

The R4R Advance Care Planning Pilot Study (R4RACP)
NCT06129149
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A. Specific Aims and Hypothesis

Long-term objectives and goals. Vanderbilt University School of Nursing (VUSN) partnered with aand Urban Housing Solutions (UHS) – the second largest provider of affordable housing in Nashville - are partners with the long-term goal of reducing health disparities among medically-underserved UHS residents in Nashville. This partnership is developing resiliency hubs that will provide essential services and support within a communal setting at the housing facility. Within the context of this partnership, we are collecting preliminary data showing that UHS residents lack information about and access to advance care planning (ACP), which specifies their **healthcare** wishes during cognitive incapacitation or end-of-life, and nationwide, research shows significant disparities regarding ACP participation among low-income populations. The short-term goal of the proposed work is to pilot test a single-arm, pre-post intervention to assess the initial efficacy and implementation outcomes of a trauma-informed care (TIC)-adapted ACP intervention to improve learning and communication for times of decisional incapacity among UHS residents, within the context of a resiliency hub model. This is a necessary first step for developing a long-term research portfolio dedicated to addressing ACP disparities and promoting equitable end-of-life planning among low-income, medically-underserved populations. The PI is an early-stage, postdoctoral-level researcher and this work would be the first opportunity to pilot this work as PI, in preparation for future studies of the efficacy and implementation of this **novel intervention** with staff, resident peers, residents, and caregivers.

Specific aims:

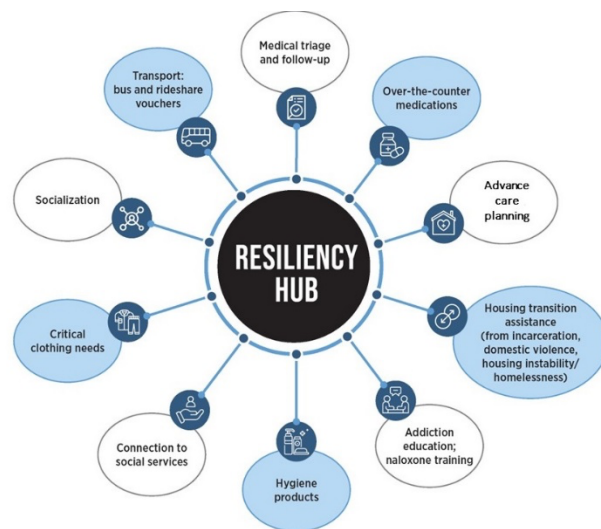
Aim 1. Pilot test a TIC-adapted ACP intervention with UHS residents in an affordable housing-located resiliency hub for initial efficacy, based on outcomes of ACP values/beliefs, processes (e.g., looking up ACP information), and actions (e.g., advance directive completion, family conversations about life-sustaining measures). We will enroll a cohort of UHS residents (n=30) to assess baseline ACP status, Adverse Childhood Experiences, and previous death-related experiences and deliver an intervention that is sensitive to past trauma following a novel standardized ACP checklist developed from a narrative synthesis of ACP conversation guides [1]. *H1. We hypothesize the intervention will decrease misconceptions about ACP (ACP values/beliefs), increase ACP processes, and increase ACP actions (e.g., advance directive completion, family conversations about life-sustaining measures).*

Aim 2. Assess intervention acceptability, appropriateness, and feasibility among residents and preliminary barriers and facilitators to implementation. Anticipated barriers and facilitators may include identifying peers and staff to facilitate ACP discussions; document management and retention; dedicating time and space to intervention delivery vs. addressing critical social determinants of health (e.g., transportation, food, healthcare), and long-term decisional support as ACP preferences change with life and health events. In addition to the residents completing a brief implementation outcomes survey, we will hold audio-recorded 15-minute debriefs with residents following the intervention to assess process concerns and barriers and facilitators. *H2: We hypothesize that UHS residents (n=30) will find the intervention to be acceptable, appropriate, and feasible.*

