Cover Page

Study Title: Resources for Resiliency (R4R) Advance Care Planning: A pilot study to test a Trauma-Informed Care-adapted advance care planning intervention among affordable housing residents in Nashville

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VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator (PI): Christine Kimpel, Co-I: Kate Clouse, PhD, MPH
Version Date: 8-20-24
Study Title: Resources for Resiliency (R4R) Advance Care Planning: A pilot study to test a Trauma-Informed Care-adapted advance care planning intervention among affordable housing residents in Nashville
Institution: Vanderbilt University School of Nursing

Name of participant: _____
Age: _____

Thank you for your interest. This form tells you about our research study. Please read carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

We are researchers from Vanderbilt University School of Nursing, working in partnership with Urban Housing Solutions (UHS). In this study, our goal is to better understand the advance care planning needs of the UHS community and to think about ways we can best meet those needs. Advance care planning is a process of learning about what kind of medical treatments may be used during a sudden illness or injury when you cannot talk or make your own decisions. To plan for times like this, you can write what you want to be done on paper, talk about your wishes with your family, friends, or healthcare team, and prepare your loved ones to make the difficult decisions if something were to happen to you. To learn more about how to help people with advance care planning, we are interested in learning more about you, your background with advance care planning, and your thoughts about a new education process that we want to try with the community. We would like to invite you to participate in this study, which will include two survey visits and a clinic visit to have an advance care planning conversation. You may want to participate in this research study to share your views and experiences. You may not want to participate in the research study if the subject is too upsetting to you. This study will involve three visits: the first will take about one hour; the second will take about one to two hours; and the third will take about 30 minutes.

Detailed Information:

Why are we doing this research and why are you asked to participate?
You are being asked to take part in this research study because you are an adult, you live in the Urban Housing Solutions community, you have not completed an advance directive or living will, and you have expressed interest in participating the study. We want to learn about the unique advance care planning needs of this community and your participation will help us reach that goal. You will be one of 30 community members to complete three visits with a study team member.

Do you have to be in this research and can you stop if you want to?

You do not have to be in this research study, and you can stop being in this study at any time. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. We will not have access to your medical records.

What will you do and how long will it take?

When you are enrolled in the study, you will complete three study visits. During the first visit, which will take about one hour, you will sit with at least two members of our study team and respond to a questionnaire. We will collect information about your age, sex, race, and other demographics, your housing, transportation, financial, and resource needs, physical and mental health, your history of advance care planning, physical and mental health, how you cope with stress, social support and safety, positive and harmful childhood experiences, how you learn and make decisions about your health, and previous death-related experiences. We will also collect your contact information to get in touch with you to remind you of scheduled visits, schedule the other two visits, if we have questions about your responses, or if we have future studies that may be of interest to you. However, this contact information will be kept separate from your anonymous questionnaire responses.

During the second visit, which will take one to two hours, you will sit with one study team member and the study PI, Christine Kimpel, to learn more about your health, what is important to you, and talk about your advance care planning needs and goals. If you have someone like a family member or friend that you want to make decisions for you if you cannot, you can ask for them to attend as well. We will not collect or store any of their information but will note that someone was present and part of the conversation. The advance care planning conversation will be audio-recorded to ensure that we are following a similar approach for every person and to see what kind of topics people like to discuss during these discussions. After this part of the visit is done, we will explain to you that we will continue to audio-record a fifteen to thirty-minute conversation wherein we will ask you about how you would change the visit to make it more comfortable for other people in the future. This information will be kept anonymous and will be audio-recorded, and transcribed (each word will be typed out), and then we will use this information to see how we can make these visits better for people.

The third and final visit will last about thirty minutes. During this visit, you will sit with two study team members and respond to a questionnaire, which will be shorter than the first visit questionnaire. We will ask you questions about advance care planning and what you thought about the second visit.

What good things might come from this study?

a) The benefits to science and humankind that might result from this study: More knowledge regarding the advance care planning needs of the community for future research and programs. This information will be very used to help understand the needs of UHS residents.

b) The benefits you might get from being in this study: The opportunity to discuss what is important to you about advance care planning in your community.

Are there any risks or discomforts for this study? Can anything bad happen to you?
The risks involved with the study are small and may include some discomfort when responding to sensitive questions, including those related to financial limits, planning for times when you are not able to make your own decisions, and traumatic childhood experiences. You may stop at any time if you are feeling anxious or uncomfortable. There is also a small risk that the information that you provide could be lost or stolen, but we minimize this risk by giving you an anonymous study ID number that we use instead of your name. We make every effort to keep your information safe and secure and will explain how we do that.

What are the unforeseeable risks?
Because this educational process is new, there may be unknown or unforeseeable risks associated with participation that we do not know about, but we will let you know if this changes and it will affect you.

How can you find out the results of the study?
Study results may be available in the Fall of 2025. If you would like to see the results of this study, when they are ready, please contact the researchers at the contact information below.

What are the alternatives to participating?
If you do not want to participate in the study, this will not affect your daily life or healthcare in any way. Simply let the researcher know that you do not wish to participate.

What compensation will you receive for participating in the study?
If you agree to take part in this research study, you will receive a $25 physical gift card (e.g., Kroger) for your time and effort with each study visit. There are three study visits, thus you will potentially receive a total of $75 for participating. Payment will be received in the form of a physical gift card (bank deposit for foreign nationals) upon the completion of the necessary payment documentation. Primarily this will mean that you will receive this for your participation and completion of the payment form, but in some rare cases this may take 2-4 weeks to process. We will let you know what timeframe to expect.

All participants who wish to accept payment for their participation will be required to submit a payment form that requests personal information (e.g., name, address, email, phone, citizenship status, etc.). This identifiable information will be securely stored, accessed only by study staff, and will be kept separately from your questionnaire answers, which are anonymous.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

If you receive $600 or more from the university in a calendar year, VU must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC.

Are there any reasons the researchers may remove you from the study?
You may be taken out of the study if the researchers decide it is best for you or if the study is stopped. We may also withdraw you if you do or say something that tells us you may not want to participate or that participating is too stressful for you.

What happens if you choose to stop being in the study?
If you decide to stop being part of the study, you should tell the Primary Investigators. Deciding to not be part of the study will not change your regular medical care in any way.

Who can you talk to about this study?
If you should have any questions about this research study or possibly injury, please feel free to contact the **PI Dr. Christine Kimpel** at **615-343-0845** or the study Co-I, **Dr. Kate Clouse** at (615) 343-5351.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

How will your confidentiality and privacy be maintained?

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name. The information collected about you during the research study will be securely stored in the School of Nursing at Vanderbilt University. You will be assigned a study ID number upon enrollment in the study. All data will be entered into a secured password-protected database.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Authorization to Use/Disclose Protected Health Information

Not applicable.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Would it be okay if we contact you in the future to see if you are interested in participating in other studies? (Select one) **Yes** **No**

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title