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

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Manuscripts

## 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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## 22 **Conflict of Interest**

23

24 The authors reported no potential conflict of interest.  
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## 29 **Authors contribution**

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## 10 11 12 **Data Statement Section** 13

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16 The datasets generated and/or analyzed during the current study  
17 are not publicly available due to PHSU and MSK's Data Sharing  
18 Policy but are available from the corresponding author on  
19 reasonable request.  
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## 28 **Introduction** 29

### 30 **Patients with advanced cancer and informal caregivers.** 31

32 As the number of cancer diagnoses increases, informal caregivers (often family members) play  
33 an essential role in providing care throughout the cancer trajectory. [1,2] Significant numbers of  
34 advanced cancer patients and their families emphasize the need for increased attention to end-  
35 of-life care. [3] Caregivers often assume the role without the necessary skills to help them  
36 address a cancer patient's complex needs. [4-9] Consequently, they can experience a substantial  
37 caregiving burden that negatively impacts family function (i.e., communication, conflict, and  
38 cohesion) and the patients' physical, emotional, and social well-being. [10-14]  
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49 Latinos have a higher intensity (i.e., hours per week and help with activities of daily living) of  
50 caregiving than non-Latino whites and Asians. [15] Our preliminary data shows that 86% of  
51 Latino advanced cancer patients reported low family function, and those with low family  
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3 cohesiveness had higher depression and anxiety levels. Several studies show that low family  
4 function negatively impacts the cancer illness trajectory (i.e., adherence, depression, poor  
5 prognostic, and stress). [16-18] Patients with advanced cancer and their families experience  
6 significant distress in four domains: physical, psychological, social, and spiritual. [19-21] These  
7 domains are often summarized by the term "quality of life (QOL)." QOL, spirituality, and  
8 reduction of distress are essential goals of cancer care. [22] A meta-analysis and systematic  
9 review found that Latino cancer patients show worse distress, depression, and overall health-  
10 related quality of life (HRQOL) than other minority patients and Whites. [23] Similarly, Latino  
11 patients report higher levels of burden, depression, and physical health problems than patients of  
12 other ethnicities. [24, 25] Therefore, addressing family issues is crucial in the adjustment and  
13 well-being of Latinos with advanced cancer and their informal caregivers.

### 29 **Cultural Adaptation of Evidence-Based Practice**

30 Cultural adaptations of interventions for ethnic minority groups are feasible and acceptable. [26-  
31 29] Meta-analytic evidence suggests that culturally adapted interventions targeting a specific  
32 cultural group are four times more effective than those provided to various cultural backgrounds,  
33 and twice as effective as English interventions if conducted in the participants' native language  
34 (if other than English). [26-29] The literature suggests that behavioral interventions must be  
35 culturally adapted for cultural groups by following the phases of information gathering,  
36 preliminary design, preliminary testing, and final trial to reduce health disparities. [29]

### 48 **Objectives**

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

### 11 **The conceptual framework for Cultural Adaptation**

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13 The unifying theoretical framework of the culturally adapted Evidence-Based Practice, [30- 33]  
14 Ecological Validity Model (EVM), [31] developed by Dr. Guillermo Bernal, the cultural  
15 adaptation process model (CAPM) [34], the Nueva Vida Framework [35] and cancer contextual  
16 model of health-related quality of life (HRQOL), [36] provides viable approaches to treating  
17 ethnic minorities and culturally diverse groups. According to EVM, to adapt an intervention for a  
18 new cultural group, seven dimensions need to be addressed: language, context, persons,  
19 metaphors, concepts, goals, and methods [42]. CAPM is a complementary process model to  
20 EVM and prescribes four phases for the adaptation process: formative, adaptation iterations,  
21 intervention, and measurement adaptation. [34] The Nueva Vida Framework and cancer  
22 contextual model of health-related quality of life (HRQOL) are outlined to specify individual,  
23 cultural and contextual influences (i.e., dyadic relationships and communication with partners) as  
24 essential determinants of QOL. [35, 36] Drawing from social cognitive (i.e., Couples  
25 Communication Skills Training) and existential theory (i.e., Meaning-Centered therapy), the  
26 Family Meaning-Centered Psychotherapy intervention is designed to increase the spiritual well-  
27 being and self-efficacy in communication between advanced cancer patients and their informal  
28 caregivers. [37-44]  
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53 To identify the foundational information necessary to culturally adapt and integrate MCP and  
54 CCST to develop FMCP for Latino patients and their informal caregivers, we will utilize a four-  
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3 phase approach guided by the Ecological Validity Model: (1) Selection of intervention  
4 components (phase 1 completed), (2) Initial adaptation (phase 2 completed), (3) Comprehension  
5 and acceptability testing ( phase 3 in progress) and (5) Protocol refinement (phase 4 planned).  
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### 10 11 **Phase 1: Selection of Intervention Components**

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14 The selection of intervention components was finalized by the cultural expert (NTB) and a group  
15 of mentors (EC, MS, RCM, GB, and LP) after careful review of the intervention's selected  
16 components. Meaning-Centered Psychotherapy (MCP) was chosen because of its supportive  
17 evidence with predominantly non-Latinos whites in increasing spiritual well-being, a sense of  
18 meaning, purpose in life, and reducing distress [38-41]. Further, the integration of the Couples  
19 Communication Skills Training (CCST) was included because prior research has found that  
20 couple-based interventions that target communication lead to positive outcomes for cancer  
21 patients and their partners [42, 43].  
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### 33 34 **Meaning-Centered Psychotherapy (MCP) for Latinos.**

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37 MCP, developed by Dr. Breitbart, aims to target specific psycho-spiritual needs of patients with  
38 advanced cancer. [38- 40] Its primary goal is to help patients enhance a sense of meaning, peace,  
39 and purpose as they approach end-of-life. The 7-session intervention focuses on assisting  
40 patients in identifying sources of meaning in their lives despite their diagnosis. In addition to its  
41 effectiveness with non-Latino whites, Dr. Costas-Muñiz demonstrated the acceptability and  
42 feasibility of MCP for Latino advanced cancer patients [41]. Preliminary findings suggested  
43 Latinos with advanced cancer identified family issues as a crucial component in adjusting to their  
44 cancer diagnosis and well-being. [44] These findings indicate the need and acceptability of a  
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3 culturally adapted family intervention for cancer patients and their informal caregivers in  
4 navigating family function and adjustment in cancer [41, 44].  
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### 11 **Couples Communication Skills Training (CCST).**

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15 CCST is a six-session intervention that provides couples with training in communication skills  
16 and encourages them to discuss illness-related concerns. The intervention includes components  
17 to assist couples in communicating effectively, decreasing avoidance of critical cancer-related  
18 issues, and supporting each other. It provides training in skills for (a) sharing one's thoughts and  
19 feelings (i.e., disclosure), (b) listening to one's partner and responding in a supportive manner,  
20 and (c) joint problem-solving. [42, 43] While CCST was developed for patient-spouse dyads, the  
21 communication skills taught in CCST have also been applied in studies targeting a broader range  
22 of patient-caregiver dyads (i.e., patients and their adult children) [42, 43].  
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### 34 **Phase 2: Initial Adaptation**

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

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

### 36 37 38 39 40 41 42 43 44 45 46 **Phase 3: Comprehension and Acceptability Testing**

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49 The questionnaire and semi-interview development are finalized. The recruitment and  
50 administration of the questionnaire, and the semi-structured interviews starts in September 2020  
51 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework, the  
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3 cultural expert (NTB) developed a questionnaire and semi-structured interview to administer to  
4 patients and their informal caregivers. The questionnaire and interview were designed to gather  
5 information from patients and informal caregivers about integrating Latino families and cultural  
6 values (i.e., spirituality, familism, and fatalism) to the FMCP manual. The intervention targets  
7 include patient and caregiver psychosocial needs, caregiving burden, and family function (i.e.,  
8 communication, conflict, and cohesion) [41], see Table 1.  
9

