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

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Protocol

Design: To achieve our Aims we will use a cluster randomized clinical trial randomizing hospitals to prevent treatment contamination that might occur if we randomized units or patients within units.

Sample and Setting: Twelve hospitals (six in Maryland and six in Pennsylvania) will be randomized to treatment (FFC-AC-EIT) or Education-Only (EO) using permuted-block randomization and 50 patients per hospital will be recruited (total 600 participants). The hypotheses for Aim 1 efficacy testing include: Patient level: **Hypothesis 1:** At discharge, hospitalized patients with ADRD on units in which FFC-AC-EIT is implemented will increase time in physical activity; maintain or improve function; perform more function focused care activities; have less incidence and severity of delirium; have less evidence of BPSD; have less pain; have fewer falls; have fewer tethers; and shorter length of stays compared to those exposed to EO; **Hypothesis 2:** Patients on units in which FFC-AC-EIT is implemented will maintain or increase time spent in physical activity; maintain or improve function; have less incidence and severity of delirium; have less evidence of BPSD; have less pain; and have fewer falls; fewer emergency room visits; fewer unplanned re-hospitalizations; and fewer new admissions to long term care at 1, 6 and 12 months post discharge when compared to those exposed to EO.

Randomization Plan: The level of engagement required for the intervention prevents random assignment at the patient level as patients could become aware of differential treatment within the same unit in the same hospital and there is the risk of carry-over of treatment by staff. Thus, after hospitals are recruited they will be randomized to cohort (See Study Timeline) and randomly assigned to treatment so that the hospital will receive either FFC-AC-EIT or EO. Random assignment will be completed by the statistician using SAS proc plan which allows for simultaneous randomization on multiple dimensions (time and hospitals). In prior research we noted no differences in implementation of function focused care based on facility related factors[111,137]. We recognize, however, that hospital differences may exist and will be controlled for in the analysis (e.g.,bed size, ownership).

Sample Size: Sample size calculation was based on prior research and our primary focus which is on physical activity and function[12,14,15,33 ,106]. For primary patient level outcomes, function based on the Barthel Index resulted in a Cohen's d=.24, for physical activity the Cohen's d=.37, and for participation in function focused care by patients Cohen's d=.31. The impact on tethering, a secondary outcome, was noted to have a Cohen's d= .61. Given a two-tailed alpha of .05, an estimated intra-class correlation coefficient (ICC) between clusters (hospitals) of .02, a correlation coefficient between repeated measures of .60, and assuming even dispersion of means, a total sample of 360 patients will provide sufficient power (>.80) to detect a small effect size (d=.24)[138] in primary patient level outcomes. Our prior research showed an attrition rate of 5-40% over a 12- month period. Therefore, we anticipate that a total of 600 patients from 12 hospitals (50 patients per hospital) will be sufficient to demonstrate outcomes. With regard to hospital level outcomes, our prior work resulted in effect sizes of 0.9 for environment and policy changes[15,33,106,139]. With the proposed sample size of 12 hospitals the statistical power for these measures will be adequate (.90 for both outcomes based on our analysis plan).

Settings: Hospitals will be invited to participate if they: (a) have at least one unit dedicated to general medical patients; (b) identify two registered nurses (RN) to be champions (one for day and one for evening shifts); (c) enable staff to access email and websites via a phone, tablet or

computer; and (d) do not have a geriatric program (e.g., Acute Care for Elders, Hospital for Elder Life Program/ HELP) on the study units. We will implement FFC-AC-EIT in 6 hospitals (on the medical unit) and EO in 6 hospitals (on the medical unit) across Maryland and Pennsylvania. (See support letters and Facilities and Resources section).

