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Title: Accurate WiFi-Based Localization of Dementia Patients For Caregiver Support

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1. Project Title:
Accurate WiFi-Based Localization of Dementia Patients For Caregiver Support: Phase II

2. Investigators:
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3. Abstract:
In this Phase II SBIR project we will enhance a wireless WiFi-based insole that was designed and successfully tested and evaluated during a Phase I trial with elderly persons with dementia and their caregivers, and then investigate its efficacy in reducing caregiver activity and burden, and improving caregiver quality of life. An estimated 5.4 million Americans had Alzheimer's disease in 2016 and a 50% increase in this number is expected by 2030. The majority of these patients (70%) will live at home where they receive 75% of their care from informal, unpaid caregivers, such as family members, friends, and neighbors. These caregivers provide valuable services, often at great economic and psychological cost to themselves. In 2015, over 18 billion hours of unpaid care were estimated to have been provided by over 15 million caregivers. Around 15% of them quit their job or reduced their hours to provide this care. This translated to nearly $222 billion dollars of unpaid care in a single year. In the absence of a cure, dementia patients and caregivers prioritize quality of life as their most valued outcome. Technological solutions to assist caregivers in locating wandering patients have been introduced. However, existing solutions lack reliable functionality for indoor environments, require significant infrastructure enhancement, or burden both patient and caregiver with the use of non-discreet electronics packages that must be worn as wristbands or belt mounts. There exists an unmet need to support caregivers by providing a comprehensive localization solution of the patient relative to the caregiver that works both indoors and outdoors with little to no additional infrastructure required.

ASTER Labs' device, called Activlink, is a patient localization solution optimized to assist monitoring by primary and secondary caregivers of dementia patients in indoor building environments. The goal is to increase quality of life for caregivers by providing a highly-accurate localization of a patient's position, combined with real-time alerts of a patient's wandering movements. Perpetual safety concerns and the demands of constantly monitoring their patient result in caregiver's often reported reduced abilities to function in normal daily activities. Activlink provides on-demand access to real-time location visualization within a home or public building, both while in relatively close proximity to the patient and remotely, for remotely-located family members or secondary caregivers wishing to monitor the patient's location. The innovative concept design for this system provides continuous localization capabilities, so that the quality of life for both patient and caregiver may be enhanced by allowing both to move throughout a home or in large indoor spaces like malls, airports, and medical centers. In this project, ASTER Labs will use WiFi and inertial sensor dead reckoning technologies to create a highly unique, accurate, and practical indoor localization solution. This Phase II SBIR will evaluate the efficacy of the WiFi-based insole to provide caregivers with augmented patient awareness, helping to improve their immediate quality of life by reducing their direct burden of continuous oversight of their person in care. Evaluation will be done using semi-structured interviews and participant observation data collected on persons with moderate to mild dementia, their family caregivers, and professional care providers via an embedded randomized controlled evaluation.

4. Background:
Recent research indicates longer life expectancy for America's seniors than at any prior time, with 65 year olds expected to live almost two additional decades. In the next 25 years, the United States' elderly population expects to see an 80 percent growth [1]. Coupling these projections with the advance of the *baby boomers*, the roughly 46 million current seniors will soon see large additions to the elderly population. For the oldest seniors, this population increase has meant a heightened prevalence of aging-

associated conditions and diseases. In 2016, 14% of all American seniors over 71 years old were diagnosed with dementia, or almost 5.5 million people [2]. In the *oldest old*, those seniors over age 90, that occurrence spiked to 37.4% [3]. Lacking methods to prevent, cure, or slow the progression of Alzheimer's disease (AD) and similar variations of the syndrome, one in every three seniors is expected to die with some form of dementia [4]. In the coming four decades, the number of functionally dependent Americans with AD, predicted to be around three times the current number, may overwhelm the eldercare system and significantly tax the availability of quality long-term healthcare. AD, the most common form of dementia, characteristically worsens significantly through its progression. The early stages involve symptoms of forgetfulness, with patients unable to recall familiar people's names or recent events [5]-[8]. In its middle stages, disorientation, memory loss, and confusion tend to see a marked increase, so that recalling appointments, recognizing family members, and remembering important tasks like taking medication becomes much more difficult [5]-[8]. It is often at these stages that patients will experience heightened anxiety associated with the cognitive loss that leads to personality changes, loss of sense of self, and frustrations with the newly imposed lack of independence [9]. Caregiver's quality of life therefore is distinctly impacted by a patient's behavioral changes like depression, fear, frustration, and grief [10].

