1) Protocol Title

Title: Case series to pilot a psychosocial intervention to support Alzheimer's family caregivers in Vietnam

Protocol Version Date: *6/5/2017*

2) Objectives

The objective of this study is to pilot test a behavioral intervention for family caregivers of persons with Alzheimer's disease in Vietnam in order to determine its feasibility and acceptability. Based on the results of this study, the behavioral intervention will be modified and then tested in a future randomized controlled trial.

3) Background

Low and middle income countries (LMIC) such as Vietnam are undergoing a dramatic demographic transition that will result in a substantial increase in the number of older adults, including those afflicted with Alzheimer's disease and related dementias, over the next several decades. Dementia is among the most disabling and costly neurodegenerative brain diseases. Strengthening LMIC capacity to support family caregivers of persons with dementia through low-cost and sustainable non-pharmacological approaches, such as education and skill-building to deal with difficult behaviors, is vital to avoid costly and ineffective alternatives such as psychotropic medications or institutionalization, and to reduce caregiver burdens and depression. While evidence-based non-pharmacological treatments exist in high income countries (HIC), these interventions have not been adapted for use in Vietnam and other LMIC. This project addresses these gaps by building capacity of investigators in Vietnam to pilot-test REACH-VA, an evidence-based model for dementia caregiver support. This project also builds on preliminary data based on interviews with key stakeholders in Vietnam, including family caregivers of persons with dementia as well as community leaders, which leads the research team to conclude that the REACH-VA is appropriate for the Vietnamese context.

4) Inclusion and Exclusion Criteria

Alzheimer's family caregivers will be identified through a registry of persons with dementia at the Vietnam National Geriatric Hospital in Hanoi.

To be eligible, the person will an adult who is the identified primary adult caregiver (i.e. the person spending the most time day-to-day providing care) to an older adult who is living in the community and has received a diagnosis of Alhzeimer's disease or another degenerative dementia. All participants will be living in the Soc Son area outside Hanoi, Vietnam.

The final sample will be 10 family caregivers of persons dignosed with dementia. The study will exclude

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Prisoners
- Pregnant women.

5) Study Timelines

- Each family caregiver will participate in 3-6 sessions delivered over the course of 2-3 months.
- We anticipate enrolling subjects from mid-July through the end of September, 2017
- We anticipate completing preliminary analsysis of the data by January of 2018.

6) Study Endpoints

This is a time-limited intervention lasting up to 2-3 months.

7) Procedures Involved

This is case series to pilot-test a culturally adapated behavioral intervention to support Alzheimer's family caregivers. The manualized intervention will consist of 3-6 one hour sessions with a trained health professional (e.g. nurse or social worker). The sessions will be administered in the home (or other setting of the subject's choice such as a clinic) and focus on psychoeducation, stress reduction, skill-building. The intervention will be tailored to the needs and preferences of the caregiver.

A research protocol will be used that includes scripts, study scales (e.g. depression, anxiety) detailed desciptions of the goals for each session, and standardized forms (see attached study manual).

8) Data and/or Specimen Management and Confidentiality

Because the main goal of the study is to pilot-test the intervention in a small number of subjects prior to a larger randomized controlled trial, there are no planned statistical analyses.

Procedures for maintenance and confidentiality include 1) assigning each participant a unique identifier, 2) data collected will be labeled using the unique identifier and will be stored separately from the key linking personal information (e.g. name, date of birth, address, phone number) and identifiers, 3) all data will be kept under lock and key or on a secure server that is only accessible to research staff, 4) at the conclusion of the study, the key linking identifiers and personal information will be destroyed, 5) all research personnel in the US who have access to the patient data will receive training on conducting human research (e.g.

NIH onlinecourse) – all investigators in Vietnam will participate in the local equivalent of this training.

9) Data and/or Specimen Banking

All data will be stored on a secure server at in Vietnam. De-identified data will be transferred to UC Davis and the University of South Carolina electronically through an encrypted zip file. At the conclusion of the study, the key linking personal identifiers to the survey data will be destroyed.

10) Provisions to Monitor the Data to Ensure the Safety of Subjects

The goal of this pilot care series is to assess feasibility and acceptability of the behavioral intervention to support Alzheimer's family caregivers. Case review will occur on a weekly basis with a team that includes the care manager and the local PI and one investigators from the UC Davis and the UofSC. The caregiver's level of distress and any indicators of elder abuse/neglect will be reviewed at each session. All adverse events to the PIs from all three institutions within 24 hours.

11) Withdrawal of Subjects

Subjects (patients and family members) may withdraw at any time. If they withdraw from the study, they will be given the option of having their records destroyed.

