Title: Care to Plan: Preliminary Efficacy of a Tailored Resource for Family Members of Persons with Dementia; NCT03901456

Phase II Consent

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Consent Form

Title of Research Study: Care to Plan: Preliminary Efficacy of a Tailored Resource for Family Members of Persons with Dementia (Phase II)

Investigator Team Contact Information: Joseph E. Gaugler, PhD

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Joseph E. Gaugler, PhD Investigator Departmental Affiliation: University of Minnesota, School of Public Health Phone Number: 612-626-2485 Email Address: gaug0015@umn.edu	Study Staff: Katie Louwagie, DNP University of Minnesota, School of Public Health Phone Number: 612-626-4776 Email Address: wocke007@umn.edu

The following telephone script will be read by the study team to the potential participant (unless the participant elects to receive a hard copy of the form prior to providing verbal consent):

I am going to read you a copy of the consent form. If you choose to enroll in the study, a copy of this completed consent form will be mailed to you. This study is being conducted by: Joseph Gaugler, PhD at the University of Minnesota School of Public Health. The contact information for Dr. Gaugler, as well as Katie Louwagie, the study coordinator, is listed at the top of the consent form.

Supported By: This research is supported by the National Institute on Aging/National Institutes of Health.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study.

What is research?

- The goal of research is learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because we are interested in learning how a new online tool, “Care to Plan,” can help you find services that are potentially beneficial to you. You were selected to be part of this study because you are a caregiver for a person with memory loss and reside in a region supported by Riverside Health Services.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.

- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this study because we want to try and provide relevant, personalized support information to family members and others who care for someone with memory loss. Many times, caregivers are not referred to the type of service that is right for them. We built Care to Plan based on recommendations of experts throughout the U.S. to identify the type of support that could be right for you. If Care to Plan works, it will offer an important tool for Riverside Health Services and other organizations to provide better support to families and others caring for those living with memory loss.

How long will the research last?

We expect that you will be in this research study for about 6 months.

What will I need to do to participate?

You will be asked to verbally consent to be a part of the project at the end of our conversation today. If you decide to be a part of the study, we will start with an initial survey. Our surveys are typically conducted over the telephone. However, if needed, you can ask us to mail you a hard copy survey instead.

Following the initial survey, the research team will randomly assign you to either the intervention group (who will be asked to review the Care to Plan tool with Riverside Health) or the control group (who will be offered standard care via Riverside Health Services).

If you are assigned Care to Plan, you will review Care to Plan with a senior care navigator at Riverside Health over the phone. No matter which group you are randomly assigned to, we will contact you to complete a shorter follow-up survey at 3 and 6 months after your initial survey.

If you are a part of the intervention group that receives Care to Plan, we will also ask additional questions that allow you provide us with feedback on your experience reviewing the tool. At the end of the study, the research team may also ask you to participate in a phone interview about how well you felt Care to Plan worked or did not work for you.

Is there any way that being in this study could be bad for me?

Answering some of the questions might make you sad or upset, as we ask about health and memory of the person you are caring for, and how you are feeling in your caregiving role. In addition, there is the risk that your information or your privacy is breached. If you have any concerns about your health or well-being during the course of the study, please let the study team know, and follow up with your healthcare provider.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. Caregivers may benefit from talking with Riverside Health Senior Care Navigation and identifying resources that may be helpful.

What happens if I do not want to be in this research?
If you decide not to participate in the study, you may continue to contact Riverside Health or Senior Care Navigation for consultation.

Detailed Information About This Research Study

How many people will be studied?
We expect about 100 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?
The study procedures last about 6 months. If you agree to be in this study, we would ask you do the following things:

- Review the consent form over the phone with the University of Minnesota research staff and verbally agree to participate in the research study (this is what we are completing now)
- If you verbally agree to participate after we finish reviewing the details of the study, we will ask you to complete an initial survey. The survey should take about 45 minutes to complete.
- After completing the survey, the research team will randomly assign you, like a flip of a coin, to either use Care to Plan with the guidance of Riverside Health or receive the usual care from Riverside Health Services.
- If you are assigned to use Care to Plan, a Riverside Health Service senior care navigator will be in touch with you to go through the Care to Plan tool. Reviewing the tool typically takes about ½ hour. If interested, you will be provided access to use the online tool on your own following review of the tool with Riverside Health.
- If you are assigned to the usual care, control group, you will be provided the information to reach out to Senior Care Navigation at Riverside Health if you'd like.
- If you contact Senior Care Navigation, any general topics or referrals may be shared with the research team.
- Three and six months after you complete your initial survey, the research team will contact you to complete a shorter, follow-up survey. If you were assigned to use Care to Plan, another team member will also reach out at 3-months to collect information on how well Care to Plan did or did not work for you. The follow-up surveys usually take about 30 minutes to complete.
- Lastly, if you were a part of the Care to Plan intervention group, at the end of the study (6 months after you complete your initial survey), the research team may ask you to participate in a telephone interview to provide additional information about how well

Care to Plan did or did not work out for you. The interview takes about 15-30 minutes. If you allow, this conversation would be recorded for data analysis.

- If you are in the control group (and do not review Care to Plan during the study), the study team will offer you the opportunity to access the online tool following your 6 month survey.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. It will not affect your relationship with the University of Minnesota or Riverside Health.

Will it cost me anything to participate in this research study?

Taking part in this research study will not cost you anything. However, some of the services recommended by the Care to Plan tool may have a cost associated with their use.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. The project's Safety Officer and National Institute on Aging may also view data reported by the study team, but these reports will not identify you by name. Your identity will remain confidential in study publications.

Additionally, if we learn of any self-harm or vulnerable adult abuse or neglect, we may be required to report this information to authorities.

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

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Data Collected
Hard-copy data collected as part of this study will be stored in Dr. Gaugler's research office at the University of Minnesota in locked file cabinets. All data collected online or entered will be stored using secure platforms.

Your data will be maintained for approximately 2-3 years after the study is completed. At that time, we will remove all identifiable private information collected during this research. Please note that the de-identified data collected as part of this study could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP.

Will I be compensated for my participation?

You will be paid $25 for each study survey you complete. These surveys are at baseline (when you begin the study), 3-months, and 6-months, for a potential total of $75 total. You will be compensated the appropriate amount at the conclusion of the study for your time and effort.

If you are selected for a telephone interview at the end of the study, an additional $25 payment will be provided (for a total of up to $100).

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card.

The debit card system is administered by an outside company (Greenphire). To register your card, Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 being issued to you and a copy sent to the IRS.

Do you have any questions about the study?

[Study team to write notes about any questions addressed]

Would you like to participate in the study?

_____***Yes***

_____***No***

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. I will read each statement and would like you to tell me whether you agree or disagree with each. [Research staff to select based on participant response].

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Joseph E. Gaugler, PhD
_____	_____	The investigator may audio record my phone interview to aid with data analysis.
_____	_____	I accept the use of unencrypted email as a way to communicate with the research team members. I understand that unencrypted email communication is not secure and can be intercepted.

Consent Form

The following participant has provided verbal consent to participate in Care to Plan.

_____
Printed Name of Participant

_____ _____
Signature of Study Staff Obtaining Consent Date

_____
Printed Name of Study Staff Obtaining Consent

Participant will be mailed a copy of this completed consent form to keep for their records.