Patient Participants: Patients will be eligible to participate if they: (a) are admitted into the hospital from any setting during the 12 month implementation period; (b) are 65 years of age or older; (c) are admitted onto a medical unit for any medical diagnosis; and (d) screen positive for dementia based on two well-validated scales: a score of ≤ 25 on the Montreal Cognitive Assessment (MoCA) and a score of >2 on the AD8 Dementia Screening Interview[140-143]; have mild to moderate stage dementia based a score of 0.5 to 2.0 on the Clinical Dementia Rating Scale (CDR)[144]; and lastly to differentiate between dementia and mild cognitive impairment eligibility is based on evidence of functional impairment with a score of 9 or greater on the Functional Activities Questionnaire (FAQ)[145]. The AD8, CDR and FAQ are all completed by an informant and all screening measures are reliable and valid and accurately differentiate those with and without dementia. Patients will be excluded if they: (1) are enrolled in Hospice; (2) have been on the unit for greater than 48 hours; (3) do not have a family member/caregiver that we can contact; (4) anticipate surgery; or (5) have a major acute psychiatric disorder, or significant neurological condition associated with cognition other than dementia.

The intervention activities continue for a 12 month period and we will recruit patients from the units starting at intervention month 3 and following completion of steps 1 and 2 of FFC-AC-EIT (following evaluation of the environment and policies and staff education) and following education in the EO settings. In prior research we have noted changes in staff behavior following the first two months of implementation of function focused care approaches[39,111,115,130] therefore we initiate recruitment following this implementation period. We will obtain information about eligible patients from a designated staff member and will recruit 50 patients over the remaining 10 months of the 12 month intervention. We estimate that approximately 7 to 8 patients per week will be eligible for the study. Based on our past recruitment activity[12,14] we will be able to enroll 1-2 patients per week which will meet our goal of approximately 5 patients per month. This will assure that patient recruitment is spread over the entire intervention period and is similar across all settings. Participants will be evaluated to determine their ability to self-consent using the Evaluation to Sign Consent questionnaire[146]. If they do not correctly respond to all five questions, verbal or written assent will be obtained and the Legally Authorized Representative will complete the consent process (see Human Subjects section).

The Implementation of FFC-AC-EIT:

FFC-AC-EIT is implemented by a Research Nurse Facilitator working with the stakeholder team and unit champions for 10 hours weekly during months one and two and then for four hours weekly starting in month three for a total of 12 months. Timing of the intervention activities will be flexible based on the needs of the unit (e.g., times that work best for champions and Research Nurse Facilitator to meet). The first meeting with the stakeholder team will be 1-2 hours and the remaining meetings will be approximately 30 minutes monthly to update the stakeholders on progress and any challenges associated with implementation of FFC-AC-EIT (Table 1). The majority of the time on the unit by the Research Nurse Facilitator will be spent with the champions helping and assuring that they are engaging staff in function focused care activities via the four steps of FFC-AC-EIT (Table 1). Once hospitals are randomized we will set up a time to meet with the identified contact to determine the stakeholder team members and champions and organize the first stakeholder team meeting. All FFC-AC-EIT related activities will be coordinated during scheduled working hours for the stakeholders. The first meeting will provide an overview of the implementation of Steps 1 to 4 [(1) Environment and Policy

Assessments; (2) Education; (3) Establishing Patient Goals; and (4) Mentoring and Motivating of Staff, Patients and Families] and will address the unit challenges to implementing function focused care using a Brainstorming approach (Table 1). Brainstorming involves having stakeholders identify the challenges to engaging patients with ADRD in function focused care activities during their hospital stay. We then complete Affinity Diagramming by clustering the ideas identified during brainstorming into themes. Once themes are developed, an Interrelationship Diagraph[147,148] will be made to determine which of the identified themes is the best or strongest driver. Drivers are established by having participants consider how each theme is connected to the other themes. For example, does staff knowledge about BPSD influence function. The theme with the most arrows going away from it is referred to as the "driver" or root cause. If there are multiple themes with the same number of arrows going out of them, they can be considered as equally important. The best driver, or the root cause, is the theme that is most likely to have an impact on why function focused care approaches are not implemented on the unit and will guide the stakeholder group in goal identification.