10  
11 Table 1 presents the adaptation process proposed by the expert (NBT) and mentors (EC, MS,  
12 RCM, GP, and LP). The language dimensions will be incorporated in the adaptation of MCP to  
13 FMCP by using preliminary themes found in Communication Skill Training and Meaning-  
14 Centered Psychotherapy. The person dimension includes specific treatment targets by assessing  
15 other possible end-of-life themes (i.e., reaction to the diagnosis, fears about death, and  
16 difficulties completing daily activities). The integration of EVM and the Nueva Vida dyadic  
17 Framework will result in metaphors, concepts, strategies, content, goals, and phrases of FMCP  
18 consonant with culture and context.  
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21 **COVID-19 Recruitment.** Due to social distancing measures during the COVID-19 pandemic,  
22 an updated recruitment plan was approved to facilitate ongoing activities and testing. This plan  
23 includes (1) utilizing open-access media (i.e., Facebook and PHSU official webpages) to recruit  
24 participants; (2) including possession of a smartphone, tablet, or computer/laptop as an eligibility  
25 criterion; and (3) providing the option of conducting informed consent, questionnaire, and semi-  
26 structured interview procedures during telehealth visits, ensuring they take place in a private  
27 location. Depending on the participant's access, one of the following platforms will be used:  
28 VidyoConnect, Zoom, VSee, or Doxy.me.  
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3 **Quantitative Phase.** Participants will be recruited through the *Programa de Apoyo Psicosocial*  
4 *Integrado al Cuidado Oncológico* (PAPSI — Integrated Psychosocial Support Program for  
5 Cancer Care), a psychosocial support program integrated into oncology care at Ponce Health  
6 Sciences University and led by EC. Advanced cancer patients who completed PAPSI's routine  
7 distress screening measure will be screened to assess whether they meet the following inclusion  
8 criteria: (1) diagnosed with stage III or IV solid tumors, (2) 21 years or older, (3) self-report  
9 being Latino or Hispanic, and (4) fluent in Spanish. With permission of the patient, their  
10 informal caregiver will be invited to participate if he/she meets the following inclusion criteria:  
11 (1) informal caregiver of a patient recruited to the study, and identified by the patient as the  
12 person he/she gets the most support, (2) 21 years or older, (3) self-report being Latino or  
13 Hispanic, and (4) fluent in Spanish.  
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29 Patients and their informal caregivers who meet the inclusion criteria will be recruited and  
30 participated in the process of informed consent when they agreed to enroll in the study.  
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33 Following informed consent, participants will be assigned a subject number. The cultural expert  
34 (NTB) will administered the cross-sectional questionnaire (Table 3) to assess the acceptability of  
35 the goals, concepts of MCP and communication skills training, and the feasibility of the  
36 proposed intervention's goals and therapeutic methods. Participants will complete assessments  
37 (validated scales) measuring spiritual well-being, depression, anxiety, hopelessness, quality of  
38 life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the survey  
39 included general demographic information (i.e., age, education, and gender) of the patient and  
40 their informal caregiver. The cultural expert (NTB) will administered the questionnaire in an  
41 interview-style to accommodate patients and their informal caregivers with limited education  
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3 and/or literacy. After completing the questionnaire, patients and their informal caregivers will be  
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5 received \$15 for their study participation.  
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9 **Qualitative Phase.** Patients (n=15) and their informal caregivers (n=15) who (1) completed the  
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11 questionnaire package, and (2) Scored  $\geq 4$  in the Distress thermometer will be invited to  
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13 participate in the qualitative phase. A priori sample size of 15 is selected based on  
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15 recommendations for qualitative studies of this nature [41]. Scores  $\geq 4$  suggest significant  
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17 distress and the need for further psychological evaluation. Among those meeting inclusion  
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19 criteria, the trained professional (interviewer) will discuss informed consent. The interviewer  
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21 will be blinded to the quantitative information before the one-session, in-depth semi-structured  
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23 interview, which will be conducted in Spanish and take approximately one hour. The interviewer  
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25 will have an interview guide with the flexibility to ask off-guided questions, which is divided  
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27 into four sections: (1) exploratory questions regarding participants' understanding of the MCP  
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29 concepts, (2) exploratory questions regarding the acceptability and feasibility of the family-based  
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31 intervention, (3) dyad's advanced cancer experience, strategies used to cope, and caregiving  
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33 burden, and (4) family function (i.e., communication, conflict, and cohesion). When necessary,  
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35 the interviewer will use follow-up probing questions to elicit patients' and informal caregivers'  
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37 full narratives. The interview will be digitally audio-recorded. After the semi-structured  
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39 interviews, participants (patient and the informal caregiver) will receive a \$30 stipend for their  
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41 participation.  
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49 **Quantitative Analysis.** Descriptive statistics will be conducted using IBM SPSS Statistics 21 to  
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51 examine survey responses. The pre-dyadic analyses occurred in three steps: (1) bivariate  
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53 correlations to calculate results between meaning, spirituality, hopelessness, QOL, and family  
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55 function, (2) 8 bivariate regression models to assess the predictive power of each predictor  
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3 variable (meaning and spirituality) on each of the four outcomes: hopelessness, QOL, anxiety,  
4 and depression, (3) multi-level models to analyze data at the dyad level to control for  
5 interdependencies. [46] The dyadic analysis will be conducted through multivariate outcome  
6 models to estimate a possible score for each member of the couple (i.e., one for the patient and  
7 one for the informal caregiver). It will be controlled for the dependent nature of couple-level data  
8 and allowed for examination of both actor and cross-partner effects. [46]  
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18 **Qualitative Analysis.** Data analysis will begin with verbatim transcripts of the 30 digital audio-  
19 recorded interviews and imported into Atlas.ti (version 8.1.3; Atlas.ti Scientific Software  
20 Development, Berlin, Germany, [www.atlasti.com](http://www.atlasti.com)). The team will follow a published qualitative  
21 data preparation and transcription protocol to ensure the transcriptions' accuracy and fidelity.  
22 [45] Observational notes taken by the interviewer will be typed and attached to the transcription  
23 documents. During the transcription, all data will be de-identified by replacing names with  
24 aliases to ensure anonymity.  
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35 Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated  
36 methods will be used to improve qualitative accuracy and validity: methods and analyst  
37 triangulation. [47-55] Method triangulation will be achieved by determining the consistency of  
38 the data generated by both the survey and the semi-structured interviews. Analyst triangulation  
39 will be attained using multiple analysts (raters) to review and analyze the qualitative data. Once  
40 transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive  
41 content analysis. Each step has three phases: preparation, organizing, and reporting. [56-58] Two  
42 bilingual raters will conduct the content analysis. The analyses, integration, and interpretation  
43 will be in Spanish.  
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3 Inductive content analysis will examine how families (advanced cancer patients and their  
4 informal caregivers) define MCP and communication skills training concepts. During the  
5 preparation phase, raters will familiarize themselves with the text. The data will be organized  
6 through open coding, creating categories, abstractions, and identifying the concepts' boundaries  
7 for inductive analysis. Categories will be generated from open coding and grouped under higher-  
8 order headings. Descriptions using content-characteristic words will be created for the  
9 abstraction. The data will be reviewed for deductive content analysis using a structured  
10 categorization matrix based on the MCP and communication skill model. All data will be  
11 reviewed for content and coded for correspondence, exemplifying the categories' categorization  
12 matrix.

#### 27 **Phase 4: Protocol refinement**

30 Phase 4 is planned for the future once phase 3 is completed (questionnaire and semi-structured  
31 interviews). The formative findings from phase 3 will provide the necessary information to adapt  
32 the FMCP intervention and further develop the protocol, following the Ecological Validity  
33 Framework. In cultural adaptation, the source text is rewritten in the target language to convey  
34 the concepts and achieve the aims of the source text, while accounting for both language and  
35 cultural considerations. [59] The cultural adaptation not only renders the text of written materials  
36 into another language but also infuses culturally relevant context and themes. [60, 61] The  
37 cultural expert (NTB), group of mentors (EC, MS, RCM, GP, and LP), and collaborators (CZ,  
38 MC, and WB) will conduct the integration of the triangulation findings to review and adapt the  
39 intervention manual (Table 2). The text will be independently reviewed, followed by "consensus  
40 meetings" to discuss every session of the intervention, provide feedback, and discuss further  
41 modifications until a consensus is reached. Dr. Guillermo Bernal will then review the text to

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3 ensure the adaptation considers the dimensions of the Ecological Validity Model. The  
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5 adaptations will be highlighted, and comments will be kept in the margin. Fidelity of Family  
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7 Meaning-Centered Psychotherapy's concepts, goals, and theoretical model will be preserved  
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9 during the adaptation process to ensure language, metaphor, strategy, cultural context, and value  
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11 acceptability by Latino families.  
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16 As shown with the transcreation of MCP for Latinos, [41] the adaptation plan for Latino families  
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18 will also include content modification, family congruence through metaphors and assignments,  
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20 cultural adaptation notes with findings from the cultural adaptation process guidelines about the  
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22 delivery of the intervention to the dyad.  
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### 26 **Public Involvement Statement**

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29 The public, specifically Latino advanced cancer patients and their informal caregivers, are at the  
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31 core of the implementation plan. The study's objective is to develop the first psychosocial family  
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33 intervention that supports Latino advanced cancer patients and their informal caregivers to cope  
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35 with cancer. The study design mentioned above was consensually agreed by the team to optimize  
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37 patients' and their informal caregivers' perceptions, experiences, and opinions to refine a  
38  
39 successful final version of the patient- and informal caregiver-centered intervention. The intent is  
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41 to involve the patients and their informal caregivers (the public) who will be the end target user  
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43 in the development and cultural adaptation of the family psychological intervention. Further, the  
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45 proposed project will directly (1) impact the Latino community, (2) contribute to the  
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47 development of culturally adapted psychosocial interventions, (3) be used in the healthcare field,  
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49 and (4) reduce disparities in access to psychosocial interventions for Latino advanced cancer  
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## 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

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

For peer review only

**Table 2**

<b>Family Meaning-Centered Psychotherapy</b>		
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**

<b>Table 3. Description of Study Scales</b>	
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/>

Page/line no(s).

### Title and abstract

<p><b>Title</b> - 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</p>	1
<p><b>Abstract</b> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</p>	3

### Introduction

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

### Methods

<p><b>Qualitative approach and research paradigm</b> - 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**</p>	7
<p><b>Researcher characteristics and reflexivity</b> - 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</p>	8
<p><b>Context</b> - Setting/site and salient contextual factors; rationale**</p>	9- 13
<p><b>Sampling strategy</b> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</p>	13
<p><b>Ethical issues pertaining to human subjects</b> - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues</p>	16- 17
<p><b>Data collection methods</b> - 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**</p>	12- 13

1 2 3 4 5	<b>Data collection instruments and technologies</b> - 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
6 7 8	<b>Units of study</b> - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	12 -13
9 10 11 12	<b>Data processing</b> - 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
13 14 15 16	<b>Data analysis</b> - 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
17 18 19 20	<b>Techniques to enhance trustworthiness</b> - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	15- 16

### Results/findings

23 24 25 26	<b>Synthesis and interpretation</b> - 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
27 28 29	<b>Links to empirical data</b> - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	n/a protocol paper

### Discussion

32 33 34 35 36 37 38	<b>Integration with prior work, implications, transferability, and contribution(s) to the field</b> - 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
39 40	<b>Limitations</b> - Trustworthiness and limitations of findings	n/a protocol paper

### Other

43 44 45	<b>Conflicts of interest</b> - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	4
46 47 48	<b>Funding</b> - 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.



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\*\*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:**

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# BMJ Open

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

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<b>Primary Subject Heading</b>:	Palliative care
Secondary Subject Heading:	Patient-centred medicine
Keywords:	MENTAL HEALTH, ONCOLOGY, Cancer pain < ONCOLOGY, PALLIATIVE CARE

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

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## 8 **ABSTRACT**

9  
10 **Introduction:** Literature suggests couple-based interventions that target quality of life and  
11 communication can lead to positive outcomes for cancer patients and their partners.  
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13  
14 Nevertheless, to date, an intervention to address the needs of Latino families coping with  
15 advanced cancer has not been developed. Our goal is to develop Family Meaning-Centered  
16 Psychotherapy (FMCP-L) for Latino families (patients and informal caregivers) dealing with  
17 advanced cancer.  
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24 **Methods and analysis:** To culturally develop a FMCP-L, we will follow an innovative hybrid  
25 research framework that combines elements of an efficacy model and best practices from the  
26 Ecological Validity Model (EVM), adaptation process model (CAPM), and the cancer contextual  
27 model of health-related quality of life (HRQOL). As a first step, following the framework of the  
28 ORBIT Model (Phase 1a: Define), we developed a novel psychosocial intervention protocol  
29 entitled Family Meaning Centered Psychotherapy for Latinx (FMCP-L). The initial FMCP-L  
30 protocol integrates two empirically based interventions, Meaning-Centered Psychotherapy and  
31 Couple Communication Skills Training, with the goals of (1) helping patients and caregivers  
32 sustain or enhance a sense of meaning, peace, and purpose as patients approach the end of life  
33 and (2) improving communication and quality of life among the patient-caregiver dyad. We will  
34 receive FMCP-L protocol feedback (Phase 1b: Refine) y conducting 114 questionnaires and 15  
35 semi-structured interviews with advanced cancer patients and their caregivers. Participants will  
36 be adult patients and caregivers coping with advanced cancer (Stage III or IV). The primary  
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3 outcomes of this study will be identifying the foundational information needed to further the  
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6 develop the FMCP-L (Phase IIa: Proof-of-Concept and Phase IIb: Pilot study).  
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9 **Ethics and dissemination:** The Institutional Review Board approved the study protocol

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12 #1907017527A002 from Ponce Research Institute. Results will be disseminated through peer-

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16 reviewed publications.  
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20 **Keywords: Cultural, Adaptation, Latinx, Families, Cancer**  
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### 23 **Strengths and limitations of this study**

