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Research Protocol

Impact of a Novel Socially Assistive Robotic Architecture on Engaging Older Adults with Mild Cognitive Impairment, Alzheimer's Disease, and Related Dementia in Long Term

I. Objectives

The overall goal of this multi-phase, multi-site clinical trial is to systematically examine the effect of two types of SARs (humanoid and animal) on apathy among older adults with cognitive impairment. We will include older adults (OAs), family members, and staff in participatory user-centered approaches to technology design and task development, a shortcoming of many studies involving technology use among older adults.[173] Our working hypothesis is that we can enhance SARs to address OAs' apathy while being versatile and easy to use in the clinical setting. To our knowledge this is the first time an SAR-based intervention will be used in a clinical trial that systematically a) matches a participant's capability with the sophistication of the SAR and b) creates tasks that combine physical, cognitive and social elements. The following Specific Aims will be addressed:

Aim 1: To improve our novel social robotic interaction architecture called ARIA through additional software and algorithm development to a) make it more versatile in combining multimodal quantitative data capturing engagement, b) more robust such that non-experts can operate it and create new tasks by concatenating task primitives, and c) expand the library of tasks to address varying degrees of cognitive and physical impairments of older adults (Months 1-18). A user-centered design approach will be employed in the development, testing and refinement of additional tasks. The planned improvements will allow for greater versatility and usefulness in real-world settings and utilize inputs from various stakeholders.

Aim 2: To compare the effect of usual care (UC) group to UC+ARIA group on reducing apathy among older adults with mild cognitive impairment (MCI), mild dementia, or moderate dementia (Months 19-48). We will conduct a randomized controlled trial to examine the effect of ARIA on apathy among older adults residing in LTC settings. 188 older adults will be randomly assigned to UC+ARIA or UC only using site-cognitive function stratified permuted block randomization. We will also conduct a nested, cross-over design within the ARIA+UC arm to explore whether cognitive function (MCI, mild dementia, moderate dementia) is a moderator for SAR type (humanoid or animal) on apathy.

Aim 3: To identify barriers and facilitators to SAR implementation across sites to address future scalability and sustainability (Months 18-42). We will gather information from direct observations, interviews and focus groups with key stakeholders in evaluating the implementation of SAR activities and procedures across the multiple sites, effect on staff workflow and activities, and acceptability among older adults, their families and staff. Results will provide direction for future implementation trials, scalability and sustainability.

This proposal is directly aligned with the NIA's research mission (Goal C) to develop effective interventions to maintain well-being and reduce the burden of age-related disorders. Our innovative interdisciplinary team has the expertise to design and conduct high-quality studies involving persons with dementia and robotic technology.

II. Background and Rationale

Apathy is common among older adults with serious consequences and engagement is a viable treatment option. This proposal is significant because it will test a novel robotic architecture to reduce apathy among older adults residing in nursing homes and assisted living facilities (i.e., long term care settings (LTCs)) that can be implemented by LTC staff. Apathy occurs in up to 72% of older adults residing in LTCs and is associated with further cognitive decline, functional deficits, reduced quality of life, social isolation, and increased mortality.[1-6] Moreover, it produces major stress, burden and

frustration for formal and informal caregivers.[7-9] Few pharmacologic options exist;[10] a major strategy is to foster older adults' ***engagement*** in social, physical and cognitive activities.[10,11] Activities in a group setting are particularly effective because older adults are engaged both in the activity stimuli and the simultaneous contact. Indeed, participation in social activities is associated with better cognitive function.[16] Meaningful activities need to be person-centered; thus, activity preferences can vary among LTC residents.[12,17-19] Last, the combination of sensory and motor based activity appears most effective for enhancing engagement and reducing apathy.[11,20,21]