Table 1: Content for First FFC-AC-EIT Meeting With the Stakeholder Team

Introduction and Overview of FFC-AC-EIT	a. Overview of project; b. Roles and responsibilities of research and stakeholder teams; c. Background support for FFC-AC-EIT: 1. Review of current care practices/philosophies of care; 2. Task and disease focused versus patient focused care; 3. Optimizing function and physical activity in acute care: identification of and solutions to challenges identified; d. Evaluation of the multilevel context that influences implementation of FFC-AC-EIT per unit, Brainstorming Activity to identify unit drivers and unit goals.
Implementation of Steps 1 and 2 in the four step process	**a. Training to complete Step 1 Environment and Policy Assessments**: Review of the Environment and Policy Assessments (Appendix A): Assessments are used to identify need for changes in environments and policies to optimize function and safe physical activity of patients with ADRD (e.g., open areas for walking). Introduce as policy the use of the Mobility Screen and Nursing Progressive Mobility Tool to guide nurses in setting patient goals; **b. Training to complete Step 2 Education:** Review educational materials for staff, patients as relevant, and families, which have been developed by the research team[12,15] and establish a plan for staff education sessions that will assure optimal staff participation (e.g., webinar, face to face). Developed education materials include powerpoints and printed materials for staff training, patients (as relevant) and families/caregivers about optimizing function and physical activity during hospital and post hospital periods.
Implementation of Steps 3 and 4 in the 4-step process	**a. Training to complete Step 3 Establishing Patient Physical Activity Goals:** 1. Demonstration of use of the Mobility Screen and the Nursing Progressive Mobility Tool[149,150]. These tools have established evidence of reliability and validity and have been used previously to establish patient goals[149,150,151]. 2. Demonstrate goal development for patients using the Mobility Screen and the Nursing Progressive Mobility Tool and discuss ways for staff to help patients achieve goals (e.g., provide chairs in the rooms; age appropriate weights; cueing; use of recreation activities that encourage physical activity); **b. Training to complete Step 4 Mentoring and Motivating Staff, Patients, and Families:** 1. Review self-efficacy techniques (e.g., verbal encouragement) that are effective for patients with ADRD and staff; 2. Demonstrate for champions how to complete the Nurse Checklist for Function Focused Care and direct them to complete this with nurses at 0-2, 4-6, and 10-12 months post implementation of FFC-AC-EIT and provide feedback to the nurse (e.g., positive reinforcement; education); review plans to view and use weekly email Tidbits which are innovative ideas emailed about ways to engage staff and patients in function focused care activities, ways to prevent and manage delirium and BPSD.
Summary of Training Day	a. Discussion of ways the stakeholder team will work with the champions and Research Nurse Facilitator and establish times for monthly meetings; c. Opportunity for questions; d. Review of timeline of project.

In the first two months the Research Nurse Facilitator completes the environment and policy assessments with the champions and implements appropriate changes on the units (e.g., clearing hallways and making them pleasant and safe, assuring that there are places to sit in the rooms) and plans and provides staff education and makes available information for patients and families/ caregivers. The education reviews function focused care, the benefits of physical activity for patients with ADRD, ways to evaluate, prevent, and manage delirium and BPSD, focuses on elimination of entrenched and inaccurate practices such as unnecessary tethering of

patients with pulse oximetry[97], completion of the Mobility Screen and establishment of patient physical activity goals using the Nursing Progressive Mobility Tool, and use of motivational techniques to engage patients with ADRD in physical activity during all care interactions without exacerbating BPSD. Ongoing work between the champions and the Research Nurse Facilitator focuses on motivating staff and patients to work toward achievement of patient goals and established unit goals.