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27 • This study will allow the development of the Family Psychotherapy Intervention to  
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29 support Latinx patients and caregivers coping with advanced cancer.  
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33 • The major strength of this study is its purpose to not solely translate a previously tested  
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35 English language intervention, but also to adapt it culturally.  
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39 • We will not measure our participants' access to technology (i.e., telephone, internet, or  
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41 computer), limiting our ability to assess some information on access to technology for the  
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47 implementation phase.  
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10 Adaptation of Meaning-Centered Psychotherapy for Latinos), 1R25CA190169-01A1(Meaning-  
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13 Centered Psychotherapy Training for Cancer Care Providers), 1R01CA229425-0A1 (Couple  
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16 Communication Skills Training for Advanced Cancer Patients), 3R01CA201179-04S1 (Couple  
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19 Communication in Cancer: A Multi-Method Examination), 5K07CA207580-04 (Culturally  
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22 Competent Communication Intervention to Improve Latinos' Engagement in Advanced Care  
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25 Planning), 5R21CA224874-02 (A communication-based intervention for advanced cancer patient-  
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27  
28 caregivers dyads to increase engagement in advance care planning and reduce caregivers burden),  
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31 5K08CA234397 (Adaptation and Pilot Feasibility of a Psychotherapy Intervention for Latinos  
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33  
34 with Advanced Cancer); and the Memorial Sloan Kettering Cancer Center grant (P30CA008748).  
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#### 48 **Conflict of Interest** 49

50  
51 The authors reported no potential conflict of interest.  
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#### 54 **Authors contribution** 55 56 57 58 59 60

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4 **Study conception and design:** Normarie Torres-Blasco, Eida Castro, Rosario Costas-Muñiz, Laura  
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7 Porter, Megan Shen, William Breitbart and Guillermo Bernal.  
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10 **Acquisition of data:** Normarie Torres-Blasco, María Claros and Rosario Costas-Muñiz  
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13 **Analysis and interpretation of data:** Normarie Torres-Blasco and Rosario Costas-Muñiz  
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22

23 **Critical revision:** Normarie Torres-Blasco, Eida Castro Carolina Zamore and Rosario Costas-  
24  
25  
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27 Muñiz.  
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### 29 30 **Data Statement Section** 31

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

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52 **Patients with advanced cancer and informal caregivers.**  
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3 As the number of cancer diagnoses increases, informal caregivers (often family members) play  
4 an essential role in providing care throughout the cancer trajectory,[1,2]. Significant numbers of  
5 advanced cancer patients and their families emphasize the need for increased attention to end-  
6 of-life care,[3]. Caregivers often assume the role without the necessary skills to help them  
7 address a cancer patient's complex needs,[4-9]. Consequently, they can experience a substantial  
8 caregiving burden that negatively impacts family function (i.e., communication, conflict, and  
9 cohesion) and the patients' physical, emotional, and social well-being,[10-14].

### 19 **Impact of cancer on family caregiver's wellbeing**

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

### 43 **Contribution of caregivers to patient's well-being**

45 The contribution of family caregivers to their patient's well-being has been evident, and several  
46 indirect partner effects are also apparent in the literature. Specifically, for Latinx, both patients and  
47 caregivers had significant direct and indirect actor effects (through family conflict) of perceived  
48 stress on depression and anxiety. Caregivers' stress was predictive of patients' depression and  
49 anxiety through survivors' increased perceptions of family conflict,[20]. A culturally centered  
50 stress on depression and anxiety. Caregivers' stress was predictive of patients' depression and  
51 anxiety through survivors' increased perceptions of family conflict,[20]. A culturally centered  
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57 anxiety through survivors' increased perceptions of family conflict,[20]. A culturally centered  
58 stress on depression and anxiety. Caregivers' stress was predictive of patients' depression and  
59 anxiety through survivors' increased perceptions of family conflict,[20]. A culturally centered  
60 stress on depression and anxiety. Caregivers' stress was predictive of patients' depression and

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3 intervention for Latinx patients should include a family-centered (partners and other family  
4 members) approach to determine the content and goals of care preferred in Latinx families  
5 coping with cancer,[21-23].  
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### 10 11 **Latinx patients and caregiver dyadic** 12

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14 Latinx have a higher intensity (i.e., hours per week and help with activities of daily living) of  
15 caregiving than non-Latinx whites and Asians,[24]. Our preliminary data shows that 86% of  
16 Latinx advanced cancer patients reported low family function, and those with low family  
17 cohesiveness had higher depression and anxiety levels. Several studies show that low family  
18 function negatively impacts the cancer illness trajectory (i.e., adherence, depression, poor  
19 prognostic, and stress),[25-27]. Patients with advanced cancer and their families experience  
20 significant distress in four domains: physical, psychological, social, and spiritual,[28-30]. These  
21 domains are often summarized by the term "quality of life (QOL)." QOL, spirituality, and  
22 reduction of distress are essential goals of cancer care,[31]. A meta-analysis and systematic  
23 review found that Latinx cancer patients show worse distress, depression, and overall health-  
24 related quality of life (HRQOL) than other minority patients and Whites,[32]. Similarly, Latinx  
25 patients report higher levels of burden, depression, and physical health problems than patients of  
26 other ethnicities,[33, 34]. Therefore, addressing family issues is crucial in the adjustment and  
27 well-being of Latinx with advanced cancer and their informal caregivers.  
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### 48 **Cultural Adaptation of Evidence-Based Practice** 49

50 Cultural adaptations of interventions for ethnic minority groups are feasible and acceptable,[35-  
51 38]. Meta-analytic evidence suggests that culturally adapted interventions targeting a specific  
52 cultural group are four times more effective than those provided to various cultural backgrounds,  
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3 and twice as effective as English interventions if conducted in the participants' native language  
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5 (if other than English),[35-38]. The literature suggests that behavioral interventions must be  
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7 culturally adapted for cultural groups by following the phases of information gathering,  
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9 preliminary design, preliminary testing, and final trial to reduce health disparities,[38].  
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### 13 **The conceptual framework**

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15 Meaning Centered Psychotherapy is grounded in theory, developed by Dr. Breitbart, aims to  
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17 target specific psycho-spiritual needs of patients with advanced cancer[39]. Its primary goal is to  
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19 help patients enhance a sense of meaning, peace, and purpose as they approach end-of-life. The  
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21 7-session intervention focuses on assisting patients in identifying sources of meaning in their  
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23 lives despite their diagnosis. In addition to its effectiveness with non-Latino whites, Dr. Costas-  
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25 Muñiz demonstrated the acceptability and feasibility of MCP for Latino advanced cancer  
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27 patients,[40, 41]. Preliminary findings suggested Latinx with advanced cancer identified family  
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29 issues as a crucial component in adjusting to their cancer diagnosis and well-being,[40, 41].  
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31 These findings indicate the need and acceptability of a culturally adapted family intervention for  
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33 cancer patients and their informal caregivers in navigating family function, communication and  
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35 adjustment in cancer,[40, 41]. Further, research indicated that communication skills for couples  
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37 improves family communication dynamics, especially among Latinx families,[42] and is there  
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39 prior data of the effectiveness of meaning-centered psychotherapy as well as Latinx prior  
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49 indications of need for meaning making such as the literature around spirituality,[41].  
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## 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

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4 progressive process, a pre-specified clinically significant milestone for forward movement and a  
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7 return to an earlier phase for refinement in event of other findings.  
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10 The unifying theoretical framework of the culturally adapted Evidence-Based Practice,[43- 47]  
11 Ecological Validity Model (EVM),[45] developed by Dr. Guillermo Bernal, the cultural  
12 adaptation process model (CAPM),[44] and cancer contextual model of health-related quality of  
13 life (HRQOL),[48] provide viable approaches to treating ethnic minorities and culturally diverse  
14 groups. According to EVM, to adapt an intervention for a new cultural group, seven dimensions  
15 need to be addressed: language, context, persons, metaphors, concepts, goals, and methods,[44].  
16 CAPM is a complementary process model to EVM and prescribes four phases for the adaptation  
17 process: formative, adaptation iterations, intervention, and measurement adaptation,[44]. Cancer  
18 contextual model of health-related quality of life (e.g., Spiritual wellbeing, depression, anxiety,  
19 hopelessness, functional assessment of cancer therapy, family relationship index, burden,  
20 fatalism, religiosity, distress and patient's needs-semi-structured interview) are outlined to  
21 specify individual, cultural, and contextual influences (i.e., dyadic relationships and  
22 communication with partners) as essential determinants of QOL,[47] Drawing from social  
23 cognitive (i.e., Couples Communication Skills Training) and existential theory (i.e., Meaning-  
24 Centered therapy), the Family Meaning-Centered Psychotherapy intervention is designed to  
25 increase the spiritual well-being and self-efficacy in communication between advanced cancer  
26 patients and their informal caregivers,[48-53].  
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50 To identify the foundational information necessary to culturally adapt and integrate MCP and  
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54 CCST to develop FMCP-L for Latinx patients and their informal caregivers, we will utilize a  
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4 four-phase approach guided by the ORBIT Model to the cultural adaptation process: (1a) Define,  
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7 (1b) Refine, (2a) Proof-of-concept, (2b) Pilot, (3) Efficacy Trial, and (4) Effectiveness Research.  
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10 The ORBIT Model for Behavioral Treatment Development model provides a progressive,  
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13 clinically relevant approach to increasing the number of evidence-based behavioral treatments  
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16 available to prevent and treat chronic diseases,[41]. The ORBIT model includes a flexible and  
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19 iterative progressive process, pre-specified clinically significant milestones for forward  
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22 movement, and return to an earlier phase for refinement in the event of suboptimal results, see  
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27 figure 1,[43].  
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### 31 **Phase Ia: Define Intervention Components**

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

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<b>Family Meaning-Centered Psychotherapy</b>
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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