The Centers for Medicare and Medicaid Services (CMS) mandates LTCs to provide individualized program of activities (§483.15(f))[22] and most LTCs provide activities for residents. However, activities are often suboptimal in degree of engagement, variety, stimulation or content.[17] Many older adults have excessive unoccupied time and spend as much as 17 hours a day in bed.[23] Documented barriers to engaging LTC older adults can be divided into older adult factors and provider/system factors. Older adult factors impacting engagement include cognitive and physical impairments.[23-26] As dementia progresses, determining the older adult's preferences can be problematic. Activities that are interactive are superior to passive activities (e.g., watching TV), but may provoke frustration. Similarly, physical impairments may limit the individual's ability to perform physical movements. Sensory deficits, such as hearing loss or visual impairments, reduce the older adult's ability to participate. Last, acute illnesses as well as chronic conditions that are painful or uncomfortable (e.g., arthritis) will limit the older adult's ability to engage in activities. LTC provider and system barriers also contribute to low engagement. LTC caregivers frequently lack the time, skill or resources to engage older adults in activities. This is problematic since multimodal strategies, which appear most successful in reducing apathy, are resource intensive.[12] Most LTCs have inadequate staffing, either in labor quantity or skill mix and provide only 0.1 to 0.6 activity staff hours/resident/day.[27] Direct care staff provide on average only 3.4 hours of staff time/resident/day, primarily by unlicensed staff. Older adults and staff should agree upon selected activities based on the older adults' interests, but this too requires time and resources.

Older adults and use of technology. Advancement in computer-based technologies have paved the way for developing intelligent systems for eldercare.[28,29,173] *Computer- and sensor-based technologies* include video telemedicine to perform neurocognitive testing,[30] sensor-based distributed systems for early signs and progression detection[31,32] ambient assisted living systems to monitor older adults' health, behaviors and activity,[33-35] and assistive systems that provide activity reminders and medication management.[36-39] The majority of systems were developed to prompt older adults to complete activities of daily living, or monitor behaviors and environment.[28,39] *Virtual reality* has been used to engage older adults in physical and rehabilitation activities, such as Wii balance board for balance training and stationary cycling.[40-42]

Use of socially assistive robots for older adults. *Robotic systems* show promise in addressing physical, cognitive, and/or social needs of older adults.[28] A number of assistive robots exist that provide support to the individual, such as those used in rehabilitation, household chores or aid independent living.[43,44] Socially assistive robots (SARs) are a type of assistive robots designed specifically for social interactions with capabilities for autonomously detecting and meaningfully responding to older adults' attention and behavior; thus, SARs have significant potential for addressing physical, cognitive, and/or social conditions. Compared to other interactive technologies, robotic technology can embed novel quantitative metrics, develop sensor-based non-invasive methodologies, and incorporate physical movement into realistically embodied interactions in ways that cannot be replicated by screen-based technologies (e.g., virtual avatars), and can facilitate interactions far beyond interactions with screen-based technologies.[13,14,45-47] While screen-based technologies have improved with the advancement of AI, recent studies indicate that people still tend to trust and comply more with robots.[13,14]

In the past 10 years, a number of approaches in SARs have emerged, for example, as pet companions,[48] as mobility aids or navigational guides,[49] and human-robot interaction (HRI.)[50] Early studies used a 'Wizard of Oz' experimental paradigm: a human operator controls the robot. In open-loop robotic platforms, the HRI is unidirectional, and the robot's behaviors do not adapt during HRI.[51,52] These open-loop platforms are limited in their capacity for HRI and lack real-time dynamic adaption based on interaction.[51-53] More advanced closed-loop robotic systems allow the robot to

dynamically alter its interaction based on real-time human interaction. Commercially available robots NAO, RoboPhilo, and Manoi-PF01 have been programmed to instruct older adults and correct their gestures during physical exercise routines.[54-57] Teams of investigators have experimented with closed loop platforms to engage older adults in eating,[58,59] cognitive stimulation,[58-61] and chair exercises.[62]

Use of Socially Assistive Robots (SARs) to address apathy may be a viable option for resource-strapped LTC settings. SARs have been created specifically for social interactions and can be embodied with features of a human or an animal.[50] The most frequently used SAR, named PARO, is an animal SAR designed specifically for those with dementia. PARO resembles a baby harp seal with fluffy white fur, weighs 2.7 kg, and has 5 types of sensors that react to touch, light, sound, temperature, and posture. A recent systematic review of 11 randomized controlled trials in LTCs revealed almost all involved PARO as the SAR intervention.[63] Studies had inconsistent results and the authors concluded the lack of significant findings were because the RCTs were of low to moderate quality, consisted of small sample sizes and varied in duration and frequency of exposure.[63] We contend that there are additional explanations for the lack of significant results.

