Northwell Health

Campus: North Shore University Hospital/Long Island Jewish Medical Center

Consent for Participation in a Research Study: Hospital Caregivers

Study Title: Reducing Behavioral and Psychological Symptoms of Dementia (BPSD) for Acutely-Ill Persons with Alzheimers Disease and Related Dementias via Patient Engagement Specialists

Principal Investigator: Liron Sinvani, MD

Sponsor: National Institute of Aging

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to evaluate whether dementia care training improves the perceived ability of nursing staff (nurses, patient engagement specialists, and nurse assistants) to care for hospitalized persons with dementia.
What will happen to me during the study?	After consenting, you will attend 7 dementia care training and education sessions (over the course of 12 weeks) that are scheduled during your shift. After the training period you will be asked to attend 12 monthly, 20 minute group sessions to discuss challenging patient behaviors and reinforce concepts from the prior training sessions. You will also be asked to complete two surveys at three different times to assess your attitude, experience, and satisfaction with working with patients with dementia. These 2 surveys will be given prior to training, immediately following the 7 training sessions, and following the 12 monthly group support sessions.

How long will I participate?	The study procedures will last approximately 16 months. You will be asked to attend 7 dementia and education training sessions (over the course of 12 weeks) that will last 20 minutes each during your shift. You will then be asked to attend 12 monthly training sessions that will last 20 minutes each.
Will taking part expose me to risks?	Some of the questions we will ask you are personal and might upset you. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.
Are there any benefits to participation?	The possible benefits you may experience from the procedures described in this study include improving your experience as a hospital caregiver and increasing your knowledge of dementia as well as tools to better engage persons with dementia. Patients with dementia will benefit from the presence of staff that have been trained in the management of symptoms that are common to persons with dementia and experience improved quality of care.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
The purpose of this research study is to test a new model of care to improve the experience and outcomes of hospitalization for both patients with dementia and their caregivers. Specifically, we are testing a new model of care that is designed to reduce behavioral and psychological symptoms of dementia and better prepare hospital caregivers to prevent and manage these behaviors. You are being asked to participate in this study because you are a hospital caregiver.

How many people will take part in this study?
This research study hopes to enroll 80 participants.

How long will you be in this study?
If you choose to take part in this study, the study procedures will last for 16 months. You will be asked to attend 7 dementia care training and education sessions (over the course of 12 weeks) that are scheduled during your shift changes. After the training period you will be asked to attend 12 monthly, 20 minute group sessions to discuss challenging patient behaviors and reinforce concepts from the prior training sessions. You will also be asked to complete two surveys at three different times to assess your attitude, experience, and satisfaction with working with patients with dementia. These surveys will be given prior to training, immediately following the 7 training sessions, and following the 12 monthly group support sessions.

What will happen in this research study?
After you agree to participate in the study, you will attend 7 dementia care training and education sessions that are scheduled during your shift. The sessions will cover the following topics: : 1) overview of dementia and dementia care; 2) addressing unmet needs; 3) avoiding restraints; 4) communicating with persons with dementia; 5) delirium; 6) the impact of the physical environment; 7) connecting to the family caregiver.. After the training period you will be asked to attend 12 monthly, 20 minute group sessions to discuss challenging patient behaviors and reinforce concepts from the prior training sessions. You will also be asked to complete two surveys at three different times to assess your attitude, experience, and satisfaction with working with patients with dementia. These surveys will be given prior to training, immediately following the 7 training sessions, and following the 12 monthly group support sessions.

What are the risks of the research study? What could go wrong?
Some of the questions we will ask you are personal and might upset you. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study. Study staff members will also be available to provide support.

Breach of Confidentiality: A possible risk is the loss of confidentiality about your medical information. We will do our best to make sure that your personal information is kept private. The chance that this information will be given to someone else is very small.

What are the benefits of this research study?
The possible benefits you may experience from the procedures described in this study include improving your experience as a hospital caregiver and increasing your knowledge of dementia as well as tools to better engage persons with dementia.

Patients with dementia will benefit from the presence of staff that have been specifically trained in the management of behaviors that are common for persons with dementia and experience improved quality of care.

Are there any costs for being in this research study?
You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?
You will be paid $25 for your time and for each survey you complete, for a possible maximum payment of $75. If you do not complete the entire study, you will be paid for the number of surveys that you have completed. Payment will be made after you take each survey.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to the IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

If the research produces marketable products, will you receive any payment?
If this research produces a marketable product, there are no plans for you to receive any money.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.
Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:
- failure to follow instructions,
- failure to show up for trainings,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What will happen with the information we collect as part of this research study?
Any study information about you will be kept private and will only be given out with your permission. If the results of this study are published, your name will not be used. Your research records will be private to the extent allowed by law. In order to make sure the research is done properly, the Human Research Protection Program (the group of people that oversees research at this institution) may need access to information about your participation in this study.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's Signature Date

_____
Investigator's Printed Name