility of the proposed intervention’s goals and therapeutic methods. Participants will complete assessments, measuring spiritual well-being, depression, anxiety, hopelessness, QOL, family relationship, burden, fatalism, religiosity and distress. Additionally, the survey includes general demographic information (ie, age, education and gender) of the patient and their informal caregiver. The cultural expert (NTB) will administer the questionnaire in an interview-style to accommodate patients and their informal caregivers with limited education and/or literacy. After completing the questionnaire, patients and their informal caregivers will be received US$15 for their study participation.

Sample qualitative phase Ib

Patients (n=15) and their informal caregivers (n=15) who (1) completed the questionnaire package, and (2) scored ≥4 in the distress thermometer will be invited to participate in the qualitative phase. A priori sample size of 15 is selected based on recommendations for qualitative studies of this nature.66–70 Scores ≥4 suggest significant distress and the need for further psychological evaluation. Among those meeting inclusion criteria, the trained professional (interviewer) will discuss informed consent. The interviewer will be blinded to the quantitative information before the one-session, in-depth semi-structured interview, which will be conducted in Spanish and last approximately 1 hour. The interviewer will have an interview guide with the flexibility to ask off-guided questions, which is divided into four sections: (1) exploratory questions regarding participants’ understanding of the MCP concepts, (2) exploratory questions regarding the acceptability and feasibility of the family-based intervention, (3) dyad’s advanced cancer experience, strategies used to cope and caregiving burden and (4) family function (ie, communication, conflict and cohesion). When necessary, the interviewer will use follow-up probing questions to elicit patients’ and informal caregivers’ full narratives. The interview will be digitally audio-recorded. After the semi-structured interviews, participants (patient and the

| Table 3 Description of study scales |
|------------------------------------|
| **Spiritual well-being scale**     | The FACIT Spiritual Well-Being Scale is a brief self-report measure designed to assess an individual’s spiritual well-being with two sub-scales: spirituality and meaning/peace, 68 69 |
| **Depression and anxiety**         | The Hospital Anxiety and Depression Scale (HADS), 70–72 |
| **Hopelessness**                   | The Beck Hopelessness Scale (BHS) comprises 20 true/false questions that assess the degree of hopelessness, 73 |
| **Quality of life**                | The Functional Assessment of Cancer Therapy-General (FACT-G) will assess the participants’ quality of life, 75 |
| **Family relationship**            | Family Relationship Index will measure cohesiveness, conflict, and expressiveness among family members, 76 |
| **Family communication**           | Holding Back subscale (HBS) of the Emotional Disclosure Scale is a 10-item measure assessing the degree to which individuals hold back from talking with their partner/caregiver about cancer-related concerns, 77–80 |
| **Burden**                         | Zarit Burden Interview (ZBI) is a 22 item, 5-point Likert scale (never=0, nearly always=4) used widely to assess caregiver burden 71–83 |
| **Fatalism**                       | Fatalism will be measured with the Mental Adjustment to Cancer Scale, which assesses cognitive responses to cancer in five dimensions, including fatalism, 84 |
| **Religiosity**                    | The Age Universal I/E scale will measure intrinsic and extrinsic religiosity, 85 86 |
| **Distress**                       | NCCN Distress Thermometer and Problem List is a rapid screening tool for assessing psychological distress in people affected by cancer, 87 88 |
informal caregiver) will receive a US$30 stipend for their participation.

**Phase IIa: proof-of-concept**

Phase IIA is planned for the future after phase Ib is completed (questionnaire and semistructured interviews). The formative findings from phase Ib will provide the necessary information to adapt the CASA intervention and further develop the fixed CASA protocol, following the Ecological Validity Framework. With the fixed CASA protocol, we will conduct a pre-pilot feasibility and acceptability study using of the ORBIT: phase IIA. The hypothesis is that CASA is feasible and acceptable, evidenced by reaching high overall retention (>75%), high satisfaction (>75%) and high overall acceptability (>75%) among patients and families.

