Duke University Health System

Caregiver-assisted pain coping skills Training for dementia
Patient Consent

KEY INFORMATION SUMMARY

The goal of this study is to develop a caregiver-assisted pain coping skills training guide for older adults who have pain and mild to moderate dementia and are living at home with a family caregiver. You and your family member will be asked to complete questionnaires at the beginning and at the end. You and your family member will have five, forty to sixty minute sessions over a six to eight week period with a therapist to learn pain coping skills.

There are no physical risks associated with this study. There is however, the potential of risk of loss of confidentiality. You may benefit from learning strategies to help your family member cope with pain. The information you provide will help us develop programs that may help other in the future. If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have been diagnosed with mild or moderate dementia and have pain. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

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Dr. Laura Porter will conduct the study. The study is funded by a grant from the National Institute of Aging. Portions of Dr. Porter's and their research team's salaries will be paid by this grant.

Why is this study being done?
The purpose of this study is to develop and refine a program that will help patients with mild to moderate dementia and their family caregivers manage pain and pain-related concerns.

How many people will take part in this study?
Approximately 60 people will take part in the study at Duke.

What is involved in the study?

- If you agree to be in this study, you will be asked to sign and date this consent.
- You will complete questionnaires about your pain and quality of life.
- Together with your family member, you will complete five, 40-60 minute pain coping skills sessions. During the session, the therapist will train you and your family member how to video-conference on a smart device. The sessions will be conducted via videoconference. We would like to complete all pain coping skills training in a 6-8 week timeframe.
- You and your family member will be asked to fill out questionnaires when the 5 pain coping skills training are completed.

How long will I be in this study?
Your participation in this study will last approximately 90 days.

You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

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Are there benefits to taking part in the study?
This study may help patients learn skills to help cope with pain. We hope to learn more about how caregiver-assisted pain coping skills training for adults with pain and mild to moderate dementia, their family caregivers living in the same household. Our plan is to use this information to optimize programs designed to help patients and their caregivers.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study may be reported to National Institute of Aging and its affiliates. In addition, your records may be reviewed, representatives and affiliates of National Institute of Aging, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to

protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

> It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
>
> It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.
>
> It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

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Will I be paid to be in the study?
You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. As a thank you for your participation, you will receive $45 compensation for completing the first set of questionnaires and $45 for completing the second set of questionnaires. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research related injuries?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact (Dr. Laura Porter) at (919-416-3436) during regular business hours and at (919-970-8234) after hours and on weekends and holidays.

What if I want to withdraw from the study?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except as needed to track your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. If you do decide to withdraw, we ask that you contact Dr. Porter in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC Box 90399, Duke University Medical Center, Durham, N.C. 27710.

Your doctor may decide to take you off this study if your condition gets worse, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time with your

consent. Reasons, why this might occur, include distress from the study interview. The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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 should I call if I have questions or problems?
You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

If applicable:

_____	_____	_____
Signature of Legal Representative	Date	Time

_____
Relationship to Participant