First is the passive nature of PARO. The seal appearance and structure limit the degrees of freedom that prevent a larger set of robotic behaviors; it can only adapt to older adults' behaviors rather than providing guidance and feedback. Second, PARO is limited since its sole intent is to provide social or emotional connectedness. Other SARs have engaged older adults in either physical or cognitive activities, but they do not combine multimodal interactions (i.e., cognitive, physical and social). More advanced closed-loop robotic systems allow the robot to dynamically alter its interaction based on real-time human interaction and progress in technology allows SARs to engage multiple users simultaneously. Third, current SARs do not respond to more than one person at a time and thus cannot facilitate social interaction. Last, engineers are restricted by the physical structure of SARs in creating engaging tasks.

Use of Virtual Environments to Augment SARs. A recent development in use of technology for older adults with cognitive impairment is virtual reality (immersive) or augmented reality (semi-immersive or non- immersive).[64] A review of mostly exploratory studies shows the potential for virtual experiences and environments to enhance quality of life and maintain cognitive function for older adults with dementia, but also demonstrates the need to assess for anxiety and fear among older adults as well as the need for LTC staff to provide assistance and encouragement. Indeed, Moyle et al. reported on an interactive virtual environment that was resource heavy due to the need for staff to focus on one resident at a time as well as troubleshooting the system; the one-to-one staff interaction may have confounded the results.[65] Moreover, people still tend to trust embodied robots compared to virtual avatars.[13,14,45,66,67] Nevertheless, virtual environments can be versatile in creating interaction scenarios that can combine cognitive, physical and social aspects among multiple users.

Rigor of Prior Research. In summary, great strides have occurred in the area of robotics and older adults. In particular, prior work has established that intelligent technology, especially SARs, has the potential in engaging older adults with numerous benefits. Additionally, LTCs are supportive of introducing new technology. However, gaps in knowledge exist: studies have been hampered by conceptualization of aging and technology as separate sciences, rather than intertwined realms to be studied together;[68] technology development for older adults has occurred with little input from geriatric specialists or older adults.[69] Few clinical trials of SARs in LTCs exist and have been hampered by lack of randomization, small study sizes, varying exposure to SARs and lack of blinding.[63] Individual, care provider and organizational factors germane to successful SAR adoption are understudied. SAR technology has been mostly passive and lacks person-centered flexibility.

Our interdisciplinary team of engineers, nurses, physicians and health services researchers propose a novel technology-based interaction framework based on our recently concluded R21 study, *Socially Assistive Robotic Architecture for Elder Care* (AG050483), which combines the power of virtual environments in creating an array of engaging tasks and socially assistive robots (SAR) in administering the tasks in an individualized manner. We will address current gaps by expanding our work of a novel SAR architecture, ARIA (Adapative Robot-mediated Intervention Architecture) utilizing input from key stakeholders. ARIA utilizes both a humanoid robot to engage older adults with cognitive impairment in physical, cognitive and social activities with and without virtual environments that

fosters human-human interaction via robot mediation, and an animal-like robot that may be more successful with older adults with greater cognitive impairment.

Significance of the Expected Research Contribution. We expect our contribution to be a detailed understanding of the extent that SARs target and engage older adults with apathy residing in LTC facilities. First, we anticipate understanding characteristics of those who benefit from types of SARs and types of activities. Second, we expect to understand the effect of SAR implementation on work flow processes and usability by LTC personnel. Designing sophisticated robotics systems that can be implemented by LTC personnel *increases the clinical and translational relevance of the work*. These findings will lead to larger cluster-randomized trials to examine the effectiveness of SAR in LTC facilities.

III. Procedures

A. Research Design

Aim 1 is a participatory research design conducted in the Vanderbilt University Engineering Laboratory. Aim 2 involves a randomize clinical trial conducted in long term care settings in Tennessee and Ohio. Aim 3 involves older adult participants, their family members and long term care staff in focus groups to determine facilitators and barriers to using the robots.

The three aims have differing designs, methods, samples, and analyses. We present each Aim separately.