B. Background and Significance

Urban Housing Solutions (UHS) a non-profit organization, is the second-largest affordable housing provider in Nashville and provides housing for over 1,000 residents on a sliding scale (30% of income) [2]. VUSN has partnered with UHS since 2012 and this experience has shown that UHS residents have little access to preventative, community-based healthcare and continue to experience other resource deficits (e.g., transportation, food, and communication technology). To address this need for more sustainable solutions to multiple and overlapping insecurities, Dr. Christian Ketel and Dr. Kate Clouse from VUSN, along with UHS, have created the Resources for Resiliency (R4R) study to develop resiliency hubs within communal settings at UHS properties. These hubs (**Figure 1**) will feature critical resources and referrals that residents need in everyday life. ACP is a critical component of comprehensive resiliency-hub model to facilitate timely, patient-centered discussions on what matters most **during times of decisional incapacity** for this disenfranchised population. Within this context, through the support of the two-year PROGRESS T32 program, Dr. Kimpel (PI of the proposed work) currently is collecting critical preliminary

Figure 1. Resiliency hub model



data about the prevalence of ACP completion and knowledge among UHS residents (n=200), as well as important potential factors that may influence ACP completion (Adverse Childhood Experiences). While this preliminary work will inform the initial development of the proposed ACP intervention, it does not include testing the intervention for initial efficacy and implementation outcomes of a pilot intervention in this setting, which is why **this funding opportunity is a critical next step of this research**. Through this pilot study, in collaboration with UHS, we will conduct essential preliminary research to develop this ACP intervention. **This work is significant** because we are directly targeting an important healthcare disparity that is often overlooked: the right to plan for times of cognitive incapacity. Research nationwide shows that adults with limited income are less likely to complete any ACP (26-33%) compared with those with high income [3, 4]. Optimal ACP is a life-long, iterative process of learning and communication about healthcare preferences for times of decisional incapacity for patients and caregivers. When equitably implemented, patients and families learn about life-sustaining care options (e.g., CPR), clarify values and preferences (e.g., Do Not Resuscitate), prepare for in-the-moment decision-making during health crises, and participate in formal and informal documentation and discussion [5]. Despite this aim, typical ACP, if it happens at all, consists of superficial discussions, incomplete documentation, and little awareness or attention to the possibility of triggering trauma from previous death-related experiences, leading to poorer patient, caregiver, and provider outcomes. ACP barriers for this population include the competing priorities of unmet basic needs, lack of ACP knowledge, limited social support, medical mistrust, and insufficiently trained clinical staff, which is why community-based ACP is so essential to facilitate early and continued learning and education [6, 7]. Early intervention is even more crucial for this population given the profound, negative health and healthcare consequences from chronic stress (e.g., early mortality) [3, 4, 7-17]. While UHS has made important strides to facilitate service connections, the services available are insufficient to support ACP in the proposed population, which makes this a **novel setting for ACP intervention** [6, 18]. Based on the PI's previous qualitative work and literature [6, 18-20], ACP is a stressful process and successful implementation with this population may depend on previous trauma (childhood experiences and previous death-related experiences). This work represents an **innovative adaptation using principles of trauma-informed care** [21]. Additionally, to our knowledge, such adaptations have yet to be explored in this **novel** affordable housing context. This **work is significant** because it will inform a larger future study that has the potential to positively **impact equitable, patient-centered, and timely healthcare**. During and after a crisis, when ACP does not happen, caregivers and other social supports may experience additional decisional conflict, emotional distress, and prolonged grief [5]. Patients from disadvantaged background are likely to experience lower-quality end-of-life care, including unnecessary hospitalizations, little to no palliative care, and hospital deaths when home deaths are often preferred [22]. The overarching goal of this research is to positively **impact** patients with the dignity of choice and will support future studies that aim to reduce the harmful outcomes resulting from this disparity.

