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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-46087
Status: Approved
Initial Submit Date: 11/27/2019
Approval Period: 8/20/2021 - 8/19/2026

Section Aa: Title & PI

A1. Main Title

A COMPREHENSIVE CARE COORDINATION AND MANAGEMENT PLATFORM FOR ALZHEIMER'S DISEASE AND RELATED DEMENTIAS.

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

Yes

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: NATIONAL INSTITUTES OF HEALTH (NIH)

A5a. Associated ESP2 funding proposal linked to this protocol:

Proposal	Status	PI	Sponsor	Congruency	Project Start Date	Project End Date	Provides monetary funds or in-kind support?	Source of tissue or data?
57311-A1	Funded	NAJAFI, BIJAN	NATIONAL INSTITUTES OF HEALTH (NIH)		6/15/2020	4/30/2021		
57311-N1	Funded	NAJAFI, BIJAN	NATIONAL INSTITUTES OF HEALTH (NIH)		6/15/2020	5/31/2022		
57311-N2	Funded	NAJAFI, BIJAN	NATIONAL INSTITUTES OF HEALTH (NIH)		6/15/2020	5/31/2023		
57311-N3	Funded	NAJAFI, BIJAN	NATIONAL INSTITUTES OF HEALTH (NIH)		6/15/2020	5/31/2024		
57311-N4	Draft	NAJAFI, BIJAN	NATIONAL INSTITUTES OF HEALTH (NIH)					

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?

The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:

NCT04308512

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Care for persons with dementia requires constant and effective management and coordination of delivery of care between caregivers and family members. A robust technology-driven solution for care management and coordination could significantly reduce the burden of caregiving and improve quality of life for patients with memory loss, including Alzheimers Disease (AD). A few attempts have been made to use technology to support care coordination but there is no integrated system to support self-care, assist caregivers with care coordination, and facilitate information sharing within a patient's caregiving team. In response to this need, BioSensics, in collaboration with Baylor College of Medicine (BCM), proposes to develop Care4AD¿; a comprehensive care coordination and management platform for people with memory loss. The Care4AD platform will allow caregivers to schedule caregiving tasks, monitor physical activity and activities of daily living (ADL), and facilitate timely completion of ADLs (e.g. taking medication, scheduled toileting, hydration and meals and attendance at scheduled appointments) through visual and voice reminders.

Recent demographic changes have led to the emergence of a ¿dementia epidemic¿ (1). The medical, psychological, social and functional sequelae of dementia cause great stress to patients and their caregivers. The extensive care for persons with dementia requires constant and effective management and coordination of delivery of care between caregivers and family members. A robust technology-based solution for care management and coordination could significantly reduce the burden of caregiving and improve quality of life and adherence to scheduled/prescribed tasks for patients with memory loss, including Alzheimers Disease (AD).

Understanding this need, the NIA has created an SBIR/STTR program to support the development of innovative, effective, scalable, and low-cost ¿assistive technology for persons with memory loss and their caregivers. In response, BioSensics, in collaboration with Baylor College of Medicine, proposes to develop Care4AD; an innovative care coordination and management system that can improve dementia care and reduce caregivers stress and burden, while improving the health and quality of life of patients.

Section D: Purpose and Objectives

In Phase I, we will develop a prototype of the Care4AD platform and carry out stakeholder interviews to assess the feasibility and acceptability of Care4AD, as well as to gather feedback that will be used to improve the platform. In Phase II, we will complete the development of Care4AD, considering feedback from Phase I, and we will carry out a randomized controlled clinical study to evaluate if using the Care4AD platform improves care coordination, increases adherence to scheduled ADLs, and reduces caregiver burden and stress.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:

Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Both patients and healthy, non-patient, normals

Which if any of the following vulnerable populations will be recruited as subjects?
Employees or lab personnel

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
The employees' status will not be affected by their participation. It is completely up to them the choice to participate in this study.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Study 1: Our clinical study would be limited to stakeholder interviews to examine stakeholders perception of benefit, ease of use, and acceptance of designed technology during Phase I. The stakeholders include individuals with dementia (IWD), their care givers, and health professionals providing care to IWDs and their caregivers. For the purpose of this study, we will interview 20 men and women older adults (Age 65+) with mild or moderate Alzheimer disease (AD) and their caregivers, as well as 10 expert clinicians (neurologists, geriatrician, neuropsychologists, or neuropsychiatrists and unaffiliated with the project).This is a face-to-face interview study. The interviews will be free-flowing. We will explain the technology, share sketches and prototypes, allow the participants to interact with the different components of Care4AD platform (sensor, tags and the tablet) and ask for any thoughts and comments. In addition, the caregivers will be asked to examine the Care4AD app and its features and provide comments about both functionality, architecture, and design of the app. We will use a Technology Acceptance Model (TAM) adopted for telehealth applications to examine perception of benefit, technology acceptance, and ease of use from the point of view of patients, their caregivers, and their physicians. Each TAM item will be graded using a 5-point Likert response question.

