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Cultural Adaptation of Meaning-Centered Psychotherapy for Latino Families: A Protocol

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ABSTRACT

Introduction: Literature suggests couple-based interventions that target quality of life and communication can lead to positive outcomes for cancer patients and their partners. Nevertheless, to date, an intervention to address the needs of Latino families coping with advanced cancer has not been developed. Our goal is to culturally and linguistically adapt two empirically supported treatments: Meaning-Centered Psychotherapy (MCP) and Couple Communication Skills Training (CCST), to develop a Family Meaning-Centered Psychotherapy (FMCP) for Latino families (patients and informal caregivers) dealing with advanced cancer.

Methods and analysis: To culturally adapt and develop a Family Meaning-Centered Psychotherapy (FMCP), the Ecological Validity Model (EVM) and Nueva Vida Framework is used. A four-phase approach is utilized to conduct the adaptation process: (1) Selection of intervention components (completed), (2) Initial adaptation(completed), (3) Comprehension and acceptability testing (in progress), and (4) Protocol refinement (planned). The initial adaptation was conducted, and aspects related to family (i.e., caregivers and communication) were included. The intervention will be further adapted by administering a survey (n=114) and adaptation will continue by conducting semi-structured interviews (n=30) with advanced cancer patients (n=15) and their informal caregivers (n=15) to test for comprehension and acceptability. Descriptive and dyadic statistical analysis will be used to analyze the quantitative data. After transcription of interviews, deductive content analysis will be conducted using Atlas.ti.

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

Keywords: Cultural, Adaptation, Latino, Families, Cancer

Strengths and limitations of this study

- This study will allow the development of the Family Psychotherapy Intervention to support Latino patients and caregivers coping with advanced cancer.
- The major strength of this study is its purpose not solely to translate a previously tested English language intervention but also to adapt it culturally.
- We will not measure our participants' access to technology (i.e., telephone, internet, or computer), limiting our ability to assess some information on access to technology for the implementation phase.

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Planning), 5R21CA224874-02 (A communication-based intervention for advanced cancer patient-caregivers dyads to increase engagement in advance care planning and reduce caregivers burden), 5K08CA234397 (Adaptation and Pilot Feasibility of a Psychotherapy Intervention for Latinos with Advanced Cancer); and the Memorial Sloan Kettering Cancer Center grant (P30CA008748). Supported in part by 133798-PF-19-120-01-CPPB from the American Cancer Society.

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Conflict of Interest

The authors reported no potential conflict of interest.

Authors contribution

Study conception and design: Normarie Torres-Blasco, Eida Castro, Rosario Costas-Muñiz, Laura Porter, Megan Shen, William Breitbart and Guillermo Bernal.

Acquisition of data: Normarie Torres-Blasco, María Claros and Rosario Costas-Muñiz

Analysis and interpretation of data: Normarie Torres-Blasco and Rosario Costas-Muñiz

Drafting of manuscript: Normarie Torres-Blasco, Eida Castro, Carolina Zamore, María Claros, Rosario Costas-Muñiz, Laura Porter, Megan Shen, William Breitbart and Guillermo Bernal

Critical revision: Normarie Torres-Blasco, Eida Castro Carolina Zamore and Rosario Costas-Muñiz.

Data Statement Section

The datasets generated and/or analyzed during the current study are not publicly available due to PHSU and MSK's Data Sharing Policy but are available from the corresponding author on reasonable request.

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 advanced cancer patients and their families emphasize the need for increased attention to end-of-life care. [3] Caregivers often assume the role without the necessary skills to help them address a cancer patient's complex needs. [4-9] Consequently, they can experience a substantial caregiving burden that negatively impacts family function (i.e., communication, conflict, and cohesion) and the patients' physical, emotional, and social well-being. [10-14]

Latinos have a higher intensity (i.e., hours per week and help with activities of daily living) of caregiving than non-Latino whites and Asians. [15] Our preliminary data shows that 86% of Latino advanced cancer patients 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 (i.e., adherence, depression, poor prognostic, and stress). [16-18] Patients with advanced cancer and their families experience significant distress in four domains: physical, psychological, social, and spiritual. [19-21] These domains are often summarized by the term "quality of life (QOL)." QOL, spirituality, and reduction of distress are essential goals of cancer care. [22] A meta-analysis and systematic review found that Latino cancer patients show worse distress, depression, and overall health-related quality of life (HRQOL) than other minority patients and Whites. [23] Similarly, Latino patients report higher levels of burden, depression, and physical health problems than patients of other ethnicities. [24, 25] Therefore, addressing family issues is crucial in the adjustment and well-being of Latinos 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. [26-29] Meta-analytic evidence suggests that culturally adapted interventions targeting a specific cultural group 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). [26-29] The literature suggests that behavioral 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. [29]

Objectives

The purpose of this study is to culturally adapt and integrate (1) Meaning-Centered Psychotherapy (MCP) and (2) Couples Communication Skills Training (CCST) to develop a Family Meaning-Centered Psychotherapy (FMCP) for Latino families. The FMCP intervention aims to improve the quality of life and spiritual well-being of advanced cancer patients and their informal caregivers. This paper describes the conceptual framework used for the cultural adaptation process, initial phases, and future plans.

Methods and Analysis

The conceptual framework for Cultural Adaptation

The unifying theoretical framework of the culturally adapted Evidence-Based Practice, [30- 33] Ecological Validity Model (EVM), [31] developed by Dr. Guillermo Bernal, the cultural adaptation process model (CAPM) [34], the Nueva Vida Framework [35] and cancer contextual model of health-related quality of life (HRQOL), [36] provides 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 [42]. CAPM is a complementary process model to EVM and prescribes four phases for the adaptation process: formative, adaptation iterations, intervention, and measurement adaptation. [34] The Nueva Vida Framework and cancer contextual model of health-related quality of life (HRQOL) are outlined to specify individual, cultural and contextual influences (i.e., dyadic relationships and communication with partners) as essential determinants of QOL. [35, 36] Drawing from social cognitive (i.e., Couples Communication Skills Training) and existential theory (i.e., Meaning-Centered therapy), the Family Meaning-Centered Psychotherapy intervention is designed to increase the spiritual well-being and self-efficacy in communication between advanced cancer patients and their informal caregivers. [37-44]

To identify the foundational information necessary to culturally adapt and integrate MCP and CCST to develop FMCP for Latino patients and their informal caregivers, we will utilize a four-phase approach guided by the Ecological Validity Model: (1) Selection of intervention components (phase 1 completed), (2) Initial adaptation (phase 2 completed), (3) Comprehension and acceptability testing (phase 3 in progress) and (5) Protocol refinement (phase 4 planned).

Phase 1: Selection of Intervention Components

The selection of intervention components was finalized by the cultural expert (NTB) and a group of mentors (EC, MS, RCM, GB, and LP) after careful review of the intervention's selected components. Meaning-Centered Psychotherapy (MCP) was chosen because of its supportive evidence with predominantly non-Latinos whites in increasing spiritual well-being, a sense of meaning, purpose in life, and reducing distress [38-41]. Further, the integration of the Couples Communication Skills Training (CCST) was included because prior research has found that couple-based interventions that target communication lead to positive outcomes for cancer patients and their partners [42, 43].

Meaning-Centered Psychotherapy (MCP) for Latinos.

MCP, developed by Dr. Breitbart, aims to target specific psycho-spiritual needs of patients with advanced cancer. [38- 40] Its primary goal is to help patients enhance a sense of meaning, peace, and purpose as they approach end-of-life. The 7-session 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 MCP for Latino advanced cancer patients [41]. Preliminary findings suggested Latinos with advanced cancer identified family issues as a crucial component in adjusting to their cancer diagnosis and well-being. [44] These findings indicate the need and acceptability of a culturally adapted family intervention for cancer patients and their informal caregivers in navigating family function and adjustment in cancer [41, 44].

