PFI: BIC Affordable Mobile Assistive Robots for Elderly Care (Protocol)

NCT #02807506

AUGUST 13, 2018

Protocol Details

Basic Info

Confirmation Number:	**chafhbce**
Protocol Number:	**820915**
Created By:	**VIVIO, NICHOLAS**
Principal Investigator:	**JOHNSON, MICHELLE J**
Protocol Title:	**PFI: BIC Affordable and Mobile Assistive Robots for Elderly Care**
Short Title:	**Affordable Mobile Robots for the Elderly**
Protocol Description:	**This project develops and tests the use of service robots to track health of the elderly over time. The objectives are to develop a low-cost mobile manipulator capable of a limited set of elder-relevant manipulation tasks (e.g. picking up dropped items). We will visualize and model the use of the service robot during deployments at an elder care facility. Feedback from focus groups with elders and clinicians will inform the necessary engineering innovation.**
Submission Type:	**Biomedical Research**
Application Type:	**EXEMPT Category 4**

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**JOHNSON, MICHELLE J**
Dept / School / Div:	**4482 - RM-Rehabilitation Medicine**
Campus Address Mail Code	**4283**
Address:	**PENN MEDICINE RITTENHOUSE 1800 LOMBARD ST., 1ST FLR.**
City State Zip:	**PHILADELPHIA PA 19146-8400**
Phone:	**215-893-2665**
Fax:	**215-893-2686**
Pager:	
Email:	**johnmic@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/07/2015**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**TORRES, WILSON O**
Dept / School / Div:	**4482 - RM-Rehabilitation Medicine**
Campus Address Mail Code	**4283**
Address:	**HUP** **3400 SPRUCE ST**
City State Zip:	**PHILADELPHIA PA 19104-4283**
Phone:	**215-893-2695**
Fax:	**-**
Pager:	
Email:	**Wilson.Torres@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**04/17/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**LIMA, KRISTINE S**
Dept / School / Div:	**4482 - RM-Rehabilitation Medicine**
Campus Address Mail Code	**4283**
Address:	**1800 Lombard St** **Penn Medicine Rittenhouse**
City State Zip:	**PHILADELPHIA PA 19146-4283**
Phone:	**215-893-2679**
Fax:	**-**
Pager:	
Email:	**Kristine.Lima@uphs.upenn.edu**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

Name:	**YIM, MARK H**
Dept / School / Div:	**1306 - Mechanical Engineering and Applied Mechanics**
Campus Address Mail Code	**6315**
Address:	**220 S. 33rd STREET** **Suite 229A TOWNE BLDG**
City State Zip:	**PHILADELPHIA PA 19104-6315**
Phone:	**215-898-5269**
Fax:	**-**
Pager:	
Email:	**yim@seas.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**05/23/2017**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4482 - RM-Rehabilitation Medicine

Key Study Personnel

Name:	**RODRIGUES MUCCHIANI, CAIO**
Department/School/Division:	**School of Engineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**12/17/2017**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SEFCIK, JUSTINE S**
Department/School/Division:	**Biobehavioral and Health Sciences**
HS Training Completed:	**Yes**
Training Expiration Date:	**02/04/2015**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**WEINSTEIN, AARON D**
Department/School/Division:	**School of Engineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/22/2018**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**CACCHIONE, PAMELA Z**
Department/School/Division:	**Family and Community Health**
HS Training Completed:	**Yes**
Training Expiration Date:	**08/27/2014**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have

a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
Yes

If yes, please provide any readily available information on such IP. For example, a brief description of the IP, any relevant docket number (if disclosed to the Penn Center for Innovation (PCI), patent application or patent numbers, inventor's names, and/or other relevant details.*
The PI's in are involved in the invention of the system.