Study 2: Our clinical study is a longitudinal randomized (6 month) cross over controlled clinical trial (RCT) intervention with two parallel arms (ratio: 1:1) with care-as-usual plus care coordination intervention. The purpose of Phase-II clinical trial is to examine effectiveness of the Care4AD platform to improve care coordination and caregivers burden and stress. For the purpose of this study, we will recruit 100 men and women older adults (Age 18+) persons with mild or moderate dementia/memory loss. Including self-reported memory loss and MOCA score of 26 or lower.

Both groups will receive identical Care4AD platform (tablet). However, all feedbacks (e.g., reminder about completed/incomplete tasks) will be activated in the intervention group (IG) and the caregiver will have companion app downloaded on their smartphone. Reminder notifications will be de-activated in the control group (CG) and no app will be supplied. CG will receive conventional care coordination intervention through bi-weekly interview and will be provided with

scheduled care tasks similar to IG. Participants will be informed that the purpose of this program is to examine effectiveness of a care coordination program to reduce stress and burden of care givers and improve adherence to scheduled care tasks and improve mobility. The type of intervention will not be disclosed to participants at baseline (blinded study design) as both groups will receive some sort of care coordination intervention. In addition, the person who will analyze the data will be blinded to the type of intervention. At the 3 month visit, participants will be crossed over to either intervention or control and follow procedures.

Inclusion Criteria:

Male and female older patients (> 18 years old) with mild or moderate memory loss, self- reported memory loss, or MOCA score 26 or lower, and who are ambulatory and are in a residential home with a caregiver/informant or in a nursing home.

Caregivers and Health Professionals will be included in the subject population.

Exclusion Criteria:

The following are the exclusion criteria for the study: 1) immobility or inability to engage in activities that are essential for independent living (e.g., patients with severe dementia). 2) any significant medical or psychiatric condition that, in the judgment of the investigators, would potentially interfere with the ability to participate in the study. 3) major hearing/visual impairment. 4) residing in skilled nursing facility or are receiving hospice care. 5) inability to communicate in English or Spanish. 6) unavailability or unwillingness of the caregiver of the patient to attend the interview.

F2. Procedure

STUDY 1: The study visit will consist of an interview between the researchers, the participant and their caregiver(s). The following procedures will be followed.

The visit will have an approximate duration of 45 minutes.

Medical History: We will record socio-demographics (e.g. age, gender, BMI, education, marital status, etc) and medical history (health status including comorbidities, history of falls, history of hospitalization, priory surgery, duration of diagnosed as MCI, co-existing medical conditions, hearing and visual performance, frailty status, etc), medication use, etc.

Questionnaires: We will ask the subject to answer a series of health related questionnaires such as quality of life (Promise Global), demographics, anxiety (Beck Anxiety Scale), instrumental daily living activities (Lawton-IADL), Pain-Mobility, fear of falling (FES-I), frailty (Fried Frailty), MOCA or MMSE for cognitive status, and depression (GSD).

Care4AD demonstration: The research will sit down with the participant and provide a short explanation of the purpose of the Care4AD platform while allowing the participant and their caregiver(s) to interact with all their components (tablet, sensors, etc). The participant and their caregivers may ask any questions during the explanation and demonstration of the platform.

Acceptability questionnaire: We will ask the subject a series of questions to evaluate acceptability as well as perceived usefulness and benefit of the platform.

Digital Photographs: We will take pictures of the subjects interacting with the platform.

STUDY 2: The study will have 3 visits over a duration of 6 months: baseline, 3 month follow up and 6 month follow up. The visits will have an approximate duration of 2 hours. The subject may be consented electronically through RedCap and enrolled either remotely or in person at the clinic.

At the baseline visit, we will perform the following measurements.

