HIC # 2000021852

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)

YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH

Study Title:
Stress Reduction Study for Partners of Early Stage Dementia

Principal Investigator: Joan Monin, PhD
Funding Source: *National Institute on Aging*

Invitation to Participate and Description of Project

We are inviting you to participate in a research study designed to look at a stress reduction program called Wish Outcome Obstacle Plan (WOOP) for spouses of persons with Alzheimer's Disease. You have been asked to participate because you have early stage Alzheimer's Disease or a related dementia. Ninety couples will participate in the study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participating in this study, you will be asked to complete three surveys asking about your well-being and relationship satisfaction in response to your partner participating in an intervention. If your partner agrees to participate, your partner will be randomly assigned to (a) start the WOOP program now, OR (b) start the WOOP program after three months (the wait list group). Either way, your partner will receive a brief one-time training about adaptive coping strategies for spouses of persons with AD and then your spouse will be asked to try out the Wish Outcome Obstacle Plan (WOOP) intervention for 16 days.

WOOP is a brief, self-guided, intervention sequence that people can use to find and fulfill their wishes and change their habits in daily life. For this intervention, we will ask your partner to focus on wishes and goals that will help maintain or enhance his/her daily well-being as you cope with the stressors of early stage AD or related dementias. WOOP is a brief intervention that involves writing down the following each day :1. Wish or goal. 2. Outcome: The most positive outcome of realizing the wish or goal. 3. Obstacle: The most critical internal, controllable, obstacle. 4. Plan: What action can I take or what thought can I think to overcome the obstacle; then you form an "if" , "then I will" plan.

APPROVED BY THE YALE UNIVERSITY IRB 7/30/2020

Specifically, at three home visits, or phone/zoom calls the investigators will ask you to complete some self-report surveys and ask you about how your partner's experience using WOOP (if he/she was in the WOOP group) has affected your well-being.

During the course of the study, you can continue with any other treatments you are currently receiving.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate. Research results will not be returned to your doctor. If research results are published, your name and other personal information will not be given.

Risks and Inconveniences

It is possible that in completing the surveys you may become more self-aware of obstacles for increasing personal and relational well-being which may increase negative feelings.

Other risks from participating in the study include the breach of confidentiality about your health status and participation in the study. This is very unlikely to occur, as all study investigators are trained and certified in research privacy.

Benefits

There are potential benefits resulting from the study including decreased psychological and physical discomfort and improved quality of life.

Economic Considerations

The intervention is provided to you free of charge. There are no costs associated with your participation in the study. To thank you for participation, we will pay you in increments, $25 for baseline, $25 for the Day 16 follow-up, and $50 for the 3-month follow-up for a total of $100.

Treatment Alternatives/Alternatives

If you choose not to participate in this study, there are no alternative treatments available, except those that are already being administered by your physician including pharmacotherapy (medications/drugs), exercise plans, and psychological treatments. You may choose not to participate.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or

APPROVED BY THE YALE UNIVERSITY IRB 7/30/2020

elderly person, or certain reportable diseases. Information will be kept confidential by using only identification numbers on study forms, storing signed forms in locked cabinets, and password protecting data stored on a computer. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific permission for this activity is obtained.

We understand that information about your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies your personal health information. This may include information that might directly identify you, such as his or her name and address, telephone number, and email address, or mobile phone number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you and your coded information, and this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Information will be kept confidential by using only identification numbers on study forms, storing signed forms in locked cabinets, and password protecting data stored on a computer. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 5 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

The information about your health that will be collected in this study includes:

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

Information about your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Subjects Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator (Dr. Joan Monin)
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information.

If you choose to participate in this study, the investigators will check your electronic medical record at Yale (EPIC) to make sure you qualify. Any access to your electronic medical record will be done consistent with HIPAA regulations.

Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. This authorization to use and disclose your health information collected during your participation in this study will never expire.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *the National Institute on Aging* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *elder abuse* and neglect, or harm to self or others.

APPROVED BY THE YALE UNIVERSITY IRB 7/30/2020

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *(your responses to the self-report surveys)*.

Voluntary Participation and Withdrawal

You are free to choose not to participate in this study. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to participate. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. You do not give up any of your legal rights by signing this form.

Withdrawing From the Study

You are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with the Yale School of Medicine and Yale New-Haven Hospital.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away permission to use and disclose your health information at any time. You do this by calling or sending written notice to the Principal Investigator, Dr. Joan Monin Department of Social and Behavioral Sciences, Yale School of Public Health, 60 College Street, New Haven, CT 06520.

When you withdraw your permission, 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 until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

You do not give up any of your legal rights by signing this form.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the permission form carefully – as long as you feel is necessary – before you make a decision.

HIC # 2000021852

Contact for Future Studies

We ask for your permission to contact you for participation in future studies that our group may conduct. We may use your telephone number, your email address or your physical address to contact you.

I agree to be contacted regarding future studies I may qualify for: (initial your choice)

_____YES _____No

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Joan Monin at 203 785 2895.

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Subjects Committee at (203) 785-4688.

APPROVED BY THE YALE UNIVERSITY IRB 7/30/2020