NCT03383289

Resident-to-Resident Elder Mistreatment Intervention for Dementia Care in Assisted Living

Informed Consent Document

Version Date: 12/22/20

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APPROVED
for use
23-Dec-2021 -
22-Dec-2022

INFORMED CONSENT and HIPAA AUTHORIZATION

Project Title: Resident to Resident Aggression in Assisted Living
Principal Investigators: Mark Lachs, MD, Weill Cornell Medical College, Karl Pillemer, PhD, Cornell University, Jeanne Teresi, EdD, PhD, Research Division of the Hebrew Home at Riverdale

INTRODUCTION

You are invited to participate in a research study. All individuals living in this assisted living residence will be invited to participate. Taking part in the study is entirely voluntary. The decision to participate or not to participate is yours. You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled. You are urged to ask any questions you have about this study with members of the research team.

This project is supported by the National Institute on Aging.

WHY IS THE STUDY BEING DONE?

We are conducting a study to determine how often residents of assisted living residences have interactions with other residents that could be considered aggressive – either through direct contact (such as hitting or kicking) or with words (such as yelling and cursing). We will be working with residents and staff at many facilities in New York to understand how common this is and what might be done to prevent it.

To help us understand this problem, we need to learn from you more about your personal experience with this problem.

WHAT IS INVOLVED IN THE STUDY?

We would like to interview you to obtain this information. The interview will take about an hour and will focus on whether or not you have been treated poorly by another assisted living resident, what happened, and what effect this may have had on you and your health. Interviews will take place in-person, via phone call, or over videoconference—depending on the needs of the participant (e.g., COVID-19 in-person restrictions). We would also like your permission to look at your records here at the facility and talk with the staff who assist you. We will ask you to participate in future follow-up interviews in about 6 months and 1 year. About 1050 participants will take part in this study.

You have, and will continue to have, the right to refuse to participate at any time and/or to refuse to answer any question(s) that you are asked.

WHAT ARE THE RISKS OF THE STUDY?

Risks of this study are considered minimal. In all research there is a risk to breach of confidentiality. However, we will try to reduce this risk by encrypting the computers and requiring a unique ID and password to open the computer. The computers will not have internet access and will be kept in a locked cabinet. However, we cannot guarantee that a breach will not occur.

If you should become upset by these questions and would like support, it will be provided for you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

There may be no benefit to participation in this study; but, knowledge gained from your participation may benefit others.

WHAT ABOUT CONFIDENTIALITY AND PRIVACY?

Federal law protects your right to privacy concerning Protected Health Information (PHI). There are certain things you need to know. As part of this study, we will collect selected Protected Health Information (PHI), such as your name, address, date of admission and health conditions.

Efforts will be made to protect your personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements. You will not be identified personally in any reports or publications resulting from this study. Organizations that oversee the research may request to see the information we collect from you; however, we don't anticipate that this will happen. If this happens, we will not include your name in the information we share.

Protected Health Information to be Used or Shared: Government rules require that researchers get your permission to use or share your protected health information. If you give permission, the researchers could use or share with oversight organizations any protected health information related to the study questionnaires for this research study.

Voluntary Choice: The choice to give the researchers permission to use or share your protected health information for their research is completely up to you. No one can force you to give permission. However, you must give permission to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research.

By signing this consent form, you authorize access to this confidential information.

CANCELING AUTHORIZATION

Unless you cancel it, permission for the researchers to use or share your protected health information for their research will never end. If you give the researchers permission to use your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used.

If you wish to cancel your permission, you may do so at any time by contacting Dr. Mildred Ramirez at 718-581-1140.

ACCESS TO RESEARCH RECORDS

During the course of this study, you will have access to your protected health information, research record and any study information that is part of that record.

COMPENSATION FOR PARTICIPATION

You will not be paid for your participation.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Should you have any questions about this study, please call Gabriel Boratgis, Project Director at 718- 581-1134, Dr. Mark Lachs, Chief of Geriatric Medicine at the Weill Cornell Medical College at 212- 746-1677, or Dr. Karl Pillemer, Director, Bronfenbrenner Center for Translational Research at Cornell University at 607-255-8086.

If you have questions about your rights as a research participant, please contact the Hebrew Home at Riverdale IRB at: (718) 581-1136.

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RESEARCHER'S STATEMENT

I have fully explained this study to the participant. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of researcher obtaining consent	Date	Print name

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PARTICIPANT'S STATEMENT

I have read/or have had the above read to me. I have had all study-related questions answered and I consent to participate in this study.

_____	_____	_____
Signature of Adult Participant	Date	Print name

NOTE: If Oral consent has been obtained, please write "oral consent" in the participant's signature field, date and print the participant's name where indicated, and indicate the reason for the oral consent in the section below the signature line.

Reason for oral consent:

- ☐ The participant has a perceptual impairment that makes it difficult for her/him to read/sign (e.g., visual impairment);
- ☐ The participant is illiterate;
- ☐ The participant has a physical impairment that prevents her/him from writing;
- ☐ The participant refuses to sign the Informed Consent Form for personal, cultural, religious, or similar reasons.

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STATEMENT OF AN INDEPENDENT WITNESS TO ORAL CONSENT*

(*cannot be a member of the study team)

I have witnessed the consent process. I confirm that the participant has been informed about this study's purpose, procedures, possible benefits and risks; and the participant has been offered a copy of the consent form. The participant has been given the opportunity to ask questions before agreeing to participate, and the participant has been told that he/she can ask other questions at any time. The participant has voluntarily agreed to participate in this study by giving oral consent.

_____	_____	_____
Signature of Witness	Date	Print name

Proxy Consent

Resident unable to provide informed consent.

☐ Letter to be sent to designated contact person or legally authorized representative requesting consent on resident's behalf.