Medical History: We will record socio-demographics (e.g. age, gender, BMI, education, marital status, etc) and medical history (health status including comorbidities, history of falls, history of hospitalization, priory surgery, duration of diagnosed as MCI, co-existing medical conditions, hearing and visual performance, frailty status, etc), medication use, etc.

Questionnaires: We will ask the subject to answer a series of health related questionnaires such as quality of life (Promise Global), demographics, anxiety (Beck Anxiety Scale), instrumental daily living activities (Lawton-IADL), Pain-Mobility, fear of falling (FES-I), frailty (Fried Frailty), MOCA, MMSE or Trail Making A&B for cognitive status, and depression (GSD). Their caregivers will also be asked to complete the Zarit Burden Interview, a validated survey for dementia caregivers. These questionnaires will be completed through RedCap.

Phone calls: Research Coordinators will call subjects to ask health-related questions. They may also call the subject for study related questions.

Gait: Gait will be assessed using LEGSys, a validated body-worn sensor system. LEGSys uses five inertial measurement units attached to right and left anterior shins, right and left anterior thighs, and posteriorly to the lower back. LEGSys uses a two-link inversed pendulum model based on the subjects height to determine spatiotemporal gait parameters such as stride velocity, stride length, stride time, double support, single support, and stride-to-stride variability, and gait initiation. In addition, COM range of motion during walking will be calculated based on the data from the sensor attached to the lower back. Gait will be assessed under 2 conditions; walking at a habitual speed and walking at maximum speed. In addition,

gait will be assessed under single task (walking without any cognitive distraction) and dual-task (walking while performing a working memory task such as counting backward from a random number). We will also perform Time-Up-and-Go (TUG) test.

Balance: Balance will be quantified using BalanSens, a validated body-worn sensor system. BalanSens measures ankle and hip motion in three dimensions, COM sway, and coordination between ankle and hip motion. Subjects will be asked to stand in different positions such as feet together and feet in semi-tandem with two conditions: eyes open and eyes closed.

Spontaneous daily physical activity monitoring : Daily mobility performance and inactivity will be objectively monitored using a validated wearable technology named PAMSys, a sensor that can be worn as a pendant around the neck. We will assess multiple parameters such as number of taken steps, longest walking bout, standing duration, sedentary behavior, etc. Subjects will be monitored for up to 1 week continuously at baseline and at the end of the study. Subjects will be provided with a prepaid fedex envelop to return the Pamsys device to the research team.

Upper Extremity Test: Investigators will measure arm motion from each participant by implementing a validated technology based on wearable sensor system named LegSys. This system will assess respectively spatio-temporal parameters of arm motion as well as gait in a clinical setting. The LegSys system will be used with one sensor to capture arm motion, the sensor will be placed at the subject's wrist. While being at a comfortable position, the subject will be asked to flex and extend their arm for 20 seconds at a fast speed. Subject will also be asked to repeat this task but counting backwards as they flex and extend their arm (dual task).

Photos and media: We will be asking permission of the subject to take photos, film videos and/or record audio during the visits.

Care4AD: The research coordinator will provide the platform and explain to the subject and their caregiver how to interact with it. Together they will set up a schedule of regular IADL to follow. Intervention group will receive reminder notifications on their tablet to complete tasks and caregivers will be able to edit tasks on companion app downloaded on their smartphone. Control group will not receive reminder notifications and caregiver companion app will not be given.

Phone calls: Research Coordinators will call subjects bi-weekly to assess compliance to IADL schedule set up on the Care4AD platform. During the phone call, the coordinator will ask questions regarding acceptability and perceived usefulness and benefit of the platform. They may also call the subject for study related questions and to assess of there have been no adverse events (falls, hospitalization, etc).

At the 3 month visit, the following procedures will be completed: Questionnaires, Gait, Balance, Motor-Cognitive Exercise program, Spontaneous physical activity monitoring, Upper Extremity Test, Photos and Media. Crossover will also happen, intervention group will become controls and controls will become part of the intervention group.