C. Preliminary Studies

During the summer of 2020, Dr. Kimpel conducted five qualitative interviews with Nashville affordable housing specialists to hone the approach for her dissertation study protocol and learn more about the population of interest. Following her dissertation, she identified that structural, life-stage, and social stressors and resources strongly influence individual stress responses and ACP motivation, which in turn affects ACP preferences and practices (**Figure 2**). The findings also emphasized the importance of trust and a general history of disenfranchisement. This finding reinforced the plan to use trusted

community partnerships, face-to-face study interactions to promote rapport, and emphasized the investigator's reliance on participant expertise to fuel the proposed study. Resident illiteracy was also major finding from these interviews and influenced the choice of investigator-administered study instruments. This work informed variable selection for the ongoing R4R study (September 2023–June 2025): healthcare access and quality, resilience, coping, and adverse/positive childhood experiences. Dr. Kimpel is serving as a Co-Investigator on the R4R study and overseeing all study ACP measures. After piloting the R4R questionnaire with 15 residents of one of UHS's sites

Figure 2. Conceptual framework of cumulative resources and stressors, individual stress responses, and advance care planning outcomes.



in September 2023, 8/15 (53%) stated they would be “very interested” in a center that provides “end-of-life planning” and 73.3 % (11/15) were “very interested” in a center that provides medical or legal planning. Although eight (53.3%) stated they had heard of ACP before, most respondents (13/15, 86.7%) had not completed an advance directive, only 7/15 (46.7) had informally identified a healthcare decision-maker, 6/15 (40%) had discussed life-sustaining measures and quality of life with family, and only 3/15 (20%) had discussed ACP with their doctor. These numbers underscore the **significant need for adaptive and early intervention** to explore patient planning needs, carefully screen for trauma and adapt approach to trauma needs, and foster appropriate follow-up for patients. The R4R Study preliminary data and procedures will inform ongoing intervention development for this proposed study.

D. Research Design and Methods

D1. Design. We will implement a single-arm, pre-post intervention to test initial efficacy of the intervention (ACP values/beliefs, processes, and actions) with the population of interest (Aim 1) and assess implementation outcomes (barriers and facilitators, resident acceptability, appropriateness, and feasibility) in the affordable housing resiliency hub setting (Aim 2).

D2. Intervention. The intervention will consist of a single one- to two-hour visit wherein the PI (Kimpel) will facilitate a flexible conversational approach with the resident (and, optionally, a healthcare decision-maker) in a quiet, private location in the resiliency hub. The conversation will follow a standardized process of ACP to assess each participant’s unique background with ACP, knowledge needs, explore values, preferences, and goals, and to identify readiness for ACP actions (e.g., AD completion) to evaluate initial knowledge. Over 34 ACP conversation guides have been developed as interventions, but all guides take different approaches that may not comprehensively address patient needs. To facilitate a comprehensive and flexible approach, the PI will create an ACP checklist that is derived from a narrative synthesis of the structure and content of the most prominent ACP conversation guides [1] The overall structure of the ACP checklist for this intervention is portrayed in **Table 1**. The **innovative approach** will include initial and ongoing adaptations of the checklist with TIC principles: safety, trustworthiness and transparency, peer support, collaboration and mutuality, empowerment, and choice, and cultural, historical, and gender issues [23-25]. Adverse Childhood Experiences and previous death-related experiences assessed during baseline data collection will be used to tailor the discussion to carefully explore relevant history to assess resident ACP values, preferences, and goals. Participants will be offered the opportunity to complete an advance directive, but some participants may not be ready for this step, as follow-up questions may arise for additional family, friends, or provider discussion. Following each intervention session, the PI will hold a fifteen- to twenty-minute, audio-recorded discussion to review the intervention for possible adaptations to align it with TIC principles and barriers and facilitators (Aim 2). While peer support will not be used in this intervention, participants will be asked for suggestions of how to involve peers to facilitate the ACP process.

D3. Eligibility. Inclusion criteria for enrollment in the intervention will include an adult (18+) residing in a UHS unit that does not have a completed advance directive and exclusion criteria include inability to provide informed consent or participate in the intervention due to cognitive, auditory, visual impairment or non-English language barrier.