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

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47 **Phase Ib: Refine Intervention Components**  
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50 With the FMCP-L protocol, we develop an acceptability and feasibility questionnaire and semi-  
51 interview of the intervention. The recruitment and administration of the questionnaire  
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53 (quantitative phase) and the semi-structured interviews (qualitative phase) started in September  
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3 2020 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework,  
4 the cultural expert (NTB) developed a questionnaire and semi-structured interview to administer  
5 to patients and their informal caregivers. The questionnaire (quantitative phase) and the semi-  
6 structured interviews (qualitative phase) were designed to gather information from patients and  
7 informal caregivers about integrating Latinx families and cultural values (i.e., spirituality,  
8 familism, and fatalism) to the FMCP-L manual. The intervention targets include: patient and  
9 caregiver psychosocial needs, caregiving burden, and family function (i.e., communication,  
10 conflict, and cohesion),[51], see Table 1.  
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22 **COVID-19 Recruitment Phase Ib.** Due to social distancing measures during the COVID-19  
23 pandemic, an updated recruitment plan was approved to facilitate ongoing activities and testing.  
24 This plan includes (1) utilizing open-access media (i.e., Facebook and PHSU official webpages)  
25 to recruit participants; (2) including possession of a smartphone, tablet, or computer/laptop as an  
26 eligibility criterion; and (3) providing the option of conducting informed consent, questionnaire,  
27 and semi-structured interview procedures during telehealth visits, ensuring they take place in a  
28 private location. Depending on the participant's access, one of the following platforms will be  
29 used: VidyoConnect, Zoom, VSee, or Doxy.me.  
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41 **Sample Quantitative Phase Ib.** Participants will be recruited through the *Programa de Apoyo*  
42 *Psicosocial Integrado al Cuidado Oncológico* (PAPSI — Integrated Psychosocial Support  
43 Program for Cancer Care), a psychosocial support program integrated into oncology care at  
44 Ponce Health Sciences University. Advanced cancer patients who completed PAPSI's routine  
45 distress screening measure will be screened to assess whether they meet the following inclusion  
46 criteria: (1) diagnosed with stage III or IV solid tumors, (2) 21 years or older, (3) self-report  
47 being Latinx or Hispanic, and (4) fluent in Spanish. With the patient's permission, their informal  
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3 caregiver will be invited to participate if they meet the following inclusion criteria: (1) informal  
4 caregiver of a patient recruited to the study and identified by the patient as the person he/she gets  
5 the most support, (2) 21 years or older, (3) self-report being Latinx or Hispanic, and (4) fluent in  
6 Spanish.  
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13 One hundred and forty patients and their informal caregivers who meet the inclusion criteria will  
14 be recruited and participate in the process of informed consent when they agree to enroll in the  
15 study. A priori sample size of 114 is selected based on recommendations for exploratory studies  
16 of this nature,[54-56]. Following informed consent, participants will be assigned a subject  
17 number. The cultural expert (NTB) will administer the cross-sectional questionnaire (Table 3) to  
18 assess the acceptability of the goals, concepts of MCP and communication skills training, and the  
19 feasibility of the proposed intervention's goals and therapeutic methods. Participants will  
20 complete assessments,[57- 75] measuring spiritual well-being, depression, anxiety, hopelessness,  
21 quality of life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the  
22 survey includes general demographic information (i.e., age, education, and gender) of the patient  
23 and their informal caregiver. The cultural expert (NTB) will administer the questionnaire in an  
24 interview-style to accommodate patients and their informal caregivers with limited education  
25 and/or literacy. After completing the questionnaire, patients and their informal caregivers will be  
26 received \$15 for their study participation.  
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47 **Table 3**

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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]

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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 Relationship Index will measure cohesiveness, conflict, and expressiveness among family members,[65]
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,[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  $\geq 4$  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  $\geq 4$  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

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3 burden, and (4) family function (i.e., communication, conflict, and cohesion). When necessary,  
4 the interviewer will use follow-up probing questions to elicit patients' and informal caregivers'  
5 full narratives. The interview will be digitally audio-recorded. After the semi-structured  
6 interviews, participants (patient and the informal caregiver) will receive a \$30 stipend for their  
7 participation.  
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### 16 **Phase IIa: Proof-of-Concept**

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20 Phase IIa is planned for the future after phase Ib is completed (questionnaire and semi-structured  
21 interviews). The formative findings from phase Ib will provide the necessary information to adapt  
22 the FMCP-L intervention and further develop the fixed FMCP-L protocol, following the  
23 Ecological Validity Framework. With the fixed FMCP-L protocol, we will conduct a pre-pilot  
24 feasibility and acceptability study of using the **ORBIT: Phase IIa**. The Hypothesis is that FMCP-  
25 L is feasible and acceptable, evidenced by reaching high overall retention (>75%), high satisfaction  
26 (>75%), and high overall acceptability (>75%) among patients and families.  
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44 **Sample Phase IIa.** Using a single-arm feasibility design, thirty dyads with patients with stage III and  
45 IV solid tumor, distressed (Distress Thermometer  $\geq 4$ ) will be enrolled from an oncology clinic in the  
46 south area of Puerto Rico. A priori sample size of 30 is selected based on recommendations for  
47 pre-pilot studies,[54-56]. The manualized protocol will be delivered across four 45-to 60 minutes  
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4 videoconference sessions by a clinical psychologist. The data will be recorded with informed  
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7 consent from participants. Data will be transcribed, coded, and analyzed for themes and sub-  
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10 categories, paying attention to challenging or incomprehensible material and meaning making and  
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13 communication skills training approaches given by participants. Participants will receive  
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16 incentives after each session and assessments.  
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20 **Procedure Phase IIa.** FMCP-L consists of four-45- 60 minute- family sessions. The four sessions  
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23 are expected to be delivered every week or every two weeks over a span of 4-8 weeks. Sessions  
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26 will be recorded to conduct fidelity checks. The PI, who is a licensed clinical psychologist with  
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29 extensive clinical training in MCP and CCST, practice delivering MCP and CCST with cancer  
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32 patients, and research experience adapting FMCP-L, will conduct the sessions. Patient-reported  
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35 outcomes will be assessed at baseline and 5- and 10-week follow-ups. Participants will be invited  
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38 to participate in in-depth exit interviews following completion of MCP-L. The data will be  
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41 recorded with informed consent from the participants. Data will be transcribed, coded, and  
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44 analyzed for themes and sub-categories, paying attention to challenging or incomprehensible  
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47 material and meaning making and communication skills training approaches given by participants.  
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54 Participants will receive incentives after each session and assessments.  
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### 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 Hypothesis 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.

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3 **Procedure Phase IIb.** FMCP-L consists of four 45- 60 minute- family sessions. The four sessions  
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7 are expected to be delivered every week or every two weeks over a span of 4-8 weeks. Sessions  
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10 will be recorded to conduct fidelity checks. The PI who is a licensed clinical psychologist with  
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13 extensive clinical training in MCP and CCST, practice delivering MCP and CCST with cancer  
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16 patients, and research experience adapting FMCP-L, will conduct the sessions in the United States  
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19 (US) or will supervise a trained doctoral level clinical psychologist trainee. In New York, Dr.  
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22 Rosario Costas (consultant), who is a clinical psychologist trained in MCP and also the principal-  
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25 investigator for the R21 MCP-L study, will conduct the sessions or will supervise a doctoral level  
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28 clinical psychologist trainee on the conducting of FMCP-L. If a doctoral level clinical psychology  
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31 trainee is involved in delivering the intervention, he/she will be first trained on conducting FMCP-  
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34 L and will receive weekly supervision from Dr. Costas, or from Dr. Torres if they are practicing  
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37 in Puerto Rico, but all trainees will receive supervision from Dr. Torres. Patient-reported outcomes  
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40 will be assessed at baseline and 5- and 10-week follow-ups. Participants will be invited to  
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43 participate in in-depth exit interviews following completion of MCP-L. The data will be recorded  
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46 with informed consent from the participants. Data will be transcribed, coded, and analyzed for  
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49 themes and sub-categories, paying attention to challenging or incomprehensible material and  
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3 meaning making and communication skills training approaches given by participants. Participants  
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7 will receive incentives after each session and assessments.  
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11 **Quantitative Analysis Phase Ib.** Descriptive statistics will be conducted using IBM SPSS

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14 Statistics 21 to examine survey responses. The pre-dyadic analyses occur in three steps: (1)  
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17 bivariate correlations to calculate results between meaning, spirituality, hopelessness, QOL, and  
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20 family function, (2) 8 bivariate regression models to assess the predictive power of each  
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23 predictor variable (meaning and spirituality) on each of the four outcomes: hopelessness, QOL,  
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26 anxiety, and depression, (3) multi-level models to analyze data at the dyad level to control for  
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29 interdependencies,[46]. The dyadic analysis will be conducted through multivariate outcome  
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32 models to estimate a possible score for each member of the couple (i.e., one for the patient and  
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35 one for the informal caregiver). It will be controlled for the dependent nature of couple-level data  
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38 and allowed for examination of both actor and cross-partner effects,[46].  
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46 **Quantitative Analysis Phase IIa.** Feasibility and acceptability will be assessed through accrual,  
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49 session/assessment completion, intervention satisfaction, and coping skills usage. Participants  
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52 completed validated measures of primary outcomes (i.e., spiritual well-being and self-efficacy)  
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55 and acceptability questionnaire at baseline, post-intervention, and four-week follow-up.  
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4 **Quantitative Analysis Phase IIb.** The primary analysis will examine whether, relative to the  
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7 CCST intervention, the FMCP-L intervention leads to greater increases in patient and caregivers'  
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10 spiritual well-being and self-efficacy in all two post-treatment assessments in a mixed-effects  
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12  
13 regression model. Pre-treatment spiritual well-being and self-efficacy scores and time  
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15  
16 (categorical) will be included as covariates. Intervention by time interactions will test the  
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18  
19 intervention effect at each follow-up time. Subject-specific random intercepts will account for  
20  
21  
22 within-subject variability. Intervention effects on patient spiritual well-being and self-efficacy at  
23  
24  
25 each follow-up are tested using F tests of combined main and interaction effects.  
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31 **Qualitative Analysis Phase Ib, IIa and IIb.** Data analysis will begin with verbatim transcripts of  
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34 the 30-digital audio-recorded interviews and imported into Atlas.ti (version 8.1.3; Atlas.ti  
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36  
37 Scientific Software Development, Berlin, Germany, [www.atlasti.com](http://www.atlasti.com)),[76]. The team will follow  
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40 a published qualitative data preparation and transcription protocol to ensure the transcriptions'  
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43 accuracy and fidelity,[77-80]. Observational notes taken by the interviewer will be typed and  
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46 attached to the transcription documents. During the transcription, all data will be de-identified by  
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49 replacing names with aliases to ensure anonymity.  
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4 Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated  
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7 methods will be used to improve qualitative accuracy and validity: methods and analyst  
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9  
10 triangulation,[76-83]. Method triangulation will be achieved by determining the consistency of  
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12  
13 the data generated by both the survey and the semi-structured interviews. Analyst triangulation  
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16 will be attained using multiple analysts (raters) to review and evaluate the qualitative data. Once  
17  
18  
19 transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive  
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21  
22 content analysis. Each step has three phases: preparation, organizing, and reporting,[84-86]. Two  
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25 bilingual raters will conduct the content analysis. The analyses, integration, and interpretation  
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28 will be in Spanish.  
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34 Inductive content analysis will examine how families (advanced cancer patients and their  
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37 informal caregivers) define FMCP-L and communication skills training concepts. During the  
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40 preparation phase, raters will familiarize themselves with the text. The data will be organized  
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42  
43 through open coding, creating categories, abstractions, and identifying the concepts' boundaries  
44  
45  
46 for inductive analysis. Categories will be generated from open coding and grouped under higher-  
47  
48  
49 order headings. Descriptions using content-characteristic words will be created for the  
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51  
52 abstraction. The data will be reviewed for deductive content analysis using a structured  
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3 categorization matrix based on the MCP and communication skill model. All data will be  
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5  
6 reviewed for content and coded for correspondence, exemplifying the categories' categorization  
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10 matrix.