12) Risks to Subjects

There are two main risks associated with this study: 1) discomfort or mild distress because of the intervention and 2) inconvenience because of the need to fill out the study questionnaires. These risks are similar to the risk of undergoing routine assessments in healthcare clinics in Vietnam. Specific steps are being taken to address each category of risk.

Discomfort due to the intervention: Even though this study builds on evidence-based strategies for support of family caregivers, subjects may experience discomfort or mild distress when discussing their caregiving experience or because of concerns about confidentiality. These risks are being minimized in several ways. First, caregiver will be given the option of discussing issues privately with the care manager during the intervention. Second, the care manager will be trained to monitor the nature of interactions between patients and family members and any serious issues that emerge will be discussed with the supervising team so that strategies can be developed to address any issues that arise. Finally, subjects will have the opportunity to drop out of the family-

centered arm of the study and complete treatment by themselves or drop out of the study altogether.

Inconvenience due to questionnaires: To address the inconvenience associate with completing study questionnaires, we will give subjects the option of completing these in the home or by phone. In addition, during the consent process, participants will be advised that they can choose not to answer any questions that make them feel uncomfortable. Risks to subjects are minimal for several reasons.

This is a behavioral intervention and does not involve drug treatment. In prior studies conducted in the US with a multi-cultural populations in the United States there have not been any serious adverse side events attributable to the intervention (personal communication with one of the PIs of a large-scale national study). It is also possible that elder/abuse or neglect may be detected during the study and require intervention. A protocol for handling cases of abuse/neglect according to local norms/resources has been developed in collaboration with our colleagues in Vietnam.

13) Potential Benefits to Subjects

There are several potential direct benefits to subjects. Subject may experience an increase in their knowledge and skills as a result of the intervention. In addition, caregivers will learn stress reduction techniques that may help reduce caregiving-related distress.

14) Multi-Site Research

This is a single-site, multiple PI, international study and Dr. Hinton is the lead investigator. Dr. Hinton will be responsible for ensuring that all sites have the most current version of the protocol and consent document. He will also be responsible for ensuring that 1) All required approvals have been obtained at each site (including approval by the site's IRB of record), 2) All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented, 3) All engaged participating sites will safeguard data as required by local information security policies, 4) All local site investigators conduct the study appropriately, and 5) All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.

15) Community-Based Participatory Research

NA

16) Provisions to Protect the Privacy Interests of Subjects

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Indicate how the research team is permitted to access any sources of information about the subjects.

17) Compensation for Research-Related Injury

NA – minimal risk study

18) Economic Burden to Subjects

There are no costs that subjects may be responsible for because of participation in the research.

19) Drugs or Devices

NA

20) ClinicalTrials.gov Registration

Section 1: NIH Funded Studies

If yes to BOTH, the study must be registered on Clinicaltrials.gov.

Yes	
☒	This study is funded by the NIH. (If this study is not funded by NIH, go to Section 2.)
☐	One or more human subjects will be prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Section 2: Studies subject to FDA jurisdiction

If yes to ANY the study must be registered on Clinicaltrials.gov.

Yes	
☐	This is a prospective clinical study of health outcomes in human subjects that compares an intervention with an FDA-regulated device against a control. This is not a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes.
☐	This is a pediatric postmarket surveillance of a device as required under section 522 of the Federal Food, Drug, and Cosmetic Act.
☐	This is a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act.

To view a flowchart describing applicable clinical trials subject to FDA jurisdiction click here.

Section 3: Publishing the results

If yes to BOTH the study must be registered on Clinicaltrials.gov.

Yes	
☐	This study prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention *and* a health outcome.
☒	The PI has access to and control over all the data from the clinical trial and has the right to publish the results of the trial and plans to publish the results in a journal that follows the ICMJE recommendations.

This requirement includes studies of behavioral interventions.

Section 4: Registration on Clinicaltrials.gov is not required

Yes	
☒	I have read sections 1-3 above and registration on clinicaltrials.gov is not required for this research.

21) Criteria for 10 Year Approval

If yes to all items below this research may qualify for a 10-year approval period.

Yes	
☒	This research involves no more than minimal risk.
☐	This research does not receive any federal or state government funding or funding from a private funder who requires annual review per contract.
☐	This research is not subject to FDA jurisdiction.
☐	This research does not include prisoners as participants.
☐	This research is not subject to SCRO oversight.
☐	This research is not subject to oversight by the Research Advisory Panel of California (RAP of C).
☐	This research does not involve identifiable information held by the State of California Department or Agency
☐	No personnel involved in the design, conduct, or reporting of this research have a new unreported related financial interest (RFI) in this study.