D4. Recruitment and enrollment. We will purposively sample from one of UHS’s properties. Participant selection will start with R4R study participants that communicated interest in future study participation and non-participants that were interested, but unable to participate in the study due to randomized selection. Residents will be contacted by phone, text, or door knocking depending on their communication preference and availability of contact information from the R4R study. If the individual does not answer the door, a letter and flyer will be left at the door with the contact information of the study team. We also will post study flyers in common spaces to advertise the study. **To promote a diverse sample, we will stratify by age (1 are 18 to 39, 14 are 40 to 59, and 15 are 60+), 16-20 identify as Black or African American, and 16-20 identify as male.** If eligible (inclusion criteria are met, and no exclusion criteria are present), the PI or Key Study personnel (KSP) will set a time to meet in person or remotely to

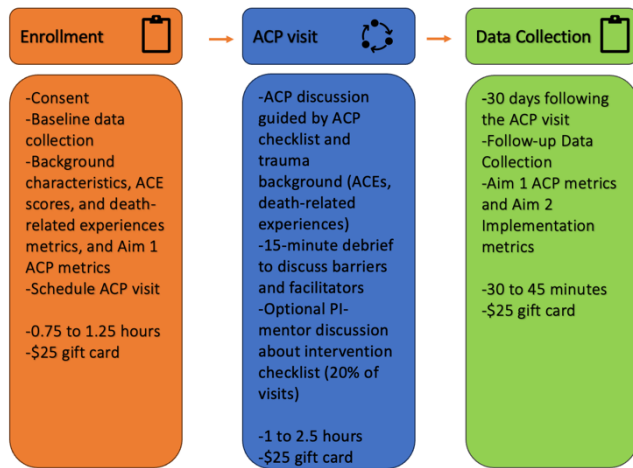
Table 1. Standardized ACP Checklist

ACP Checklist Sections	Main Topics	Sub-Topics
Initiation	<ul style="list-style-type: none"> -Patient readiness -Rapport-building -Introduction to ACP concepts 	<ul style="list-style-type: none"> -Address health status -Assess attitudes and beliefs about future care planning -Obtaining permission to discuss ACP -Establish relationship and trust -Introduce ACP concepts and potential positive effects of ACP -Set up future scenarios -Set expectations for discussion -Reflect on who patient would want to join future conversations
Exploration	<ul style="list-style-type: none"> -Perceptions of illness -Perceptions of living -Beliefs about death and dying -Psychosocial well-being -Decision-making preferences -Involvement of others 	<ul style="list-style-type: none"> -Comprehension of health status and illness -Explore daily life with illness -Explore quality of life meaning -Explore prior experiences of death-related experiences (TIC-adaptation) -Explore hopes for end-of-life experiences -Explore topics of coping, fear, hope, and religion and spirituality around planning for cognitive incapacity or end-of-life -Explore prior experiences with decision-making (TIC-adaptation) -Identify patient’s preferences for who will make the decisions (doctors, family, etc.) -Set goals for different health scenarios -Discuss level of willingness to trade off for a longer time -Explore treatment preferences and other preferences (e.g., dying at home) -Discuss plans for involving family, friends, providers, or other professionals
Action	<ul style="list-style-type: none"> -Summarize -Agreements -Follow-up 	<ul style="list-style-type: none"> -Examine patient understanding of conversation and facilitator’s understanding of preferences -Review major themes from conversation and any points that need clarified -Make recommendations based on conversation, which may include completing paperwork or discussing matters further with family or a provider -Identify surrogate-decision-maker i.e., Healthcare decision-maker) -Write questions down for patient to take to family, friends, or provider to clarify plans -Provide a plan of next steps for patient

complete informed consent and other study procedures. Recruitment flyers and word-of-mouth will be used to raise study awareness.

D5. Data collection procedures.

Figure 3. Study Activities across Three Visits



D5.1 Pre-data collection procedures. During the study team member will inform the candidate that incentives will be given in person and the participant will receive a total of \$75 in physical gift cards for study participation (\$25 for baseline outcome measure completion (Visit 1), \$25 for completion of the 15-20 minute debrief interview (Visit 2), and \$25 for the follow-up data completion at 30-days post-intervention (Visit 3)). If eligible, the study team member will schedule a convenient time to meet with the candidate to complete informed consent prior to data collection, within approximately 14 days of initial contact. During Visit 1: with the participant, electronic consent and any identifier data will be entered directly into REDCap [7]. A signed consent copy will be given to the participant. A unique study ID will be created for the questionnaire procedures and kept separate from any participant identifiers. Consent procedures will take

10 to 30 minutes. Prior to audio-recording the qualitative interview, the PI ask permission to record.