**Sample phase IIa**

Using a single-arm feasibility design, 30 dyads with patients with stage III and IV solid tumour, distressed (distress thermometer >4) will be enrolled from an oncology clinic in the south area of Puerto Rico. A priori sample size of 30 is selected based on recommendations for pre-pilot studies. The manualised protocol will be delivered across four 45–60 min videoconference sessions by a clinical psychologist. The data will be recorded with informed consent from participants. Data will be transcribed, coded and analysed for themes and subcategories, paying attention to challenging or incomprehensible material and meaning making and communication skills training approaches given by participants. Participants will receive incentives after each session and assessments.

**Procedure phase IIa**

CASA consists of four—45–60 min—family sessions. The four sessions are expected to be delivered every week or every 2 weeks over a span of 4–8 weeks. Sessions will be recorded to conduct fidelity checks. The Principal Investigator, who is a licensed clinical psychologist with extensive clinical training in MCP and CCST, practice delivering MCP and CCST with patients with cancer, and research experience adapting CASA, will conduct the sessions in the USA or will supervise a trained doctoral level clinical psychologist trainee. In New York, Dr. Rosario Costas (consultant), who is a clinical psychologist trained in MCP and also the principal investigator for the R21 Meaning Centered Psychotherapy-for Latinos study, will conduct the sessions or will supervise a doctoral level clinical psychologist trainee on the conducting of CASA. If a doctoral level clinical psychology trainee is involved in delivering the intervention, he/she will be first trained on conducting CASA and will receive weekly supervision from Dr. Costas, or from Dr. Torres if they are practicing in Puerto Rico, but all trainees will receive supervision from Dr. Torres. Patient-reported outcomes will be assessed at baseline and post intervention. Participants will be invited to participate in in-depth exit interviews following completion of CASA intervention. The data will be recorded with informed consent from the participants. Data will be transcribed, coded and analysed for themes and subcategories, paying attention to challenging or incomprehensible material and meaning making and communication skills training approaches given by participants. Participants will receive incentives after each session and assessments.

**Phase IIb: pilot study**

Phase IIb is planned for the future once phase IIA is completed. The pre-pilot (ORBIT: phase IIb) will provide the necessary information to assess the preliminary efficacy of the CASA versus usual care (behavioural placebo) with quality-of-life and patient-reported outcomes (spiritual well-being and self-efficacy) in 100 Latinx families. We will used usual care that include usual psychotherapy intervention as a comparison condition to measure the effect of the adapted intervention. The hypothesis is that those assigned to CASA will report better outcomes than those assigned to the attention control condition at post intervention.

**Sample phase IIb**

One hundred Latinx families, from Puerto Rico and New York, will be randomised placed in a two-group pilot design with pretest and repeated post-test measures used to accomplish the study aims. Patients with stage III and IV (N=100) and their caregivers are randomised in one of two intervention conditions with equal allocation: ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA) or usual care. A priori sample size of 100 is selected based on recommendations for pilot studies. Randomisation is stratified by age at diagnosis and recruitment site. Both interventions are manualised, of equivalent duration, and delivered by a trained counsellor to the couples jointly over videoconference sessions. Web-based self-report outcome measures are administered to participants at baseline and post intervention.

**Procedure phase IIb**

CASA consists of four 45–60 min family sessions. The four sessions are expected to be delivered every week or every 2 weeks over a span of 4–8 weeks. Sessions will be recorded to conduct fidelity checks. The PI who is a licensed clinical psychologist with extensive clinical training in MCP and CCST, practice delivering MCP and CCST with patients with cancer, and research experience adapting CASA, will conduct the sessions in the USA or will supervise a trained doctoral level clinical psychologist trainee. In New York, Dr. Rosario Costas (consultant), who is a clinical psychologist trained in MCP and also the principal investigator for the R21 Meaning Centered Psychotherapy-for Latinos study, will conduct the sessions or will supervise a doctoral level clinical psychologist trainee on the conducting of CASA. If a doctoral level clinical psychology trainee is involved in delivering the intervention, he/she will be first trained on conducting CASA and will receive weekly supervision from Dr. Costas, or from Dr. Torres if they are practicing in Puerto Rico, but all trainees will receive supervision from Dr. Torres. Patient-reported outcomes will be assessed at baseline and post intervention. Participants will be invited to participate in in-depth exit interviews following completion of CASA intervention. The data will be recorded with informed consent from the participants. Data will be transcribed, coded and analysed for themes and subcategories, paying attention to challenging or incomprehensible material and meaning making and communication skills training approaches given by participants. Participants will receive incentives after each session and assessments.
Quantitative analysis phase Ib

