Protocol: Testing the Efficacy of FFC-AC-EIT in Patients with Alzheimer's Disease and Related Dementias.

NCT: 04235374

Approval Date: August 11, 2021

UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Testing the Efficacy of FFC-AC-EIT in Patients with Alzheimer's Disease and Related Dementias

Study No.: HP-00089301

Principal Investigator: Barbara Resnick, PhD, CRNP 410 706 5178

Sponsor: National Institute of Aging

If you are consenting for someone else, someone unable to provide consent themselves, then the word "you" means that person.

CONCISE SUMMARY:

This is a research study to test an approach to help nurses working with patients who have medical problems and memory problems to participate in activities such as bathing and walking during their hospital stay. You will be asked some memory related questions to determine if you are eligible to participate in the study. If you are eligible, some additional information will be obtained about your mood, behavior, function, physical activity, pain, medications, medical history, and medical interventions. This will take about 30 minutes and we will repeat these measures again at the time of discharge. You will be asked to wear an activity monitor that is like wearing a watch during your hospital stay. The nurses will work with you to identify goals related to your participation in personal care such as bathing, dressing, walking and other types of physical activity. At 1, 6 and 12 months after you are discharged we will call you to evaluate your mood, behavior, function, physical activity, pain and whether or not you have been rehospitalized, admitted to a nursing home, or experienced a fall.

Participation in this study is voluntary and will not alter the medical care you receive during hospitalization. The only risks to participation in this study is that you may find the questions tiring or you may worry about someone finding out that you are part of this study and your outcomes on any of the measures. You may have some discomfort wearing the Motionwatch8 consistent with the discomfort of wearing a wristwatch and you may experience some fatigue or frustration during the interview. Participation may help you maintain or improve your function during the hospital stay.

If you are interested in learning more about this study please continue reading below.

PURPOSE OF STUDY

The purpose of this study is to consider how to best help staff provide care to hospitalized patients to prevent common symptoms associated with changes in memory such as anxiety and help them maintain their ability to perform daily activities such as bathing, dressing and walking. The hospital you are in will be assigned to one of two approaches to work with the staff. A total of 600 patients from 12 hospitals will be recruited for this study and up to 50 patients from this facility.

PROCEDURES

In this facility a research nurse will work with the investigators from the University of Maryland, School of Nursing or the Penn State College of Nursing to test the best way to help nursing staff provide care that will help you participate in activities such as bathing and dressing, walking to the bathroom and walking on the unit as you are able. The decision for how this will

be done in your hospital will be chosen by chance, like flipping a coin. At the time you consent to participate in the study we will:

-ask you some questions about your memory and mood
-check your medical record for information about your medical problems, medications and some treatments like the use of oxygen.
-evaluate your bathing, dressing, and walking or physical activity
-evaluate your pain
-have you wear an activity monitor during your hospital stay. The activity monitor is like wearing a watch

We will evaluate these same things close to the day of discharge.

After you are discharged from the hospital we will call you, or someone who helps provide care for you, at 1, 6 and 12 months and ask you about:
-your mood
-your bathing, dressing, walking and physical activity
-if you experienced a fall
-if you have gone to the emergency
-if you have been hospitalized
-if you have been in a nursing home
-have you wear the activity monitor again for 5 days

These interviews will not take more than 30 minutes and will be done via the phone. In addition, if you are willing, a research staff will bring you the same activity monitor you wore in the hospital and ask you to wear this for 5 days. Information that might identify you such as your name or date of birth will be removed from our database so that the data can be used for future research or shared with other researchers without additional informed consent from you.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to: answer the questions we ask during the course of the study and wear the activity monitor.

POTENTIAL RISKS/DISCOMFORTS:

Although not likely, it is possible that during your participation in this study you will become frustrated or fatigued when being asked some questions. Our research staff will give you plenty of time to answer questions and allow you to take a break at any time. It is possible, although not likely, that you will find the activity monitor uncomfortable. We will work with you to assure that this is as comfortable as possible by altering the watchband if needed. There is a low 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; and 4) Information that you provide during the interviews will not be shared with the facility staff or administration. Although we do not anticipate any other risks, there may be risks in this study that are not yet known.

POTENTIAL BENEFITS

There may be a benefit to you directly for participating in this study. Your participation may help you maintain or improve your function during the hospitalization. Your participation may help others admitted to the hospital to receive care that best meets their individual needs and helps them maintain their ability to do personal care activities and participate in physical activity while hospitalized and during the post hospital period.

ALTERNATIVES TO PARTICIPATION

You may choose to not participate in this study. You will continue to receive nursing and medical care routinely provided to all patients 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 for participation in this 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 as a group 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 http://www.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 research. 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.

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 concerns on the part of the research staff that participation in the study is no longer in your best interest. The sponsor can also end the research study early. The principal investigator will tell you about this and you will have the chance to ask questions if this were to happen.

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
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	Signature of Legally authorized representative *(When applicable)*
Date:_____	Relationship:_____
	Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

_____
Witness*

Date:_____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____
_____

Date of Birth: _____

NAME OF THIS RESEARCH STUDY: TESTING THE EFFICACY OF FFC-AC-EIT IN PATIENTS WITH ALZHEIMER'S DISEASE AND RELATED DEMENTIAS

UMB IRB APPROVAL NUMBER: **HP-00089301**

RESEARCHER'S NAME: **BARBARA RESNICK, PHD, CRNP**

RESEARCHER'S CONTACT INFORMATION:

University of Maryland School of Nursing
655 West Lombard Street Room 390
Baltimore, MD 21201
Telephone: 410 706 5178; cell 443 812 2735

This research study will use health information that identifies you/your loved one. If you/your loved one agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Date of birth*
- *Admission and discharge dates*
- *Telephone number*

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Resnick and her research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc.

(UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS).

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. She will stop collecting health information about you/your loved one. This researcher might not allow you/your loved one to continue in this study. She can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you/your loved one receive at:
    - University of Maryland Medical System (UMMS)
    - Other participating hospitals

  It will not cause any loss of benefits to which you/your loved one are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your/your loved one's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, or UMMS.
- Except for certain special cases, you/your loved one have the right to a copy of your/your loved one's health information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from her.

My signature indicates that I authorize the use and sharing of my/my loved one's protected health information for the purposes described above. I also permit my doctors and other health care providers to share my/my loved one's protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/your loved one's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.