D5.2 Data collection procedures. During Visit 1 and Visit 3, the questionnaire will be administered to each participant in-person by the study team member. For in-person questionnaire administration, a copy of the questions and responses will be available to the participant to reference. The KSP will enter participant responses directly into REDCap using a tablet computer. If internet is inaccessible, responses will be recorded on paper using the participant's study ID. If in-person procedures are not possible, but the participant has access to a computer and internet (i.e., to complete e-consent), and a telephone, interviews will be completed remotely by telephone. The Visit 1 questionnaire procedures will take approximately 45 minutes and the Visit 3 questionnaire of fewer items will take approximately 30 minutes. Qualitative Debrief Interview: The PI will complete the intervention and then commence the 15-20-minute audio-recorded interview using a semi-structured interview guide. This interview will focus on the participant's perceptions of the intervention, any moments of discomfort, stress, or discomfort, and suggestions for how to align the intervention with TIC principles (e.g., how can we make you feel safer during this discussion).

Intervention Fidelity: Members of the PI's mentor team or a peer at the Vanderbilt University School of Nursing will attend a random visit for approximately 20% (6) of the visits to observe the interaction, record conversational content using the ACP checklist, and, after the intervention and debrief visit are complete, will discuss observations with the PI and discuss ongoing adaptations to the checklist to align it with TIC principles.

D5.3 Post-data collection procedures. After each time of data collection is complete, the KSP will facilitate the \$25 gift card incentive as a token of gratitude for each participant's time. This amount is in line with other studies operating at the study site. The study team will audit quantitative data within 1-2 days following data collection to ensure completeness and accuracy. If REDCap data collection was not possible during the interview, quantitative data will be entered into REDCap immediately. A copy of the paper survey will be scanned into the REDCap record, to promote data integrity, and then shredded. We will facilitate data transparency by sharing results with participants per their preference. Audio-recorded data will be professionally transcribed by Rev.com and securely stored.

D6. Limitations. This innovative single-arm, pre-post intervention study will include both qualitative and quantitative methods, gather preliminary data on initial efficacy and implementation outcomes, and will be a vital step for future work adapting our intervention and conducting larger studies assessing the effectiveness within marginalized communities. This study is limited by collecting data from a single arm, which does not allow for between group comparison, however, this approach is appropriate for introductory studies to explore within-group differences in efficacy outcomes and initial acceptability, feasibility, and adaptability of an ACP intervention. Face-to-face data collection methodology is subject to biased responses from social desirability and racial discordance, which will be handled by using trust-building techniques from instrument experts and community-engaged researchers (e.g., using community partnerships for recruitment, framing the participant as the expert informant, and asking for their help) [26, 27]. The mode of in-person, questionnaire delivery will assist participants with health or reading literacy challenges and prevent exclusion of participants with insufficient technology or transport [26]. The intervention delivery within the novel resiliency hub model will enable a safe, private, and supportive setting to explore planning needs and goals. Additionally, the strong community partnership, robust experience of the research team, and

previous research success with this community enable a **rigorous approach that will enable completion of all study activities within the 12-month funding period.**

D7. Instruments and variables.

Validated measures will be used for Aim 1 and the quantitative portion of Aim 2 [28-30]. Background characteristics will include demographics, social determinants of health (PRAPARE-18) [31], Health Literacy (BHLS-3) [32], and anxiety/depression (PHQ-4) [33]. Intervention variables that will be used to shape the TIC adaptation include adverse childhood experiences (ACE-10) [34] and death-related experiences (6 items) [35]. All variables were selected per the relevant ACP, TIC, and Implementation Science literature [23, 30, 36].