Descriptive statistics will be conducted using IBM SPSS Statistics V.21 to examine survey responses. The predyadic analyses occur in three steps: (1) bivariate correlations to calculate results between depression, anxiety, meaning, spirituality, hopelessness, QOL and family function. (2) eight bivariate regression models to assess the predictive power of each predictor variable (meaning and spirituality) on each of the four outcomes: hopelessness, QOL, anxiety and depression. (3) multilevel models to analyse data at the dyad level to control for interdependencies. The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (ie, one for the patient and one for the informal caregiver). It will be controlled for the dependent nature of couple-level data and allowed for examination of both actor and cross-partner effects.

Quantitative analysis phase Ila

Feasibility and acceptability will be assessed through accrual, session/assessment completion, intervention satisfaction and coping skills usage. Participants completed validated measures of primary outcomes (ie, spiritual well-being and self-efficacy) and acceptability questionnaire at baseline, and post intervention.

Quantitative analysis phase IIb

The primary analysis will examine whether, relative to the usual care intervention, the CASA intervention leads to greater increases in patient and caregivers’ spiritual well-being and self-efficacy in all two post-treatment assessments in a mixed-effects regression model. Pretreatment spiritual well-being and self-efficacy scores and time (categorical) will be included as covariates. Intervention by time interactions will test the intervention effect at each follow-up time. Subject-specific random intercepts will account for within-subject variability. Intervention effects on patient spiritual well-being and self-efficacy at each follow-up are tested using F tests of combined main and interaction effects. Descriptive statistics will be conducted using IBM SPSS Statistics V.21 to examine survey responses. The predyadic and postdyadic analyses occur in three steps: (1) bivariate correlations to calculate results between meaning, spirituality, hopelessness, QOL and family function, (2) eight bivariate regression models to assess the predictive power of each predictor variable (meaning and spirituality) on each of the four outcomes: hopelessness, QOL, anxiety and depression, (3) multilevel models to analyse data at the dyad level to control for interdependencies. The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (ie, one for the patient and one for the informal caregiver). It will be controlled for the dependent nature of couple-level data and allowed for examination of both actor and cross-partner effects.

Qualitative analysis phase Iib, Ila and Iib

Data analysis will begin with verbatim transcripts of the 30-digital audio-recorded interviews and imported into Atlas.ti (V.8.1.3; Atlas.ti Scientific Software Development, Berlin, Germany, www.atlasti.com). The team will follow a published qualitative data preparation and transcription protocol to ensure the transcriptions’ accuracy and fidelity. Observational notes taken by the interviewer will be typed and attached to the transcription documents. During the transcription, all data will be deidentified by replacing names with aliases to ensure anonymity.

Atlas.ti will be used to analyse the transcription of semistructured interviews. Two triangulated methods will be used to improve qualitative accuracy and validity: methods and analyst triangulation. Method triangulation will be achieved by determining the consistency of the data generated by both the survey and the semistructured interviews. Analyst triangulation will be attained using multiple analysts (raters) to review and evaluate the qualitative data. Once transcribed, the text will be analysed in two steps: (1) inductive followed by (2) deductive content analysis. Each step has three phases: preparation, organising and reporting. Two bilingual raters will conduct the content analysis. The analyses, integration and interpretation will be in Spanish.

Inductive content analysis will examine how families (patients with advanced cancer and their informal caregivers) define CASA and communication skills training concepts. During the preparation phase, raters will familiarise themselves with the text. The data will be organised through open coding, creating categories, abstractions and identifying the concepts’ boundaries for inductive analysis. Categories will be generated from open coding and grouped under higher-order headings. Descriptions using content-characteristic words will be created for the abstraction. The data will be reviewed for deductive content analysis using a structured categorisation matrix based on the MCP and communication skill model. All data will be reviewed for content and coded for correspondence, exemplifying the categories’ categorisation matrix.

