University Health Network

CONSENT TO PARTICIPATE IN A RESEARCH STUDY PATIENT FORM

TITLE: A pilot study assessing the benefits of a dementia caregiver educational brochure on decreased empathy and emotion recognition in patients with neurodegenerative disease

PRINCIPAL INVESTIGATOR: Dr. Carmela Tartaglia
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INTRODUCTION:

You are being asked to take part in a research study. This information tells you why we are doing the study and how we will do it. It explains the possible benefits, discomforts, risks and precautions the study might have. It also tells you about your right to refuse to participate or withdraw from the study at any time. To decide whether to participate in this study, make sure you understand enough of this information to make your decision. This is known as 'informed consent'. Ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered before you sign this consent form. Participation in this study is voluntary and you can withdraw your consent to participate at any time.

BACKGROUND AND PURPOSE:

You have been asked to take part in this study because you have been diagnosed with a dementia at the UHN Memory Clinic. The purpose of this research is to assess the practicality of evaluating an educational intervention on emotion recognition deficits and empathy (ability to understand and share the feelings of others) impairment for dementia caregivers and its effect on caregiver understanding of deficits, burden, mood and quality of life. The goal of this research study is to develop appropriate resources and interventions to assist care-partners in understanding a particular symptom of dementia: decreased empathy and emotion detection. If care-partners have a better understanding of these symptoms, this may lead to improved relationships between the care-partner and the person with dementia, improved care and decreased distress and burden for the care-partner.

STUDY DESIGN:

As part of this research study, you will be shown a video with vignettes expressing different emotions, and you will be asked to answer multiple choice questions about the vignettes.

PARTICIPANTS:

We are looking to recruit 75 care-partners for this research study. There will be rolling enrollment over the course of several months so participants can be enrolled at any time, and new participants can be found after the study has already begun.

STUDY PROCEDURES:
Once you consent to participating in this research study, you will be shown a video with vignettes expressing different emotions, and you will be asked to answer multiple choice questions about the vignettes. This video only needs one study visit. This video and questions will take approximately 30 minutes to complete plus the time needed to read over the consent forms. There is no follow up required for the study.

RISKS OF PARTICIPATING IN THIS RESEARCH STUDY:

There are minimal risks for individuals who choose to participate in this study. This study does not alter usual clinical care. There are no health risks of participating in this study but the videos take time to watch and may evoke emotional responses such as anxiety or sadness. If this happens, you will be advised to stop watching the videos. The principal investigator will be on site to speak with you about your feelings and offer support, if needed.

You can refuse to answer questions.

BENEFITS TO PARTICIPATING IN THIS RESEARCH STUDY:

While you will not receive any direct benefit from being in this study, your participation will help better our understanding of an intervention that will be used to educate caregivers on the symptoms of a person with a neurodegenerative disease, specifically the decreased emotion detection ability and change in empathy.

CONFIDENTIALITY:

Personal Health Information: If you agree to participate in this study, we will look at your personal health information and collect only the information needed for the study. Personal health information is any information that can be used to identify you and includes your name and date of birth (month and year). Patient data will be kept strictly confidential.

Representatives of UHN, including the Research Ethics Board, may come to the hospital to look at the study records and at your personal health information to ensure that the information collected in the study was done well and that it is following ethical guidelines.

Data collected from you will be recorded anonymously. Your name will not be recorded on the questionnaire. You will be identified with a study number only. Your name will not be associated in any way with the findings of this study if they are publicly presented and published. Your identifying information will not be transferred outside the investigators in this study or this hospital.

Consent forms will be filed in a separate location. The questionnaire and consent form will be linked by using a study number for the participant. All identifying information will be kept in a locked cabinet accessed only by the Principle investigator and co-investigators until the study has been completed. Information will be stored for 10 years.

WITHDRAWAL FROM STUDY:

If you decide to leave this study, the information that was collected about you before you left the study will still be used. No new information will be collected without your permission.

EXPENSES ASSOCIATED WITH THE STUDY:
You will not receive any monetary compensation for participating in this study.

VOLUNTARY PARTICIPATION:
Your participation in this study is voluntary. You may choose not to participate or you can withdraw at any time. You may also refuse to answer any question you do not wish to answer.

RIGHTS OF THE PARTICIPANT:
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. By signing this form, you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

CONFLICT OF INTEREST:
The researcher and research assistants have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel any pressure to join this study.

ALTERNATIVES TO BEING IN THIS STUDY:
The alternative to this study is not to participate.

QUESTIONS ABOUT THE STUDY:
If you have any questions or concerns about the research study, please call Maria Martinez at the University Health Network Memory Clinic at 416-603-5800 ext. 3582. If you have any questions about your rights as a research participant or have concerns about this study, please call the Chair of the UHN Research Ethics Board (REB) or the Research Ethics Office at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not involved with the research project in any way and calling them will not affect your participation in the study. You will be given a signed copy of this consent form.

CONSENT:
This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

_____	_____	_____
STUDY PARTICIPANT'S NAME	SIGNATURE	DATE

I confirm that I have explained the nature and purpose of the study to the participant named above. I have answered all questions.

_____	_____	_____
NAME OF PERSON OBTAINING CONSENT	SIGNATURE	DATE