The stakeholder team will continue to meet with the Research Nurse Facilitator monthly (approximately 30 minutes) over the 12-month intervention period to review progress and to help champions overcome any identified multilevel challenges (Figure 1). We will keep minutes of these meetings to describe the implementation process on the unit in each hospital. This cyclic feedback pattern of review of progress and challenges will help guide staff intervention activities to best respond to contextual changes on the unit and in the hospital over time. In addition to monthly visits, weekly emails containing motivational Tidbits will be sent to all stakeholder team members within the cohort. The Tidbits include such things as: updates about benefits of engaging patients with ADRD in physical activity while hospitalized; information to support de-implementation of entrenched and inaccurate practices(e.g., support for removal of tethers)[97,98,152]; symptom management (e.g., management of pain and BPSD); prevention and identification of delirium; motivation techniques such as using patients' prior work life or leisure activities to serve as a source of motivation to engage in physical activities[153]; and motivational contests for nurses (e.g., reward for the nurse who provides the most innovative approach to engaging a patient in bathing, dressing, or ambulating). To further facilitate implementation we will give each treatment site: 1) a 100 dollar gift certificate from Nasco (Nasco.com) to buy supplies for the unit to engage patients with ADRD in physical activities (e.g., age-appropriate weights; soft horseshoe toss game); 2) 1000 dollars at the end of the study for each champion to attend a conference and submit an abstract focused on optimizing function and physical activity of hospitalized older adults with ADRD.

Education Only (EO) Control Intervention: Hospitals randomized to EO will be provided with an in-service for nursing staff on function focused care in patients with ADRD by an EO Research Nurse Facilitator using our developed PowerPoint presentations in 30-minute sessions as is currently done in usual practice. We will provide the education in the preferred format (e.g., face-to-face; webinar). No further interaction with the staff or the units will occur. We recognize that there will be differences in time exposure to the Research Nurse Facilitators but we are deliberately testing two different approaches to implementation of function focused care on hospital units with older adults with ADRD (FFC-AC-EIT versus EO). Time/exposure to the Research Nurse Facilitators is part of the approach and we will consider exposure time differences between the treatments.

Hospital descriptive data: The following data will be obtained at baseline to describe the hospitals and consider confounders: state; bed size; ownership status; urban or rural; Magnet™ Status; teaching status.
Unit descriptive data: We will obtain staff/patient ratios and mix (registered, licensed practical nurses, and nursing assistants) at baseline, 6, 12 and 18 months and bed size.
Patient descriptive data: Data will include age, race, sex, cognitive status based on the MoCA[140,141], marital status, education, admission diagnosis, admission living situation, the Cumulative Illness Rating Scale (CIRS)[154], medications, length of stay, and discharge location and living location at each follow up period.

Measures for Aim 1 (Appendix A): Bolded measures are based on subjective data from informants (nurse/family); other measures are completed by evaluators based on observation or

chart abstracting. Environment and policy assessments are completed by evaluators who are blind to randomization.

Efficacy Data (see hypotheses 1-5 above):