At 6 months, the following procedures will be completed: Questionnaires, Gait, Balance, Spontaneous physical activity monitoring, Upper Extremity Test, Photos and Media. At the end of the visit, the subject will return the platform to the research team.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 130 Worldwide: 130

Please indicate why you chose the sample size proposed:

Phase I: N=30 total subjects including 10 eligible Individuals With Dementia, at least one of the caregivers (n=10), and 10 expert clinicians unaffiliated with this project, who are providing care for Individuals With Dementia and their caregivers. The sample size for Phase I is chosen based on our experience with assessing technologies for older populations and also considering the timeline and budget limitation for Phase I. Over the past decade, we have evaluated the usability of a number of such technologies and we have found that the proposed sample size is adequate for identifying potential shortcomings that might require design or implementation modifications.

Phase II: N=100 total subjects, Individuals With care-givers, age 18+, who are supporting an individual with memory loss, aged 50+, male and female, who satisfied inclusion and exclusion criteria described in the following. The required sample size for Phase II was calculated based on our primary endpoints: 1) reduce burden for the caregivers in the Intervention group, 2) better adherence in the Intervention group compared to control group, and 3) change in functional performance over 6 month.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Study 1 (Grant Phase I): We will use a Technology Acceptance Model (TAM) adopted for telehealth applications to examine perception of benefit, technology acceptance, and ease of use from the point of view of patients, their caregivers, and their physicians. Results of the user experience questionnaires will be calculated as median (range) for each Likert-scale question.

Study 2: Results of the user experience questionnaires will be calculated as median (range) for each Likert-scale question. Unpaired t-tests, Mann-Whitney u-tests, and Chi-square will be used for baseline between groups comparison to verify effectiveness of randomization. Linear mixed models will be used to test the effect of the Care4AD care coordination intervention on caregiver burden/stress at 6 months compared to baseline and between groups. Mixed models that accommodate the longitudinal design, allow for testing differences between groups in patterns over time, as well as at specific time points are consistent with an intention to treat analysis, and are valid for data which are missing at random. Appropriate mixed models (linear for continuous or Generalized Estimating Equations (GEEs) for non-continuous or non-parametric variables) will be used to test the intervention effect for each of the secondary outcomes (depression, cognitive function, QoL, fear of falls, neurotic tendency including fatigue, physical activity, adverse events, missing appointments). Univariate linear regression analyses will be performed to delineate predictive factors of training response for the primary study endpoint (pre- to post- changes in care coordination outcomes). Baseline values include age, gender, BMI, fear of falling, ADL-status, comorbidity, cognitive performance, depression, stage of AD, and baseline motor variables (e.g., balance and gait speed). We will use Spearman correlation of coefficient to compare changes in quantitative metrics of exercise performance over the course of the program with in clinic assessments of functional performance (e.g., gait speed) and cognitive performance (e.g., MoCA). We will assess the agreement between Care4AD derived ADL, the Katz Index, and the Lawton-ADL. To demonstrate the acceptability of Care4AD application, we will use TAM model described above using 5-point Likert response questions. For all assessments, a p-value of 0.050 or less will be considered as statistically significant level. To evaluate the effect of sex as biological variable, we will examine whether acceptability and benefits of Care4AD platform to improve care coordination outcomes (between groups as well as compared to baseline) are different between men and women.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

This is an observational, minimally invasive study. We believe that there are no significant psychological, legal, or social risks. Participation is entirely voluntary and the participants could stop/leave the study at any time.

The measuring systems including LEGSys (for assessing gait and balance), BalanSens (for assessing balance), and PAMSys (for monitoring spontaneous daily physical activities) , as well as the iTMT platform are battery-powered, self-contained units and used in many clinical studies including patients with MCI and AD, and no adverse report were reported. Except activity monitoring, the rest of assessments including gait and balance will be performed in a control environment. As these devices are attached using elastic straps, research staff will ensure these are comfortably tight on the participant to avoid any pain or poor blood flow.

For home assessment, PAMSys (will be used for daily physical activity monitoring and daily motor performance such as postural transition) is worn in a shirt or vest pocket and does not rest directly against subjects¿ skin. Thus, wearing the PAMSys¿ poses no risks to subjects. All wearable sensors, which will be used in this study meet the requirements for IDE exemption under 21 CFR 812.2(c), Category 3.

This is an observational, minimally invasive study. We believe that there are no significant psychological, legal, or social risks. Participation is entirely voluntary and the participants could stop/leave the study at any time.