Couples Communication Skills Training (CCST).

CCST is a six-session intervention that provides couples with training in communication skills and encourages them to discuss illness-related concerns. The intervention includes components to assist couples in communicating effectively, decreasing avoidance of critical cancer-related issues, and supporting each other. It provides training in skills for (a) sharing one's thoughts and feelings (i.e., disclosure), (b) listening to one's partner and responding in a supportive manner, and (c) joint problem-solving. [42, 43] While CCST was developed for patient-spouse dyads, the communication skills taught in CCST have also been applied in studies targeting a broader range of patient-caregiver dyads (i.e., patients and their adult children) [42, 43].

Phase 2: Initial Adaptation

The initial adaptation's objective was to understand the sources of meaning, hope, legacy, and identity in Latino patients with advanced cancer. [41] RCM and NTB, the cultural adaptation experts, conducted a study with 99 Latino patients with advanced cancer between August 2015 and March 2020. They tested the association between spirituality, including meaning, faith, psychological adjustment (depression and anxiety), QOL, hopelessness, and explored possible moderator factors. Patients were from two cancer clinics in New York City: Memorial Sloan Kettering Cancer Center and Lincoln Medical and Mental Health Center, and another from Ponce, Puerto Rico: Ponce Health Sciences University. Twenty-four patients were invited to a subsequent interview between August 2017 and March 2017. Patients explored their sources of meaning following their cancer diagnosis, understanding the MCP model's concepts, and helping discern the acceptability and feasibility of the goals, ideas, methods, and metaphors of the MCP manual. Key findings included (1) simplifying definitions, questions, and reflections; (2) changing challenging to translate and comprehend phrases; (3) modifying the metaphors to be culturally congruent; (4) incorporate common words relatable to all Latino cultures, such as modifying content to make it responsive to Latino cultural values and norms and (5) providing more than one option. [41] After gathering data from this two-phase mixed-method design, the MCP manual was adapted and translated to conduct a pilot feasibility study with Spanish-speaking Latinos coping with cancer. [41] As a result, findings demonstrated patients reported high acceptance of family members' integration to their treatment. [44]

Prior to the quantitative and qualitative phases (phase 3 - survey and semi-structured interview), the Family Meaning-Centered Psychotherapy protocol was reviewed by the cultural experts, who translated the materials. The initial adaptation was completed and the following are examples of changes after this early review: (1) integrated Communication Skills training to the Family Meaning-Centered Psychotherapy protocol; (2) limited the session content to 4 sessions; (3) incorporated another possible end-of-life theme, and (4) intervention focus changed from individual to family.

Phase 3: Comprehension and Acceptability Testing

The questionnaire and semi-interview development are finalized. The recruitment and administration of the questionnaire, and the semi-structured interviews starts in September 2020 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework, the cultural expert (NTB) developed a questionnaire and semi-structured interview to administer to patients and their informal caregivers. The questionnaire and interview were designed to gather information from patients and informal caregivers about integrating Latino families and cultural values (i.e., spirituality, familism, and fatalism) to the FMCP manual. The intervention targets include patient and caregiver psychosocial needs, caregiving burden, and family function (i.e., communication, conflict, and cohesion) [41], see Table 1.

Table 1 presents the adaptation process proposed by the expert (NBT) and mentors (EC, MS, RCM, GP, and LP). The language dimensions will be incorporated in the adaptation of MCP to FMCP by using preliminary themes found in Communication Skill Training and Meaning-Centered Psychotherapy. The person dimension includes specific treatment targets by assessing other possible end-of-life themes (i.e., reaction to the diagnosis, fears about death, and difficulties completing daily activities). The integration of EVM and the Nueva Vida dyadic Framework will result in metaphors, concepts, strategies, content, goals, and phrases of FMCP consonant with culture and context.

COVID-19 Recruitment. 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) utilizing open-access media (i.e., Facebook and PHSU official webpages) to recruit 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.

Quantitative Phase. 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 program integrated into oncology care at Ponce Health Sciences University and led by EC. Advanced cancer patients 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 tumors, (2) 21 years or older, (3) self-report being Latino or Hispanic, and (4) fluent in Spanish. With permission of the patient, their informal caregiver will be invited to participate if he/she meets 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 Latino or Hispanic, and (4) fluent in Spanish.

Patients and their informal caregivers who meet the inclusion criteria will be recruited and participated in the process of informed consent when they agreed to enroll in the study. Following informed consent, participants will be assigned a subject number. The cultural expert (NTB) will administered 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 (validated scales) measuring spiritual well-being, depression, anxiety, hopelessness, quality of life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the survey included general demographic information (i.e., age, education, and gender) of the patient and their informal caregiver. The cultural expert (NTB) will administered 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 $15 for their study participation.

Qualitative Phase. 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 [41]. 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 take approximately one 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 (i.e., 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 informal caregiver) will receive a $30 stipend for their participation.

Quantitative Analysis. Descriptive statistics will be conducted using IBM SPSS Statistics 21 to examine survey responses. The pre-dyadic analyses occurred in three steps: (1) bivariate correlations to calculate results between meaning, spirituality, hopelessness, QOL, and family function, (2) 8 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) multi-level models to analyze data at the dyad level to control for interdependencies. [46] The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (i.e., 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. [46]

Qualitative Analysis. Data analysis will begin with verbatim transcripts of the 30 digital audio-recorded interviews and imported into Atlas.ti (version 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. [45] Observational notes taken by the interviewer will be typed and attached to the transcription documents. During the transcription, all data will be de-identified by replacing names with aliases to ensure anonymity.

Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated methods will be used to improve qualitative accuracy and validity: methods and analyst triangulation. [47-55] Method triangulation will be achieved by determining the consistency of the data generated by both the survey and the semi-structured interviews. Analyst triangulation will be attained using multiple analysts (raters) to review and analyze the qualitative data. Once transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive content analysis. Each step has three phases: preparation, organizing, and reporting. [56-58] Two bilingual raters will conduct the content analysis. The analyses, integration, and interpretation will be in Spanish.

Inductive content analysis will examine how families (advanced cancer patients and their informal caregivers) define MCP and communication skills training concepts. During the preparation phase, raters will familiarize themselves with the text. The data will be organized 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 categorization matrix based on the MCP and communication skill model. All data will be reviewed for content and coded for correspondence, exemplifying the categories' categorization matrix.

Phase 4: Protocol refinement

Phase 4 is planned for the future once phase 3 is completed (questionnaire and semi-structured interviews). The formative findings from phase 3 will provide the necessary information to adapt the FMCP intervention and further develop the protocol, following the Ecological Validity Framework. 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. [59] The cultural adaptation not only renders the text of written materials into another language but also infuses culturally relevant context and themes. [60, 61] The cultural expert (NTB), group of mentors (EC, MS, RCM, GP, and LP), and collaborators (CZ, MC, and WB) will conduct the integration of the triangulation findings to review and adapt the intervention manual (Table 2). 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 Ecological Validity Model. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of Family Meaning-Centered Psychotherapy's concepts, goals, and theoretical model will be preserved during the adaptation process to ensure language, metaphor, strategy, cultural context, and value acceptability by Latino families.

As shown with the transcreation of MCP for Latinos, [41] the adaptation plan for Latino families will also include content modification, family congruence through metaphors and assignments, cultural adaptation notes with findings from the cultural adaptation process guidelines about the delivery of the intervention to the dyad.

Public Involvement Statement

The public, specifically Latino advanced cancer patients and their informal caregivers, are at the core of the implementation plan. The study's objective is to develop the first psychosocial family intervention that supports Latino advanced cancer patients and their informal caregivers to cope with cancer. The study design mentioned above was consensually agreed by the team to optimize patients' and their informal caregivers' perceptions, experiences, and opinions to refine a successful final version of the patient- and informal caregiver-centered intervention. The intent is to involve the patients and their informal caregivers (the public) who will be the end target user in the development and cultural adaptation of the family psychological intervention. Further, the proposed project will directly (1) impact the Latino 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 Latino advanced cancer patients.