Aim 1: To improve our novel social robotic interaction architecture called ARIA through additional software development to a) make it more versatile in combining multimodal quantitative data capturing engagement, b) more robust such that non-experts can operate it and create new tasks by concatenating task primitives, and c) expand the library of tasks to address varying degrees of cognitive and physical impairments of older adults (Months 1-18).

Introduction. We expanded ARIA with NAO humanoid robots that interact with older adults through speech and gestures, provide meaningful feedback, and encourage communication between two older adults. We developed algorithms to detect task action, speech duration, gaze direction, and gestures to estimate engagement and social interaction. Aim 1 is designed to reduce operating burden, increase the number of tasks, allow for the creation of new tasks on the fly, and get it ready for field testing, essential activities for emerging technologies.[173]

Participants: A convenience sample of 12 older adults with mild cognitive impairment or mild dementia and 4 staff members from two Nashville LTCs will be involved in the participatory design sessions. Exclusion criteria include: unable to travel to VU, difficulty hearing or seeing with corrective aids, unable to walk independently, and difficulty communicating in English. Staff volunteers will receive permission from LTC administrators to attend the participatory design sessions.

Participants can choose to a) make 3-4 one-hour visits to the VU laboratory for sequential alpha testing and feedback on the various tasks involving two types of socially assistive robots (SAR) or b) have the VU engineers come to the LTC to conduct the alpha testing.

To make ARIA more versatile and robust in HRI capabilities: a) *A multimodal sensory module that collects and fuses rich information from the users during HRI.* Currently ARIA collects task action, speech, gaze and gesture data for offline analysis of each modality separately. Because fusing multimodal information leads to more robust estimation,[90] we will fuse the results from each individual sensing module to generate a more robust estimation of older adults' task engagement and social interaction. We will modify existing algorithms from our previous work that fused electrophysiological, gaze, and task performance data to predict user's cognitive load and affective states.[91] For example, from gaze data and speech data the system could reliably infer whether older adults were communicating with each other. Adding task action to this information will lead to the estimate of intentional collaboration. b) *Closed-loop HRI using older adults' engagement and social interaction.* Currently, ARIA provides feedback based only on older adults' task performance. We will integrate the estimation of engagement and social interaction to further adapt robot response behavior. This will be realized by modifying our existing hierarchical finite state machine (HSM) to incorporate states, events, and robot actions related to engagement and social interaction. c) *An intention*

detection module that keeps track of the interaction data and predicts user intention to personalize HRI. Users' interaction data are generated due to their intentions. We will use sequences of their interaction data to estimate the intention that drives these behaviors. As the system collects new interaction data, the probability distribution for each intention candidate will be updated using the maximum entropy algorithm.[92] The intention detection module will allow the system to provide user specific feedback. d) *User specific task profile will be designed based on a user's intention.* When users have no intention to play a specific game, probabilities for all intentions related to the game will be low, which will indicate that the user interaction data are random and there is no goal-directed behavior. This information could be used to adjust the task for the specific user. e) *A task management module that allows seamless integration of NAO and Aibo in the architecture.* We will expand the content of robotic interaction tasks as well as the robotic platforms. To realize seamless integration of NAO and Aibo in ARIA, we will add a task interface module in between the task management module and the robot behavior module.

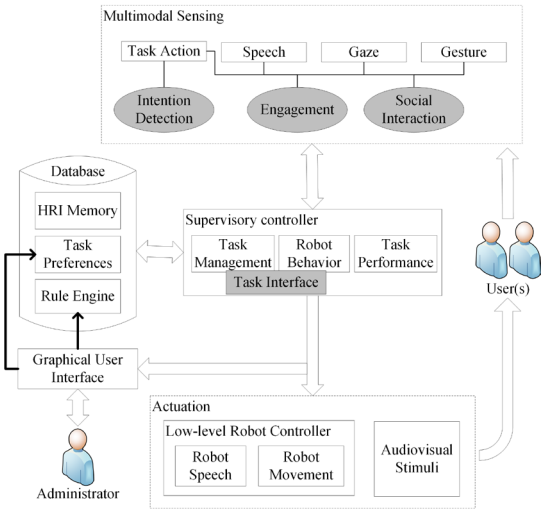


Figure 5. Adaptive Robot-mediated Intervention Architecture (ARIA) System and Subsystems