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13  
14 **Integration Phase.** In cultural adaptation, the source text is rewritten in the target language to  
15  
16  
17 convey the concepts and achieve the aims of the source text, while accounting for both language  
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19  
20 and cultural considerations,[87]. The cultural adaptation not only renders the text of written  
21  
22  
23 materials into another language but also infuses culturally relevant context and themes. [88, 89]  
24  
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26  
27 The cultural expert (NTB), group of mentors (EC, MS, RCM, GP, and LP), and collaborators  
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29  
30 (CZ, MC, and WB) will conduct the integration of the quantitative and qualitative findings to  
31  
32  
33 develop the FMCP-L fixed protocol (Table 1). The text will be independently reviewed,  
34  
35  
36 followed by "consensus meetings" to discuss every session of the intervention, provide feedback,  
37  
38  
39 and discuss further modifications until a consensus is reached. Dr. Guillermo Bernal will then  
40  
41  
42 review the text to ensure the adaptation considers the dimensions of the Ecological Validity  
43  
44  
45 Model. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of  
46  
47  
48 Family Meaning-Centered Psychotherapy's concepts, goals, and theoretical model will be  
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4 preserved during the adaptation process to ensure language, metaphor, strategy, cultural context,  
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6  
7 and value acceptability by Latinx families.  
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10  
11 As shown with the transcreation of MCP for Latinx, the adaptation plan for Latinx families will  
12  
13  
14 also include content modification, family congruence through metaphors and assignments, and  
15  
16  
17 cultural adaptation notes with findings from the cultural adaptation process guidelines about the  
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19  
20  
21 delivery of the intervention to the dyad.  
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## 24 25 **Summary and Conclusions**

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28 Once the fixed protocol of FMCP-L is acceptable, feasible, and effective, we will finalize the  
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30  
31 development process with an Efficacy Trial (ORBIT: Phase III) and later Effectiveness Research  
32  
33  
34 Trial (ORBIT: Phase IV). This process will facilitate the development of culturally sensitive  
35  
36  
37 intervention and mitigate the cost of developing effective and durable behavioral treatment. All  
38  
39  
40 the identified phases currently bring the needed elements to go from ideas to efficacy trial with a  
41  
42  
43 well-defined pathway for doing it. Specifically, the proposed behavioral intervention framework  
44  
45  
46 pushes the identified need to sight on the chain of evidence needed to support the progressive  
47  
48  
49 program of intervention development. Finally, the recognized framework is flexible in both the  
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52 design and methodologies for treatment development, which facilitates development,[41].  
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## 60 **Strengths and weaknesses/ limitations of the study**

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4 The first limitation is that the qualitative interviews are the main source of information for the  
5  
6  
7 adaptation. Thus, we will include observation of sessions in the next phases of adaptation process  
8  
9  
10 (Phase IIa: Proof-of-Concept and Phase IIb: Pilot study). Second, patients were predominantly  
11  
12  
13 recruited from Puerto Rico. Thus, the results may not generalize to all Latinx, and future studies  
14  
15  
16 will include samples from different geographical locations. Third, the selection of patients was  
17  
18  
19 not homogeneous in terms of diagnosis and stages, and patients with stages III and IV cancer  
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21  
22 will be invited to participate. The cancer experience of patients and caregivers at different  
23  
24  
25 disease stages with different prognoses could vary significantly. In future studies, analyses  
26  
27  
28 should be stratified by stage and prognosis. The final identified limitation is the access to  
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31 technology. Thus, we will include the possibility of conducting the questionnaire and  
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34 intervention in person.  
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### 41 **Public Involvement Statement**

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44 The public, specifically Latinx advanced cancer patients and their informal caregivers, are at the  
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46  
47 core of the implementation plan. The study's objective is to develop the first psychosocial family  
48  
49  
50 intervention that supports Latinx advanced cancer patients and their informal caregivers to cope  
51  
52  
53 with cancer. The study design mentioned above will constantly include the consultation of  
54  
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56 patients' and their informal caregivers' perceptions, experiences, and opinions to refine a  
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58  
59 successful final version of Family Meaning Centered Psychotherapy for Latinx families (FMCP-  
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3 L). The intent is to involve the patients and their informal caregivers (the public), who will be the  
4 target user in the development and cultural adaptation of the family psychological intervention  
5  
6 (ORBIT: Phase IIa: Proof-of-Concept and Phase IIb: Pilot study). Further, the proposed project  
7  
8 will directly (1) impact the Latinx community, (2) contribute to the development of culturally  
9  
10 adapted psychosocial interventions, (3) be used in the healthcare field, and (4) reduce disparities  
11  
12 in access to psychosocial interventions for Latinx advanced cancer patients.  
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### 19 **Ethics and Dissemination**

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21  
22 This project is the first development of a culturally and linguistically adapted intervention for  
23  
24 Latinx families coping with advanced cancer. The results of this adaptation plan will guide the  
25  
26 specific dyadic intervention for advanced cancer patients and caregivers. It will advance the field  
27  
28 of cultural adaptation of psychosocial interventions in the medical field to reduce health  
29  
30 inequalities. Furthermore, it will result in peer-reviewed publications, conference presentations,  
31  
32 and reports. The information will also be shared with non-academic community members  
33  
34 involved in outreach activities; i.e., "Hablemos de Cáncer," *El Puente (The Bridge)*, newsletters,  
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36 and social media; i.e., "Yo Puedo," of the Support Group of American Cancer Society in Puerto  
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38 Rico.  
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### 44 **Figure 1 Legend**

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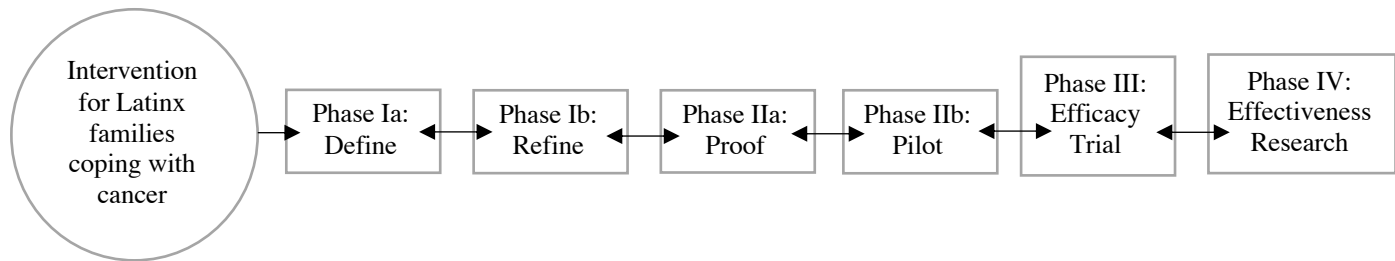


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**Figure 1**

**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.

# BMJ Open

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

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<b>Primary Subject Heading</b>:	Palliative care
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## Cultural Adaptation of Meaning-Centered Psychotherapy for Latino Families: A Protocol

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## 8 **ABSTRACT**

9  
10 **Introduction:** Literature suggests couple-based interventions that target quality of life and  
11 communication can lead to positive outcomes for cancer patients and their partners.  
12

13  
14 Nevertheless, to date, an intervention to address the needs of Latino families coping with  
15 advanced cancer has not been developed. Meta-analytic evidence suggests that culturally adapted  
16 evidenced based intervention targeting a specific cultural group are four times more effective.  
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19 Our goal is to culturally adapt a novel psychosocial intervention protocol entitled “Caregivers-  
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22 Patients Support to Latinx coping advanced-cancer” (CASA). We hypothesized that combine  
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25 two evidence-based interventions and adapting them we will sustain a sense of meaning and  
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28 improving communication as patients approach the end of life among the patient-caregiver dyad.  
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32 **Methods and analysis:** To culturally adapt CASA, we will follow an innovative hybrid research  
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36 framework that combines elements of an efficacy model and best practices from the Ecological  
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Validity Model (EVM), adaptation process model (CAPM), and intervention mapping. As a first  
step, we adapt a novel psychosocial intervention protocol entitled protocol entitled “Caregivers-  
Patients Support to Latinx 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,

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3 a priori size of 114 is selected. We will receive CASA protocol feedback (Phase 1b: Refine) by  
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7 conducting 114 questionnaires and 15 semi-structured interviews with advanced cancer patients  
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10 and their caregivers. The primary outcomes of this study will be identifying the foundational  
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13 information needed to further the develop the CASA (Phase IIa: Proof-of-Concept and Phase IIb:  
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15  
16 Pilot study).

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21 **Ethics and dissemination:** The Institutional Review Board of Ponce Research Institute  
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23  
24 approved the study protocol #1907017527A002. Results will be disseminated through peer-  
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26  
27 reviewed publications.  
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32 **Keywords: Cultural, Adaptation, Latinx, Families, Cancer**  
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### 35 36 **Strengths and limitations of this study**

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39 • This study will allow the development of the patients-caregiver Psychotherapy  
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42 Intervention to support Latinx patients and caregivers coping with advanced cancer.  
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46 • The major strength of this study is its purpose to not solely translate a previously tested  
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49 English language intervention, but also to adapt it culturally.  
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4 • We will not measure our participants' access to technology (i.e., telephone, internet, or  
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7 computer), limiting our ability to assess some information on access to technology for the  
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10 implementation phase.  
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27 Adaptation of Meaning-Centered Psychotherapy for Latinos), 1R25CA190169-01A1 (Meaning-  
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30 Centered Psychotherapy Training for Cancer Care Providers), 1R01CA229425-0A1 (Couple  
31  
32  
33 Communication Skills Training for Advanced Cancer Patients), 3R01CA201179-04S1 (Couple  
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36 Communication in Cancer: A Multi-Method Examination), 5K07CA207580-04 (Culturally  
37  
38  
39 Competent Communication Intervention to Improve Latinos' Engagement in Advanced Care  
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43 Planning), 5R21CA224874-02 (A communication-based intervention for advanced cancer patient-  
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46 caregivers dyads to increase engagement in advance care planning and reduce caregivers burden),  
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53 5K08CA234397 (Adaptation and Pilot Feasibility of a Psychotherapy Intervention for Latinos  
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56 with Advanced Cancer); and the Memorial Sloan Kettering Cancer Center grant (P30CA008748).  
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7 **Word count** 4,413  
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## 10 11 **Conflict of Interest** 12

13  
14 The authors reported no potential conflict of interest.  
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16

## 17 18 **Authors contribution** 19

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21 **Study conception and design:** Normarie Torres-Blasco, Eida Castro, Rosario Costas-Muñiz, Laura  
22  
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24 Porter, Megan Shen, William Breitbart and Guillermo Bernal.  
25  
26

27  
28 **Acquisition of data:** Normarie Torres-Blasco, María Claros and Rosario Costas-Muñiz  
29  
30