Ethics and Dissemination

This project is the first development of a culturally- and linguistically-adapted intervention for Latino families coping with advanced cancer. The results of this adaptation plan will guide the specific dyadic intervention for advanced cancer patients 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, i.e., "Hablemos de Cáncer," *El Puente* (*The Bridge*), newsletters, and social media, i.e., "Yo Puedo," of the Support Group of American Cancer Society in Puerto Rico.

Table 1

Ecological Validity Model		Adaptations
Language	Culturally appropriate and culturally syntonic	Translate the MCP to a FMCP by using the dyadic communication intervention skills and themes of Meaning-Centered Psychotherapy
Persons	Role of similarities and differences	Inclusion of specific treatment targets by assessing other possible ends of life themes (i.e., different ends of life themes)
Goals	Supportive of adaptive values of culture	Integration of Communication skills training and Meaning-Centered Psychotherapy, to improve quality of life and spiritual well-being
Metaphors	Culturally consonant sayings and stories	Integration of EVM and the Nueva Vida dyadic Framework
Concepts	Concepts consonant with culture and context	Integration of Culturally consonants Meaning-Centered Psychotherapy Themes
Content	Values, traditions, and uniqueness	Family values, traditions and uniqueness

Methods	Strategies consonant with patients' culture	Use of visual aids and simple definitions
Context	Consideration of contextual factors	Education, age, gender and diagnosis

Table 2

Family Meaning-Centered Psychotherapy		
Session	Session Title	Content
1	Meaning and Communication	Introduction: We will conduct this intervention between the patient and their caregiver, so it is crucial to know how to share thoughts and feelings
		Possible Meaning-Centered Themes: The will to meaning, freedom of will and life has meaning
		Homework: Encountering Life's Limitations
2	Identity, Experiential and Creative sources of Meaning	This session will reinforce the use of communication skills
		Possible Meaning-Centered Themes: Identity before Cancer/ Identity after Cancer, Creative Sources of Meaning and Experiential Sources of Meaning
		Homework: Share Your Legacy ~ Tell Your Story and Legacy Project
3	Legacy Project	Behavioral rehearsal will reinforce the couple's communication skills, the meaning-centered, and end-of-life themes.
		Homework: Connecting with Life
4	Reflections and Hopes for the Future	The last session will also include discussions of the couple's progress during treatment and future issues the couple anticipates addressing relative to meaning
		Review of sources of meaning
		Reflections on the lesson learned and hopes
		Goodbyes for patients and caregivers

Table 3

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 [62, 63]
Depression and Anxiety	The Hospital Anxiety and Depression Scale (HADS) [64-66]
Hopelessness	The Beck Hopelessness Scale (BHS) comprises 20 true/false questions that assess the degree of hopelessness [67, 68]
Quality of life	The Functional Assessment of Cancer Therapy-General (FACT-G) will assess the participants' quality of life [69]
Family Relationship	Family Relationship Index will measure cohesiveness, conflict, and expressiveness among family members [70]
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 [71-74]
Burden	Zarit Burden Interview (ZBI) is a 22 item, 5-point Likert scale (never = 0, nearly always = 4) used widely to assess caregiver burden [75, 76]
Fatalism	Fatalism will be measured with the Mental Adjustment to Cancer Scale, which assesses cognitive responses to cancer in five dimensions, including fatalism [77]
Religiosity	The Age Universal I/E scale will measure intrinsic and extrinsic religiosity [78]
Distress	NCCN Distress Thermometer and Problem List is a rapid screening tool for assessing psychological distress in people affected by cancer [79, 80]

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Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

Title and abstract

	Page/line no(s).
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	3

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	5
Purpose or research question - Purpose of the study and specific objectives or questions	6

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	7
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	8
Context - Setting/site and salient contextual factors; rationale**	9- 13
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	13
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	16- 17
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	12- 13

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	12- 13
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	12 -13
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	13-15
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	13- 15
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	15- 16

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	n/a protocol paper
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	n/a protocol paper

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	n/a protocol paper
Limitations - Trustworthiness and limitations of findings	n/a protocol paper

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	4
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	4

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
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Cultural Adaptation of Meaning-Centered Psychotherapy for Latino Families: A Protocol

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ABSTRACT

Introduction: Literature suggests couple-based interventions that target quality of life and communication can lead to positive outcomes for cancer patients and their partners. Nevertheless, to date, an intervention to address the needs of Latino families coping with advanced cancer has not been developed. Our goal is to develop Family Meaning-Centered Psychotherapy (FMCP-L) for Latino families (patients and informal caregivers) dealing with advanced cancer.

Methods and analysis: To culturally develop a FMCP-L, we will follow an innovative hybrid research framework that combines elements of an efficacy model and best practices from the Ecological Validity Model (EVM), adaptation process model (CAPM), and the cancer contextual model of health-related quality of life (HRQOL). As a first step, following the framework of the ORBIT Model (Phase 1a: Define), we developed a novel psychosocial intervention protocol entitled Family Meaning Centered Psychotherapy for Latinx (FMCP-L). The initial FMCP-L protocol integrates two empirically based interventions, Meaning-Centered Psychotherapy and Couple Communication Skills Training, with the goals of (1) helping patients and caregivers sustain or enhance a sense of meaning, peace, and purpose as patients approach the end of life and (2) improving communication and quality of life among the patient-caregiver dyad. We will receive FMCP-L protocol feedback (Phase 1b: Refine) y conducting 114 questionnaires and 15 semi-structured interviews with advanced cancer patients and their caregivers. Participants will be adult patients and caregivers coping with advanced cancer (Stage III or IV). The primary outcomes of this study will be identifying the foundational information needed to further the develop the FMCP-L (Phase IIa: Proof-of-Concept and Phase IIb: Pilot study).

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

Keywords: Cultural, Adaptation, Latinx, Families, Cancer

Strengths and limitations of this study

- This study will allow the development of the Family Psychotherapy Intervention to support Latinx patients and caregivers coping with advanced cancer.
- The major strength of this study is its purpose to not solely translate a previously tested English language intervention, but also to adapt it culturally.
- We will not measure our participants' access to technology (i.e., telephone, internet, or computer), limiting our ability to assess some information on access to technology for the implementation phase.

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Conflict of Interest

The authors reported no potential conflict of interest.

Authors contribution

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Critical revision: Normarie Torres-Blasco, Eida Castro Carolina Zamore and Rosario Costas-Muñiz.

Data Statement Section

The datasets generated and/or analyzed during the current study are not publicly available due to PHSU and MSK's Data Sharing Policy but are available from the corresponding author on reasonable request.

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 advanced cancer patients and their families emphasize the need for increased attention to end-of-life care,[3]. Caregivers often assume the role without the necessary skills to help them address a cancer patient's complex needs,[4-9]. Consequently, they can experience a substantial caregiving burden that negatively impacts family function (i.e., communication, conflict, and cohesion) and the patients' physical, emotional, and social well-being,[10-14].

Impact of cancer on family caregiver's wellbeing

Caregiver research in recent years has identified the need to identify at-risk sub-groups of family caregivers based on demographics, stage, and assessing caregiving stress as a priority,[15, 16]. By considering at-risk sub-groups, literature suggested that ethnic minority caregivers,[15, 16] and caregivers of advanced cancer stage patients,[17] uniquely reported poorer mental functioning and a more significant impact on daily activity. Specifically, caregivers identified needs in psychosocial services and described the importance of including content related to communication and spirituality,[18] with patients and other family members,[17]. It is essential to include content that patients identify in the literature to prevent caregivers' depressive symptoms and burnout that may exacerbate physical health decline,[19].