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x	**Sociobehavioral (i.e. cognitive or behavioral therapy)**
	Drug
	Device - therapeutic
x	**Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)**
	Surgical
x	**Diagnostic test/procedure (research-related diagnostic test or procedure)**
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Department budget code

None

Protocol

Objectives

Overall objectives
The goal is to develop in three stages a new affordable robot with the participation of Living Independently for Elders (LIFE) members and clinicians. The robot will be developed by a multidisciplinary team headed by Dr Yim at UPENN (PI), Dr Lau at Savioke, and Drs. Johnson and Cacchionne at UPENN PM&R and UPENN Nursing respectively. We aim to build a low-cost robot platform that will focus on the simple, but key, repetitive, data-driven tasks that robots do well. Rather than attempt to create a robot helper that mimics humans, we aim to free human caregivers from the time-consuming tasks that robots can accomplish with facility, thereby allowing humans to focus on tasks that humans do best (i.e. human contact). Participatory reviews of the developed prototypes will be completed at each stage (each year) with the LIFE members and clinicians. There are three research questions we hope to answer all while building an effective system to synergistically satisfy the business needs: R1) Although activities of daily living (ADLs) for elder health have previously been documented and categorized, no research has been done to characterize them from the perspective of their feasibility of automation using an affordable mobile manipulation robot. How can we characterize known ADLs according to how much they would benefit from robotic assistance given varying levels of

robot capabilities (mobility, limited manipulation, full manipulation)? R2) A manipulator arm must be safe, affordable, and performant enough to assist in ADLs for elder heath. What new breakthroughs are required to develop new manipulation technology that satisfies these constraints? What are the concomitant key usability and acceptance of service features required? R3) A data-driven service robotics system has the potential to affect elder health in a positive way. How can predictive service robotics best be used to maintain and improve elder health? Which specific robot behaviors have the most impact on elders' well-being?

Background

A growing elderly population coupled with low birth rates in the developed world is creating a crisis in healthcare. The number of senior citizens is outgrowing the number of working-age adults to care for them. In the US alone, the number of seniors over age 65 is projected to double from year 2000 to 2030, reaching 71.5 million. Similar statistics are found throughout the world. With the scarcity of care options available, robots are a welcome solution for assisting elders with small tasks that would normally be done by a caregiver. With an estimated 17,000 elder care facilities nationwide, merely placing a single affordable robot in each facility would result in a $170m business. In this vein, the past decades have seen an enormous amount of robotics research funded by institutions such as the NSF and DARPA, including a notable multi-million dollar effort by the European Union in the RoboEarth project which aims at hospital service. A variety of companies have also explored robots in the healthcare space. Aethon, Vecna, and Helpmate have automated materials transport/delivery with varying success. They have limited service capability in that they are not capable of manipulation. On the other side of capability, research robots such as Willow Garage's PR2 and Care-o-bot from Fraunhofer IPA have demonstrated mobile manipulation, but have costs between $100-500K. Fortunately, a number of factors are converging to make cost-effective robots possible now. Previous efforts have exploited rapid prototyping low-cost hardware such as 3D printing and mass customization of electronics to lower hardware costs. Additionally, the software necessary to power mobile manipulation robots and hardware costs, such as low-cost depth sensors (i.e. Microsoft's Kinect) are becoming better and cheaper each year. Through our own novel design and innovation coupled with capitalizing on the various factors that are precipitously driving down the costs of necessary components, we aim to develop an affordable and capable robot that will address the demographic shift towards the need for more elderly care. One key to making this system viable is maintaining effectiveness at low cost. This work will build on existing navigation and control software for mobile robots using a platform being commercialized by Savioke. On top of this, a new low-cost expanding prismatic joint arm developed at University of Pennsylvania will add manipulation capabilities. This hardware and software platform will enable the study of the usefulness of robots in an elder care facility. Limited tasks such as the delivery of water to patients can be used to monitor hydration of individuals over-time and pro-actively predict required service to aid in healthcare. The information gathered by these robots and how elders use them during field use will help to learn how robots can help create a larger data-driven health monitoring system. The partners include the University of Pennsylvania's School of Engineering and Applied Science, School of Medicine, School of Nursing (Philadelphia PA), and Savioke (Sunnyvale, CA, a small business concern) along with LIFE, Living Independently For Elders (Philadelphia PA).

Study Design

Design

We plan to tackle the myriad aforementioned challenges in three stages. First, based on focus group feedback, we will design a data collection plan for the robot to collect information about service tasks. This may include information such as the time it takes the robot to perform a task, when the task was requested, whether the robot succeeded at performing the task, etc. This data collection component will be deployed at LIFE or a LIFE-affiliated retirement community during the various trials. Additionally, our partners at Savioke (Dr. Lau is a co-PI on the NSF grant) will conduct additional focus groups in elderly care facilities in California, in order to get faster feedback on their prototype designs. The focus group methodology will be employed throughout to assess user needs and evaluate user experiences with the robot system being developed. Second, we will develop interactive data visualizations of the collected data and share these with the LIFE and LIFE-affiliated administrators, staff, and residents. These interactive data visualizations will make use of best practices in medical informatics and visualization and enable stakeholders to explore the data we have collected and from initial conclusions about resident's health and service needs. Based on feedback from the visualizations, we will fine-tune our data collection process which will likely impact the robot design. The final step will be to develop

predictive models of when people want services performed so that our system can proactively deliver services when they are needed. By tracking residents' requests over time - a machine learning problem - we aim to build a model of what features in the environment trigger the service requests over time.