In the absence of a cure, dementia patients and caregivers prioritize quality of life as their most valued outcome [11]. Safety concerns impact quality of life and are a primary reason for dementia patients' relocation from home [12]. Significant economic cost is associated with the treatment and care of AD patients, who can expect to pay near triple the cost for healthcare and long-term care [3],[13]. Recent estimates indicate informal, unpaid caregivers, such as family members, friends and neighbors, provide three-quarters of the care for patients suffering from dementia, 70% of whom are cared for at home full or part time [15],[16]. New studies show that informal in-home patient monitoring has the potential to reduce frequency of hospital and emergency room visits and delay institutionalization [17], [18]. Despite this benefit, the economic cost has become overwhelming. In 2015 alone, an estimated 18.1 billion hours of informal, unpaid care were provided by over 15 million caregivers, numbers which translated to almost $221.3 billion in unpaid caregiving in the United States [19],[1]. Accompanying the financial burden, informal caregivers cite lost work hours, leaves of absence, and career abandonment as common work-related issues associated with the conflict between caregiving and career [20]. In more serious cases, psychological effects and shortened lifespan have been attributed to the demands of caregiving [15],[16],[20]. Monitoring dementia patients typically requires diligent and continuous attention, making feelings of isolation common [21]–[23]. Inabilities to interact in normal social settings and activities and difficulty caring for non-mobile dementia patients add to the list of stress factors associated with caregiving [24],[25].

While progression of each patient's dementia varies, one of the most common and burdensome similarities in behavior is wandering, or *dementia elopement* [14],[25]. It is estimated that 60% of AD patients exhibit this behavior and are at risk of disorientation and associated injuries [26],[27]. Studies show that half of all wanderers lost for 24 hours or more will be injured or die [28],[29]. The advancement of AD tends to increase the disorientation in time and space, increasing the probability of elopement behavior [2],[30],[31]. A system providing caregivers the ability to localize a wandering patient would reduce the emotional burdens of caregiving and enhance the safety of dementia patients. This localization tool, which automates the monitoring process and provides rapid alerts when a patient's movement indicates undesired wandering, holds significant potential. The tool would renew caregiver's abilities to function in normal daily activities and increase economic freedom from the great cost associated with caring for a patient or loved one suffering from dementia.

5. Specific aims:
The efficacy of the Activlink system offering localization information to improve caregiver will be evaluated in two studies. Study 2a will use the insole system with dementia patients residing in skilled or memory care. Data regarding caregiving activity will be collected from their paid professional care providers. Study 2b will use participant localization data collected on 80 independently dwelling mild dementia patients. In this case data will be collected from their unpaid family caregivers. Both studies will result in evaluating the efficacy of the WiFi-based insole to provide caregivers with augmented patient awareness, helping to improve their immediate quality of life by reducing their direct burden of continuous oversight of their person in care.

6. Research plan:
The proposed study is the second phase of a larger, multi-phase study: Accurate WiFi-Based Localization of Dementia Patients For Caregiver Support. The first phase involved assessing the feasibility and utility of the *Activlink* insole. The specific aims of the first phase were to define the architecture and build a prototype *Activlink* insole, develop the software solution of the WiFi-based localization, and evaluate the feasibility of using the insole and associated application for providing caregivers a method to monitor the location of their demented patient (see page 15 of 57 of the NIH Grant Proposal). Phase I goal was fully accomplished and feasibility was successfully shown via both technical evaluation of the insole prototype system as well as positive responses in the Phase I focus study evaluation (see page 19-24 of the NIH Grant Proposal. As all the Phase I aims were achieved, Phase II builds upon the discoveries and enhancements raised during Phase I, and results in the development of a market-ready insole device tested and evaluated in a large human study. There are two aims in Phase II. The first aim targets the creation of a market-ready insole sensory system with cross-platform mobile application. The second aim of Phase II relates specifically to the purpose of the proposed study. This study which encompasses aim two of Phase II, focuses on evaluating the efficacy of the *Activlink* system by offering localization and wandering status of individuals with dementia to improve caregiver quality of life. Specifically, this study (Phase II, aim 2) will be completed using two separate studies, Studies 2a and 2b. Study 2a will use the insole system with dementia patients residing in skilled or memory care. Data regarding caregiving activity will be collected from their paid professional care providers. Study 2b will use participant localization data collected on 80 independently dwelling mild dementia patients. Both studies will result in evaluating the efficacy of the WiFi-based insole to provide caregivers with augmented patient awareness, helping to improve their immediate quality of life by reducing their direct burden of continuous oversight of their person in care.