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,[20]. A culturally centered intervention for Latinx patients should include a family-centered (partners and other family members) approach to determine the content and goals of care preferred in Latinx families coping with cancer,[21-23].

Latinx patients and caregiver dyadic

Latinx have a higher intensity (i.e., hours per week and help with activities of daily living) of caregiving than non-Latinx whites and Asians,[24]. Our preliminary data shows that 86% of Latinx advanced cancer patients 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 (i.e., adherence, depression, poor prognostic, and stress),[25-27]. Patients with advanced cancer and their families experience significant distress in four domains: physical, psychological, social, and spiritual,[28-30]. These domains are often summarized by the term "quality of life (QOL)." QOL, spirituality, and reduction of distress are essential goals of cancer care,[31]. A meta-analysis and systematic review found that Latinx cancer patients show worse distress, depression, and overall health-related quality of life (HRQOL) than other minority patients and Whites,[32]. Similarly, Latinx patients report higher levels of burden, depression, and physical health problems than patients of other ethnicities,[33, 34]. 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,[35-38]. Meta-analytic evidence suggests that culturally adapted interventions targeting a specific cultural group 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),[35-38]. The literature suggests that behavioral 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,[38].

The conceptual framework

Meaning Centered Psychotherapy is grounded in theory, developed by Dr. Breitbart, aims to target specific psycho-spiritual needs of patients with advanced cancer[39]. Its primary goal is to help patients enhance a sense of meaning, peace, and purpose as they approach end-of-life. The 7-session 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 MCP for Latino advanced cancer patients,[40, 41]. Preliminary findings suggested Latinx with advanced cancer identified family issues as a crucial component in adjusting to their cancer diagnosis and well-being,[40, 41]. These findings indicate the need and acceptability of a culturally adapted family intervention for cancer patients and their informal caregivers in navigating family function, communication and adjustment in cancer,[40, 41]. Further, research indicated that communication skills for couples improves family communication dynamics, especially among Latinx families,[42] and is there prior data of the effectiveness of meaning-centered psychotherapy as well as Latinx prior indications of need for meaning making such as the literature around spirituality,[41].

Objectives

The purpose of this study is to culturally adapt and integrate (1) Meaning-Centered Psychotherapy (MCP) and (2) Couples Communication Skills Training (CCST) to develop a Family Meaning-Centered Psychotherapy for Latinx families (FMCP-L). The FMCP intervention aims to improve the quality of life and spiritual well-being of advanced cancer patients 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 FMCP-L protocol integration of two empirically based interventions, Meaning-Centered Psychotherapy and Couple Communication Skills Training, with the goals of (1) helping patients and caregivers sustain or enhance a sense of meaning, peace, and purpose as patients approach the end of life and (2) improving communication among the patient-caregiver dyad. We hypothesized 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 quality of life. Overview Figure 1 presents the ORBIT model,[43] applying for the development of the FMCP-L and includes a flexible and interactive progressive process, a pre-specified clinically significant milestone for forward movement and a return to an earlier phase for refinement in event of other findings.

The unifying theoretical framework of the culturally adapted Evidence-Based Practice,[43- 47] Ecological Validity Model (EVM),[45] developed by Dr. Guillermo Bernal, the cultural adaptation process model (CAPM),[44] and cancer contextual model of health-related quality of life (HRQOL),[48] 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,[44]. CAPM is a complementary process model to EVM and prescribes four phases for the adaptation process: formative, adaptation iterations, intervention, and measurement adaptation,[44]. Cancer contextual model of health-related quality of life (e.g., Spiritual wellbeing, depression, anxiety, hopelessness, functional assessment of cancer therapy, family relationship index, burden, fatalism, religiosity, distress and patient’s needs-semi-structured interview) are outlined to specify individual, cultural, and contextual influences (i.e., dyadic relationships and communication with partners) as essential determinants of QOL,[47] Drawing from social cognitive (i.e., Couples Communication Skills Training) and existential theory (i.e., Meaning-Centered therapy), the Family Meaning-Centered Psychotherapy intervention is designed to increase the spiritual well-being and self-efficacy in communication between advanced cancer patients and their informal caregivers,[48-53].

To identify the foundational information necessary to culturally adapt and integrate MCP and CCST to develop FMCP-L for Latinx patients and their informal caregivers, we will utilize 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 Behavioral Treatment Development model provides a progressive, clinically relevant approach to increasing the number of evidence-based behavioral treatments available to prevent and treat chronic diseases,[41]. The ORBIT model includes a flexible and iterative progressive process, pre-specified clinically significant milestones for forward movement, and return to an earlier phase for refinement in the event of suboptimal results, see figure 1,[43].

Phase Ia: Define Intervention Components

The selection of intervention components was defined by the cultural expert (NTB) and a group of mentors (EC, MS, RCM, GB, and LP) after careful review of the intervention's selected components. The rationale for selecting the Meaning-Centered Psychotherapy and Couple Communication Skills Training 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 is there prior data of the effectiveness of meaning-centered psychotherapy as well as Latinx prior indications of need for meaning making such as the literature around spirituality,[48-53]. Specifically, there is only one intervention in the adaptation process for Latinx dealing with advanced cancer, the Individual Meaning-Centered Psychotherapy,[40, 41]. We decided to optimize and further the development of the adapted Meaning-Centered Psychotherapy for Latinx by incorporating the patient's reported needs in training for communication skills and the inclusion of other family members. By using the Couple Communication Skills Training (CCST) approach, we enhanced the MCP session by adding taught coping skills (e.g., how to communicate and listen) as well as how to increase their self-efficacy (i.e., confidence) for sharing through behavioral practice, goal setting, and monitoring progress,[52, 53]. The Couple Communication Skills Training approach was adapted for non-spousal patients' caregivers by eliminating spousal terms (e.g., taking care of your partner-spouse) and changing it to general caregiving terms (e.g., taking care of your significant other). Overview Table 1 presents the FMCP-L content.

Table 1

Family Meaning-Centered Psychotherapy

Session	Session Title	Content
1	Meaning and Communication	Introduction: We will conduct this intervention between the patient and their caregiver, so it is crucial to know how to share thoughts and feelings
		Possible Meaning-Centered Themes: The will to meaning, freedom of will and life has meaning
		Homework: Encountering Life's Limitations
2	Identity, Experiential and Creative sources of Meaning	This session will reinforce the use of communication skills
		Possible Meaning-Centered Themes: Identity before Cancer/ Identity after Cancer, Creative Sources of Meaning and Experiential Sources of Meaning
		Homework: Share Your Legacy ~ Tell Your Story and Legacy Project
3	Legacy Project	Behavioral rehearsal will reinforce the couple's communication skills, the meaning-centered, and end-of-life themes.
		Homework: Connecting with Life
4	Reflections and Hopes for the Future	The last session will also include discussions of the couple's progress during treatment and future issues the couple anticipates addressing relative to meaning
		Review of sources of meaning
		Reflections on the lesson learned and hopes
		Goodbyes for patients and caregivers

Table 2 presents the adaptation process proposed by the expert (NBT) and mentors (EC, MS, RCM, GP, and LP). The language dimensions will be incorporated in the adaptation of MCP to FMCP-L by using preliminary themes found in Communication Skill Training and Meaning-Centered Psychotherapy. The person dimension includes specific treatment targets by assessing other possible end-of-life themes (i.e., reaction to the diagnosis, fears about death, and difficulties completing daily activities). The integration of EVM Framework will result in metaphors, concepts, strategies, content, goals, and phrases of FMCP-L consonant with culture and context. This optimized version of the FMCP-L protocol was reviewed by the cultural experts, who translated the materials. The initial adaptation was completed, and the following are examples of changes after this early review: (1) integrated Communication Skills training to the

Family Meaning-Centered Psychotherapy protocol; (2) limited the session content to 4 sessions; (3) incorporated another possible end-of-life theme, and (4) intervention focus changed from individual to family.