Study duration
1) We estimate that it will take three years from the date of IRB approval to enroll all subjects and complete the study. 2) A subject may choose to participate for as little as one focus group (1.5 - 2 hours) or may choose to participate in each part of the larger study over the course of three years. 3) 8/15/2014 - 8/15/2017

Characteristics of the Study Population

Target population
1. Three populations will be involved: 1. Elders who are members of Living Independently For Elders (LIFE) run by the University of Pennsylvania, School of Nursing and their caregivers will be recruited for the study. The elder members will be drawn from those participating in the LIFE-affiliated retirement community (Mercy Douglas or Kearsley) or those on the Council of Elders for LIFE or those at LIFE. Elders must be members of LIFE and live at a LIFE-affiliated retirement community or participate in the elder council. Members of LIFE are age 55 and older, in need of medical care or supportive services, are state-certified as nursing home eligible, live in certain areas in Philadelphia County, Pennsylvania, prefer to continue living in their community for as long as possible, can be safely served and able to pay privately or through Medicare. Members of LIFE at Kearsley and Mercy Douglas require more assistance with physical, cognitive and social functioning and are provided a 24-hour interdisciplinary clinical staff to assist them in meeting needs. Members are 62 years and older, in imminent risk of a nursing home placement, attends LIFE center daily (day program), able to have activities of daily living (ADL) needs met by caregivers, able to pay required rent for apartment, and able to function safely in community with other elders. And for the purpose of earlier prototyping and obtaining faster feedback on designs, Savioke may conduct additional focus groups at The Forum at Rancho San Antonio a Continuing Care Retirement Community located in Silicon Valley. 2. Clinicians: Clinicians will be recruited from the clinical staff working at LIFE, Kearsley, and Mercy Douglas which consists of primary care physicians, nurses and nurse practitioners, certified nursing assistants, home health aides, licensed social workers, physical and occupational therapists, personal care workers, etc. Subjects will also be excluded if they do not understand the study and refuse to comply with procedures. Subjects will be excluded if they are unable to cognitively give consent. For the corn toss game, 30 participants will be recruited who are able to use both arms and reach up towards a cabinet, have a minimental score of 20 or higher, and are able to stand and reach

Subjects enrolled by Penn Researchers
155

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment
Dr. Cacchione (UPENN Nursing Professor) and Ms. Ingrid Sidorov (Interim Chief Nursing Officer) are affiliated with LIFE and will be responsible for reviewing LIFE's medical records. After potential study participants are identified, the commonly used Short Blessed Test (measures cognitive function in the elderly), SF-12, etc., may be administered for additional screening purposes. LIFE members will then be consented prior to participation in the focus groups by a member of the research team. For any focus groups at The Forum at Rancho San Antonio, Savioke will liase with the Director of Wellness, Sharon Fay, with whom they have an established relationship. Residents at The Forum will then be consented using the same consent form used for any LIFE members. Recruitment will be word of mouth, direct solicitation, and informational sessions convened with the assistance of the Council of Elders' and the research committee overseeing participant activities.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

25 dollars will be provided to each participant for her/his participation in year 1. An additional $25 will be provided in year 2 and year 3 should they continue to participate in focus groups and evaluation sessions. Subjects participating in only the evaluation session with the walking task will be paid $5.00 per walk taken with the robot. Subjects participating in only the corn toss session will be paid $10.00. Subjects participating at The Forum at Rancho San Antonio will not be compensated financially, however, snacks and beverages will be provided. No compensation will be provided due to the fact that the focus groups will be considerably shorter and limited in scope.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Year 1: Need-finding focus groups of clinicians and elders will be conducted, consisting of no more than 8-10 persons at each session. The aim of the initial focus groups is to reconcile the needs of elders with the robot requirements in order to determine the robot behaviors. The focus groups will help define a set of robot behaviors critical to meeting the needs of elders. Some behaviors that may emerge are transporting objects, telecommunication, following, leading, monitoring, playing, coaching, escorting persons, etc. In a typical focus group session, participants will explain life at their location, create a prioritized list of key activities and needs in physical, cognitive and social domains, hear about the research and the current capabilities of the robot, describe how they could use the robot to meet needs and what may be lacking, and set-robot tasks list. The elders in the needs assessment focus group will

