H-46087- A COMPREHENSIVE CARE COORDINATION AND MANAGEMENT PLATFORM FOR ALZHEIMER'S DISEASE AND RELATED DEMENTIAS.

Concise and Focused Presentation

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

The purpose of this study is to assess a new platform that will be used to help caregivers to coordinate care for individuals with Alzheimer's disease or dementia.

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.c

There might be a slight risk of confidentiality loss. The research team will minimize the possibility of loss of confidentiality.

You may choose not to participate in this study. 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.

Employment status will not be affected by participation.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Dementia is a chronic disease of aging and its progression can interfere with the ability of the individual to be independent in their daily activities. This can lead to anxiety and frustration in the individual and their caregivers and/or family members. We would like to propose a platform (Care4AD) which would assist to coordinate care and activities for caregivers and individuals with dementia.

This research study is funded by NIHThe Principal Investigator BIJAN NAJAFI for this study:receives personal income for other work for Biosensics LLC, such as payments for lectures or for consultations A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of the study is examine the practicality of the Care4AD platform. Specifically, the research team would like you to review and comment on the platform after a brief presentation on the system.

Your comments would help us understand how the platform could help individuals with dementia and

how the platform could be improved.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

The study will have one visit only. Approximate duration of the visit it 45 minutes.

Described below are the procedures that will take place during the visit.

Care4AD: A research coordinator will sit down with you and show a brief presentation on the Care 4AD. This will include an explanation of its purpose, how it works and how one would be able to use it and receive feedback from it. You will be able to ask questions during this presentation or make any other comments. At the end of the presentation, the coordinator will ask some questions regarding your opinion on the platform.

Medical History: The coordinator will as a series of health-related questionnaires regarding your quality of life, demographics, anxiety, activities of daily living, pain, fear of falling, frailty, depression and a mental exam.

The researchers will take digital photographs/videos/audio of you on the study. This is done using a normal digital camera for visual images. This method is non- invasive. ** We will NOT blur your face out in the photographs/videos. While we do all our efforts to mask your face in some cases (for example. journal policy) this may not be practical. We will only use videos, audio and photos of you for scientific presentations or scientific publications.

Initial your decision below.

____I agree to have my photographs/videotape presented in scientific presentation or scientific publication.

____I do NOT agree to have my photographs/videotape presented in scientific presentation or scientific publication

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC) may still use or disclose health information

they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Bijan Najafi, PhD
One Baylor Plaza MS:BCM390
Houston TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

This is an observational, minimally invasive study. Except baseline assessment, which required for determining the eligibility, no study visit is required and all follow up assessments will be done at your home or via phone interview by the research coordinators. We believe that there are minimal psychological, legal, or social risks. Participation is entirely voluntary and the participants can stop/leave the study at any time. The tasks associated with this protocol are of no more physical demand than is routinely encountered during participant's daily physical activity. The subjects will wear very small waterproof pendant device to monitor physical activity and proximity with pTAGS. There is a minimal risk subjects might be confused about the use of the device and whether it is a medical alert device that is linked to emergency services. There is also a minimum risk associated with privacy and hacking risk associated with transferring the data to the cloud. To minimize the risk, your data will be uploaded to a secure server. The servers will be hosted by secure and reliable cloud computing services (e.g. Amazon Web Services). We will use cloud services that offer auditing, data backup, and disaster recovery that are required for HIPAA compliance.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand how daily activities may help a person identify mental status and have appropriate care according to their needs .

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose to not participate in this study. .

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not come to the research visits) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will be paid $50 for the research visit.

You will be given a debit card called "ClinCard" at the first day of your visit. Each time you complete a visit, the coordinator will load $50 to your card. Please note that it may take up to 72 hours for the amount to be loaded in the card. The research coordinator will provide you with some instructions and useful information about your card. The research team will be requesting your SSN to issue the payments.

At every visit at the research site, we will validate your parking.

