Consent Form Cover Page for Study NCT03881631

NCT Identifier: NCT03881631

Brief Title: Improving Well-Being for Older Adult Family Dementia Caregivers

Consent Form IRB Approval Date: 7/27/2022

UNIVERSITY of ROCHESTER MEDICAL CENTER
MEDICINE of THE HIGHEST ORDER

Improving Well-Being for Older Adult Family Dementia Caregivers

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This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your loved one's medical care will not be affected in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you are aged 55 or older and are the primary caregiver for a loved one with dementia. You also may be experiencing a moderate or higher level of stress which may be related to your caregiving role.

This study is being conducted by Dr. Kathi Heffner of the University of Rochester's Department of Psychiatry and the School of Nursing.

Purpose of Study

The purpose of the study is to examine the effects of the Mindfulness-Based Stress Reduction (MBSR) program and the Living Well (LW) program, compared to any usual care, to see if the programs might be associated with better immune function, physical and emotional health, and well-being. We are especially interested in using the current influenza vaccine, which is commonly administered yearly, as a way to examine immune system health.

Caring for a loved one with dementia can be a significant source of stress for the caregiver. Chronic stress has been shown to hasten the normal aging of our immune systems, which is made up of special cells, proteins, tissues, and organs and defends against germs and viruses, including influenza. Developing strategies aimed at addressing stress and promoting a healthy immune system might lead to a reduction in the occurrence of disease and enhance physical and psychological well-being.

Information about study participation during the COVID-19 pandemic:
The University of Rochester provides researchers with guidelines to help ensure study procedures are conducted safely during the COVID-19 pandemic. Our study team follows these guidelines carefully for the protection of our subjects, staff, and the community, and will keep you informed of the current safety guidelines as they apply to your participation in this study.

Description of Study Procedures

You are being asked to participate in this study because the research team has determined you may be eligible. Participation involves completing study questionnaires about your general background and history, as well as your physical and emotional health and well-being. There will be some brief assessments of your memory and thinking. You will be asked about your role as a caregiver for your loved one, and what it has been like for you. You will also be asked about any medications you are taking, as well as dosages of these medications. Certain medications will need to be maintained at a stable level for the duration of the study. At most of the study visits you will have your blood drawn by a trained phlebotomist who will perform the procedure using a standard needle to draw approximately 2.4 tablespoons (four test tubes) of blood. Your blood is first collected today, or at your next visit (baseline, also called 'Time 1'), to evaluate the health of your immune system and especially your ability to respond to influenza virus. Blood samples will be collected on four more occasions throughout the study (described below).

The term "study visit" as used in this form can refer to a collection of various assessment procedures intended to occur on, or very close to, the same date. To increase safety in this time of COVID-19, portions of an assessment visit can be done remotely through a secure online survey system (called REDCap) and over the phone with study staff. Thus, a complete "visit" may often involve both a remote (online and by phone) *and* an in-person set of procedures.

In-person visits can be done either at the U of R or, the visits can occur in your home. If you prefer a visit to occur in your home, study staff will be accompanied by a research assistant who can attend to your loved one during the interview, if needed. These assistants will have attended training sessions in this care from Alzheimer's Association staff. The initial "baseline" visit procedures (Time 1) may last about two hours when completed in a single visit. However, if the initial visit occurs more than six weeks prior to the start of the eight-week program phase, those procedures will be divided into two shorter visits (Time 1a & 1b) with the second visit (Time 1b) occurring within six weeks of the program phase.

Additional study visits. After your initial visit(s), and the 8-week program phase, you will meet with study personnel an additional three points in time. These remaining three visits will take about 1 hour each and will involve only some of the interview measures used at the initial visit. As much as possible, study visits will be scheduled to occur at the same time of day to avoid issues with normal daily fluctuations of certain proteins in your blood.

Your next study interview (Time 2b) will occur within a few days following the end of the 8-week program phase and your influenza vaccination. The following visit (Time 3) will occur less than two weeks later and involves only a blood draw, no interview. The third interview (which is actually 'Time 4') will occur approximately 4 weeks later, roughly 6 weeks after your influenza vaccination. The fourth and final interview (Time 5) will occur approximately 6 months following the end of the 8-week program phase and your influenza vaccination, typically in April.