31  
32 **Analysis and interpretation of data:** Normarie Torres-Blasco and Rosario Costas-Muñiz  
33  
34

35 Drafting of manuscript: Normarie Torres-Blasco, Eida Castro, Carolina Zamore, María Claros,  
36  
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38 Rosario Costas-Muñiz, Laura Porter, Megan Shen, William Breitbart and Guillermo Bernal  
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40

41  
42 **Critical revision:** Normarie Torres-Blasco, Eida Castro Carolina Zamore and Rosario Costas-  
43  
44  
45 Muñiz.  
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47

## 48 **Data Statement Section** 49 50 51 52 53 54 55 56 57 58 59 60

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

### 20 **Patients with advanced cancer and informal caregivers.**

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23 As the number of cancer diagnoses increases, informal caregivers (often family members) play  
24 an essential role in providing care throughout the cancer trajectory,[1,2]. Significant numbers of  
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26 advanced cancer patients and their families emphasize the need for increased attention to end-  
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28 of-life care,[3]. Caregivers often assume the role without the necessary skills to help them  
29  
30 address a cancer patient's complex needs,[4-9]. Consequently, they can experience a substantial  
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32 caregiving burden that negatively impacts family function (i.e., communication, conflict, and  
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34 cohesion) and the patients' physical, emotional, and social well-being,[10-14].  
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### 40 **Impact of cancer on family caregiver's wellbeing**

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42 A substantial body of research has examined how caregiving processes are linked to the  
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44 emotional health of family caregivers,[15]. Researchers continue to investigate how poor mental  
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46 functioning in family caregiving among Latinx may affect patients' outcomes; however, it is  
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53 equally important to attend to the well-being of family caregivers. A consistent pattern of unmet  
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4 need,[16, 17] and impact on mental functioning have been identified in recent year,[18].  
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7 Findings indicate that Latinx-caregivers ethnicity is associated with higher levels of clinically  
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10 significant depression,[18] and more caregiving demands are associated with higher levels of  
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13 caregivers' feelings of burden and psychological distress,[19]. Compounding this problem,  
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16 Latinx contextual and cultural influences on caregivers present an unmet need for emotional  
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19 support,[20] especially when Latinx individuals are less likely to have adequate access to  
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22 culturally congruent psychosocial interventions,[21-32]. Latinx cancer research had identified  
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25 the psychosocial need of Latinx caregivers and described the importance of including  
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28 psychosocial content related to communication and spirituality,[33-35].  
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### 34 **Contribution of caregivers to patient's well-being**

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37 The contribution of family caregivers to their patient's well-being has been evident, and several  
38  
39 indirect partner effects are also apparent in the literature. Specifically, for Latinx, both patients and  
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41 caregivers had significant direct and indirect actor effects (through family conflict) of perceived  
42  
43 stress on depression and anxiety. Caregivers' stress was predictive of patients' depression and  
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45 anxiety through survivors' increased perceptions of family conflict,[36]. A culturally centered  
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47 intervention for Latinx patients should include a family-centered (partners and other family  
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49 members) approach to determine the content and goals of care preferred in Latinx families  
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51 coping with cancer,[37-39].  
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### **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

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3 groups by following the phases of information gathering, preliminary design, preliminary testing,  
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5 and final trial to reduce health disparities,[54].  
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### 8 9 **The conceptual framework**

10 Our conceptual framework, grounded in theory, developed by Dr. Breitbart, aims to target  
11 specific psycho-spiritual needs of patients with advanced cancer,[55]. Its primary goal is to help  
12 patients enhance a sense of meaning, peace, and purpose as they approach end-of-life. The  
13 intervention focuses on assisting patients in identifying sources of meaning in their lives despite  
14 their diagnosis. In addition to its effectiveness with non-Latino whites, Dr. Costas-Muñiz  
15 demonstrated the acceptability and feasibility of Meaning Centered Psychotherapy (MCP) for  
16 Latinx advanced cancer patients,[33, 34]. Preliminary findings suggested that Latinx with  
17 advanced cancer identified family and communication issues as crucial in adjusting to their  
18 cancer diagnosis and well-being,[33, 34]. Further, we identified evidence of communication skill  
19 training that indicated that communication skills for couples improve family communication  
20 dynamics, especially among Latinx families,[56] and there is data on the effectiveness of Couple  
21 Communication Skills Traing (CCST) in Caucasian couples; however, literature is absent about  
22 effectivity in Latinx coping with advanced cancer [52]. These findings indicate the need to  
23 explore the integration of Couples Communication Skill Training (components) for patients  
24 dealing with advanced cancer to a MCP.  
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### 46 47 **Objectives**

48 The purpose of this study is to culturally adapt and integrate (1) Meaning-Centered  
49 Psychotherapy (MCP) and (2) Couples Communication Skills Training (CCST) a novel  
50 psychosocial intervention protocol entitled “Caregivers-Patients Support to Latinx coping advanced-  
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3 cancer” (CASA). The CASA intervention aims to improve the quality of life and spiritual well-  
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6 being of advanced cancer patients and their informal caregivers. This paper describes the  
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8 conceptual framework used for the cultural adaptation process, initial phases, and future plans.  
9

## 10 11 12 **Methods and Analysis**

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14 This significant milestone for forward movement lead to the initial CASA protocol integration of  
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17 two empirically based interventions, Meaning-Centered Psychotherapy and Couple  
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21 Communication Skills Training, with the goals of (1) helping patients and caregivers sustain or  
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24 enhance a sense of meaning and (2) improving communication to improve health-related  
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27 outcomes. We hypothesized that helping patients and caregivers sustain a sense of meaning and  
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31 improving communication as patients approach the end of life among the patient-caregiver dyad  
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34 will improve spirituality and communication and, in turn, improve quality of life. This is an  
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37 exploratory study and pre-pilot study, and its treatment components including (MCP and CCST)  
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41 will be adapting and forward movement by the findings and grounding in theory. For the Pilot  
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44 phase we will easily translate and adapt the intervention for Latinx sample living in the US by  
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47 conducting a pilot study in Puerto Rico and New York, see Phase IIb: Pilot study.  
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3 The unifying theoretical framework of the culturally adapted Evidence-Based Practice,[57-60]  
4 Ecological Validity Model (EVM),[58] developed by Dr. Guillermo Bernal, the cultural  
5 adaptation process model (CAPM),[59] and intervention mapping,[61] provide viable  
6 approaches to treating ethnic minorities and culturally diverse groups. According to EVM, to  
7 adapt an intervention for a new cultural group, seven dimensions need to be addressed: language,  
8 context, persons, metaphors, concepts, goals, and methods,[57]. CAPM is a complementary  
9 process model to EVM and prescribes four phases for the adaptation process: formative,  
10 adaptation iterations, intervention, and measurement adaptation,[57]. Cancer contextual model of  
11 health-related quality of life (e.g., Spiritual wellbeing, depression, anxiety, hopelessness,  
12 functional assessment of cancer therapy, family relationship index, burden, fatalism, religiosity,  
13 distress and patient's needs—semi-structured interview) are outlined to specify individual,  
14 cultural, and contextual influences (i.e., dyadic relationships and communication with partners)  
15 as essential determinants of QOL,[60] Drawing from social cognitive (i.e., Couples  
16 Communication Skills Training) and existential theory (i.e., Meaning-Centered therapy), the  
17 “Caregivers-Patients Support to Latinx coping advanced-cancer” (CASA) intervention is  
18 designed to increase the spiritual well-being and self-efficacy in communication between  
19 advanced cancer patients and their informal caregivers,[61-66].

20  
21 To identify the foundational information necessary to culturally adapt and integrate MCP and  
22 CCST to adapt de CASA intervention for Latinx patients and their informal caregivers, we will  
23 utilize a four-phase approach guided by the ORBIT Model to the cultural adaptation process:

24 (1a) Define, (1b) Refine, (2a) Proof-of-concept, (2b) Pilot, (3) Efficacy Trial, and (4)



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3 Effectiveness Research. The ORBIT Model for Behavioral Treatment Development model  
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7 provides a progressive, clinically relevant approach to increasing the number of evidence-based  
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10 behavioral treatments available to prevent and treat chronic diseases,[67]. The ORBIT model  
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13 includes a flexible and iterative progressive process, pre-specified clinically significant  
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16 milestones for forward movement, and return to an earlier phase for refinement in the event of  
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19 suboptimal results, see figure 1,[67].  
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#### 24 **Phase Ia: Define Intervention Components**

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27 The selection of intervention components was defined by the cultural expert (NTB) and a group  
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29 of mentors (EC, MS, RCM, GB, and LP) after careful review of the intervention's selected  
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31 components. The rationale for selecting the Meaning-Centered Psychotherapy and Couple  
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33 Communication Skills Training approaches, out of numerous other psychotherapeutic  
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35 approaches, is that research indicated that communication skills for couples improves family  
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37 communication dynamics, especially among Latinx families and is there prior data of the  
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39 effectiveness of meaning-centered psychotherapy as well as Latinx prior indications of need for  
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41 meaning making such as the literature around spirituality,[61-66]. Specifically, there is only one  
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43 intervention in the adaptation process for Latinx dealing with advanced cancer, the Individual  
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4 Meaning-Centered Psychotherapy,[33,34]. We decided to optimize and further the development  
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7 of the adapted Meaning-Centered Psychotherapy for Latinx by incorporating the patient's  
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10 reported needs in training for communication skills and the inclusion of other family members.  
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12  
13 By using the Couple Communication Skills Training (CCST) approach, we enhanced the MCP  
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15  
16 session by adding taught coping skills (e.g., how to communicate and listen) as well as how to  
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18  
19 increase their self-efficacy (i.e., confidence) for sharing through behavioral practice, goal setting,  
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21  
22 and monitoring progress,[65,66]. The Couple Communication Skills Training approach was  
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24  
25 adapted for non-spousal patients' caregivers by eliminating spousal terms (e.g., taking care of  
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28 your partner-spouse) and changing it to general caregiving terms (e.g., taking care of your  
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31 significant other). Overview Table 1 presents the MCP and CCST components that will be  
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34 cultural and linguistic adapted and integrated for the CASA adapted protocol,  
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41 **Table 1**

42 Caregivers-Patients Support to Latinx 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

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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

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Psychotherapy goals, (4) Metaphors: we will include culturally consonant stories by adapting the Communication skills training and Meaning Centered components, (5) Concepts: Integration of Culturally consonant 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 2 Ecological Validity Model		Adaptations
Language	Culturally appropriate and culturally syntonic	Translate the CCST into Spanish and we also <i>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)</i> ".
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 culturally consonant stories by adapting the Communication skills training and Meaning Centered components
Concepts	Concepts consonant with culture and context	Integration of Culturally consonant 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

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### Phase Ib: Refine Intervention Components

