“Adaptation of Ca-HELP Intervention in Rural Geriatric Cancer Patient Population”

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TITLE: Ca-HELP Intervention in Rural Geriatric Cancer Patient Population

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Confidentiality Statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from WCM.

Maury Regional Medical Center

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Institution Name

Planetree

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Institution Name

Megan Johnson Shen, PhD	Megan Johnson Shen	04-25-2019
Principal Investigator's Name	**Principal Investigator's Signature**	**Date**

List of Abbreviations

AE	Adverse Event
Ca-HELP	Cancer Health Empowerment for Living without Pain
CFR	Code of Federal Regulations
CRF	Case Report Form
CTSC	Clinical Translational Science Center
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRBFA	Human Research Billing Analysis Form
HUD	Humanitarian Use Device
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M-PACE	Method for Program Adaptation through Community Engagement
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
UIRTSO	Unanticipated Problem Involving Risks to Subjects or Others
WCM	Weill Cornell Medicine

1. Protocol Summary

Full Title:	Ca-HELP Intervention in Rural Geriatric Cancer Patient Population
Short Title:	Ca-HELP Intervention
Principal Investigator:	Megan Shen, PhD
Study Description:	The proposed study will involve our multi-stakeholder team of researchers, patients, and rural setting healthcare providers and administrators to conduct critical groundwork needed to inform adaptation of the Ca-HELP intervention in rural settings.
Sample Size:	***No participants will be enrolled or recruited at WCM*** **Phase 1:** Geriatric Cancer Patients: N=10 Caregivers: N=10 Providers: N=10 **Phase 2:** Geriatric Cancer Patient: N=30
Enrollment:	***No participants will be enrolled or recruited at WCM*** **Phase 1:** Geriatric Cancer Patients: Enroll 10, Screen 40 Caregivers: Enroll 10, Screen 40 Providers: Enroll 10, Screen 30 **Phase 2:** Geriatric Cancer Patients: Enroll 30, Screen 110
Study Population:	Geriatric Cancer Patients; Caregivers of Geriatric Cancer Patients; Providers of Geriatric Cancer Patients
Enrollment Period:	**Phase 1:** 2 months **Phase 2:** 3 months
Study Design:	**Phase 1:** Semi-Structured qualitative feedback interview **Phase 2:** Pre-Post Intervention Study
Description of Sites/ Facilities Enrolling Participants:	Maury Regional Medical Center will be recruiting all participants. WCM and Planetree will be analyzing the data.
Study Duration:	July 1, 2022 *Projected end date for the completion of the study (including data analysis).*
Participant Duration:	**Phase 1:** 1 day **Phase 2:** 1 year

Primary Objective:	**Phase 1:** To adapt the Ca-HELP intervention for use with older adults with cancer in rural settings. This intervention adaptation will be informed by: (1) social-cognitive theory; (2) mixed methods analysis; and (3) semi-structured interviews from key stakeholder groups including patients, caregivers, and providers and hospital administration staff in rural clinic settings. **Phase 2a:** To evaluate the feasibility and acceptability of the adapted Ca-HELP intervention among older adults with cancer in rural clinic settings. **Phase 2b:** To test the preliminary efficacy of the Ca-HELP intervention adaptation on older adults with cancer to improve pain self-management (primary outcome) as well as pain misconceptions; self-efficacy to communicate with their physicians regarding pain severity, pain-related impairment, and pain severity (secondary outcomes).
Secondary Objectives:	Not applicable
Exploratory Objectives:	Not applicable
Endpoints:	**All Phases: Demographics** will be measured via self-report assessing: age, gender, race, ethnicity, marital and parental status, employment status, education, income, religious affiliation, and insurance coverage. **Clinical variables** will be assessed using records from medical charts and will include the following: cancer diagnosis and stage, treatment received, co-morbid conditions, and Karnofsky performance status.[15] **Phase 2a**: **Feasibility** will be assessed by accrual rates and rate of intervention completion. **Acceptability** will be assessed with Likert scale and a semi-structured interview assessing perceived helpfulness, satisfaction, usability, readability, and intervention impact. **Treatment fidelity** will be assessed with a checklist that captures whether session content was delivered and appropriate techniques were utilized. **Phase 2b: Pain self-management** will be measured using two items from the pain management subscale of the Chronic Pain Self-Efficacy scale.[11] **Pain misconceptions** will be assessed using the 11 items based on the SBQ.[16] **Self-efficacy** for communicating with physicians about pain severity will be assessed using the 5-item Perceived Efficacy in Patient-Physician Interactions scale[17] as modified to refer to communication with oncologists.[11] **Pain-related impairment** will be measured using the 6-item Medical Outcomes Study (MOS) Pain Impairment Scale.[18] **Pain severity** will be assessed as the mean of the average and worst pain over the past two weeks on a 0 to 10 scale (0 = no pain and 10 = worst pain imaginable).[11]

1.1 Study Objectives

1.1.1 Objectives

Phase 1: To adapt the Ca-HELP intervention for use with older adults with cancer in rural settings. This intervention adaptation will be informed by: (1) social-cognitive theory;[12,13] (2) mixed methods analysis; and (3) semi-structured interviews from key stakeholder groups including patients, caregivers, and providers and hospital administration staff in rural clinic settings.