Table 2

Ecological Validity Model		Adaptations
Language	Culturally appropriate and culturally syntonic	Translate the MCP to a FMCP-L by using the dyadic communication intervention skills and themes of Meaning-Centered Psychotherapy
Persons	Role of similarities and differences	Inclusion of specific treatment targets by assessing other possible ends of life themes (i.e., different ends of life themes)
Goals	Supportive of adaptive values of culture	Integration of Communication skills training and Meaning-Centered Psychotherapy, to improve quality of life and spiritual well-being
Metaphors	Culturally consonant sayings and stories	Integration of EVM Framework
Concepts	Concepts consonant with culture and context	Integration of Culturally consonants Meaning-Centered Psychotherapy Themes
Content	Values, traditions, and uniqueness	Family values, traditions and uniqueness
Methods	Strategies consonant with patients' culture	Use of visual aids and simple definitions
Context	Consideration of contextual factors	Education, age, gender and diagnosis

Phase Ib: Refine Intervention Components

With the FMCP-L 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 semi-structured interviews (qualitative phase) started in September

2020 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework, the cultural expert (NTB) developed a questionnaire and semi-structured interview to administer to patients and their informal caregivers. The questionnaire (quantitative phase) and the semi-structured interviews (qualitative phase) were designed to gather information from patients and informal caregivers about integrating Latinx families and cultural values (i.e., spirituality, familism, and fatalism) to the FMCP-L manual. The intervention targets include: patient and caregiver psychosocial needs, caregiving burden, and family function (i.e., communication, conflict, and cohesion),[51], 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) utilizing open-access media (i.e., Facebook and PHSU official webpages) to recruit 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 program integrated into oncology care at Ponce Health Sciences University. Advanced cancer patients 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 tumors, (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 enroll in the study. A priori sample size of 114 is selected based on recommendations for exploratory studies of this nature,[54-56]. 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,[57- 75] measuring spiritual well-being, depression, anxiety, hopelessness, quality of life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the survey includes general demographic information (i.e., 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 $15 for their study participation.

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,[57, 58]
Depression and Anxiety	The Hospital Anxiety and Depression Scale (HADS),[59-61]

Hopelessness	The Beck Hopelessness Scale (BHS) comprises 20 true/false questions that assess the degree of hopelessness,[62, 63]
Quality of life	The Functional Assessment of Cancer Therapy-General (FACT-G) will assess the participants' quality of life,[64]
Family Relationship Family Communication	Family Relationship Index will measure cohesiveness, conflict, and expressiveness among family members,[65] 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,[66-69]
Burden	Zarit Burden Interview (ZBI) is a 22 item, 5-point Likert scale (never = 0, nearly always = 4) used widely to assess caregiver burden [70, 71]
Fatalism	Fatalism will be measured with the Mental Adjustment to Cancer Scale, which assesses cognitive responses to cancer in five dimensions, including fatalism,[72]
Religiosity	The Age Universal I/E scale will measure intrinsic and extrinsic religiosity,[73]
Distress	NCCN Distress Thermometer and Problem List is a rapid screening tool for assessing psychological distress in people affected by cancer,[74, 75]

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,[55-59]. 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 one 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 (i.e., 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 informal caregiver) will receive a $30 stipend for their participation.

Phase IIa: Proof-of-Concept

Phase IIa is planned for the future after phase Ib is completed (questionnaire and semi-structured interviews). The formative findings from phase Ib will provide the necessary information to adapt the FMCP-L intervention and further develop the fixed FMCP-L protocol, following the Ecological Validity Framework. With the fixed FMCP-L protocol, we will conduct a pre-pilot feasibility and acceptability study of using the **ORBIT: Phase IIa**. The Hypothesis is that FMCP-L 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, thirty dyads with patients with stage III and IV solid tumor, 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,[54-56]. The manualized protocol will be delivered across four 45-to 60 minutes videoconference sessions by a clinical psychologist. The data will be recorded with informed consent from participants. Data will be transcribed, coded, and analyzed for themes and sub-categories, 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. FMCP-L consists of four-45- 60 minute- family sessions. The four sessions are expected to be delivered every week or every two 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 cancer patients, and research experience adapting FMCP-L, will conduct the sessions. Patient-reported outcomes will be assessed at baseline and 5- and 10-week follow-ups. Participants will be invited to participate in in-depth exit interviews following completion of MCP-L. The data will be recorded with informed consent from the participants. Data will be transcribed, coded, and analyzed for themes and sub-categories, 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 FMCP-L versus psychoeducation in communication (behavioral placebo) with quality-of-life and patient-reported outcomes (spiritual well-being and self-efficacy) in 100 Latinx families. The Hypothesi*s* is that those assigned to FMCP-L will report better outcomes than those assigned to the attention control condition at both follow-ups.

Sample Phase IIb. One hundred Latinx families will be randomized placed in a two-group pilot design with pre-test and repeated post-test measures used to accomplish the study aims. Patients with stage III and IV (N = 100) and their caregivers are randomized in one of two intervention conditions with equal allocation: Family Meaning Centered Psychotherapy for Latinx families (FMCP-L) or Couple Communication Skills Training (CCST). A priori sample size of 100 is selected based on recommendations for pilot studies,[54-56]. Randomization is stratified by age at diagnosis and recruitment site. Both interventions are manualized, of equivalent duration, and delivered by a trained counselor to the couples jointly over videoconference sessions. Web-based self-report outcome measures are administered to participants at baseline and 5- and 10-week follow-ups.

Procedure Phase IIb. FMCP-L consists of four 45- 60 minute- family sessions. The four sessions are expected to be delivered every week or every two 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 cancer patients, and research experience adapting FMCP-L, will conduct the sessions in the United States (US) 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 MCP-L study, will conduct the sessions or will supervise a doctoral level clinical psychologist trainee on the conducting of FMCP-L. If a doctoral level clinical psychology trainee is involved in delivering the intervention, he/she will be first trained on conducting FMCP-L 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 5- and 10-week follow-ups. Participants will be invited to participate in in-depth exit interviews following completion of MCP-L. The data will be recorded with informed consent from the participants. Data will be transcribed, coded, and analyzed for themes and sub-categories, 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 21 to examine survey responses. The pre-dyadic analyses occur in three steps: (1) bivariate correlations to calculate results between meaning, spirituality, hopelessness, QOL, and family function, (2) 8 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) multi-level models to analyze data at the dyad level to control for interdependencies,[46]. The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (i.e., 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,[46].

Quantitative Analysis Phase IIa. Feasibility and acceptability will be assessed through accrual, session/assessment completion, intervention satisfaction, and coping skills usage. Participants completed validated measures of primary outcomes (i.e., spiritual well-being and self-efficacy) and acceptability questionnaire at baseline, post-intervention, and four-week follow-up.

Quantitative Analysis Phase IIb. The primary analysis will examine whether, relative to the CCST intervention, the FMCP-L 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. Pre-treatment 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.

Qualitative Analysis Phase Ib, IIa and IIb. Data analysis will begin with verbatim transcripts of the 30-digital audio-recorded interviews and imported into Atlas.ti (version 8.1.3; Atlas.ti Scientific Software Development, Berlin, Germany, www.atlasti.com),[76]. The team will follow a published qualitative data preparation and transcription protocol to ensure the transcriptions' accuracy and fidelity,[77-80]. Observational notes taken by the interviewer will be typed and attached to the transcription documents. During the transcription, all data will be de-identified by replacing names with aliases to ensure anonymity.

Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated methods will be used to improve qualitative accuracy and validity: methods and analyst triangulation,[76-83]. Method triangulation will be achieved by determining the consistency of the data generated by both the survey and the semi-structured interviews. Analyst triangulation will be attained using multiple analysts (raters) to review and evaluate the qualitative data. Once transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive content analysis. Each step has three phases: preparation, organizing, and reporting,[84-86]. Two bilingual raters will conduct the content analysis. The analyses, integration, and interpretation will be in Spanish.

Inductive content analysis will examine how families (advanced cancer patients and their informal caregivers) define FMCP-L and communication skills training concepts. During the preparation phase, raters will familiarize themselves with the text. The data will be organized 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 categorization matrix based on the MCP and communication skill model. All data will be reviewed for content and coded for correspondence, exemplifying the categories' categorization 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,[87]. The cultural adaptation not only renders the text of written materials into another language but also infuses culturally relevant context and themes. [88, 89] The cultural expert (NTB), group of mentors (EC, MS, RCM, GP, and LP), and collaborators (CZ, MC, and WB) will conduct the integration of the quantitative and qualitative findings to develop the FMCP-L 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 Ecological Validity Model. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of Family Meaning-Centered Psychotherapy's 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 transcreation of MCP for Latinx, 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 and Conclusions

Once the fixed protocol of FMCP-L is acceptable, feasible, and effective, we will finalize 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 behavioral intervention framework pushes the identified need to sight on the chain of evidence needed to support the progressive program of intervention development. Finally, the recognized framework is flexible in both the design and methodologies for treatment development, which facilitates development,[41].

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 IIa: Proof-of-Concept and Phase IIb: Pilot study). Second, patients were predominantly recruited from Puerto Rico. Thus, the results may not generalize 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 experience 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 advanced cancer patients and their informal caregivers, are at the core of the implementation plan. The study’s objective is to develop the first psychosocial family intervention that supports Latinx advanced cancer patients 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 Family Meaning Centered Psychotherapy for Latinx families (FMCP-

L). 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 family psychological intervention (ORBIT: Phase IIa: Proof-of-Concept and Phase IIb: 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 advanced cancer patients.

Ethics and Dissemination

This project is the first development of a culturally and linguistically adapted intervention for Latinx families coping with advanced cancer. The results of this adaptation plan will guide the specific dyadic intervention for advanced cancer patients 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; i.e., "Hablemos de Cáncer," *El Puente* (*The Bridge*), newsletters, and social media; i.e., "Yo Puedo," of the Support Group of American Cancer Society in Puerto Rico.

Figure 1 Legend

Figure 1: Summary of the ORBIT model,[43] applying for the development of the FMCP-L for forward movement and a return to an earlier phase for refinement in event of other findings.

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Figure 1

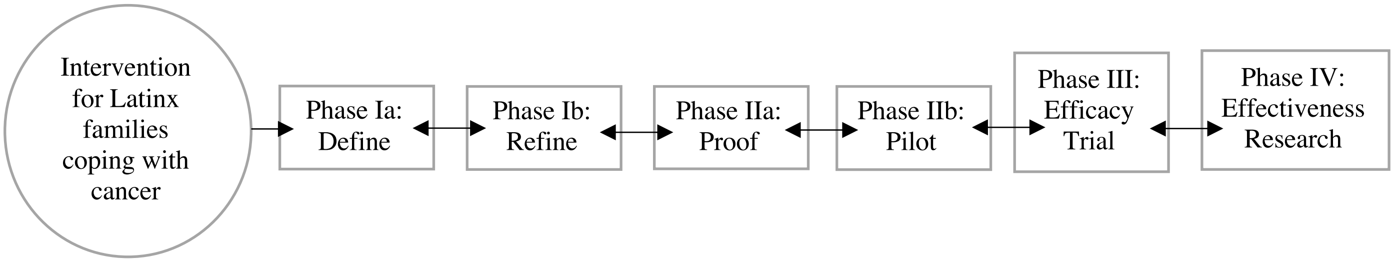

Figure 1: Summary of the ORBIT model,[43] applying for the development of the FMCP-L for forward movement and a return to an earlier phase for refinement in event of other findings.

Cultural Adaptation of Meaning-Centered Psychotherapy for Latino Families: A Protocol

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ABSTRACT

Introduction: Literature suggests couple-based interventions that target quality of life and communication can lead to positive outcomes for cancer patients 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 are four times more effective. Our goal is to culturally adapt a novel psychosocial intervention protocol entitled "**C**aregivers-P**a**tients **S**upport to L**a**tinx coping advanced-cancer" (CASA). We hypothesized that combine 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 (EVM), adaptation process model (CAPM), and intervention mapping. As a first step, we adapt a novel psychosocial intervention protocol entitled protocol entitled "**C**aregivers-P**a**tients **S**upport to L**a**tinx coping advanced-cancer" (CASA). The initial CASA protocol integrates two empirically based interventions, Meaning-Centered Psychotherapy and Couple Communication Skills Training, This is an exploratory and pre-pilot study, and it's 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 semi-structured interviews with advanced cancer patients and their caregivers. The primary outcomes of this study will be identifying the foundational information needed to further the develop the CASA (Phase IIa: Proof-of-Concept and Phase IIb: 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.

Keywords: Cultural, Adaptation, Latinx, Families, Cancer

Strengths and limitations of this study

- This study will allow the development of the patients-caregiver Psychotherapy Intervention to support Latinx patients and caregivers coping with advanced cancer.
- The major strength of this study is its purpose to not solely translate a previously tested English language intervention, but also to adapt it culturally.

- We will not measure our participants' access to technology (i.e., telephone, internet, or computer), limiting our ability to assess some information on access to technology for the implementation phase.

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Conflict of Interest

The authors reported no potential conflict of interest.

Authors contribution

Study conception and design: Normarie Torres-Blasco, Eida Castro, Rosario Costas-Muñiz, Laura Porter, Megan Shen, William Breitbart and Guillermo Bernal.

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Critical revision: Normarie Torres-Blasco, Eida Castro Carolina Zamore and Rosario Costas-Muñiz.

Data Statement Section

The datasets generated and/or analyzed during the current study are not publicly available due to PHSU and MSK's Data Sharing Policy but are available from the corresponding author on reasonable request.

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 advanced cancer patients and their families emphasize the need for increased attention to end-of-life care,[3]. Caregivers often assume the role without the necessary skills to help them address a cancer patient's complex needs,[4-9]. Consequently, they can experience a substantial caregiving burden that negatively impacts family function (i.e., communication, conflict, and cohesion) and the patients' physical, emotional, and social well-being,[10-14].

Impact of cancer on family caregiver's wellbeing

A substantial body of research has examined how caregiving processes are linked to the emotional health of family caregivers,[15]. 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,[16, 17] and impact on mental functioning have been identified in recent year,[18]. Findings indicate that Latinx-caregivers ethnicity is associated with higher levels of clinically significant depression,[18] and more caregiving demands are associated with higher levels of caregivers' feelings of burden and psychological distress,[19]. Compounding this problem, Latinx contextual and cultural influences on caregivers present an unmet need for emotional support,[20] especially when Latinx individuals are less likely to have adequate access to culturally congruent psychosocial interventions,[21-32]. Latinx cancer research had identified the psychosocial need of Latinx caregivers and described the importance of including psychosocial content related to communication and spirituality,[33-35].

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,[36]. A culturally centered intervention for Latinx patients should include a family-centered (partners and other family members) approach to determine the content and goals of care preferred in Latinx families coping with cancer,[37-39].

