UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: TESTING THE IMPLEMENTATION OF EIT-4-BPSD
Study No.: HP-00069354

Principal Investigators: Barbara Resnick, PhD, CRNP; 410 706 5178;
Kimberly Van Haitsma 267 980 4388

This is a research study and participation is voluntary. You may ask questions and/or decide you no longer want to participate at any time. If you are consenting for someone else, someone unable to provide consent themselves, then the word "you" means that person.

PURPOSE OF STUDY

The purpose of this study is to consider how to best help staff in nursing homes provide care to residents that is person-centered and prevents common symptoms associated with changes in memory such as anxiety. The facility you live in will be randomly assigned to one of two approaches to work with the staff. You have been invited to participate in this study because you live in this facility, are 55 years of age and older, have some problems with memory and have experienced symptoms associated with memory changes such as anxiety, and you plan to be in this facility for at least 6 months and are not in Hospice. A total of 625 residents will be recruited for this study and up to 20 residents will be from this facility.

PROCEDURES

In this facility a group of individuals will work with the investigators from the University of Maryland, School of Nursing or the Penn State College of Nursing to develop the best ways to help nursing staff provide care that will meet your individual needs around such things as bathing and dressing, walking to the dining room, participating in recreational activities and other types of daily activities. The nurses will be working with you to identify the best ways in which to do this. Depending on your needs you will get assistance to perform your activities of daily living including eating, bathing, dressing, and walking in a way that your prefer such as at 10 am versus 8 am. You will be encouraged to participate with the staff in all of these activities.

At the time you consent to participate in the study you will be asked some questions about your memory and we will check your medical record for information about your medical problems and medications. In addition at the beginning of the study and 4 and 12 months later a research staff member will visit with you and the staff in the facility to learn about your physical activity, mood and behavior. Information collected from you at baseline will include a brief interview that will only take 10 or 15 minutes.

If you decide not to participate in any aspect of this study, you will receive the usual nursing care your facility provides. Specifically, the nurses will continue to implement all treatments and care that is usually done such as providing medications and helping with personal care activities.

POTENTIAL RISKS/DISCOMFORTS

It is possible that during your participation in this study you will become frustrated or fatigued when being asked some questions.

There is a potential risk of a loss in confidentiality and breach of privacy since you are sharing personal information with the study staff. Several measures will be taken to safeguard your personal information:

1) All study documents are coded with a special identifier number assigned to you. Your name will not be used on study documents.
2) Study data will be stored on secured electronic system, referred to as RedCap. Only the study team will have access to the data on this electronic system.
3) Study related interviews will take place in a private setting, away from others.
4) Information that you provide during the interviews will not be shared with the facility staff or administration.

There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

There may be no benefit to you directly for participating in this study. Your participation may help others living in nursing homes to receive care that best meets their individual needs and preferences.

ALTERNATIVES TO PARTICIPATION

You may choose to not participate in this study. You will continue to receive nursing care routinely provided to all residents in this facility.

COSTS TO PARTICIPANTS

There are no costs to you as a consequence of your participation in this research study.

PAYMENT TO PARTICIPANTS

You will not be paid to participate in this research study.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve confidential information. Several measures will be taken to safeguard your personal information:

1) All study documents are coded with a special identifier number assigned to you. Your name will not be used on study documents. At the end of the study all data will destroyed via shredding.
2) Study data will be stored on secured electronic system, referred to as RedCap. Only the study team will have access to the data on this electronic system.
3) Study related interviews and observations will take place in a private setting, away from others.
4) Information that you provide during the interviews will not be shared with the facility staff or administration. Only the principal investigator and research staff will have access to the information.
5) When reporting the findings from this study, all results will be described in the aggregate and no individual names or ways in which to identify you will be used.
6) Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

A description of this clinical trial will be available on 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.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this study. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator:

Barbara Resnick, PhD, CRNP 410 706 5178; cell 443 812 2735; or
Kimberly Van Haitsma, PhD cell 267 980 4388

HP-00069354 UM IRB Approval Date 5/25/2018
Do Not Sign this Form after this Date 3/18/2019

There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide to withdraw from the research.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data

You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include the research staff or anyone of your health care providers deciding that the research study is no longer in your best interest.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
Telephone: 410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

_____
LAR
(When applicable)

Relationship:_____

Date:_____

_____
Witness*

Date:_____