Phase 2a: To evaluate the feasibility and acceptability of the adapted Ca-HELP intervention among older adults with cancer in rural clinic settings.

Phase 2b: To test the preliminary efficacy of the Ca-HELP intervention adaptation on older adults with cancer to improve pain self-management (primary outcome) as well as pain misconceptions; self-efficacy to communicate with their physicians regarding pain severity, pain-related impairment, and pain severity (secondary outcomes).

1.1.2 Hypotheses / Research Questions

Hypothesis Phase 2a: To evaluate feasibility, ≥70% of participants will meet the benchmark for feasibility defined by participant retention and adherence to the intervention.

Hypothesis Phase 2b: To evaluate acceptability, ≥70% of participants will meet the benchmark for acceptability defined by responses on self-report measures of perceived helpfulness, satisfaction, and impact.

Hypothesis Phase 2c: We hypothesize that the intervention will reduce patients' pain misconceptions, pain-related impairment, and pain severity and improve pain self-management and self-efficacy to communicate about pain with their physicians.

2. Background and Significance

Effective pain management is one of the largest population health problems among older adults in the U.S.[1-8] Older adults living in rural areas are disproportionately affected due to the following factors: less access to care,[4] patients' concerns around the over-use of pain medication,[3] and patients' preferences for non-pharmacological interventions.[6] Among the growing older adult population in the U.S.—under treated cancer pain is very common.[7,9] ***There is an urgent need for pain management interventions that can be implemented effectively among these vulnerable communities****.*

The Cancer Health Empowerment for Living without Pain (Ca-HELP) is an evidence-based communication tool that empowers and engages patients to communicate effectively with their physicians about pain.[10,11] The Ca-HELP intervention is rooted in social-cognitive theory[12,13] which posits that behavior change and maintenance depends largely on individuals' ability and self-efficacy to execute a specific behavior. Ca-HELP coaches patients to ask questions, make requests, and signal distress to their physicians in order to achieve improved pain control. Previous research indicates significant improvement among cancer patients in their self-efficacy to communicate about their pain to their oncologists and reductions in pain misconceptions and pain-related impairment.[11] Although a promising tool among geriatric cancer patients, Ca-HELP is not currently designed for optimal dissemination in rural settings.

3. Study Design and Methods

3.1 Overall Design

No participants will be recruited or enrolled at WCM, all recruitment and enrollment will be at Maury Regional Medical Center under their approved IRB.

Phase 1: Patients, caregivers, and providers will first provide informed consent. Next, we will provide participants with drafts of intervention workbook content to review. We will then conduct semi-structured qualitative interviews in-person or over the telephone with 10 geriatric cancer patients, 10 informal caregivers, and 10 providers in which they will answer questions about how they might use the intervention workbooks, the clarity and readability of the workbooks, and the feasibility and utility of the structure of the intervention (e.g., number of sessions, session frequency). Additionally, participants will be probed about necessary modifications in order to make the Ca-HELP intervention workbook content appropriate for the geriatric cancer patient population. As outlined in the research strategy, this feedback will be obtained through semi-structured interviews, through a steering committee, and through implement the un-adapted program to obtain recommendations for necessary change. Patients, caregivers and providers will be compensated with $35.00 for their participation.

Phase 2: Patients and caregivers will first provide informed consent and then will be administered pre-intervention study surveys over the telephone. They will then participate in the intervention in person or over the telephone, depending on the recommended results from completion of Aim 1. Following intervention completion, post-intervention study surveys will be administered over the telephone. Study staff will extract data (e.g., disease stage, etc.) from the electronic health record. Patients will be compensated with $25.00 for completing pre-intervention assessments and $25.00 for completing post-intervention assessments.