Design
Both studies will involve a counterbalanced within-subject design. Specifically, each target patient will randomly be assigned to either have the technology or not have the technology applied for a period of three months, followed by three months of the opposite condition. Caregivers will provide caregiver ratings twice monthly during these two epochs. For Study 2a we will deploy 5 units during the initial 3 months and have 5 patients unmonitored. Then these patients will switch conditions. For Study 2b, we will deploy 20 units at a time and have a total of 4 cohorts (monitored then unmonitored months 13-18, unmonitored then monitored months 13-18, monitored then unmonitored months 19-24, unmonitored then monitored months 19-24). For Study 2b, caregivers will be mailed questionnaires related to caregiver activities, caregiver burden, and quality of life on a weekly basis throughout the six month span of the study.

Settings and Targeted Population
Ambulatory dementia patients will wear the localization device in these studies. However, the study participants actually providing data in these studies will be paid and unpaid caregivers. Study 2a will be conducted in the memory and skilled care units at Oak Hammock Senior Living Center in Gainesville, FL. Five ambulatory patients with moderate dementia (Mini-mental State Exam (MMSE) scores of 10-18) in each setting (memory/skilled) will be identified and with consent of their legal proxies included in

their study. Participants in Study 2a will include 10 persons with moderate dementia and their six paid caregivers at Oak Hammock Senior Living Center. These professional caregivers preside over multiple patients at one time, so only six paid caregivers are needed for these 10 patients. Separate day and evening shift assigned primary caregivers (typically certified nursing assistants) will be provided the smartphone tool used for monitoring location. Study 2b will be conducted with community dwelling dementia patients with mild dementia (MMSE 19-25). Participants in Study 2b will include 80 community dwelling persons with mild dementia and their 80 unpaid, family caregivers who all reside in the Gainesville, Florida area. Caregivers for these patients will have at least 3-times weekly contact with the patients. Cohabitation will not be required but will be recorded will caregiver relationship (spouse, adult child, other family, friend) as covariates. Presumed etiology of the dementia will be recorded but will not be a selection factor (Alzheimer's, vascular dementia, Lewy body dementia).

Study 2a
Persons With Dementia
Inclusion Criteria

- Resides in memory care or skilled nursing at Oak Hammock Senior Living Center
- Moderate dementia (MMSE of 10-18)
- Ambulatory (without or with cane, walker or wheelchair assist)
- A legal proxy that can provide consent

Study 2b
Persons With Dementia
Inclusion Criteria

- Resides in independent living setting in community.
- Mild dementia (MMSE of 19-25)
- Ambulatory (without or with cane, walker or wheelchair assist).
- Has a legal proxy that can provide consent.

Care Partners
Inclusion Criteria

- Speaks English
- Be 21 years of age or over
- Has at least three times per week direct contact with person with dementia (PWD)
- Consents to participate in the study

Exclusion Criteria

- Is not fluent in written or spoken English
- Indicate an unwillingness to use the *Activlink*
- History of Major Mental Illness for patient or caregiver

Vulnerable Population
Pregnant women, decisionally impaired individuals, and UF/OneFlorida Institution Students may be vulnerable populations that may be included in this study but not purposely targeted. In fact, it is unlikely that our subjects will be pregnant because of the age the majority of our participants will be. Pregnant woman are not excluded from the study but are unlikely to be participants as those females of childbearing age generally fall outside the range of the typical family member of a person with dementia (PWD). However, it is important to include pregnant women in this project because we would be losing family members of PWD if we exclude women under the age of 62. Nonetheless, the study will use no drugs or devices that are potentially harmful to the fetus. These individuals will be fully disclosed and will understand they can refrain from participating in the study at any time. They will also be told that no drugs or devices are used in the study that could be harmful to the fetus.

As for decisionally impaired individuals, the primary goal of this study is to provide a practical solution of monitoring the location of individuals with dementia to reduce caregiver stress and burden and improve quality of life. Early stage dementia symptoms include forgetfulness, patients unable to recall familiar people's names or recent events. These individuals can often function independently or with minor assistance from others. Monitoring location in these individuals who continue to reside in community could be extremely advantageous to the individual themselves and to their possible caregiver to avoid them getting lost in unfamiliar environments and also to assure they are following routines. In the moderate stages of dementia, marked increases occur in disorientation, memory loss, and confusion exaggerating the need for monitoring. We believe these individuals, along with their caregivers, would significantly benefit in location monitoring as problems with disorientation become more prevalent. All individuals will dementia must have a legal proxy that can provide consent to support the patients assent. Both patients with dementia and their caregivers will be informed that their participation in the study is entirely voluntary, and though no harm is expected from their participation, they can stop participating at any point of the study. Furthermore, both patients and caregivers will be told that their choice of whether or not to participate will not affect their clinical care.