Please note that there is also the possibility for loss of confidentiality. The PI and the research team will minimize the possibility of for loss of confidentiality by keeping all the physical data locked in cabinets only accessible to the research team. The electronic data will be kept on network password protected institutional computers. Data collected during the study may be published and made publicly available. Data may also be shared with other research groups. However, data that could in any way identify the subject will not be made public or shared. And, subject PHI will be coded as much as possible to minimize the potential for loss of confidentiality.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

The main benefit to subjects is the positive feeling that they will have by participating in a study that will potentially help other people by developing new technology that could improve the care of dementia and older adults and could assist in coordinating care, reducing burden and stress of caregivers, as well as improving safety and autonomy of individuals with dementia. They might eventually directly benefit from this technology if the device became validated and available for clinical use in the future. In addition, during the study all participants will receive care coordination intervention, which have been shown to be effective in reducing stress and burden of caregivers, which showed to be effective in improving balance and mobility in people with dementia. The subjects will be compensated for their time ($50 for Phase I, and $100 per month for the Phase II). Except baseline screening, no other visits to the clinic is needed for the intervention group.

Describe potential benefit(s) to society of the planned work.

The proposed work has the potential to advance the science of `care coordination, support to caregivers, ADL monitoring, telemedicine, digital health, and effective strategy to promote aging in place and life independency among older adults with cognitive decline and dementia. This study will also guide future scale-up efforts, contribute to D&I science by providing sorely needed information on contextual determinants in home settings, and inform the science of dementia by laying out a systematic process for the implementation of mobile or app-based EBIs for older adults and those with chronic illness. Given the recent demographic changes led to sharp increase in dementia population in our nation and the associated cost with dementia, the proposed study could have significant impact in our nation healthcare system and could promote healthy aging and empower older adults to continue living independently instead of institutions. Furthermore, the remote monitoring of some of the key ADLs and functional performance will be beneficial as they provide a quantifiable means to track changes in physical capability and needed services and supports. The project will also help in determining the predictive validity of adherence to scheduled ADL algorithms to diagnosis dementia and its severity. Given the large and growing number of older people at risk of developing cognitive impairment and dementia, this knowledge would be important to health providers, clinicians, older people, and their caregivers. One of the possible benefits to society is that our proposed tele-health could lessen the burden of disability and facilitate delivery of care (for both IWDs and their caregivers) to those who live in rural and remote areas and maybe too frail to travel, or have limited transportation and often are unable to participate in clinic-based educational programs

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

While the risk is anticipated to be minimal as described above, the gained knowledge is significant and may assist us to learn more about a low cost and interactive way of assessing cognitive status.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

In order to recruit or identify subjects, we will screen our patient charts for eligible subjects. The subjects may complete electronic consent through RedCap which would be sent to their email.

The subject will be fully informed about the study, and will verbalize understanding and voluntarily agree to participate with the guidelines as stipulated in the informed consent. The subject will be informed if he/she can withdraw from the study at any time without loss of benefits. Consent forms will be signed and dated by the subject and by the Principal Investigator or Investigators. The original (with patient's signature) will be maintained per IRB policy. A signed copy of the consent form will be provided to the patient. Informed consent will be obtained prior to performance of any study procedures. Specifically: 1. No minors will be consented. 2. Subjects are given as much time as needed to ask questions and read over

the consent. All subjects will be performing the same procedures. They will be given a copy of the ICF and can return at a later date if they need to discuss it with relatives, etc.

Subjects will be recruited from study sites. We may get some referrals from colleagues that work in the same clinic. We have included a Waiver of Partial Consent to cover our screening process. Collaborators will identify eligible subjects and alert the coordinator. The coordinator will review all the details of the study with the subject and/or their family. If the subject agrees to participate in the study, they will be screened and then enrolled into the study.

The judgement about the capacity and incapacity to consent, will be done according to the recommendation proposed by the Alzheimer Europe, Informed Consent to dementia research. Those who cannot make autonomous decisions are excluded from the study. The decision making ability will be determined by capacity to understand, expressing a choice, appreciation, and reasoning. All subjects will be referred by BCM geriatric clinic.Hospitalized patients who are also at risk due to significant cognitive impairment from chronic diseases and delirium will be excluded as well. Attempts will be made to involve the spouse or partner in the consent procedure (e.g. through joint discussions).

Are foreign language consent forms required for this protocol?
Yes

Which of the following ways will you document informed consent in languages other than English?
A full-length informed consent document

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?
No

J4. Children

Will children be enrolled in the research?
No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
The physical research will be kept in our BCM offices housed in the Mcnair Building room B10.401.