The following steps will be taken to minimize participant burden. First, significant effort will be made to coordinate in-person study contacts (e.g., to provide information on the study and administer informed consent) with existing appointments to minimize the number of trips to Maury Region Medical Center required of participants. Second, with the participant's permission, these study visits (for Aim 1) can be conducted during scheduled chemotherapy infusions (if applicable, as some cancer patients will not be receiving chemotherapy). Chemotherapy infusion appointments are often long (multiple hours) and patients are unable to leave the clinic during the appointment. In a previous R01 study (Co-I: Dr. Shen) of psychosocial distress in adults with advanced cancer, patients often elected to conduct research meetings during infusion appointments to provide activity during the appointment and reduce the overall time spent at the hospital. Prior to conducting visits during infusion appointments, participants will be reminded that infusion clinics are often not private and their permission to conduct the visit during infusion will be obtained. Participants will also be informed that they can discontinue at any time if they become uncomfortable due to the setting. If participants are not comfortable conducting visits during infusion appointments, separate appointments will be scheduled in person or over the telephone. Similar measures will be taken to reduce the burden on caregivers participating in this study and all efforts will be made to coordinate study visits during times when they are already at the hospital with the patient. Third, participants will be given the option to complete the semi-structured interviews for Aim 1 over the telephone and administration of all study measures for Phase 2 will occur in person or over the telephone, depending on patient preference. This method will eliminate the need for participants to travel to the clinic to complete study measures. Finally, intervention sessions may be conducted over the telephone with patients, depending on the results of Phase 1 and preferences of the patient

population. Telephone delivery may allow patients to participate in the intervention without traveling to the clinic multiple times for intervention sessions.

3.2 Interviews, Focus Groups, Surveys, and/or Observations
No participants will be recruited or enrolled at WCM, all recruitment and enrollment will be at Maury Regional Medical Center under their approved IRB.

A. Administration

- *Timing and Frequency*
  Phase 1: 1 interview
  Phase 2: Pre-interview/Baseline assessment, intervention call, and post assessment each approximately 1 week apart for a total of 3 weeks.
- *Location*
  All phases: Telephone interview at a convenient location to the participants. Cancer patients may opt to have their interview(s) during infusion at Maury Regional Medical Center
- *Procedures For Audio And Visual Recording*
  Not Applicable
- *Person Identifiers*
  Clinical variables will be collected from medical records and will include the following: cancer diagnosis and stage, treatment received, co-morbid conditions, and Karnofsky performance status.

B. Study Instruments

All Phases: **Demographics** will be measured via self-report assessing: age, gender, race, ethnicity, marital and parental status, employment status, education, income, religious affiliation, and insurance coverage. **Clinical variables** will be assessed using records from medical charts and will include the following: cancer diagnosis and stage, treatment received, co-morbid conditions, and Karnofsky performance status.[15]

Phase 2a: **Feasibility** will be assessed by accrual rates and rate of intervention completion. **Acceptability** will be assessed with Likert scale and a semi-structured interview assessing perceived helpfulness, satisfaction, usability, readability, and intervention impact. **Treatment fidelity** will be assessed with a checklist that captures whether session content was delivered and appropriate techniques were utilized.

Phase 2b: **Pain self-management** will be measured using two items from the pain management subscale of the Chronic Pain Self-Efficacy scale.[11] **Pain misconceptions** will be assessed using the 11 items based on the SBQ.[16] **Self-efficacy** for communicating with physicians about pain severity will be assessed using the 5-item Perceived Efficacy in Patient-Physician Interactions scale[17] as modified to refer to communication with oncologists.[11] **Pain-related impairment** will be measured using the 6-item Medical Outcomes Study (MOS) Pain Impairment Scale.[18] **Pain severity** will be assessed as the mean of the average and worst pain over the past two weeks on a 0 to 10 scale (0 = no pain and 10 = worst pain imaginable).[11]

4. Study Design

4.1 Study Population

Patient subjects with a cancer diagnosis who meet the inclusion and exclusion criteria will be eligible for this study. Caregivers and Providers who meet the inclusion and exclusion criteria will be eligible for the study. Providers will include social workers, nurses, oncologists, and healthcare administrators.

4.2 Inclusion Criteria

Patients:

1. 65 years of age or older
2. Diagnosed with cancer
3. English speaking
4. Resides in non-institutional, rural settings
5. Receives care at a community-based clinic in a rural area
6. Ability to provide informed consent
7. Have an identified informal Caregiver

Caregivers:

1. Person (family member or friend) whom the patient indicates provides most of their informal care
2. Ability to provide informed consent

Providers:

1. Currently works with geriatric cancer patients
   OR
2. Currently works in a healthcare system serving geriatric cancer patients

4.3 Exclusion Criteria

Patients:

1. Severe cognitive impairment (Short Portable Mental Status Questionnaire<6)
2. Receiving hospice at time of enrollment

Caregivers and Providers: None

4.4 Strategies for Recruitment and Retention

No participants will be recruited or enrolled at WCM, all recruitment and enrollment will be at Maury Regional Medical Center under their approved IRB.