Latinx patients and caregiver dyadic

Latinx have a higher intensity (i.e., hours per week and help with activities of daily living) of caregiving than non-Latinx whites and Asians,[40]. Our preliminary data shows that 86% of Latinx advanced cancer patients 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 (i.e., adherence, depression, poor prognostic, and stress),[41-43]. Patients with advanced cancer and their families experience significant distress in four domains: physical, psychological, social, and spiritual,[44-46]. These domains are often summarized by the term "quality of life (QOL)." QOL, spirituality, and reduction of distress are essential goals of cancer care,[47]. A meta-analysis and systematic review found that Latinx cancer patients show worse distress, depression, and overall health-related quality of life (HRQOL) than other minority patients and Whites,[48]. Similarly, Latinx patients report higher levels of burden, depression, and physical health problems than patients of other ethnicities,[49, 50]. 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,[51-54]. Meta-analytic evidence suggests that culturally adapted interventions targeting a specific cultural group (e.g. 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),[51-54]. The literature suggests that behavioral 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,[54].

The conceptual framework

Our conceptual framework, grounded in theory, developed by Dr. Breitbart, aims to target specific psycho-spiritual needs of patients with advanced cancer,[55]. 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 Centered Psychotherapy (MCP) for Latinx advanced cancer patients,[33, 34]. Preliminary findings suggested that Latinx with advanced cancer identified family and communication issues as crucial in adjusting to their cancer diagnosis and well-being,[33, 34]. Further, we identified evidence of communication skill training that indicated that communication skills for couples improve family communication dynamics, especially among Latinx families,[56] and there is data on the effectiveness of Couple Communication Skills Traing (CCST) in Caucasian couples; however, literature is absent about effectivity in Latinx coping with advanced cancer [52]. These findings indicate the need to explore the integration of Couples Communication Skill Training (components) for patients dealing with advanced cancer to a MCP.

Objectives

The purpose of this study is to culturally adapt and integrate (1) Meaning-Centered Psychotherapy (MCP) and (2) Couples Communication Skills Training (CCST) a novel psychosocial intervention protocol entitled "**C**aregivers-P**a**tients **S**upport to L**a**tinx coping advanced-cancer" (CASA). The CASA intervention aims to improve the quality of life and spiritual well-being of advanced cancer patients 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, Meaning-Centered Psychotherapy and Couple Communication Skills Training, 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 hypothesized 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 quality of life. This is an exploratory study and pre-pilot 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 US 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,[57-60] Ecological Validity Model (EVM),[58] developed by Dr. Guillermo Bernal, the cultural adaptation process model (CAPM),[59] and intervention mapping,[61] 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,[57]. CAPM is a complementary process model to EVM and prescribes four phases for the adaptation process: formative, adaptation iterations, intervention, and measurement adaptation,[57]. Cancer contextual model of health-related quality of life (e.g., Spiritual wellbeing, depression, anxiety, hopelessness, functional assessment of cancer therapy, family relationship index, burden, fatalism, religiosity, distress and patient's needs-semi-structured interview) are outlined to specify individual, cultural, and contextual influences (i.e., dyadic relationships and communication with partners) as essential determinants of QOL,[60] Drawing from social cognitive (i.e., Couples Communication Skills Training) and existential theory (i.e., Meaning-Centered therapy), the "**C**aregivers-P**a**tients **S**upport to L**a**tinx coping advanced-cancer" (CASA) intervention is designed to increase the spiritual well-being and self-efficacy in communication between advanced cancer patients and their informal caregivers,[61-66].

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 utilize 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 Behavioral Treatment Development model provides a progressive, clinically relevant approach to increasing the number of evidence-based behavioral treatments available to prevent and treat chronic diseases,[67]. The ORBIT model includes a flexible and iterative progressive process, pre-specified clinically significant milestones for forward movement, and return to an earlier phase for refinement in the event of suboptimal results, see figure 1,[67].

Phase Ia: Define Intervention Components

The selection of intervention components was defined by the cultural expert (NTB) and a group of mentors (EC, MS, RCM, GB, and LP) after careful review of the intervention's selected components. The rationale for selecting the Meaning-Centered Psychotherapy and Couple Communication Skills Training 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 is there prior data of the effectiveness of meaning-centered psychotherapy as well as Latinx prior indications of need for meaning making such as the literature around spirituality,[61-66]. Specifically, there is only one intervention in the adaptation process for Latinx dealing with advanced cancer, the Individual

Meaning-Centered Psychotherapy,[33,34]. We decided to optimize and further the development of the adapted Meaning-Centered Psychotherapy for Latinx by incorporating the patient's reported needs in training for communication skills and the inclusion of other family members. By using the Couple Communication Skills Training (CCST) approach, we enhanced the MCP session by adding taught coping skills (e.g., how to communicate and listen) as well as how to increase their self-efficacy (i.e., confidence) for sharing through behavioral practice, goal setting, and monitoring progress,[65,66]. The Couple Communication Skills Training approach was adapted for non-spousal patients' caregivers by eliminating spousal terms (e.g., taking care of your partner-spouse) and changing it to general caregiving terms (e.g., 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,

Table 1

Caregivers-P**a**tients **S**upport to L**a**tinx coping advanced-cancer" (CASA).

	MCP Components	CCST Components	Cultural Adaptation	Linguistic Adaptation
Treatment Goal	X	X	X	X
Communication Skill: Speaker		X	X	X
Communication Skill: Listen		X	X	X

The will to Meaning	X		X	
Freedom of will	X		X	
Life has meaning	X		X	
Homework: Encountering Life's Limitations	X		X	
Identity	X		X	
Experiential Sources of Meaning	X		X	
Creative Sources of Meaning	X		X	
Homework: Share Your Legacy ~ Tell Your Story and Legacy Project	X		X	
Homework: Connecting with Life	X		X	
4 session		X	X	
Other to related to End-of-life care		X	X	X

The cultural and linguistic adaptation 7 dimensions need to be addressed: language, context, persons, metaphors, concepts, goals, and methods,[58]. Table 2 presents how we addressed 7 dimension (1) Language: translate the CCST into Spanish and eliminating spousal terms, (2) Person: assessing other possible ends of life themes (i.e., different ends of life themes), (3) Goals: Access the integration of Communication skills training and Meaning-Centered

Psychotherapy goals, (4) Metaphors: we will include culturally consonants stories by adapting the Communication skills training and Meaning Centered components, (5) Concepts: Integration of Culturally consonants Meaning-Centered Psychotherapy concepts and important end-of-life care topics, (6) Methods: Use of visual aids and simple definitions to describe the content, and (7) Context: Integration of Latino Family (caregivers-patients) values, traditions and uniqueness in communication and meaning.

Table 2Ecological Validity Model		**Adaptations**
Language	Culturally appropriate and culturally syntonic	Translate the CCST into Spanish and we also *adapted for non-spousal patients' caregivers by eliminating spousal terms (e.g., taking care of your partner-spouse) and changing it to general caregiving terms (e.g., taking care of your significant other)".*
Persons	Role of similarities and differences	Assessing other possible ends of life themes (i.e., different ends of life themes)
Goals	Supportive of adaptive values of culture	Access the integration of Communication skills training and Meaning-Centered Psychotherapy goals.
Metaphors	Culturally consonant sayings and stories	We will include culturaly consonants stories by adapting the Communication skills training and Meaning Centered components
Concepts	Concepts consonant with culture and context	Integration of Culturally consonants Meaning-Centered Psychotherapy concepts and important end-of-life care topics
Methods	Strategies consonant with patients' culture	Use of visual aids and simple definitions to describe the content
Context	Consideration of contextual factors	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 semi-structured interviews (qualitative phase) started in September 2020 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework, the cultural expert (NTB) developed a questionnaire and semi-structured interview to administer to patients and their informal caregivers. The questionnaire (quantitative phase) and the semi-structured interviews (qualitative phase) were designed to gather information from patients and informal caregivers about integrating Latinx families and cultural values (i.e., spirituality, familism, and fatalism) to the CASA manual. The intervention targets include: patient and caregiver psychosocial needs, caregiving burden, and family function (i.e., communication, conflict, and cohesion),[65,66], 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) utilizing open-access media (i.e., Facebook and PHSU official webpages) to recruit 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 program integrated into oncology care at Ponce Health Sciences University. Advanced cancer patients 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 tumors, (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 enroll in the study. A priori sample size of 114 is selected based on recommendations for exploratory studies of this nature,[68-70]. 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,[71-91] measuring spiritual well-being, depression, anxiety, hopelessness, quality of life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the survey includes general demographic information (i.e., 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 $15 for their study participation.