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3 With the CASA protocol, we develop an acceptability and feasibility questionnaire and semi-  
4 interview of the intervention. The recruitment and administration of the questionnaire  
5 (quantitative phase) and the semi-structured interviews (qualitative phase) started in September  
6 2020 and is ongoing until recruitment goals are met. Using the Ecological Validity Framework,  
7 the cultural expert (NTB) developed a questionnaire and semi-structured interview to administer  
8 to patients and their informal caregivers. The questionnaire (quantitative phase) and the semi-  
9 structured interviews (qualitative phase) were designed to gather information from patients and  
10 informal caregivers about integrating Latinx families and cultural values (i.e., spirituality,  
11 familism, and fatalism) to the CASA manual. The intervention targets include: patient and  
12 caregiver psychosocial needs, caregiving burden, and family function (i.e., communication,  
13 conflict, and cohesion),[65,66], see Table 1.  
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29 **COVID-19 Recruitment Phase Ib.** Due to social distancing measures during the COVID-19  
30 pandemic, an updated recruitment plan was approved to facilitate ongoing activities and testing.  
31 This plan includes (1) utilizing open-access media (i.e., Facebook and PHSU official webpages)  
32 to recruit participants; (2) including possession of a smartphone, tablet, or computer/laptop as an  
33 eligibility criterion; and (3) providing the option of conducting informed consent, questionnaire,  
34 and semi-structured interview procedures during telehealth visits, ensuring they take place in a  
35 private location. Depending on the participant's access, one of the following platforms will be  
36 used: VidyoConnect, Zoom, VSee, or Doxy.me.  
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49 **Sample Quantitative Phase Ib.** Participants will be recruited through the *Programa de Apoyo*  
50 *Psicosocial Integrado al Cuidado Oncológico* (PAPSI — Integrated Psychosocial Support  
51 Program for Cancer Care), a psychosocial support program integrated into oncology care at  
52 Ponce Health Sciences University. Advanced cancer patients who completed PAPSI's routine  
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3 distress screening measure will be screened to assess whether they meet the following inclusion  
4  
5 criteria: (1) diagnosed with stage III or IV solid tumors, (2) 21 years or older, (3) self-report  
6  
7 being Latinx or Hispanic, and (4) fluent in Spanish. With the patient's permission, their informal  
8  
9 caregiver will be invited to participate if they meet the following inclusion criteria: (1) informal  
10  
11 caregiver of a patient recruited to the study and identified by the patient as the person he/she gets  
12  
13 the most support, (2) 21 years or older, (3) self-report being Latinx or Hispanic, and (4) fluent in  
14  
15 Spanish.  
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20 One hundred and forty patients and their informal caregivers who meet the inclusion criteria will  
21  
22 be recruited and participate in the process of informed consent when they agree to enroll in the  
23  
24 study. A priori sample size of 114 is selected based on recommendations for exploratory studies  
25  
26 of this nature,[68-70]. Following informed consent, participants will be assigned a subject  
27  
28 number. The cultural expert (NTB) will administer the cross-sectional questionnaire (Table 3) to  
29  
30 assess the acceptability of the goals, concepts of MCP and communication skills training, and the  
31  
32 feasibility of the proposed intervention's goals and therapeutic methods. Participants will  
33  
34 complete assessments,[71-91] measuring spiritual well-being, depression, anxiety, hopelessness,  
35  
36 quality of life, family relationship, burden, fatalism, religiosity, and distress. Additionally, the  
37  
38 survey includes general demographic information (i.e., age, education, and gender) of the patient  
39  
40 and their informal caregiver. The cultural expert (NTB) will administer the questionnaire in an  
41  
42 interview-style to accommodate patients and their informal caregivers with limited education  
43  
44 and/or literacy. After completing the questionnaire, patients and their informal caregivers will be  
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46 received \$15 for their study participation.  
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### 53 **Table 3**

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<b>Description of Study Scales</b>	
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 Relationship Index will measure cohesiveness, conflict, and expressiveness among family members,[79]
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,[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  $\geq 4$  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  $\geq 4$  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

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3 will have an interview guide with the flexibility to ask off-guided questions, which is divided  
4  
5 into four sections: (1) exploratory questions regarding participants' understanding of the MCP  
6  
7 concepts, (2) exploratory questions regarding the acceptability and feasibility of the family-based  
8  
9 intervention, (3) dyad's advanced cancer experience, strategies used to cope, and caregiving  
10  
11 burden, and (4) family function (i.e., communication, conflict, and cohesion). When necessary,  
12  
13 the interviewer will use follow-up probing questions to elicit patients' and informal caregivers'  
14  
15 full narratives. The interview will be digitally audio-recorded. After the semi-structured  
16  
17 interviews, participants (patient and the informal caregiver) will receive a \$30 stipend for their  
18  
19 participation.  
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### 25 **Phase IIa: Proof-of-Concept**

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30 Phase IIa is planned for the future after phase Ib is completed (questionnaire and semi-structured  
31  
32 interviews). The formative findings from phase Ib will provide the necessary information to adapt  
33  
34 the CASA intervention and further develop the fixed CASA protocol, following the Ecological  
35  
36 Validity Framework. With the fixed CASA protocol, we will conduct a pre-pilot feasibility and  
37  
38 acceptability study of using the **ORBIT: Phase IIa**. The Hypothesis is that CASA is feasible and  
39  
40 acceptable, evidenced by reaching high overall retention (>75%), high satisfaction (>75%), and  
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42 high overall acceptability (>75%) among patients and families.  
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4 **Sample Phase IIa.** Using a single-arm feasibility design, thirty dyads with patients with stage III and  
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7 IV solid tumor, distressed (Distress Thermometer  $\geq 4$ ) will be enrolled from an oncology clinic in the  
8  
9  
10 south area of Puerto Rico. A priori sample size of 30 is selected based on recommendations for  
11  
12  
13 pre-pilot studies,[68-70]. The manualized protocol will be delivered across four 45-to 60 minutes  
14  
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16  
17 videoconference sessions by a clinical psychologist. The data will be recorded with informed  
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20 consent from participants. Data will be transcribed, coded, and analyzed for themes and sub-  
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23 categories, paying attention to challenging or incomprehensible material and meaning making and  
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26 communication skills training approaches given by participants. Participants will receive  
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29 incentives after each session and assessments.  
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34 **Procedure Phase IIa.** CASA consists of four-45- 60 minute- family sessions. The four sessions are  
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37 expected to be delivered every week or every two weeks over a span of 4-8 weeks. Sessions will  
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40 be recorded to conduct fidelity checks. The PI, who is a licensed clinical psychologist with  
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43 extensive clinical training in MCP and CCST, practice delivering MCP and CCST with cancer  
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46 patients, and research experience adapting CASA, will conduct the sessions. Patient-reported  
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48  
49 outcomes will be assessed at baseline and post-intervention. Participants will be invited to  
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52 participate in in-depth exit interviews following completion of CASA intervention. The data will  
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4 be recorded with informed consent from the participants. Data will be transcribed, coded, and  
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7 analyzed for themes and sub-categories, paying attention to challenging or incomprehensible  
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10 material and meaning making and communication skills training approaches given by participants.  
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14 Participants will receive incentives after each session and assessments.  
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### 16 17 **Phase IIb: Pilot study**