A total of 40 geriatric cancer patients will be recruited across both phases once they have been identified by research and medical staff and confirmed to meet eligibility criteria. Based on prior work with cancer patient populations in rural clinic settings, we conservatively estimate that 50% of the approached patients (n=160) will be eligible to participate and consent to participate (n=80). Caregivers of these patients will then be screened for eligibility (for Phase 1). Based on current work by the study team on cancer caregivers, we estimate that 50% of approached caregivers will be eligible and consent to participate (n=40), ensuring we hit our recruitment goal of n=10 caregivers for Phase 1. Thus, in total, 40 geriatric cancer patients and 10 informal, unpaid caregivers will participate in this study. Finally, we seek to recruit 10 oncology providers working within rural settings with the geriatric cancer patient population. In prior studies, our recruitment rates of providers have been in line with prior provider-based studies (35-50%). Thus, we conservatively estimate an accrual rate of 35%.

To recruit patients (Phase 1 and 2): Research staff will review the electronic health record to identify potentially eligible patients and will contact the treating physician to confirm initial eligibility and obtain permission to approach these patients about the study. Patients approved for contact by the treating physician will be approached in clinic or sent a letter in the mail that includes a brief description of the study and contact information of study staff. Research staff will meet these patients in the clinic, introduce themselves, and provide the patient with a study information sheet and consent form. Patients who indicate they want to participate will be consented at that time or provided a pre-paid postmarked return envelope in which to return the consent form and contacted within one week via telephone for follow-up. Patients who study staff are unable to meet during clinic appointments will be contacted by study staff over the telephone and will be provided with information on the study and administered informed consent. Once consented, participants will be enrolled in the study.

To recruit caregivers (Phase 1 only): After an eligible patient agrees to participate, we will approach his/her designated informal caregiver to participate as well. If the caregiver is present during the patient's clinic appointment, study information will be provided at that time. If the caregiver is not present, study staff will contact the caregiver over the telephone. We will provide caregivers with information about the study, address any questions or concerns they may have, obtain consent for participation, and enroll them in the study.

To recruit providers (Phase 1 only): The MPIs will send an introductory email to providers working the participating site (Maury Regional Medical Center) as well as listservs of professional societies and networks of study team members requesting that interested providers contact the study team who meet inclusion criteria (i.e., working with geriatric cancer patients in rural clinic settings). Providers who express interest will be contacted by the team and provided with information about the project and its potential risks and benefits. Providers who indicate an interest in participating will be consented.

Phase 1 participants will be compensated $35.00 for their participation. Phase 2 participants will be compensated $25.00 for completing pre-intervention assessments and $25.00 for completing post-intervention assessments.

5. Registration Procedures

5.1 Subject Registration (WCM only)

Subjects will be not be registered within the WRG-CT as per the standard operating procedure for Subject Registration because subject enrollment will be at and under the IRB of Maury Regional Medical Center.

5.2 Subject Registration (Sub-sites)

Not applicable

6. Study Procedures

6.1 Schedule of Assessments

Table 1. Schedule of trial events

	Phase 1		Phase 2				All Phases
	Pre-Study	Visit 1	Pre-Study	Wk 1	Wk 2	Wk 3	Off Study
Informed consent	X		X				
Review of Intervention Draft		X					
Qualitative Interview		X					
Demographics		X		X			
Clinical Variables							X
Intervention					X		
Feasibility				X		X	
Feasibility				X		X	
Treatment Fidelity				X		X	
Pain Self-Management				X		X	
Pain Misconceptions				X		X	
Self-efficacy for communicating w/physicians about pain severity				X		X	
Pain-Related Impairment				X		X	
Pain Severity				X		X	
Intervention					X		

7.0 Data Reporting / Regulatory Considerations

7.1 Data Collection

Data will be collected and stored at Maury, on their secured servers on password protected computers under their IRB protection. Only de-identified data will be shared with Planetree and WCM, and will not include PHI or MRNs. etc. All data will be stored on secure servers on password protected computers. Only IRB approved study staff will have access to these data.

7.1.1 REDCap

Not Applicable

7.2 Regulatory Considerations

7.2.1 Institutional Review Board/Ethics Committee Approval

As required by local regulations, the Investigator will ensure all legal aspects are covered, and approval of the appropriate regulatory bodies obtained, before study initiation.