It is important that we include UF/Shands/VA/OneFlorida Institution Staff in the study because these individuals could potentially be caregivers of people with dementia. These individuals will be fully disclosed and will understand they can refrain from participating in the study at any time. They will also be told that no drugs or devices are used in the study that could elicit harm. They will also be told that their participation in the study will remain confidential and not affect their position as UF/Shands/VA/OneFlorida staff.

Measures and Devices Proposed

Dementia patients will wear the provided insole inserted into their own shoes. The insole will have a small electronic sensor that measures acceleration, foot force, and/or orientation. The subject will then walk for a series trials to determine the wearability while in motion. Data will be transmitted securely from the sensor system to the data collection device, a laptop or desktop computer. Once collected, the data file will be securely stored. Caregivers will complete paper records of caregiver activity, burden, and quality of life.

Location Validation Measures in Study A. For one-week prior to the formal efficacy trial, the technology will be deployed to all 10 participants. Once per shift at a randomly generated time, the paid caregivers a notification (a buzz on the smartphone) and asked to respond 1) location visually verified to be correct 2) location visually verified as incorrect or 3) unable to provide verification at that time due to other responsibilities. In the case of the last response, the system will auto generate another notification latter in that shift. Caregivers will be asked to verify location as either correct or incorrect at least one time per shift. Ten patients tracked at least twice per day over 7 days will provide 140 data points to assess the accuracy of the system at tracking patient location. An accuracy of less than 95% will result in our delaying the efficacy study until technical improvements can improve the accuracy of the deployed system.

Primary Efficacy Outcome. Primary outcome measure in both studies will be the Caregiver Activity Survey (Davis, et al., 1997). This well validated scale requires caregivers to report on amount of time spent caregiving for a particular patient. It has high test-retest reliability (.88) and documents an increase in time spent in supervision as MMSE declines overtime (Marin et al., 2000). Caregivers will be asked to complete this instrument once every two weeks.

Secondary Efficacy Outcomes in Study b. Caregivers in study b will also complete the short-form of the Zarit Caregiver Burden scale [32] and the AD Quality of Life Scale [33]. Both scales are reliable, well validated, and the most widely used measures of careburden and AD-QoL.

Recruiting Procedure

Dr. Smith will identify persons from his clinical practice as well as those referred by other neuropsychologists and neurologists. Flyers will may be given to other physicians as well as psychologists at the University of Florida. If a psychologist or a clinician has a patient that appear eligible for the study, they may provide their patients with a study flyer. Approved flyers will may also be posted at the abovementioned sites (UF Health Clinics) such as the Memory Disorder Clinics, behavioral neurology and neuropsychology practices at the University of Florida, as well as at Oak Hammock. Potential participants and their partners may contact the study coordinators if they wish they wish to participate. For participants in phase one, an appointment will be set up to gather informed consent with participant and legal proxy at Oak Hammock. If informed consent is obtained, screening will follow. For participants in the second phase, a brief screening will take place over the phone, followed by setting up an appointment to gather informed consent in person, at the University of Florida or, if more convenient for the participant, at the participants' home. Once informed consent is obtained, an additional screener of dementia will then follow.

We may table at community events (e.g. Vitality Fair at Oak Hammock), where flyers would be provided and sub-investigators would be present, tabling, to provide a brief summary of the study. In these instances, flyers will be handed out to individuals. Potential participants would get any questions answered and see and hear about the inclusion/exclusion criteria. If potential participants show interest, they will be told to call the number on the flyer to set an appointment to obtain consent. During this phone call, a brief screener will take place. After consent is obtained in person, an additional screening (administration of the MMSE) would occur after informed consent is obtained. Graduate assistants will be obtaining consent, and will emphasize both the participant's option to not participate as well as their ability to withdraw at any time with no consequences or repercussions.

Data Safety Monitoring Board

As the proposed project will pose minimal risks to study participants the Principal Investigator (PI), Dr. Smith, will serve as the primary monitoring entity of this study. The proposed study involves no invasive procedures and there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver a relative with dementia. However, potential participants with a history of serious mental illness (i.e., any major psychiatric disorder) will not be included in the study and since the research team has considerable experience providing psychosocial support to dementia caregivers on various research protocols, serious psychological risks are unlikely to occur. The potential social or legal risks for the participants relate only to possible violations of confidentiality. Additional monitoring support will be provided by the Independent Study Monitor (ISM), Shellie-Anne Levy.