Expand the library of tasks to address varying degrees of cognitive and physical impairments of older adults. In order to have enough task variation to engage older adults over repeated sessions, we will design a library of tasks with 8 hours of interaction material. There are three main components in the tasks: *physical*, *cognitive*, and *social* **(Figure 6)**. The physical component consists of arm, hand, leg, and head movement. The cognitive component involves elements to perceive, attend, memorize, conceive, and reason. The social component focuses on communication and collaboration during HRI. Subtasks will involve one or multiple essential elements. Examples of physical movement are raising one arm up, extending arms to the sides, moving a virtual book by arm movement and hand grasping gesture, and head turning. Matching, sorting, and question and answer type activities will require essential elements from cognitive components. Collaborative rules are embedded to encourage communication and collaboration. These subtasks are then combined to form various tasks. For example, a chair exercise is a physical task realized by a combination of motor movements. Sequencing the order of chair exercises is a physical and cognitive task that combines physical movement with matching the order. The virtual book sorting task is a physical, cognitive, and social task that combines movement, sorting, and embedded collaborative rules. We have already designed various tasks and subtasks that are composed of these essential elements. In the proposed study, we will expand on the existing subtasks and combine subtasks to create variations of tasks. For Aibo, the subtasks will be modified based on its capabilities. For example, physical activity with Aibo will be throwing a ball or reaching and touching Aibo's head and body. Aibo can be combined with a virtual environment with a storyline so that older adults could interact with Aibo to make progress in the virtual environment, combining social, cognitive and physical activities. Potential tasks could be a fetch game where older adult throws a ball and Aibo moves it back (physical), a dance game where older adult touches different body parts of Aibo to activate a dance behavior (physical and cognitive), and a following game where older adults rotate their heads following the movements of Aibo (physical). These tasks could be extended to involve two older adults and to elicit social communication.

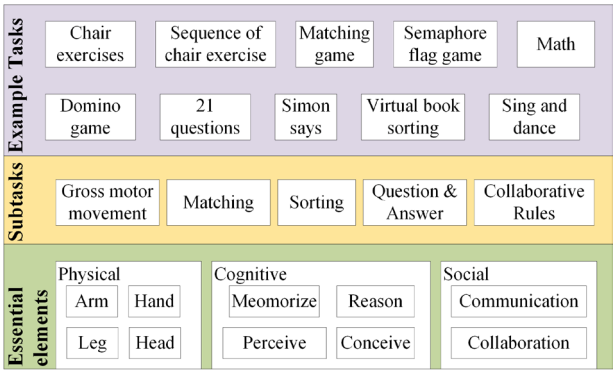


Figure 6. Multimodal Task Structure

Vary the task difficulty levels to take into account differences in physical and cognitive abilities. Each task will have adjustable task difficulty levels to accommodate cognitive and physical capabilities.[93] For example, an older adult with limited physical abilities will play a physical game that requires less range of motion. For individuals with moderate dementia who may not be able to participate in

physical, cognitive, and social tasks, behavior-based tasks will be designed to have Aibo engage with them in a free-form interaction.

Validation of Algorithms. Algorithms will be validated by participants, staff members, and a graduate student rater. The system will generate quantitative data regarding activity and social engagement during HRI with start and end timestamps of each detected event. Given these quantitative data, the rater will manually check whether the detected events are correct (precision) and the number events are detected (recall). The intention detection algorithm will be validated by computing the correlation between the detected intention and the true intention of the participants as estimated by a rater. The adaptive behavior of the robot will be validated by staff members on whether they agree with each robot prompt and feedback. The task and the graphical user interface will be validated by participants and staff members.