If you have no transportation to bring you to the research site, and you do not want the research team going for the visit to your home, we may arrange an Uber trip to pick you up from your house and take you to the research site.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire

(ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Bijan Nafi at 713-798-7536 and Maria Noun at 713-798-7538 during work hours and after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Subject ID _____ Subject initial _____

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

Subject ID _____ Subject initial _____

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Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Dementia is a chronic disease of aging and its progression can interfere with the ability of the individual to be independent in their daily activities. This can lead to anxiety and frustration in the individual and their caregivers and/or family members. We would like to propose a platform (Care4AD) which would assist to coordinate care and activities for caregivers and individuals with dementia.
This research study is funded by NIH. The Principal Investigator BIJAN NAJAFI for this study receives personal income for other work for Biosensics LLC, such as payments for lectures or consultations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Purpose

Caregivers have to manage many aspects of care such as medication management, maintaining

appointments, and being sure the person they care for completes their activities of daily living such as having their meals and maintaining hygiene. It is also possible a person with dementia has multiple caregivers who need to aid in their care.

The purpose of the study is examine the benefit and feasibility of the care coordination system called Care4AD platform. The Care4AD platform is meant to ease the caregivers' burden by having the tools needed to maintain care onto one platform.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

The study will have 3 visits over a duration of 6 months: baseline, 3 month follow up and 6 month follow up.

At the baseline visit, you will be randomized into the intervention or control group for the first 3 months of enrollment. Intervention group will receive reminder notifications about their tasks and control group will not receive notifications about their tasks. You also be provided a companion app to download on the caregiver's phone to manage tasks for the intervention group. 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 you 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). Your caregivers will also be asked to complete the Zarit Burden Interview, a validated survey for dementia caregivers.

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

Gait: Gait, which is walking pattern, will be assessed using LEGSys, a validated body-worn sensor system. LEGSys uses five sensors attached to right and left ankles, right and left thighs, and waist. Gait will be assessed under 2 conditions; walking at a normal 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. 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 you and your caregiver how to interact with it. Together we will set up a schedule of regular IADL to follow.

Phone calls: Research Coordinators will call you bi-weekly to assess compliance to IADL schedule set up on the Care4AD platform. They may also call you for study related questions and to assess if 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 at the 3 month visit, you'll either start to receive notifications on your tablet or stop receiving notifications on your tablet.

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, you will return the platform to the research team.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Research related health information

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The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you

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Use or Disclosure Required by Law

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Medicine, and Baylor St. Luke's Medical Center (BSLMC) may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

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One Baylor Plaza MS:BCM390, Houston, TX 77030

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Potential Risks and Discomforts

This is an observational, minimally invasive study. Except baseline assessment, which required for determining the eligibility, no study visit is required and all follow up assessments will be done at your home or via phone interview by the research coordinators. We believe that there are minimal psychological, legal, or social risks. Participation is entirely voluntary and the participants can stop/leave the study at any time. The tasks associated with this protocol are of no more physical demand than is routinely encountered during participant's daily physical activity. The subjects will wear very small waterproof pendant device to monitor physical activity and proximity with pTAGS. There is a minimal risk subjects might be confused about the use of the device and whether it is a medical alert device that is linked to emergency services. There is also a minimum risk associated with privacy and hacking risk associated with transferring the data to the cloud. To minimize the risk, your data will be uploaded to a secure server. The servers will be hosted by secure and reliable cloud computing services (e.g. Amazon Web Services). We will use cloud services that offer auditing, data backup, and disaster recovery that are required for HIPAA compliance.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

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Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand how daily activities may help a person identify mental status and have appropriate care according to their needs ..

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will be paid $100 for each research visit.

You will be given a debit card called "ClinCard" at the first day of your visit. Each time you complete a visit, the coordinator will load $100 to your card. Please note that it may take up to 72 hours for the amount to be loaded in the card. The research coordinator will provide you with some instructions and useful information about your card. The research team will be requesting your SSN to issue the payments.

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The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 713-798-7536 during the day and Maria Noun at 713-798-7538 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative - Adult	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date