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,[71, 72]
Depression and Anxiety	The Hospital Anxiety and Depression Scale (HADS),[73-75]
Hopelessness	The Beck Hopelessness Scale (BHS) comprises 20 true/false questions that assess the degree of hopelessness,[76,77]
Quality of life	The Functional Assessment of Cancer Therapy-General (FACT-G) will assess the participants' quality of life,[78]
Family Relationship Family Communication	Family Relationship Index will measure cohesiveness, conflict, and expressiveness among family members,[79] 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,[80-83]
Burden	Zarit Burden Interview (ZBI) is a 22 item, 5-point Likert scale (never = 0, nearly always = 4) used widely to assess caregiver burden [84-86]
Fatalism	Fatalism will be measured with the Mental Adjustment to Cancer Scale, which assesses cognitive responses to cancer in five dimensions, including fatalism,[87]
Religiosity	The Age Universal I/E scale will measure intrinsic and extrinsic religiosity,[88,89]
Distress	NCCN Distress Thermometer and Problem List is a rapid screening tool for assessing psychological distress in people affected by cancer,[90, 91]

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,[69-73]. 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 one 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 (i.e., 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 informal caregiver) will receive a $30 stipend for their participation.

Phase IIa: Proof-of-Concept

Phase IIa is planned for the future after phase Ib is completed (questionnaire and semi-structured 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 of using 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, thirty dyads with patients with stage III and IV solid tumor, 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,[68-70]. The manualized protocol will be delivered across four 45-to 60 minutes videoconference sessions by a clinical psychologist. The data will be recorded with informed consent from participants. Data will be transcribed, coded, and analyzed for themes and sub-categories, 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 minute- family sessions. The four sessions are expected to be delivered every week or every two 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 cancer patients, and research experience adapting CASA, will conduct the sessions. 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 analyzed for themes and sub-categories, 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 (behavioral 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 Hypothesi*s* 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 randomized placed in a two-group pilot design with pre-test and repeated post-test measures used to accomplish the study aims. Patients with stage III and IV (N = 100) and their caregivers are randomized in one of two intervention conditions with equal allocation: "**C**aregivers-P**a**tients

Support to L**a**tinx coping advanced-cancer" (CASA) or usual care. A priori sample size of 100 is selected based on recommendations for pilot studies,[68-70]. Randomization is stratified by age at diagnosis and recruitment site. Both interventions are manualized, of equivalent duration, and delivered by a trained counselor 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 minute- family sessions. The four sessions are expected to be delivered every week or every two 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 cancer patients, and research experience adapting CASA, will conduct the sessions in the United States (US) 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 MCP-L 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 analyzed for themes and sub-categories, 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 21 to examine survey responses. The pre-dyadic analyses occur in three steps: (1) bivariate correlations to calculate results between depression, anxiety, meaning, spirituality, hopelessness, QOL, and family function, (2) 8 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) multi-level models to analyze data at the dyad level to control for interdependencies,[69]. The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (i.e., 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,[69].

Quantitative Analysis Phase IIa. Feasibility and acceptability will be assessed through accrual, session/assessment completion, intervention satisfaction, and coping skills usage. Participants completed validated measures of primary outcomes (i.e., 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. Pre-treatment 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 21 to examine survey responses. The pre- and post-dyadic analyses occur in three steps: (1) bivariate correlations to calculate results between meaning, spirituality, hopelessness, QOL, and family function, (2) 8 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) multi-level models to analyze data at the dyad level to control for interdependencies,[69]. The dyadic analysis will be conducted through multivariate outcome models to estimate a possible score for each member of the couple (i.e., 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,[69].

Qualitative Analysis Phase Ib, IIa and IIb. Data analysis will begin with verbatim transcripts of the 30-digital audio-recorded interviews and imported into Atlas.ti (version 8.1.3; Atlas.ti Scientific Software Development, Berlin, Germany, www.atlasti.com),[92]. The team will follow a published qualitative data preparation and transcription protocol to ensure the transcriptions' accuracy and fidelity,[93-96]. Observational notes taken by the interviewer will be typed and attached to the transcription documents. During the transcription, all data will be de-identified by replacing names with aliases to ensure anonymity.

Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated methods will be used to improve qualitative accuracy and validity: methods and analyst triangulation,[94-98]. Method triangulation will be achieved by determining the consistency of the data generated by both the survey and the semi-structured interviews. Analyst triangulation will be attained using multiple analysts (raters) to review and evaluate the qualitative data. Once transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive content analysis. Each step has three phases: preparation, organizing, and reporting,[99-102]. Two bilingual raters will conduct the content analysis. The analyses, integration, and interpretation will be in Spanish.

Inductive content analysis will examine how families (advanced cancer patients and their informal caregivers) define CASA and communication skills training concepts. During the preparation phase, raters will familiarize themselves with the text. The data will be organized 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 categorization matrix based on the MCP and communication skill model. All data will be reviewed for content and coded for correspondence, exemplifying the categories' categorization 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,[103]. The cultural adaptation not only renders the text of written materials into another language but also infuses culturally relevant context and themes,[103-105]. The cultural expert (NTB), group of mentors (EC, MS, RCM, GP, 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 Ecological Validity Model. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of "**C**aregivers-P**a**tients **S**upport to L**a**tinx 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 transcreation 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 finalize 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 behavioral intervention framework pushes the identified need to sight on the chain of evidence needed to support the progressive program of intervention development. Finally, the recognized framework is flexible in both the design and methodologies for treatment development, which facilitates development,[67].

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 IIa: Proof-of-Concept and Phase IIb: Pilot study). Second, patients were predominantly recruited from Puerto Rico. Thus, the results may not generalize 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 experience 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 advanced cancer patients 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 advanced cancer patients 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 "**C**aregivers-P**a**tients **S**upport to L**a**tinx 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 IIa: Proof-of-Concept and Phase IIb: 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 advanced cancer patients.

Ethics and Dissemination

This project is the first development of a culturally and linguistically adapted intervention for Latinx families coping with advanced cancer. The results of this adaptation plan will guide the specific dyadic intervention for advanced cancer patients 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; i.e., "Hablemos de Cáncer," *El Puente* (*The Bridge*), newsletters, and social media; i.e., "Yo Puedo," of the Support Group of American Cancer Society in Puerto Rico.

Figure 1 Legend

Figure 1: Summary of the ORBIT model,[67] applying for the development of the CASA for forward movement and a return to an earlier phase for refinement in event of other findings.

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Figure 1

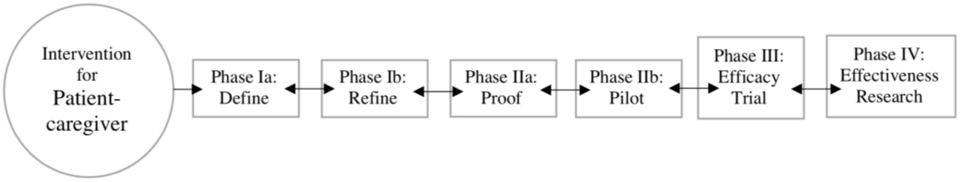

Figure 1

Figure 1. The ORBIT model includes a flexible and iterative progressive process, pre-specified clinically significant milestones for forward movement, and return to an earlier phase for refinement in the event of suboptimal results, see figure 1,[67].

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