Protection of Privacy:

All information obtained from the participants will remain strictly confidential and will not be released except at the express written request of the study participant. All electronic data will be maintained on Dr. Smith's office computer and the Department of Clinical and Health Psychology shared project folder. Per University of Florida, all data on Dr. Smith's computer and the research staff's computers are protected by strong password only accessible to Dr. Smith or the research team. The data will be maintained on Dr. Smith's research team's computers and on the Department of Clinical and Health Psychology secure project folder for approximately 2-3 years, which is the duration anticipated it will take to disseminate any and all research papers or presentations from these data. Similarly, paper forms of the data will be located in a locked file cabinet in room within the Department of Clinical and Health Psychology only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

Insole localization data is recorded and packaged to be sent to a remote file server. Each data set will be time-tagged, however, will only be identified by the unique identifier given by the Activlink Phone App. No individual person data will be connected or associated with this data. File servers will likely be Google Firebase or Amazon Web Services, and data will be encrypted and secured so that no external access is provided to any individual data. Remote persons selected to view a patient's location will use password protection and only persons associated with that patient such as caregivers or physicians will be provided login information. ASTER Labs personnel will have access to the stored location only data, but not the relationship of the data to a specific individual participant. University of Florida will maintain the relationship of unique data identifiers per individual.

Subjects will be assigned a study number that will be used in lieu of any identifying information. All other paper copies of information used in this study will be kept in a locked file cabinet with access given only to those conducting the study. To minimize potential breach of confidentiality, data will be identified by study number only in a filing system completely separate from any identifying information about the subjects. All data obtained in this study will remain confidential. The identification key to each research ID will be maintained under lock and key at each participating site. Database information will be password protected, and hardcopies of patient information will be kept in a locked cabinet at University of Florida. Only the PI and research assistant site will have access to patient identities. Furthermore, the collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected.

7. Possible Discomforts and Risks:

This study focuses on the utility of a technology that tracks the location of a person with dementia. The first primary risk is a loss of privacy for the person with dementia. The technology will track throughout the environment, so it will be possible to infer when he or she uses the bathroom, goes to bed, etc. The second primary risk could be a false sense of security for the caregiver about the whereabouts of the patient. For example if the insole is not operating correctly or is not worn, the caregiver may believe the person with dementia is in a safe location when they are not.

Participation in this study is considered to be of minimal risk compared to the standard unmonitored living arrangement of the persons with dementia and their caregivers. Nevertheless, we will engage in thorough safety monitoring. Furthermore, Dr. Smith has considerable experience working with older adults and is equipped to handle all emergencies. Given our extensive research on dementia caregiving populations as well as the general literature, it is unlikely care partners or persons with dementia will be under the age of 30; therefore, we do not anticipate requiring additional consent mechanisms or protections of risk for individuals under the age of 21. All interviews will be conducted by either Dr. Smith or a research assistant. These interviews will be in-person. Staff and procedures for handling medical emergencies are in place at Oak Hammock. Medical emergencies occurring for community dwelling residents will be addressed using the standard 911 system.

8. Possible Benefits:

We believe that participation in the Activlink evaluation will yield benefits for participants. The expected benefits for participants are the feeling one might experience knowing they are helping to advance an aid that may potentially reduce the burden of caregivers. Utilization of the Activlink insole and mobile application will provide caregivers of PWD with greater opportunities to continue with their daily activities with reduced concern that they must directly and continuously view their PWD, as the new device can assist them by notifying the caregiver where the PWD is located at any given moment.

This aiding and supporting the advancement of new technology to further support caregiver operation is sufficient for the subjects to understand the risks associated with this study.

Studies that evaluate the efficacy of assistive technologies to enhance living with dementia are underdeveloped. The proposed project aims to fill this scientific and clinical gap by evaluating a novel, insole sensor system with its associated mobile application that will allow caregivers of PWD to more fully engage in necessary activities other than constant monitoring. We anticipate that Activlink will offer robust support for care partners, professional staff, and families of PWD in various communities.

9. Conflict of Interest

Prior to the onset of the study the Principal Investigator will provide clinical care to subjects. One method of recruitment is to approach individuals seen as clinical patients about research. Care will not continue to be provided during or after the study. No other conflict of interest are present.

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Statistical Analysis Plan

Practical considerations related to limited availability of the device determined the sample size. We can only recruit as many people as the number of devices we have to deploy over the course of the study.

Research assistants will review all data forms at time of collection and query participants immediately if data is missing. Research staff will double enter participant reported data in an electronic database (RedCap). Any data inconsistencies will be corrected by review of the source material. All data analysis will be conducted under the supervision of Dr. Smith using established statistical packages (e.g. SPSS).