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SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:*** **07/25/2018**
PARTHA BHATTACHARYYA ***Revised Date:***
[redacted]

Application Number: 1 R44 AG062014-01

Principal Investigator

WANG, VICTOR

Applicant Organization: CARE.COACH CORPORATION

Review Group: **ZRG1 ETTN-G (12)**
Center for Scientific Review Special Emphasis Panel
Small Business: Aging and Development, Auditory, Vision and Low Vision Technologies

Meeting Date: **06/28/2018** ***RFA/PA:*** **PAR18-186**
Council: **AUG 2018** ***PCC:*** **2CTECPB**
Requested Start: **01/01/2019**

Project Title: **A Specialized Automatic Speech Recognition and Conversational Platform to Enable Socially Assistive Robots for Persons with Mild-to-Moderate Alzheimer's Disease and Related Dementia**
SRG Action: **Impact Score:58**
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **1A-Both genders, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **3A-No children included, scientifically acceptable**

Project Year	Direct Costs Requested	Estimated Total Cost
1	[redacted]	[redacted]
2		
3		
TOTAL	[redacted]	[redacted]

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R44AG062014-01 Wang, Victor

RESUME AND SUMMARY OF DISCUSSION: This FastTrack SBIR application is aimed at further improving a human-operated socially assistive robot (SAR)-like avatar called care.coach by refining the automatic speech recognition (ASR) engine for conversing with elderly and AD patients. The developed platform will have a large subset of interactions automated to make it more cost effective although the human-in-the-loop will maintain the personalizing aspect of the system. The application receives mixed ratings for its significance from reviewers. Some of the reviewers think that this undertaking is of high significance as it is likely to improve the effectiveness of a system that is already in use and has a strong marketing potential whereas other reviewers think that the project requires technical developments on multiple fronts in addition to ASR and are unsure how this device will reduce slip-and-falls as the PI claims. The research team is well qualified to conduct the proposed research endeavor, but reviewers point out that expertise in speech recognition and deep learning needs to be strengthened. The research plan is well written and the data collection plan in Phase I is reasonably put together. Additionally, the plan is equipped with adequate discussions of potential pitfalls, alternative plans and benchmarks for success. However, some of the reviewers raise concerns about the research plan, which include the overly ambitious nature of the research scope. In addition, it is unclear about strategies to maintain the long-term effectiveness of the system as larger proportion of conversations become automated. Due to the disagreement among reviewers in evaluations of significance and research strategy, the application as proposed receives a wide range of enthusiasm from the review committee members.

DESCRIPTION (provided by applicant): 1 in 3 seniors in the United States dies with dementia, of which Alzheimer's disease (AD) is the most common form. AD patients suffer from decreased ability to meaningfully communicate and interact, which causes significant stress and burden for both professional caregivers and family members. Socially assistive robots (SARs) have been designed to promote therapeutic interaction and communication. Unfortunately, artificial intelligence (AI) has long been challenged by the speech of elderly persons, who exhibit age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers that can be exacerbated by the neurological changes associated with AD, further complicated by common environmental noises such as the ceiling fan, television, etc. Because of the resulting poor real-world speech and language understanding by available SAR technologies, scarce human caregivers are often required to guide AD patients through SAR interactions, limiting SARs to small deployments, mostly as part of research studies. Unlike existing approaches relying purely on AI, care.coach™ is developing a SAR-like avatar that converses with elderly and AD patients through truly natural speech. Each avatar is controlled by a 24x7 team of trained human staff who can cost-effectively monitor and engage 12 or more patients sequentially (2 simultaneously) through the audio/visual feeds from the patient's avatar device. The staff communicate with each patient by sending text commands which are converted into the avatar's voice through a speech synthesis engine. The staff contribute to the system their human abilities for speech and natural language processing (NLP) and for generating free-form conversational responses to help patients build personal relationships with the avatar. The staff are guided by a software-driven expert system embedded into their work interface, which is programmed with evidence-based prompting and protocols to support healthy behaviors and self-care. This SBIR Fast-Track project will leverage the unique data generated by our human- in-the-loop platform to develop new ASR capabilities, enabling fully automatic conversational protocols to engage and support AD patients without human intervention. We aim in Phase I to leverage our unique prior work dataset to train an automatic speech recognition (ASR) engine to enable the understanding of certain types of elderly and AD patient speech more successfully than any currently available engine. We aim in Phase II to incorporate this new engine along with an NLP module into our existing human-in-the-loop avatar system, recruiting a population of AD patients to further train and validate with during a 2-year human subjects study so that we can demonstrate full automation of a significant portion of our avatar conversations with mild- to-moderate level AD patients. Thus, we will improve the commercial