be those serving on the council of ELDERs for LIFE. A member check (respondent validation) will take place with certain members of the various focus groups. Development partners will be identified from the focus group sessions. They will meet quarterly with the team to address development issues with the robot .This team will function as the early assessors and will provide real time feedback. Additionally, residents at The Forum at Rancho San Antonio in Silicon Valley will provide feedback via need-finding focus groups during year 1. Year 2: The robot prototype, consisting of the mobile base and a limited gripper, will be tested at a LIFE-affiliated retirement community with the elders and caregivers. The robot tasks evaluated will be involve services aimed at providing reminders, transport, telepresence, games, etc. Later that year, another version of the robot prototype, consisting of the mobile base incorporating improvements from the 1st round of assessments and an arm plus an articulated gripper, will be tested with elders and clinicians for 3 weeks. The robot tasks evaluated will be those involving mobility and some manipulation services such as hydration, picking up and transport etc. Data will be analyzed and results on robots usability will be provided as feedback to the development team in order to improve the system. THE ABOVE SUMMARY PARAGRAPH WAS INCLUDED IN OUR INITIAL IRB SUBMISSION, APPROVED OVER ONE YEAR AGO. BELOW ARE SOME ADDITIONAL DETAILS WHICH ARE THE MAIN MODIFICATION TO THE PROTOCOL. 1.) Subjects will be consented and be provided with a demographic survey (see attached). 2.) The robot prototype will be pre-programmed to complete key activities while located on site (Mercy Douglas or LIFE). The key activities are: (1) Encouraging exercise and companionship via walking; and (2) Helping elders remain hydrated by transporting them water at a scheduled time. Clinicians and caregivers will be consulted to determine how to tailor robot tasks to each consented patient. 3.) During the walking companion task, the robot will ask ambulatory participants to walk with the robot for the recommended 15 minutes of exercise time, at least one time per day. The robot will arrive at the elder's apartment at a prescheduled time selected by him/her. The amount of time the elder spends walking with the robot may be adjusted should the clinician/caregiver recommend a shorter time period (e.g. the walk time may be decreased if a patient suffers from sciatica). 4.) During the hydration task, the robot will bring a an 8 oz. bottle of water and a bottle opener to the elder. The frequency in which the robot bring water to the elder will be based upon the recommendation of the clinician/caregiver. The base recommendation will be 6, 8 oz. glasses of water outside of meal times. An example of a modification to the base recommendation would be to increase the number of water bottles for those who have dry mouth, are on dialysis, or tend to forget to drink water (this is very common among the elderly population). For both the walking and hydration tasks, the patient can instruct the robot to return at a later time or to go away. All tasks will take place in the hallway either just outside of the participant's apartment or inside the apartment. There will be one observer on our team who will watch the robot-participant interaction and complete a checklist of usability and issues. There will be another observer on our team who will immediately ask the participant to complete a post robot assessment survey tailored to the task they just experienced. Example Procedure for the Walking Task Scenario: The robot approaches a participant and asks them if they want to go for their scheduled walk. The participant can say "yes" and go for the walk, "no", or reschedule the robot to come back at a later time. Observer #1 takes notes on the interaction and completes the relevant checklist items. If the participant goes for the walk, observer #2 asks them to complete the post-encounter survey. After each usability test period, participants and their caregivers will have the opportunity to fill out a global interaction survey about the experience and provide information on how to improve the robot for future usability testing periods. Procedure for corntoss game: 1.) Subjects will be consented and be provided with a demographic survey (see attached). 2.) The robot prototype will be pre-programmed to complete key activities while located on site (Mercy Douglas or LIFE). Participants will first play the corn toss game without the assistance of the robot. They will retrieve the 3 bags from an upper cabinet, and play game against another participant. The participants will throw 3 bags and scores will be assessed. The participants will retrieve their own bags. In the second session, participants will repeat these steps; however someone from the research team will retrieve bags for the participant. At this point, there will be a pause and participants will be asked survey questions. Next, the same steps will be repeated, however the robot will retrieve the bags with a gripper from the upper cabinet and hand to the participant. Finally, the game will be repeated, but the robot will retrieve the bags at the end. Evaluations will then be repeated at the end. Clinicians and caregivers will be consulted to determine how to tailor robot tasks to each consented patient. After each usability test period, participants and their caregivers will have the opportunity to fill out a global interaction survey about the experience and provide information on how to improve the robot for future usability testing periods. The entire interaction will last for 1.5-2 hours maximum. Year 3: An improved prototype, consisting of the mobile base incorporating improvements from the 1st round of assessments and an arm plus articulated gripper will be tested with elders and clinicians at LIFE and/or a LIFE-affiliated retirement community for 4 weeks. The robot tasks evaluated will involve mobility and