Study treatment groups. If you are eligible and agree to participate following your initial study visits, you will be randomly assigned (like flipping a coin) to participate in: **1**) Mindfulness-Based Stress Reduction (MBSR) for dementia caregivers; **2**) Living Well (LW) for dementia caregivers; or **3**) maintain your usual care (UC). Both MBSR and LW programs are held at Lifespan and involve weekly group meetings of 10-15 individuals. All groups, including UC, will follow the same general schedule for the study visit time points.

To better enable your attendance at MBSR and LW sessions (if you are randomized to either of those groups), optional respite care for your loved one, during the time of MBSR and LW meetings, may be available for you through Lifespan. This can include a respite activity room on-site at Lifespan; or, if eligible, in-home respite care may be covered by a Lifespan scholarship program. You will be given information about the optional respite care, eligibility requirements, and how to request it.

The *Usual Care (**UC**)* control condition is an important group to include in this trial. If you are in this group, after completion of the study you will be offered free participation in an MBSR program available through the UR Center for Community Health & Prevention. If you decide to take part in the program at that time, it will *not* involve repeating the other study procedures such as study interviews, blood draws, etc.

The *Mindfulness-Based Stress Reduction (**MBSR**)* program is designed to teach you how to take better care of yourself and to participate fully in improving your health and quality of life as an addition to the more traditional care you may be receiving. It employs methods aimed at promoting relaxation and awareness of your physical experiences, emotions and thoughts in a nonjudgmental manner.

The *Living Well (**LW**)* program involves a series of presentations and discussions on a variety of topics related to the promotion of health and well-being in the context of dementia caregiving. Similar to MBSR, LW is designed to teach you how to improve your physical and emotional health and well-being as a complement to traditional medical treatments.

Both MBSR and LW programs consist of eight weekly, 90 minute sessions, plus one half-day (about 4 hours) session, consisting of a group of roughly 10-15 study participants. The MBSR and LW sessions will be held at the Lifespan main office in Rochester (1900 S Clinton Ave, 14618), with the exception of the “half-day” session. You will be provided a detailed schedule of the days, times, and locations for each of these sessions. Subjects randomized to the MBSR and LW groups will begin the programs typically in late August; in 2022 programs are expected to begin Sep 1 (the diagram on the next page summarizes the general study timeline).

(T1) Jun-Aug	Aug/Sep-Oct	(T2a) Oct	(T2b) Oct	(T3) Oct/Nov	(T4) Nov/Dec	(T5) Apr
enrollment/ baseline	*8-week Program phase*	End of program phase	< 1 week post flu vac	2 weeks post flu vac	6 weeks post flu vac	6 months post flu vac
Blood draw 1 Interview 1	*MBSR/LW/UC*	**Blood draw 2 Flu vaccination**	**Interview 2**	**Blood draw 3**	**Blood draw 4 Interview 3**	**Blood draw 5 Interview 4**

Influenza vaccination. One of the ways that we will examine how your immune system is working over time will be by using the influenza vaccine as a “read-out” of changes in your immune function. The Centers for Disease Control and Prevention (CDC) recommend that influenza vaccination, particularly for vulnerable older adults, should commence soon after the

vaccine becomes available, and ideally by October. The flu season in the United States can begin as early as October and may last until May. If you remain in the study in any of the three groups (MBSR/LW/UC), you will be vaccinated with the appropriate CDC-recommended licensed influenza vaccine, by injection into the deltoid muscle, at the end of the 8-week program phase around mid Oct. If you are age 65 or older you may receive one of the licensed higher dose or recombinant ('senior dose') vaccines, if you prefer. If you have an *egg allergy*, a licensed egg-free vaccine can be provided—please inform study personnel immediately if you will require an egg-free vaccine. Vaccination will be at no cost to you or your health care insurer, and will be performed at Lifespan by trained nurses.

Number of Subjects

Approximately 240 English-speaking women and men, aged 55 and older, who are the primary caregiver for a community-dwelling dementia patient, will complete this study.

Duration of the Study

Your participation in the study will last approximately 9 months.

Risks of Participation

1) There are some risks to having your blood drawn (**phlebotomy**). These risks include possible discomfort and/or a bruise at the needle puncture site. Once in a while, some people may faint; please inform the study personnel before having your blood drawn if this has happened to you in the past. It is rare, but some people may get an infection, form a small blood clot, get swelling of the vein and surrounding tissue or bleeding at the site of the needle puncture.