Before initiation of the study at each study center, the protocol, the ICF, other written material given to the patients, and any other relevant study documentation will be submitted to the appropriate Ethics Committee. Written approval of the study and all relevant study information must be obtained before the study center can be initiated or the IP is released to the Investigator. Any necessary extensions or renewals of IEC/IRB approval must be obtained for changes to the study, such as amendments to the protocol, the ICF, or other study documentation. The written approval of the IEC/IRB together with the approved ICF must be filed in the study files.

The Investigator will report promptly to the IEC/IRB any new information that may adversely affect the safety of the subjects or the conduct of the study. The Investigator will submit written summaries of the study status to the IEC/IRB as required. On completion of the study, the IEC/IRB will be notified that the study has ended.

Neither the Investigator nor BMS will modify or alter this protocol without the agreement of the other. All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional IEC/IRB for approval before implementation, as required by local regulations. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

Once protocol amendments or consent form modifications are implemented at the lead site, Weill Cornell Medicine, updated documents will be provided to participating sites. Weill Cornell Medicine must approve all consent form changes prior to local IRB submission.

Relevant study documentation will be submitted to the regulatory authorities of the participating countries, according to local/national requirements, for review and approval before the beginning of the study. On completion of the study, the regulatory authorities will be notified that the study has ended.

7.2.2 Ethical Conduct of the Study

The Investigators and all parties involved should conduct this study in adherence to the ethical principles based on the Declaration of Helsinki, GCP, ICH guidelines and the applicable national and local laws and regulatory requirements.

This study will be conducted under a protocol reviewed and approved by the applicable ethics committees and investigations will be undertaken by scientifically and medically qualified persons, where the benefits of the study are in proportion to the risks.

7.2.3 Informed Consent

The investigator or qualified designee must obtain documented consent according to ICH-GCP and local regulations, as applicable, from each potential subject or each subject's legally authorized representative prior to participating in the research study. Subjects who agree to participate will sign the approved informed consent form and will be provided a copy of the signed document.

The initial ICF, any subsequent revised written ICF and any written information provided to the subject must approved by IRB prior to use. The ICF will adhere to IRB/IEC requirements, applicable laws and regulations.

Informed Consent will occur under the IRB of Maury Regional Medical Center.

7.2.4 Compliance with Trial Registration and Results Posting Requirements

Under the terms of the Food and Drug Administration Modernization Act (FDAMA) and the Food and Drug Administration Amendments Act (FDAAA), the Sponsor-Investigator of the trial is solely responsible for determining whether the trial and its results are subject to the requirements for submission to http://www.clinicaltrials.gov. Information posted will allow subjects to identify potentially appropriate trials for their disease conditions and pursue participation by calling a central contact number for further information on appropriate trial locations and trial site contact information.

7.2.5 Record Retention

Essential documents are those documents that individually and collectively permit evaluation of the study and quality of the data produced. After completion of the study, all documents and data relating to the study will be kept in an orderly manner by the Investigator in a secure study file. Essential documents should be retained for 2 years after the final marketing approval in an ICH region or for at least 2 years since the discontinuation of clinical development of the IP. In addition, all subject medical records and other source documentation will be kept for the maximum time permitted by the hospital, institution, or medical practice.

8. Statistical Considerations

We will employ thematic analysis using an iterative process for all qualitative analyses.[19-23] **Phase 1.** Data coding and analysis will be informed by a responsive interviewing model in which data units are combined based on the theme they represent.[24] Trained raters will independently review the transcripts and identify passages that include suggestions for modifications to the intervention. Raters will categorize and discuss themes, and make revisions until consensus is reached. Identified themes will inform modifications to the intervention. **Phase 2a.** Feasibility and acceptability will be examined by conducting frequency and descriptive statistics (i.e., mean, median, standard deviation, range) for enrollment rates, number of sessions completed, number of weeks required to complete the intervention, and Likert-scale items assessing satisfaction with the intervention and perceived helpfulness. **Phase 2b.** Aim 3 will be addressed using a pre-post design. To determine the degree to which the Ca-HELP intervention is likely to improve patient outcomes, a post-versus-pre- difference will be sought to estimate the change in patients' outcomes (e.g, pain self-management). **Missing data.** To reduce missing data, study staff will conduct interviews rather than relying on written self-reports. All missing data will be assessed for missingness (e.g., random or non-random) and appropriate imputation methods will be used.

9. Adverse Event Reporting Requirements

Not Applicable – No subjects will be enrolled at WCM.

10. Unanticipated Problems Involving Risks to Subjects or *Others*

Not Applicable – No subjects will be enrolled at WCM

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