scalability of our avatars, while validating our new ASR/NLP engine as the most accurate platform for enabling the next generation of AD-focused SARs.

PUBLIC HEALTH RELEVANCE Narrative Artificial intelligence (AI) has long been challenged by the speech of elderly persons, and especially persons with dementia, due to age-related voice tremors, hesitations, imprecise production of consonants, increased variability of fundamental frequency, and other barriers. Unlike existing approaches to socially assistive robots (SARs) relying purely on limited AI for conversation, care.coach™ has been commercializing a SAR-like avatar that converses with elderly and AD patients through truly natural speech, powered by a 24x7 team of trained human staff. The unique data sets that our solution enables us to gather at commercial scale will be leveraged in this SBIR project to develop an automatic speech recognition (ASR) and natural language processing (NLP) engine that is best-in-class for AD applications, improving the commercial scalability of our avatars by reducing our dependence on human staff, while serving as a new AI platform for enabling the next generation of AD- focused, conversational SARs.

CRITIQUE 1

Significance: 3
Investigator(s): 7
Innovation: 5
Approach: 7
Environment: 3

Overall Impact: This proposal presents a bold system idea, one that will solve critical weaknesses with automated speech recognition (ASR) with elderly populations. This will be used to enable a NLP-based healthcare dialog system which will partially-address the scalability gap this company is likely to have as they have more elders using their system. This will help this company provide companionship and healthcare-related advice for more people using less personnel. However, this bold goal is not well-justified in their approach, and several weaknesses can be identified in their commercialization plan between what results they have and what their system will actually do. Finally, the investigators make frequent references to socially assistive robotics (SAR), however, they are not developing a robot, only a computer agent.

1. Significance:

Strengths

- **Minor strength:** Phase II SA-1, 2: If successful, this project would address critical technological weaknesses necessary for autonomous agents in the eldercare domain.
- **Major strength:** It brings a key population that is underrepresented in the implementation of ASR into active research.

Weaknesses

- **Major weakness:** It not clear how this project relates the major gain that the project achieved in its preliminary work described in the commercialization plan.

2. Investigator(s):

Strengths

- **Major strength:** The project team has demonstrated in-depth clinical, research, and gerontology experience. This directly relates the participant population identified in the study.

The project team has experience necessary for the development of healthcare computer agents.

Weaknesses

- **Major weakness:** The technological innovation for this proposal is developing a new ASR system, yet none of the company or academic personnel have identified experience in ASR methods, development, or use.

3. Innovation:

Strengths

- ASR systems specialized for the elderly are not commercially available.

Weaknesses

- **Major weakness:** ASR development is the chief deliverable for this proposal, yet even if we assume speech recognition works, the NLP, and autonomy challenges are also large. It would appear to be included in the scope of work for this proposal, however, and it is likely to not be completed during this project's timeline.

4. Approach:

Strengths

- **Minor strength:** The proposal lays out a feasible approach for data collection (phase I) for the initial project data. The project team has reasonable expectations for the data collection phase.