   Subjects will be encouraged to drink plenty of water prior to **phlebotomy**. Phlebotomy will be performed at the antecubital fossa to minimize pain and bruising. Subjects will be seated during the blood draw to minimize dizziness and any risk of falling. Pressure will be applied to the site after the draw and a bandage will be applied to minimize the risk of bleeding and infection.

2) Mild side effects of **influenza vaccination** usually begin soon after vaccination and last one to two days. Possible mild side effects include: soreness, redness, and swelling at the injection site; headaches; fever; and nausea.

   Subjects will be instructed to contact their primary care providers if side effects of vaccination are severe.

3) Subjects are reminded that they may request that measures be read aloud for any reason, including reading difficulties, fatigue, attention problems, or simple preference. Because you will be answering questions about your physical and emotional health and well-being on the questionnaires, you may experience some **emotional discomfort**. You are free to not answer any questions with which you feel uncomfortable. If we become concerned about your mental health or safety based on your responses to our questions and surveys, we may contact your primary care physician or other relevant health care provider. If you have a serious, acute risk for suicide, you will be referred or transported to the Psychiatric Emergency Services at Strong Memorial Hospital for evaluation. We will notify your physician if risk for self-harm is revealed in our research interviews. We will notify you of any of these concerns prior to contacting your provider.

4) There is minimal risk involved in participating in the MBSR program portion of the study. Some yoga exercises are involved, but these can all be adapted to accommodate any physical disabilities.

5) Some of the program sessions (MBSR/LW) may be video recorded. The videos will be used to establish that there is good fidelity or conformity to the program manuals.
The video recordings will be viewed only by research personnel working on this study. The videos will be stored on DVDs labeled with the session number and date, and kept in locked files in our research offices at the University of Rochester Medical Center until five years after completion of data collection, at which time they will be destroyed. No identifying or other information about you will be included with the DVDs. Signing this consent form indicates that you agree to have the program sessions video recorded for the purposes of quality assurance.

Benefits of Participation
You might not benefit from being in this research study. A potential benefit to you from being in this study is you might feel less stress and anxiety.

Sponsor Support
The University of Rochester is receiving payment from The National Institute on Aging of the National Institutes of Health for conducting this research study.

Costs
There will be no cost to you to participate in this study.

Payments
For your participation in the study, you will receive $40 for completion of each of the four study interviews, and $20 for each of the two blood draws that are done without interviews, for a possible total of $200. All payments will be in the form of checks mailed to your home.
If it is determined early in the initial visit (Time 1) that you do not qualify to continue, the interview will end and you will be compensated $10 for your time.
Payment for participation is based on a pro-rated system; thus, partial payment will be given if you do not complete the entire study. Please note that a study interview, most commonly the initial (Time 1) interview, may require two separate visits to complete; in such cases you will receive $20 for each half-visit to total $40 for the full interview.

Circumstances for Dismissal
Participation in this study may be terminated without your consent if you fail to complete study activities, or you no longer meet study requirements.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we have a documented plan for the collection, storage, protection and analysis of research data. All research files will be coded using a study identification number. Subject identifying information (name, address, etc.) will be stored separately from other data collected for this study and will only be accessible to investigators and CRCs. All identifying data will be

stored in locked cabinets and locked offices or in password-encrypted files. Access to these files is limited to investigators and support personnel with the need to enter or analyze data.

Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and laboratory information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Results of lab tests

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The National Institutes of Health
- The University of Rochester

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Kathi Heffner, PhD, at (585) 273-4786.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation
Taking part in this study is voluntary. You are free to not take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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SIGNATURE/DATES (on next page)

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Saving your blood samples for future research:
It is possible that future analyses of your blood samples will be useful in better understanding possible links between immune system health and caregiver well-being. Therefore, after tests are done on your blood samples for the present study, we would like your permission to keep any remaining blood to use in possible future research studies. The remaining sample would be stored in a laboratory at the University of Rochester Medical Center, and would be used for future research purposes only; it will not be sold or used directly for the production of commercial products.

Your blood samples will be coded (made anonymous) and will not be linked to your name or other information that could identify you. Future reports about research that utilized your sample will not be added to your health records, and you will not be informed of the results of the future research as the sample will no longer be linked to your identity.

You can decide if you will allow your samples to be used for future research. *Indicate (✓) below:*

- ❒ **I consent** to have my de-identified specimen(s) saved for an indefinite period of time for future research as described above.
- ❒ **I do not consent** to have my unused specimens used for other future studies. Destroy my unused specimen(s) after analysis is complete for the present study.

Subject Consent
I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent
I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date