For patients**: **Barthel Index (BI)[155] will be used to evaluate function. The BI is a 10 item measure of ability to perform activities of daily living (e.g., bathing, dressing) with evidence of internal consistency (alpha coefficients .62-.80), inter-rater reliability (r=.89) and validity based on correlations with the Functional Inventory Measure (r=.97)[155]. Items are weighted to account for the amount of assistance required. A total score of 100 indicates complete independence. ***The Physical Activity Survey*** [33,156] is a subjective measure of time spent in physical activities over 24 hours based on input from an informant. Activities include locomotion (e.g., walking, wheelchair mobility), personal care (e.g., bathing), structured exercise (e.g., physical and occupational therapy), recreational activity (music), and repetitive behavior (moving objects repeatedly). Prior use of the measure provided evidence of criterion-related validity (r=.55 -.60, p<.05) and inter-rater reliability (r=.82 -.94, p<.05)[33,156]. *The MotionWatch 8* (only obtained during hospitalization) is a compact, lightweight, wrist-worn activity monitoring device used to document physical movement. The MotionWatch 8 contains a miniature accelerometer to allow measurement and recording of physical movement of the wrist which provides a close correlation to whole body movement. Reliability, validity, and cutpoints for different levels of activity have been established for older adults[157]. We will place the MotionWatch 8 on at baseline and leave this on till discharge so that we can capture baseline activities (the first 24 hours of measurement), mean daily activity while hospitalized and discharge activities (the 24 hours prior to discharge). Specifically we will collect counts of activity and time spent in sedentary, moderate, and vigorous activity during these time periods. *Patient Checklist for Function Focused Care* (only completed during hospitalization) is a 19-item measure in which nurse-patient interactions are evaluated over a 30 minute period to determine if the patient performs function focused care (e.g., participates in bathing at his or her highest level). Patients either do or do not perform the activity (e.g., patient refuses to perform). If the item/activity is not observed it is marked as not observed. Percentage scores are calculated based on function focused care performed/observed activities. Prior testing supported inter-rater reliability (r =.92) and validity based on correlations with function (r =.89)[158]. Delirium occurrence will be based on structured interviews consisting of questions from the MoCA[140,141] first to establish if there is evidence of cognitive impairment and then the *Confusion Assessment Method (CAM)* to establish if there is delirium[151]. A review of studies testing the psychometric properties of the CAM noted that in seven high quality studies there was an overall sensitivity of 94% (95% confidence interval, CI, 91–97%), and specificity of 89% (95% CI, 85–94%)[159] and evidence of inter-rater reliability[160]. Delirium severity will be determined based on the ***Delirium Rating Scale*** which is a 10 item scale that is completed by an informant[161]. Prior testing supported the validity of this measure based on differentiation of delirium among different groups of patients and reliability based on inter-rater reliability (r=.97). Scores can range from 0-26 with higher scores indicative of more severe delirium. BPSD will be evaluated using the ***Brief Neuropsychiatric Inventory (NPI-Q)***[162] which is a 12-item, reliable and valid informant-based assessment of neuropsychiatric symptoms. Each of the 12 NPI-Q domains contains a survey question that reflects symptoms of that domain and if present then severity is rated (symptoms include resistance to care, apathy, anxiety, depression, motor disturbance, disinhibition, agitation, sleep issues, hallucinations, and delusions). The informant (nurse/caregiver) providing care to the patient on the day of testing will be asked to respond to the items based on the past 24 hours. Prior testing has established evidence of validity of the measure with a sensitivity of 74% and specificity of 80% and test retest reliability (r=.99)[163]. Pain will be evaluated using the *Pain Assessment in Advanced Dementia (PAINAD)*[164]. The PAINAD includes 5 behaviors that are

commonly noted among individuals with pain. Observations will be done, as recommended, during periods of activity such as transferring or ambulating. Scoring ranges from 0 to 2 for each specific pain behavior. A total score of 1-3 is indicative of mild pain, 4-6 is moderate pain and 7-10 is severe pain. Prior testing provided evidence of inter-rater-reliability (kappa=.74) and concurrent validity (p<.001)[165]. *Tethering:* Tethering of patients will be based on chart review of orders for: indwelling urinary catheters, sequential compression devices, continuous intravenous, bed/chair alarms, cardiac monitoring and pulse oximetry, physical restraints, bedrest orders or negative pressure wound therapy devices. The total number of tethers will be calculated. ***Patient Falls*** will be based on chart review and documentation of the falls that occur during the acute care stay. Post hospitalization falls will be based on informant recall of number of falls during the course of the follow up period (discharge to 1 month; 2-6 months; and 7-12 months post discharge). ***Emergency room visits, unplanned re-hospitalizations, and new long term care admissions*** will be based on informant recall at follow up (discharge to 1 month; 2-6 months; and 7-12 months post discharge).
For hospitals*: Environment Assessment* includes 18 items that have an impact on engaging patients in function and physical activity[15,166]. Examples of items include evidence of having clear pathways; pleasant areas to walk; pleasant destinations to walk to; safe footwear; appropriate height of chairs and beds to facilitate transfers. Items are scored as present or not present and summed. There was prior evidence of inter-rater reliability (r=.89) and validity based on hypothesis testing and prior evidence of change in environments following exposure to FFC-AC[15,33,166]. *Policy Assessment* includes 15 items that reflect policies that support engaging patients in function and physical activity and support dementia friendly environments[15,33,166,167]. Examples of items include evidence of policies around use of restraints, indwelling urinary catheters, and ambulation on the unit. Items are scored as present or not present and summed. There was prior evidence of inter-rater reliability (r=.84) and validity based on evidence of improvement in policies to optimize function and physical activity following exposure to FFC-AC[15,33,166].