More robust such that non-experts can operate it and create new tasks. We will modify the architecture to place a minimal burden on the administrator, who will primarily need to calibrate the system and then initiate the session. We will conduct additional two separate participatory design sessions with LTC staff, lasting 1 ½ hour each. Participatory design is commonly used in technology and engineering fields because it aligns technology design with users and the environment and empowers the user to find a better fit.[94] We will conduct in-situ testing of prototypes. The first session will focus on a priming activity in which the participants observe the engineer operate ARIA with two volunteers and instructed to take notes. Following the demonstration, participants will be educated on the limitations of the robots to make more realistic design suggestions. We will engage the staff in identifying potential problems and issues and use their input in the design of the graphical user interface. We will develop a visual programming language based intuitive user interface[108] to simplify SAR operation and reduce system burden. An iterative cycle of the design is planned with a minimum second session in which participants return and re-analyze the system for ease of use. In addition, we will create a visual user interface (UI) where a user can concatenate several already designed task primitives to create new tasks. The task primitives are defined to be the basic building blocks of a task.[95] For example, raising an arm, orient towards a target, and looking at your partner are task primitives in physical, cognitive and social domains, respectively. The visual UI will allow a user to link several such primitives to create tasks of her choice without programming burden. Sarkar has created similar easy task creation UI in his prior work.[95]

Data Collection Procedures. In addition to the ARIA system feedback, older adults and long term care staff will complete questionnaires at baseline before or at start of Session 1 and feedback after each session. Older Adults will complete a Baseline Demographics Survey, the Apathy Evaluation Scale – Self and the Self-Administered Gerocognitive Examination at baseline. At the end of each session, the older adult will complete the Lab Testing Field Notes and Questionnaire for Older Adults. Long term care staff will complete a basic demographics survey at the first visit. LTC staff will also complete a feedback questionnaire after each session.

Aim 2: To compare the effect of usual care (UC) group to UC+ARIA group on reducing apathy among older individuals with mild cognitive impairment (MCI), mild dementia, or moderate dementia (Months 19-48).

Rationale. 1) We propose activities involving more than one person since activities done with others results in greater improvements in engagement, which in turn may reduce apathy.[10,83,96,97] 2) We focus solely on apathy since a) neuropsychiatric symptoms (NPS) are heterogeneous and may have different underlying etiologies; [10,98] b) apathy is manifested by decreased engagement,[5,10,20] thus the intervention of enhancing engagement has the most potential to impact apathy versus other NPS; c) apathy is among the most prevalent and persistent of NPS across all neurodegenerative diseases,[10] thus we can explore the effectiveness regardless of underlying disease states. 3) SAR dosing and duration (2x/week for 8 weeks) was based on a) our initial experience demonstrating sustained interest and participation after 3 weeks, b) lack of consensus with variations of 2 or 3/x week frequency, 10-45 minute sessions and duration 2-12 weeks;[63,99-106] and c) chronicity of apathy requires ongoing intervention to maintain effects;[10,98] 8 weeks will

allow sufficient exposure to determine the SAR's effectiveness on apathy as well as ability to maintain the older adult's interest. 4) We will examine the short term effect on executive measures of cognition as a secondary outcome because a) apathy represents frontal cortex dysfunction b) reducing apathy through engagement may improve executive measures and focused attention (both ways to assess frontal brain regions) or delay decline and c) cognitive stimulation activities in general are known to improve focused attention and executive measures in older adults with dementia.[2,10,20,107-110]

Design (Figure 7). We will conduct an 8-week 2-arm RCT, with nested cross over design in the intervention arm, using stratified randomization by site and level of cognitive impairment. Older adults in each site by cognitive function stratum will be randomized to ARIA+UC arm or UC arm in a ratio of 1:1 using permuted block randomization of varying block sizes of 2 or 4. The ARIA+UC arm will have 4 weeks exposure to each robot type (NAO or Aibo); ; order will be randomized by site. Using sites as the units of randomization for the nested cross over trial in the ARIA+UC arm is decided based on logistical considerations to reduce barriers (e.g., pairing of two participants allocated to the same robot type) in intervention delivery. All randomization will occur after baseline data collection.

Study Participants The sample will consist of 188 OAs who meet the following criteria: 60 and older, residing >3 months in the LTC facility, evidence of mild cognitive impairment, mild dementia, moderate dementia, and symptoms of apathy (score ≥25 on AES-C). Exclusion criteria are cognitive or physical impairments that would impede participation: unable to provide assent; uncorrected hearing or vision; unable to speak or understand English; unable to sit comfortably in chair; acute illness, terminally ill or nonresponsive; cannot be moved to activity location; aggressive or combative; other neuropsychiatric conditions impairing participation (example hallucinations); unable to use arms.