Weaknesses

- **Major weakness:** The chief value proposition identified in the commercialization plan is to reduce slip-and-falls. However, while the preliminary data show that the participants experienced fewer slip-and-falls, the investigators do not identify how this system actually reduced slip and falls. This means that the chief commercial goal might not be replicable in the new system. If the system is changed to include an autonomous agent (phase II, SA 1,2) does that preserve whatever caused patients to be more stable?
- **Major weakness:** The NLP and healthcare autonomous agent goals (SA 2) could be proposals in themselves. This makes it unlikely that the entire project scope would be completed. While the proposal does include some backup plans, the end-result of the failure of any of the milestones would likely be that an autonomous support agent would not be effective in the field.

5. Environment:

Strengths

- Facilities seem appropriate to meet project goals.

Weaknesses

- None noted

Fast Track (Type 1 R42 and Type 1 R44 applications):

Acceptable

- Phase I goals are clear and measurable. They directly relate to required elements for Phase II. Necessary commitments were obtained from necessary partners in order to complete project.

Protections for Human Subjects

Acceptable Risks and Adequate Protections

- Risks are appropriately considered and data protection is adequate

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18;justified scientifically
- elder population, reflective of community.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Not Applicable (No Relevant Resources)

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 1
Investigator(s): 1

Innovation: 3
Approach: 2
Environment: 1

Overall Impact: The investigators propose to enhance the performance of a human-operated avatar that converses with elderly and AD patients by incorporating automatic speech recognition technology into existing conversational protocols. The proposal is likely to have a large impact due to its innovative and practical approach to providing conversational interactions with older adults. The strengths of the proposal include compelling preliminary research, a qualified investigative team, an existing data set that can be exploited in Phase I, and a well-designed approach. Enthusiasm for the proposal is only slightly diminished based on the fact that the proposed research represents an incremental improvement to an existing product.

1. Significance:

Strengths

- Minor strength: The project addresses an important problem of providing care and support to the growing population of older adults with AD/ADRD.
- Major strength: The scientific premise for the project is strong. The investigators have successfully evaluated and commercialized a patient engagement system. The proposed research will increase the effectiveness of their existing product.
- Major strength: The investigators propose to keep a human "in the loop" as opposed to developing a fully autonomous system, increasing the likelihood of success.
- Major strength: The proposed project has commercial potential to lead to a marketable service and the technology that will also be of interest to companies developing other products that require voice interaction.
- Minor strength: The proposal discusses related research and products and how the proposed research fills an existing gap.

Weaknesses

- None noted

2. Investigator(s):

Strengths

- Major strength: The investigative team is extremely well qualified and has successfully collaborated on previous research.

Weaknesses

- None noted

3. Innovation:

Strengths

- Major strength: A "human-in-the-loop" approach, instead of a fully automated approach, is an innovative means of compensating for the limitations of existing speech recognition technologies.

Weaknesses

- Minor weakness: The research represents an incremental improvement to an existing product

4. Approach:

Strengths

- Major strength: Scientific rigor is strong. The strategy, methods, and analyses well-reasoned and appropriate to accomplish the aims.
- Major strength: Potential problems, alternative strategies, and benchmarks for success are presented.
- Minor strength: Plans to address the protection of human subjects from research risks are presented.
- Minor strength: The inclusion of individuals on the basis of sex/gender, race, and ethnicity, as well as the exclusion of children are justified in terms of the scientific goals and research strategy proposed.

Weaknesses

- Minor weakness: Sex and other biological variables are not considered. It is possible that speech recognition accuracy may be affected by gender or age.

5. Environment:

Strengths

- Major strength: The investigators have access to the necessary facilities for the proposed research.