How will such physical research data be secured?
Data will be kept in locked file cabinets that only the research team has access to.

At what institution will the electronic research data be kept?
Data will be kept locked on network computers in our BCM offices, under the password protected server.

Address:\\discovery1.ad.bcm.edu\bcm-dept-icamp

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
Transmissions, if any, will only happen via secure emails.

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
There are no further confidentiality issues related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.
Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling. There will be no cost to the subject for all procedures. If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

350

Distribution Plan:

The subjects will be compensated for their time $50 (one time) for Phase I.

Phase II: 3 visits - baseline, 3 month follow up, and 6 month follow, each visit 100$ total for 300$.

Note: Study 2 is NOT the continuation of Study 1. Subjects who participate in Study 1 may become eligible to participate in Study 2 only when they have met inclusion criteria. Please refer to inclusion/exclusion criteria.

Subjects will be given a Clincard where payments will be loaded after a study visit or monthly phone call are completed. Additional information will be provided to the subject about how to manage the card.

We will be validating the subject's parking expense at every visit. If the subject does not have a method of transportation, and declines our offer to perform the visit at their home, we will request an Uber trip for them to come to the research site.

Research staff will be requesting the subject's SSN in order to payments to the ClinCard.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Device 1: LEGSys

Name of Device (Including HDE # if applicable):
LEGSys

FDA intended use of the device in use
Gait assessment

Actual use of the device in this clinical trial
Gait assessment

Manufacturer of the device :
BIOSENSICS, LLC (US)

FDA number for the device (IDE for investigational device, HDE #, or 510K #) :
NA

Method of proof of the validity of this IDE, HDE, or 510K (check all that apply):

Sponsor Investigator

Is the BCM investigator serving as sponsor/investigator for this study?
No

Device Risk

This clinical trial is exempt from the IDE requirements as it meets one of the exemptions outlined in 21 CFR 812.2(c) Please enter a brief description of why the device is considered to be exempt from the IDE regulations below:
This device is non-invasive, non-toxic, and non-ionizing and only intended for research purposes. It does not present a potential for serious risk to the health, safety or welfare of a subject.

Control, storage, and use of the device

How does the PI plan to store, control, and use the device?

Storage, control and use under supervision of the Principal Investigator

Device 2: Balansens

Name of Device (Including HDE # if applicable):
Balansens

FDA intended use of the device in use
Balance Assessment

Actual use of the device in this clinical trial
Balance Assessment

Manufacturer of the device :
BIOSENSICS, LLC (US)

FDA number for the device (IDE for investigational device, HDE #, or 510K #) :
NA

Method of proof of the validity of this IDE, HDE, or 510K (check all that apply):

Sponsor Investigator

Is the BCM investigator serving as sponsor/investigator for this study?
No

Device Risk

This clinical trial is exempt from the IDE requirements as it meets one of the exemptions outlined in 21 CFR 812.2(c) Please enter a brief description of why the device is considered to be exempt from the IDE regulations below:

This device is non-invasive, non-toxic, and non-ionizing and only intended for research purposes. It does not present a potential for serious risk to the health, safety or welfare of a subject.

Control, storage, and use of the device

How does the PI plan to store, control, and use the device?

Storage, control and use under supervision of the Principal Investigator

Device 3: Pamsys

Name of Device (Including HDE # if applicable):

Pamsys

FDA intended use of the device in use

Physical Activity Monitoring

Actual use of the device in this clinical trial

Physical Activity Monitoring

Manufacturer of the device :

BIOSENSICS, LLC (US)

FDA number for the device (IDE for investigational device, HDE #, or 510K #) :

NA

Method of proof of the validity of this IDE, HDE, or 510K (check all that apply):

Sponsor Investigator

Is the BCM investigator serving as sponsor/investigator for this study?
No

Device Risk

This clinical trial is exempt from the IDE requirements as it meets one of the exemptions outlined in 21 CFR 812.2(c) Please enter a brief description of why the device is considered to be exempt from the IDE regulations below:

This device is non-invasive, non-toxic, and non-ionizing and only intended for research purposes. It does not present a potential for serious risk to the health, safety or welfare of a subject.

Control, storage, and use of the device

How does the PI plan to store, control, and use the device?

Storage, control and use under supervision of the Principal Investigator

Section Q: Consent Form(s)

Care4AD Interview

Phase II: 6 Month Care Coordination Platform Project

Section R: Advertisements

None