Sex Differences: There does not appear to be an association between the sexes and apathy.[10] Sex can have an impact on activity participation only to the extent the activity is not personalized to the individual's preferences and former work experiences.[26,111] Nor does there appear to be differences between the sexes in response to robots.[50,63] Thus, we propose to keep data from each sex separate and explore sex as a biological variable in our analysis plan.

Settings and Recruitment: Aim 2 will take place at 8 or more long term care facilities (nursing home and/or assisted living) in TN and OH that 1) have physical space for the robot set-up, 2) activity personnel willing to interact with research staff, 3) within an hour's drive from the PIs' offices, 4) licensed by their respective state, and 5) CMS-certified. Inclusion criteria were chosen to facilitate implementation of the SAR and enhance similarly required standards of care. Exclusion criteria are designated as subacute care, rehabilitation or hospice and lack of dedicated space for using and storing the equipment. Besides the sites used in our R21 study, we are engaging two large retirement communities that include numerous assisted living and nursing home settings (see letters of support). United Church Homes has 19 assisted living or nursing home facilities in OH and TN; Ohio Living has 13 LTCs in OH (see letters of support). The PIs have established relationships with these two systems; Sarkar and Mion are on the UHC Innovation Committee and Mion was on the Board of the Ohio Living Westminster Thurber community in Columbus. Sites have agreed to discuss the study with potentially eligible residents and gain residents' approval for research staff to approach. RCs will contact residents to explain the study, conduct screening eligibility, obtain informed consent (from participant or family member) and/or assent, conduct baseline data collection and then randomize to UC or ARIA+UC. In the event, that family members/LARs cannot be physically present during the Informed Consent process, there will be an option to complete the Informed consent process either by mail or electronically via REDCap. Sites will be added in waves (see **Timeline**).

Usual Care (UC). CMS requires all residents to have programs and activities to improve or maximize the older adult's mental and psychosocial functioning, enhance quality of life and are enjoyable to the person.[22] LTCs are required to have sufficient space to accommodate activities and CMS mandates that all residents have a documented activity plan using the Minimum Data Set 3.0 (MDS) Preference Assessment Tool (PAT) as a standardized assessment.[22] MDS 3.0 PAT evaluates the importance for selected personal care (8 items, e.g. choosing bedtime) and activity categories (8 items, e.g., do things with groups). Responses range from 1 (very important) to 4 (not important at all) with an additional category for 'important but can't do'. The PAT is used to customize activities based on the importance to the resident. Interrater reliability for the PAT was 85% and demonstrated sufficient variation among residents.[112,113] For those randomized to UC arm, we will collect information on a) specific types of activities noted in the plan of care, b) the

frequency of the activity as noted in the plan of care, and c) documented attendance in activities during the 8 weeks of the study (type and duration).

ARIA+UC Intervention Description. For the ARIA+UC arm, ARIA experiments will be delivered in a designated space determined by the participating facility. Each site will be equipped for internet access, two cameras for video recording, and a Kinect for Windows. For the humanoid SAR sessions, a 6 foot long table and 32 inch monitor will be used. For the animal SAR activities, a projector will be used to display interactive activities on the floor.

Each participant will wear an unobtrusive monitoring wristband (see **Equipment**) to detect heart rate variability, motion based activity and peripheral skin temperature. In addition to UC activities, each participant will attend two robotic sessions per week for a total of 8 weeks (4 weeks with NAO and 4 weeks with Aibo). The sequence of whether a participant will receive NAO or Aibo first will be randomly assigned using sites as units of randomization. A participant will be paired with another study participant of the same level of cognitive impairment. Pairing two individuals is not fixed and will be determined based on their availability to maximize participation and relieve scheduling burden. For each session, the trained RC (who is not an engineer or computer specialist) will deliver the SAR session with a designated staff person. SAR sessions are based on a standardized framework that combines cognitive, physical, and social interaction activities. Given the field testing nature of the study, an engineer will be linked via video in the event troubleshooting is needed; events will be logged to inform ongoing development and deployment of the system.