Data Analysis:

Efficacy (see hypotheses 1-3 above):

Descriptive statistics including measures of central tendency, dispersion and appropriate visualization approaches (e.g., box plots and spaghetti plots) will be performed on each outcome variable for patients and hospitals. This will be done to ascertain distributional characteristics and ensure that the assumptions (e.g., normality) associated with the planned statistical procedures are met. When necessary, transformations will be performed. All analyses will be done using an intent-to-treat philosophy. Baseline characteristics (both patient and setting levels) will be compared between intervention and control groups and the relevant variables (e.g., age) that differ by group will be included as covariates in hypotheses testing. In particular, we will control for the variables that correlate with function and physical activity including sex, comorbidities and cognitive impairment. Linear mixed models (LMMs)[170] for longitudinal data (admission, discharge, 1, 6 and 12 months) will be used to assess the intervention effect on continuous outcomes (e.g., physical activity, function, and length of stay) accounting for clustering of patients that may occur within the same hospital and for correlations between repeated measurements of each patient. Generalized Linear Mixed Model (GLMM) analyses will be conducted to assess the effect of the intervention on count outcomes (e.g., falls) or binary outcomes (e.g., readmission or not). The fixed effects included in the models will be treatment group (FFC-AC-EIT versus EO), time (admission, discharge, 1, 6, and 12 months post discharge for patients depending on the time points when the effects are evaluated), group-by-time interaction term and the aforementioned relevant covariates, such as age, sex, race, staffing, hospital size etc., identified from the baseline analyses will be included in the mixed

model to adjust for their influences. Random effects will include hospitals and patients. The hypotheses will be tested by evaluating the interaction term for each outcome variable. For each hypothesis, exploratory analyses will be performed to assess model assumptions. Post-analysis diagnostic measures (e.g., residuals) will be explored to assess model fit. All tests will use a 5% significance level. The use of LMM will provide flexibility with regard to assumptions related to the covariance structure of the residuals and the presence of missing data for the repeated measures[171]. As secondary analyses, we will also consider three-way interactive effects among demographic variables of interest (e.g., sex, age), and treatment condition, and time to identify moderators of the treatment effects. All of the Research Nurse Facilitators are women so we do not anticipate an effect of sex on outcomes. Generalized estimating equation (GEE) models will be used to compare changes in hospital level measures (i.e., environments, policies) (Hypothesis 3) from baseline to 6,12, and 18 months as GEE is more robust than LMMs when the sample size is relatively small (n=12)[172].

Missing data. In prior research we had a 5-40% rate of attrition at the patient level and 0% at the hospital level[12,33]. If there is significant dropout, we will identify baseline characteristics that differ between persons or hospitals that drop out. Maximum likelihood methods will be used for primary analyses, which address non-informative dropout [missing at random (MAR)]. If "informative" dropout is present, we will consider sensitivity analyses that add these relevant baseline covariates to make the MAR assumption more plausible[173].