Weaknesses

- None noted

Phase II (Type 2 R42 and Type 2 R44 applications):

Not Applicable

Fast Track (Type 1 R42 and Type 1 R44 applications):

Acceptable

- The Phase I application specifies clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II

Protections for Human Subjects

Acceptable Risks and Adequate Protections

- Risks and protections are addressed.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically

- For NIH-Defined Phase III trials, Plans for valid design and analysis:
- Inclusion/Exclusion of Children under 18: Excluding ages <18;justified scientifically
- Demographics of the subject population will reflect the local population.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Not Applicable (No Relevant Resources)

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 3
Investigator(s): 3
Innovation: 2
Approach: 5
Environment: 1

Overall Impact: This fast-track application aims to enhance a human-in-the-loop socially assisted robot (SAR) monitoring and care delivery tool, care.coach, to include a greater proportion of interactions that are automated. Currently, the care.coach system uses human agents to interact with, and monitor, the activities of care.coach elder adult users through crafting text to speech interaction elements in interactions with remote users. The applicants propose to use natural language processing (NLP) keyword extraction techniques to program the SAR system to perform affirmative/negative intent parsing allowing automation of a greater proportion of interactions between the SAR and the human participant. Specifically, the applicants propose to use already collected interaction data and deep neural network processing to train a speech recognition system to recognize interaction content which can be processed via automatic scripts. Following development of this system, the applicants propose to use the enhanced system in two-year observational study to assess the ability of the system to meet a goal of one-third of interactions processed automatically without deteriorations in quality or user perceptions. The care.coach system offers one solution for the need for cost-effective monitoring and interaction approaches for individuals with Alzheimer's Disease (AD) or other dementias. The human-

in-the-loop artificial intelligence (AI) approach is innovative and the strong human element has great potential for “humanizing” and “personalizing” computer-human interactions. The commercialization plan is sound and there is limited competition for their unique human-in-the-loop AI process. The research and development approach is generally sound in drawing upon a large database of already collected computer-human interactions, extant open source speech recognition software, and testing in a longitudinal observational study of individuals with mild-moderate AD. Aspects of the proposal which dampen enthusiasm somewhat include an underdeveloped plan for monitoring and evaluating the quality and users’ perceptions of the quality of automated and non-automated interactions and a lack of data on long-term use of the care.coach system (e.g., ability to sustain engagement with the system, how perceptions might change over time with repeated exposure to automated interactions).

1. Significance:

Strengths

- Alzheimer’s Disease (AD) and other dementias are a prevalent and growing health condition that puts considerable strain on healthcare and caregiving systems.
- Socially assistive robots (SARS) show promise in assisting in the care monitoring, care, and social interaction of those with AD and other dementias.
- The care.coach model of a remote caregiver who can guide computerized avatar interactions with a care recipient provides a potentially more personalized form of care as compared to a fully automated SAR interaction. However, the proposal to automate a larger subset of interactions with care recipients would allow a cost-effective expansion of this form of monitoring and care.
- The proposal to develop a system capable of automated communications for simpler care and communication routines via natural speech has the potential to not only enhance the care.coach platform but also that of other SAR systems.
- The use of remote staff who serve as interaction/care agents will facilitate expansion of care.coach to serve a large number of users.
- The applicants already have patents in place for some components/processes of the care.coach platform.

Weaknesses

- The value of this system is dependent upon the receptivity of the user and care providers (e.g., family caregivers, hospitals, residential care facilities) to interact and utilize the system. The pilot study results do not indicate prior demonstration of long-term interaction with a care.coach avatar. It is not clear how likely it is that the attention of a user could be held over long periods of time thereby potentially eliminating the effectiveness of this tool.
- How would the automation of a larger subset of interactions affect users’ affinity for and connection to the care.coach avatar? It seems that scripted interactions that repeat frequently (e.g., the same script deployment following query of whether user needs to go to the bathroom) may dampen individuals’ connection to the avatar as the interactions may seem less interactive and organic over time. It would be useful to see data which suggests the approximate percent of interactions that can be automated with no appreciable difference in users’ perceptions of their interactions/the system.
- Although the use of remote staff allows care.coach to widen its customer base, it also increases the likelihood of experiencing staff-client interaction challenges as the staff size grows. It is not clear that a plan is in place to monitor the quality of staff-client interactions given the future projected growth.