complex manipulation services such as opening doors etc. Data will be analyzed and results on robots usability will be provided as feedback to the development team in order to improve system. Overall, focus groups will be used throughout to assess and evaluate users interaction and experiences. Data will be collected by the robot during user interactions and aspects of the data will be evaluated and discussed with focus group members to critically assess robot's utility and progress. Research questions R2 and R3 will be addressed. a. Key usability and acceptance of service features required for the development of new manipulation technology are affordable, safe, and usable will be identified and appropriate metrics developed. b. Health status of subject participant will be tracked over years 2 and 3 and correlated with robot service record with the participant. Training and evaluation: Before each version of the robot is placed into service, demonstration and training sessions will occur where all potential clinical and elder users will be invited to learn about the robot and the experiment. Those willing to participate in a week-long study will sign informed consents. Data will be collected from the robot during the testing service and post -interviews will be conducted with a subset of participants to assess acceptance, problems and productivity issues. Participating elder members must agree to wear a tracking bracelet that will serve as an identifier allowing the robot to recognize a person and as alternate means of gathering activity data.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
The audio recorded tapes will be transcribed by a professional transcriptionist after each focus group session, and conversations will be preserved exactly as they occurred. Video may also be recorded. Digital video and audio files will be copied to a University of Pennsylvania secured research drive which will be established specifically for this project. The audio files will then be sent to a transcriptionist through Penn Secure Share. Upon receipt of he transcripts, the researchers will confirm accuracy of each transcription against the recordings. Recordings and transcriptions will be kept in a password protected file/locked cabinet. Transcriptions will be uploaded to Atlas.ti, which is a data management software specifically designed for the qualitative analysis of large bodies of textual, graphical, audio and video data. Use of Atlas.ti will support coding units of text required for level one codes and synthesizing them into multiple levels of codes culminating in theme identification. Analysis of the transcripts will be done on an on-going basis using content analysis. This process begins with level one coding in which the researchers analyze the text line by line. At this level coding is substantive, codifying the substance of the data using both the actual words participants used themselves and implicit codes the researchers develop. Following level one coding, level two coding requires comparing level one codes and developing categories. During the level two categorization phase, researchers ensure that categories appropriately reflect the concepts suggested by level one codes and are mutually exclusive. The final phase of coding, level three coding, identifies the central themes that emerge from the data. Summary statistics on the demographics questionnaire will also be calculated as part of the analysis plan. Anticipated Outcomes: The validation phase will provide answers to the key questions: 1. How does the robot impact the clinical staff? We anticipate that the robot service would provide a benefit to the clinical staff by increasing their productivity measured in terms of its impact on cost of service, use of time, and number of people able to be served. 2. How does the robot impact the elders? We anticipate that the robot service would provide a benefit to the elders and increase their overall quality of life measured in terms of its ability to increase their overall mood, increase their engagement with the staff and each other, as well as help them to feel more competent/ independent. 3. How usable was the robot? We anticipate that the usefulness and usability of the robot is key to acceptance and satisfaction. We will measure usability in terms of ease of use, set-up time, # of faults/errors, and # of hours in operation without errors. We will evaluate our research questions define final metrics for assessment of outcomes.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Subject Confidentiality
All study personnel wil have access to a locked file cabinet containing consent forms, evaluation assessments, and collected data. The locked file cabinet will be located at Living Independently For Elders (LIFE) at 4508 Chestnut Street, Philadelphia, PA, 19139. Both electronic data and hard copy records will be kept for a minimum of 10 years. Electronic data will be kept on password protected computers. After 10 years, any documents no longer needed will be destroyed by secure shredding at Penn Rittenhouse and electronic data will be deleted from computers. Research subjects will be identified in the research data by code and at no time will a direct link exist between collected data and research subjects. When data results are reported they will be presented in aggregate form (i.e. group characteristics only) and no individual identifiers will be used. Additionally, all hard copy data collected by Dr. Lau (i.e. consent forms and questionnaires), will be stored in the same aforementioned manner, but will be kept at Savioke's offices located at 2900 Gordon Ave., Ste 201, Santa Clara, CA 95051. Any video recordings collected by Savioke at The Forum and Rancho San Antonio will first be analyzed for non-verbal cues and after analysis, faces will blurred and data stored on password protected computers located at Savioke in Santa Clara, CA. Participants will be asked to create their own pseudonyms for use during the focus group sessions. This will help to ensure anonymity of participants during transcription and data analysis.The audio recorded tapes will be transcribed by a professional transcriptionist, and conversations will be preserved exactly how they occurred. Digital audio files will be copied to a University of Pennsylvania secured research drive which will be established specifically for this project. The files will then be sent to the transcriptionist through Penn Secure Share. Upon receipt of the transcripts, the researchers will confirm accuracy of each transcription against the audio recordings. Audio recordings and transcriptions will be kept in a password protected file/locked cabinet within a locked office at LIFE.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Dr. Tessa Lau, co-founder of Savioke Inc., and a co-PI on this study will have access to the data. She is HIPAA and CITI certified. Additionally, a PhD-level intern under Dr. Lau's supervision, Mike Chung, will have access to the study data. He is also HIPAA and CITI certified. Caspar Nguyen, a high school intern in Dr. Johnson's Rehab Robotics Lab, has been added to the protocol. She will be helping the team with data entry during her time at the lab.