Integration phase

In cultural adaptation, the source text is rewritten in the target language to convey the concepts and achieve the aims of the source text, while accounting for both language and cultural considerations. The cultural adaptation not only renders the text of written materials into another language but also infuses culturally relevant context and themes. The cultural expert (NTB), group of mentors (EMC, MJS, RCM, GB and LP), and collaborators (CZ, MC and WB) will conduct the integration of the quantitative and qualitative findings to develop the CASA fixed protocol (table 1). The text will be independently reviewed, followed by ‘consensus meetings’ to discuss every session of the intervention, provide feedback and discuss further modifications until a consensus is reached. Dr. Guillermo Bernal will then review the text.
to ensure the adaptation considers the dimensions of the EVM. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ concepts, goals and theoretical model will be preserved during the adaptation process to ensure language, metaphor, strategy, cultural context and value acceptability by Latinx families.

As shown with the transcration of CASA intervention for Latinx, we will include information of Latinx living in Puerto Rico and New York, the adaptation plan for Latinx families will also include content modification, family congruence through metaphors and assignments, and cultural adaptation notes with findings from the cultural adaptation process guidelines about the delivery of the intervention to the dyad.

Summary

Once the fixed protocol of CASA is acceptable, feasible and effective, we will finalise the development process with an efficacy trial (ORBIT: phase III) and later effectiveness research trial (ORBIT: phase IV). This process will facilitate the development of culturally sensitive intervention and mitigate the cost of developing effective and durable behavioral treatment. All the identified phases currently bring the needed elements to go from ideas to efficacy trial with a well-defined pathway for doing it. Specifically, the proposed behavioural intervention framework pushes the identified need to sight on the chain of evidence needed to support the progressive programme of intervention development. Finally, the recognised framework is flexible in both the design and methodologies for treatment development, which facilitates development.

Strengths and weaknesses/limitations of the study

The first limitation is that the qualitative interviews are the main source of information for the adaptation. Thus, we will include observation of sessions in the next phases of adaptation process (phase Ia: proof-of-concept and phase Ib: pilot study). Second, patients were predominantly recruited from Puerto Rico. Thus, the results may not generalise to all Latinx, and future studies will include samples from different geographical locations. Third, the selection of patients was not homogeneous in terms of diagnosis and stages, and patients with stages III and IV cancer will be invited to participate. The cancer experiences of patients and caregivers at different disease stages with different prognoses could vary significantly. In future studies, analyses should be stratified by stage and prognosis. The final identified limitation is the access to technology. Thus, we will include the possibility of conducting the questionnaire and intervention in person.

Public involvement statement

The public, specifically Latinx patients with advanced cancer and their informal caregivers, are at the core of the implementation plan. The study’s objective is to develop the first psychosocial patient–caregiver intervention that supports Latinx patients with advanced cancer and their informal caregivers to cope with cancer. The study design mentioned above will constantly include the consultation of patients’ and their informal caregivers’ perceptions, experiences and opinions to refine a successful final version of ‘Caregivers-Patients Support to Latinx coping advanced-cancer’ (CASA). The intent is to involve the patients and their informal caregivers (the public), who will be the target user in the development and cultural adaptation of the patient–caregiver psychological intervention (ORBIT: phase Ia: proof-of-concept and phase Ib: pilot study). Further, the proposed project will directly (1) impact the Latinx community, (2) contribute to the development of culturally adapted psychosocial interventions, (3) be used in the healthcare field and (4) reduce disparities in access to psychosocial interventions for Latinx patients with advanced cancer.

Ethics and dissemination

This project is the first development of a culturally and linguistically adapted intervention for Latinx families coping with advanced cancer. This adaptation plan will guide the specific dyadic intervention for patients with advanced cancer and caregivers. It will advance the field of cultural adaptation of psychosocial interventions in the medical field to reduce health inequalities. Furthermore, it will result in peer-reviewed publications, conference presentations and reports. The information will also be shared with non-academic community members involved in outreach activities; that is, ‘Hablemos de Cáncer’, El Puente (The Bridge), newsletters and social media; that is, ‘Yo Puedo’, of the Support Group of American Cancer Society in Puerto Rico.

Contributors

Study conception and design: NTB, EMC, RCM, LP, MJS, WB and GB. Acquisition of data: NTB, MC and RCM. Analysis and interpretation of data: NTB and RCM. Drafting of manuscript: all authors. Critical revision: NTB, EMC, CZ and RCM.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Consent obtained directly from patient(s).

Provenance and peer review

Not commissioned; externally peer reviewed.

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