2. Investigator(s):

Strengths

- Applicant PI, Wang, CEO of care.coach, has a high level of productivity and experience as a relatively junior investigator and entrepreneur.
- Chief Technology Officer, Deng and Program Manager, Weng, at care.coach have the relevant expertise and experience for their respective roles.
- Dr. Boustani, Professor, Indiana University, Founding Director and Chief Innovation and Implementation Officer of the Center for Brain Care Innovation at Eskenazi Health, and PI of the Great Lakes Practice Transformation Network, is well suited to oversee implementation of the observational study proposed for Phase II activities. He has a distinguished profile of publications and federal grant funding.
- Dr. Wexler, Associate Professor of Nursing, and Dr. Drury, Professor of Nursing, at Pace University, note experience as a co-investigator on previous technology grants in older adult populations. They have collaborated on previous research on the care.coach system.

Weaknesses

- PI, Wang, lacks SBIR or similar grant experience as a PI.
- Dr. Wexler's and Dr. Drury's publication histories are not detailed in their biosketches.

3. Innovation:

Strengths

- An innovative strength of the care.coach system lies in its combination of SAR-delivered automated/scripted interactions with a real-time human caregiver/interaction partner ("human-in-the-loop AI system).

Weaknesses

- None noted.

4. Approach:

Strengths

- A significant strength of proposed development work is access to [redacted] of conversations between avatars and older adult users which can be used for deep neural network (DNN) training of the speech recognition system.
- Use of an open source and currently deployed speech recognition system (e.g., Mozilla DeepSpeech) should facilitate more timely DNN analysis and development.
- A two-year observational study of human interaction with the care.coach system will provide important information regarding how humans' perceptions of and interactions with the system change over time. For example, how does interest in, and engagement with, the care.coach system change over time?
- Collaborating with Indiana University and Eskenazi Health/Regenstrief Institute to conduct the two-year observational study is a strength given the expertise and experience of proposed collaborators and access to a large pool of potential research participants.

Weaknesses

- It is not entirely clear why the applicants DNN approach will be better able to address the challenges of noisy environments and elders' speech characteristics over currently available technology.
- Human actors will review any interaction tagged by the system as having low confidence for speech intent. It is stated that the human reviewers will observe the ongoing interaction and that the system will bring in automated scripts so that human observers can execute the correct automation or intervene with further interaction, as necessary. Is there data to indicate how long it takes human actors to play this "human-in-the loop" monitoring role and how that affects the perceived responsive of the support agent and overall quality of human-avatar interactions?
- It is unclear if there is a plan to integrate variety into scripted interactions.
- Unclear how the quality of interactions and users' perceptions of scripted and non-scripted interactions will be monitored and evaluated. Although applicants state that the goal is to automate a larger proportion of interactions without degrading the quality or users' perceptions of the interactions, a clear assessment strategy was not outlined to assess achievement of this goal.

5. Environment:

Strengths

- The environments are excellent for the proposed work.

Weaknesses

- None noted

Phase II (Type 2 R42 and Type 2 R44 applications):

Not Applicable

Fast Track (Type 1 R42 and Type 1 R44 applications):

Acceptable

Protections for Human Subjects

Acceptable Risks and Adequate Protections

- One concern is the withdrawal of the care coach system after such a prolonged period of use. The applicants note an additional 3-month period to decrease usage and wean off the system but if the system does provide the monitoring and interaction that it purports, it seems that a more ethical plan would be continuous access to the system until no longer needed or wanted by the participant or a reduced-fee continuation of the system.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable

- Inclusion/Exclusion of Children under 18: Excluding ages <18;justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Select Agents:

Not Applicable (No Select Agents)

Resource Sharing Plans:

Not Applicable (No Relevant Resources)

Authentication of Key Biological and/or Chemical Resources:

Not Applicable (No Relevant Resources)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 R44 AG062014-01; PI Name: Wang, Victor

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile

ranking. For details on the review process, see
http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
Small Business: Aging and Development, Auditory, Vision and Low Vision Technologies
ZRG1 ETTN-G (12)
06/28/2018 - 06/29/2018

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html and NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, including removal of the application from immediate review.

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