Data Protection*

x	**Name**
x	**Street address, city, county, precinct, zip code, and equivalent geocodes**
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
x	**Telephone and fax number**
x	**Electronic mail addresses**
x	**Social security numbers**
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
x	**Biometric identifiers, incl. finger and voice prints**
x	**Full face photographic images and any comparable images**
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Consent

1. Consent Process

Overview
Subjects will receive a consent form at least 24 hours prior to the study session. This will allow subjects sufficient time to read over the form on their own, and come up with any questions or concerns prior to the commencement of sessions. Before a session begins, study personnel will review the consent form and experimental procedure with subjects and answer any questions. All participants will then be given the opportunity to sign the consent form with study personnel witnessing. Any subjects that decline to sign the consent form will be dismissed at that time.

Risk / Benefit

Potential Study Risks
The risks are minimal and all testing will be non-invasive. Subjects may experience frustration using the robot due to difficulty understanding instructions and multi-component directives. Care will be taken to use 8th grade language this is often an IRB requirement and to deliver surveys verbally and in person. The robot interface will be as simple as possible to enable elder interaction and use. Additional

Significant Risks: Still a minimal risk study. 1. Fatigue for user due to walking 2. Risk of falls during exercise 3. Frustration during use with the robot 4. Interaction with Robot gripper when passing an object Subjects may experience discomfort or embarrassment due to actions by the robot. Efforts will be made to ensure privacy in communication of sensitive reminders. Subjects may experience discomfort or embarrassment sharing their thoughts in a focus group setting. Efforts will be made to foster an atmosphere of impartiality, confidentiality and sensitivity to allow subjects to feel free to communicate their opinions. Subjects may bump into robot and experience pain or muscle bruising. The robot will be equipped with obstacle avoidance sensors, alarms etc to allow it to alert and avoid elders. In the case of failure, an emergency stop button can be applied. Subjects may experience fatigue due to walking, frustration while interacting with the robot, and while we will do everything possible to avoid fails, the risk does increase slightly. For unforeseen challenges, we will work closely with LIFE and the staff to resolve.

Potential Study Benefits
The benefit is not to the individual subjects as it would be to the overall outcome of elderly care. We anticipate that Elders and clinicians will provide valuable insights into the development process of this robot. If successful, the robot will be able to be commercialized in the future.

Risk / Benefit Assessment
Minimal risk

General Attachments

The following documents are currently attached to this item:

Additional forms (kristinelima-citicompletionreport.pdf)