E. Statistical Analysis Plan and Sample Size:

Aim 1: Randomly missing item responses within measures will be handled via each measure’s specific scoring protocol. Although minimal missing data are anticipated based on preliminary descriptive research using in-person data collection, missing responses for entire measures will not be assumed random and imputations will not be conducted. Quantitative data analysis will be conducted using SAS or IBM SPSS statistics software and performed by Dr. Kimpel, with additional guidance from Dr. Mary Dietrich, as needed. Descriptive summaries of participant characteristics will be generated to inform the generalizability of our population estimates. Bootstrapped bias-corrected 95% confidence intervals will be generated around the observed sample proportions (categorical data), means (normally distributed continuous), and medians (skewed continuous). We have specified clinically important standards for demonstrating efficacy in Table 1. Frequency distributions summarizing the proportion of participants meeting the standards for demonstrating efficacy at 30-days follow-up will inform whether at least 80% met the standard. Furthermore, we will generate effect statistics with a 90% confidence interval to inform the powering of subsequent work. We will conduct tests of differences between pre and post-intervention ACP scores (e.g., Wilcoxon Signed-Rank Tests) as another preliminary test of the initial effect of the intervention on key outcomes. **Aim 2:** We will statistically and visually describe scores on each implementation measure and compare scores to the benchmarks decided on with our stakeholders as indicating adequate acceptability, appropriateness, and feasibility. **Sample Size Justification and Power:** The primary outcomes of the study are initial efficacy and acceptability, appropriateness, and feasibility of the ACP intervention. To optimize the information gleaned about the intervention, we have by design did not include any “control” condition and have not used a power analysis to motivate sample size. We are justifying our sample size based on the number of participants that we anticipate can reasonably enroll and complete all study measures during the funded period. Furthermore, 30 participants will suffice for generating relative stable parameter estimates of efficacy for informing future work. For the qualitative analysis, thirty interviews will more than suffice to reach data saturation, when no new themes emerge.

Table 2. Study Timeline Over Two Years

	2024				2025			
Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Protocol development								
IRB approval/renewal								
Prepare study database								
Team training								
Purchase gift cards and distribute								
Intervention and data collection								
Data analysis								
Manuscript preparation and dissemination								
Grant development and submission								

Table 2. Key Outcomes

Variable (Measure)	Time Period	Aim	Purpose
ACP Processes: ACP Processes Scale (15-items, 5-point Likert scale (1 = almost never, 5 = almost always, participants rate how often they participate in different ACP processes. Higher summed scores indicate higher participation in ACP processes, e.g., I review my advance care documents so that I know what they say))	Baseline, 30-day follow-up	Aim 1	This scale assesses the frequency of participation in ACP processes. We hypothesize that at 30-day follow-up ≥80% of the participants will endorse ACP process scores as anticipated compared with <80% at baseline. Possible scores: 15-75 Anticipated scores at baseline: <37; at 30-day follow-up: ≥37
ACP Values/Beliefs: ACP Values and Beliefs scale (7-item, 5-point	Baseline, 30-day	Aim 1	This scale assesses ACP misconceptions. We hypothesize

Likert (1=strongly agree, 5=strongly disagree, lower scores=fewer ACP misconceptions)	follow-up		that at 30-day follow-up at least 80% of participants will hold ACP misconceptions as anticipated compared with <80% at baseline. Possible scores: 7-35 Anticipated scores at baseline: <28; at 30-day follow-up: ≥28
ACP Actions: ACP Stages of Change Scale (6-items, 5-point Likert (0=no, not at all, 4=yes, I've done that months or years ago, higher scores on individual items and overall=higher ACP participation)	Baseline, 30-day follow-up	Aim 1	This scale indicates the stage of change (precontemplation to maintenance) that each participant is in for the six core ACP actions/behaviors. We hypothesize that at 30-day follow-up ≥80% of participants will report ACP actions as anticipated compared with <80% at baseline. Possible overall scores: 0-24 Anticipated overall scores at baseline: <14, at 30-day follow-up: ≥14 Possible scores for individual ACP actions: 0-4 Anticipated individual scores at baseline: 0-2, at 30-day follow-up: 3-4
Implementation outcomes: Acceptability (4-item, AIM), Appropriateness (4-item, IAM), and Feasibility (4-item, FIM)	30-day follow-up	Aim 2	Each of these scales indicates participant perceptions of acceptability (agreeableness, appropriateness (good fit), and feasibility (implementability) of the intervention. We hypothesize that 80% of participants will find the intervention to be acceptable, appropriate, and feasible as reflected in the anticipated scores. Possible Scores for each subscale: 5-20 Anticipated scores at 30-day follow-up: 80% of the participants will rate the intervention ≥15 for each of the subscales

F. Literature cited

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