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20 Phase IIb is planned for the future once phase IIa is completed. The pre-pilot (ORBIT: Phase  
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22  
23 IIb) will provide the necessary information to assess the preliminary efficacy of the CASA  
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25  
26 versus usual care (behavioral placebo) with quality-of-life and patient-reported outcomes  
27  
28  
29 (spiritual well-being and self-efficacy) in 100 Latinx families. We will use usual care that  
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31  
32 include usual psychotherapy intervention as a comparison condition to measure the effect of the  
33  
34  
35 adapted intervention. The Hypothesis is that those assigned to CASA will report better outcomes  
36  
37  
38 than those assigned to the attention control condition at post-intervention.  
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43 **Sample Phase IIb.** One hundred Latinx families, from Puerto Rico and New York, will be  
44  
45  
46 randomized placed in a two-group pilot design with pre-test and repeated post-test measures used  
47  
48  
49 to accomplish the study aims. Patients with stage III and IV (N = 100) and their caregivers are  
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51  
52 randomized in one of two intervention conditions with equal allocation: “Caregivers-Patients  
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3 **Support to Latinx coping advanced-cancer” (CASA) or usual care. A priori sample size of 100 is**  
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6  
7 selected based on recommendations for pilot studies,[68-70]. Randomization is stratified by age at  
8  
9  
10 diagnosis and recruitment site. Both interventions are manualized, of equivalent duration, and  
11  
12  
13 delivered by a trained counselor to the couples jointly over videoconference sessions. Web-based  
14  
15  
16 self-report outcome measures are administered to participants at baseline and post-intervention.  
17  
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19  
20 **Procedure Phase IIb.** CASA consists of four 45- 60 minute- family sessions. The four sessions are  
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22  
23 expected to be delivered every week or every two weeks over a span of 4-8 weeks. Sessions will  
24  
25  
26 be recorded to conduct fidelity checks. The PI who is a licensed clinical psychologist with  
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28  
29 extensive clinical training in MCP and CCST, practice delivering MCP and CCST with cancer  
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32 patients, and research experience adapting CASA, will conduct the sessions in the United States  
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34  
35 (US) or will supervise a trained doctoral level clinical psychologist trainee. In New York, Dr.  
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37  
38 Rosario Costas (consultant), who is a clinical psychologist trained in MCP and also the principal-  
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40  
41 investigator for the R21 MCP-L study, will conduct the sessions or will supervise a doctoral level  
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43  
44 clinical psychologist trainee on the conducting of CASA. If a doctoral level clinical psychology  
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46  
47 trainee is involved in delivering the intervention, he/she will be first trained on conducting CASA  
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51 and will receive weekly supervision from Dr. Costas, or from Dr. Torres if they are practicing in  
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4 Puerto Rico, but all trainees will receive supervision from Dr. Torres. Patient-reported outcomes  
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6  
7 will be assessed at baseline and post-intervention. Participants will be invited to participate in in-  
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9  
10 depth exit interviews following completion of CASA intervention. The data will be recorded with  
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12  
13 informed consent from the participants. Data will be transcribed, coded, and analyzed for themes  
14  
15  
16 and sub-categories, paying attention to challenging or incomprehensible material and meaning  
17  
18  
19 making and communication skills training approaches given by participants. Participants will  
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21  
22 receive incentives after each session and assessments.  
23  
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28 **Quantitative Analysis Phase Ib.** Descriptive statistics will be conducted using IBM SPSS  
29  
30  
31 Statistics 21 to examine survey responses. The pre-dyadic analyses occur in three steps: (1)  
32  
33  
34 bivariate correlations to calculate results between depression, anxiety, meaning, spirituality,  
35  
36  
37 hopelessness, QOL, and family function, (2) 8 bivariate regression models to assess the  
38  
39  
40 predictive power of each predictor variable (meaning and spirituality) on each of the four  
41  
42  
43 outcomes: hopelessness, QOL, anxiety, and depression, (3) multi-level models to analyze data at  
44  
45  
46 the dyad level to control for interdependencies,[69]. The dyadic analysis will be conducted  
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48  
49 through multivariate outcome models to estimate a possible score for each member of the couple  
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51  
52 (i.e., one for the patient and one for the informal caregiver). It will be controlled for the  
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4 dependent nature of couple-level data and allowed for examination of both actor and cross-  
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6  
7 partner effects,[69].  
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11 **Quantitative Analysis Phase IIa.** Feasibility and acceptability will be assessed through accrual,  
12  
13  
14 session/assessment completion, intervention satisfaction, and coping skills usage. Participants  
15  
16  
17 completed validated measures of primary outcomes (i.e., spiritual well-being and self-efficacy)  
18  
19  
20 and acceptability questionnaire at baseline, and post-intervention.  
21  
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25 **Quantitative Analysis Phase IIb.** The primary analysis will examine whether, relative to the usual  
26  
27  
28 care intervention, the CASA intervention leads to greater increases in patient and caregivers'  
29  
30  
31 spiritual well-being and self-efficacy in all two post-treatment assessments in a mixed-effects  
32  
33  
34 regression model. Pre-treatment spiritual well-being and self-efficacy scores and time  
35  
36  
37 (categorical) will be included as covariates. Intervention by time interactions will test the  
38  
39  
40 intervention effect at each follow-up time. Subject-specific random intercepts will account for  
41  
42  
43 within-subject variability. Intervention effects on patient spiritual well-being and self-efficacy at  
44  
45  
46 each follow-up are tested using F tests of combined main and interaction effects. Descriptive  
47  
48  
49 statistics will be conducted using IBM SPSS Statistics 21 to examine survey responses. The pre-  
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52 and post-dyadic analyses occur in three steps: (1) bivariate correlations to calculate results  
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3 between meaning, spirituality, hopelessness, QOL, and family function, (2) 8 bivariate regression  
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6  
7 models to assess the predictive power of each predictor variable (meaning and spirituality) on  
8  
9  
10 each of the four outcomes: hopelessness, QOL, anxiety, and depression, (3) multi-level models  
11  
12  
13 to analyze data at the dyad level to control for interdependencies,[69]. The dyadic analysis will  
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15  
16 be conducted through multivariate outcome models to estimate a possible score for each member  
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18  
19 of the couple (i.e., one for the patient and one for the informal caregiver). It will be controlled for  
20  
21  
22 the dependent nature of couple-level data and allowed for examination of both actor and cross-  
23  
24  
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26  
27 partner effects,[69].  
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31 **Qualitative Analysis Phase Ib, IIa and IIb.** Data analysis will begin with verbatim transcripts of  
32  
33  
34 the 30-digital audio-recorded interviews and imported into Atlas.ti (version 8.1.3; Atlas.ti  
35  
36  
37 Scientific Software Development, Berlin, Germany, [www.atlasti.com](http://www.atlasti.com)),[92]. The team will follow  
38  
39  
40 a published qualitative data preparation and transcription protocol to ensure the transcriptions'  
41  
42  
43 accuracy and fidelity,[93-96]. Observational notes taken by the interviewer will be typed and  
44  
45  
46 attached to the transcription documents. During the transcription, all data will be de-identified by  
47  
48  
49 replacing names with aliases to ensure anonymity.  
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4 Atlas.ti will be used to analyze the transcription of semi-structured interviews. Two triangulated  
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6  
7 methods will be used to improve qualitative accuracy and validity: methods and analyst  
8  
9  
10 triangulation,[94-98]. Method triangulation will be achieved by determining the consistency of  
11  
12  
13 the data generated by both the survey and the semi-structured interviews. Analyst triangulation  
14  
15  
16 will be attained using multiple analysts (raters) to review and evaluate the qualitative data. Once  
17  
18  
19 transcribed, the text will be analyzed in two steps, (1) inductive followed by (2) deductive  
20  
21  
22 content analysis. Each step has three phases: preparation, organizing, and reporting,[99-102].  
23  
24  
25  
26  
27 Two bilingual raters will conduct the content analysis. The analyses, integration, and  
28  
29  
30 interpretation will be in Spanish.  
31  
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35 Inductive content analysis will examine how families (advanced cancer patients and their  
36  
37  
38 informal caregivers) define CASA and communication skills training concepts. During the  
39  
40  
41 preparation phase, raters will familiarize themselves with the text. The data will be organized  
42  
43  
44 through open coding, creating categories, abstractions, and identifying the concepts' boundaries  
45  
46  
47 for inductive analysis. Categories will be generated from open coding and grouped under higher-  
48  
49  
50 order headings. Descriptions using content-characteristic words will be created for the  
51  
52  
53  
54  
55 abstraction. The data will be reviewed for deductive content analysis using a structured  
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3 categorization matrix based on the MCP and communication skill model. All data will be  
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6  
7 reviewed for content and coded for correspondence, exemplifying the categories' categorization  
8  
9  
10 matrix.

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12  
13  
14 **Integration Phase.** In cultural adaptation, the source text is rewritten in the target language to  
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16  
17 convey the concepts and achieve the aims of the source text, while accounting for both language  
18  
19  
20 and cultural considerations,[103]. The cultural adaptation not only renders the text of written  
21  
22  
23 materials into another language but also infuses culturally relevant context and themes,[103-  
24  
25  
26  
27 105]. The cultural expert (NTB), group of mentors (EC, MS, RCM, GP, and LP), and  
28  
29  
30 collaborators (CZ, MC, and WB) will conduct the integration of the quantitative and qualitative  
31  
32  
33 findings to develop the CASA fixed protocol (Table 1). The text will be independently reviewed,  
34  
35  
36 followed by "consensus meetings" to discuss every session of the intervention, provide feedback,  
37  
38  
39 and discuss further modifications until a consensus is reached. Dr. Guillermo Bernal will then  
40  
41  
42 review the text to ensure the adaptation considers the dimensions of the Ecological Validity  
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44  
45 Model. The adaptations will be highlighted, and comments will be kept in the margin. Fidelity of  
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51 “Caregivers-Patients Support to Latinx coping advanced-cancer” concepts, goals, and theoretical  
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4 model will be preserved during the adaptation process to ensure language, metaphor, strategy,  
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6  
7 cultural context, and value acceptability by Latinx families.  
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10  
11 As shown with the transcreation of CASA intervention for Latinx we will include information of  
12  
13  
14 Latinx living in Puerto Rico and New York, the adaptation plan for Latinx families will also  
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16  
17 include content modification, family congruence through metaphors and assignments, and  
18  
19  
20  
21 cultural adaptation notes with findings from the cultural adaptation process guidelines about the  
22  
23  
24  
25 delivery of the intervention to the dyad.  
26  
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## 28 29 **Summary**

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32 Once the fixed protocol of CASA is acceptable, feasible, and effective, we will finalize the  
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34 development process with an Efficacy Trial (ORBIT: Phase III) and later Effectiveness Research  
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36 Trial (ORBIT: Phase IV). This process will facilitate the development of culturally sensitive  
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38 intervention and mitigate the cost of developing effective and durable behavioral treatment. All  
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40 the identified phases currently bring the needed elements to go from ideas to efficacy trial with a  
41  
42 well-defined pathway for doing it. Specifically, the proposed behavioral intervention framework  
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44 pushes the identified need to sight on the chain of evidence needed to support the progressive  
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46 program of intervention development. Finally, the recognized framework is flexible in both the  
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48 design and methodologies for treatment development, which facilitates development,[67].  
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## 53 54 **Strengths and weaknesses/ limitations of the study**

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4 The first limitation is that the qualitative interviews are the main source of information for the  
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7 adaptation. Thus, we will include observation of sessions in the next phases of adaptation process  
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10 (Phase IIa: Proof-of-Concept and Phase IIb: Pilot study). Second, patients were predominantly  
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12  
13 recruited from Puerto Rico. Thus, the results may not generalize to all Latinx, and future studies  
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16 will include samples from different geographical locations. Third, the selection of patients was  
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19 not homogeneous in terms of diagnosis and stages, and patients with stages III and IV cancer  
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22 will be invited to participate. The cancer experience of patients and caregivers at different  
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25 disease stages with different prognoses could vary significantly. In future studies, analyses  
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28 should be stratified by stage and prognosis. The final identified limitation is the access to  
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31 technology. Thus, we will include the possibility of conducting the questionnaire and  
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34 intervention in person.  
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### 41 **Public Involvement Statement**

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44 The public, specifically Latinx advanced cancer patients and their informal caregivers, are at the  
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47 core of the implementation plan. The study's objective is to develop the first psychosocial  
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50 patient-caregiver intervention that supports Latinx advanced cancer patients and their informal  
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53 caregivers to cope with cancer. The study design mentioned above will constantly include the  
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56 consultation of patients' and their informal caregivers' perceptions, experiences, and opinions to  
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3 refine a successful final version of “Caregivers-Patients Support to Latinx coping advanced-  
4 cancer” (CASA). The intent is to involve the patients and their informal caregivers (the public),  
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6  
7 who will be the target user in the development and cultural adaptation of the patient-caregiver  
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10 psychological intervention (ORBIT: Phase IIa: Proof-of-Concept and Phase IIb: Pilot study).  
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15 Further, the proposed project will directly (1) impact the Latinx community, (2) contribute to the  
16 development of culturally adapted psychosocial interventions, (3) be used in the healthcare field,  
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18 and (4) reduce disparities in access to psychosocial interventions for Latinx advanced cancer  
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20 patients.  
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## 24 25 **Ethics and Dissemination**

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28 This project is the first development of a culturally and linguistically adapted intervention for  
29 Latinx families coping with advanced cancer. The results of this adaptation plan will guide the  
30 specific dyadic intervention for advanced cancer patients and caregivers. It will advance the field  
31  
32 of cultural adaptation of psychosocial interventions in the medical field to reduce health  
33  
34 inequalities. Furthermore, it will result in peer-reviewed publications, conference presentations,  
35  
36 and reports. The information will also be shared with non-academic community members  
37  
38 involved in outreach activities; i.e., "Hablemos de Cáncer," *El Puente (The Bridge)*, newsletters,  
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40 and social media; i.e., "Yo Puedo," of the Support Group of American Cancer Society in Puerto  
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42 Rico.  
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## 50 51 **Figure 1 Legend**

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

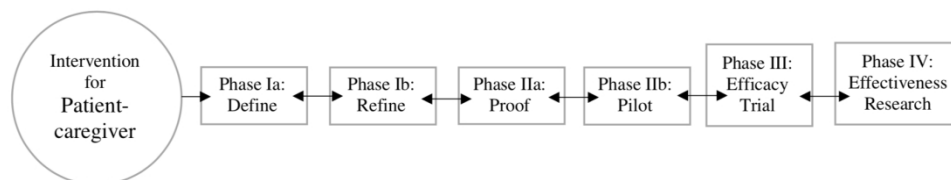


Figure 1

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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