Ensuring Treatment Fidelity. We incorporated recommendations from the NIH Behavior Change Consortium to maximize treatment fidelity across multiple sites.[114,115] *A) Design.* Our study is designed using theoretical models (Figure 1) to address apathy in older adults with cognitive impairment through the use of robotic architecture.[50,70,73,83,84,86,111,116] *B) Training*. Prior to implementation, the PIs and the two sites' (VU and OSU) RCs will conduct a 2-day standardized training session and video record it for quarterly reviews. In the event of RC turnover, the same training and materials will be used for new RCs. *C) Delivery*. A standardized implementation protocol will be used. RCs will alternate travel quarterly to conduct simultaneous sessions to minimize drift. In addition, all sessions with the robots are video recorded; RCs will review a session with one another at least once a month during their RC weekly videoconference meetings and complete a session-specific checklist. Any discrepancies will be discussed at the weekly PI-RC meetings as well as monthly full investigator meetings. *D) Receipt.* RCs will complete web-based field notes after completing each session documenting the session date, time began and ended, and notes on issues encountered during the session. *E) Enactment* will be measured by the amount of effort exerted by the older adults to accomplish tasks using measures from our R21.

Variables and Data Collection Procedures. Data sources for concepts and variables identified in **Figure 4 Conceptual Framework** include observations, interviews, and physiologic responses as detailed below. Data collection times will be at baseline, 4 weeks and 8 weeks.

Baseline data collection of **Individual Characteristics** will consist of staff interviews. Variables will include *demographics; physical function, comorbidity and medications.* Barthel Index will be used to quantify *physical function*. This validated scale consists of 10 activities rated from independence to total dependence for a total score ranging from 0 to 100.[117,118] *Comorbidity* will be assessed by number of active conditions for which they are being treated. Dementia, depression, and mild cognitive impairment diagnoses will be noted (present/not present). *Medications* will be collected from the medication administration record as sum of medications and classified in psychoactive categories: a) psychotropic, b) medications used for Alzheimer's (e.g., Aricept), c) opioid, d) antidepressives, e) sedative hypnotics, f) anxiolytics, and g) benzodiazepines.

Staff Interviews will be conducted to collect *baseline apathy*, *overall cognitive function*, and *neuropsychiatric behaviors*.

- The Apathy Evaluation Scale-Clinician (AES-C) consists of 18 items ranging from 1 (not at all characteristic) to 4 (a lot characteristic) with a range of 18 (low) to 72 (extreme apathy). AES-C is designed as a generic neurodegenerative scale to measure behavioral, cognitive and emotional domains for apathy in the prior 4 weeks. Information is gathered from both the resident and formal caregiver in semi-structured interviews. AES-C has good internal consistency (Cronbach's alpha = 0.86-0.94), retest reliability (r = 0.89-0.94) and convergent and discriminate validity.[121,122]
- *Overall cognitive function* will be assessed using two instruments that are valid, reliable and require minimal staff time and training. AD8 is a brief 8-item, informant-report questionnaire that assesses memory and function. Scores of 0-1 indicate normal cognition. It has good sensitivity (74%-93%), specificity (86-94%), and area under the curve (0.83-0.96) in detecting dementia.[128-130] Dementia Severity Rating Scale (DSRS)[131] is an 11-item, informant-report questionnaire that assesses cognitive abilities and function and is recommended as the research measurement tool to establish baseline.[132] Scores range from 0 to 54 and has shown to accurately discriminate (82%) normal controls and MCI from dementia (mild dementia 16 < 19, moderate dementia scores 19-36).[133-136]
- *Neuropsychiatric Behaviors* will be assessed using the Neuropsychiatric Inventory Nursing Home Version (NPI-NH). This validated instrument gathers information from professional caregivers on ten behavioral areas and two neurovegetative changes; conditions include hallucinations, sleep disorders, and agitation.

Participant Interviews will be conducted to assess *global cognitive function and frontal lobe cognitive function*. Self-Administered Gerocognitive Examination (SAGE),[123-125] developed by co-I Scharre, is a brief cognitive test that does not require any special equipment or caregiver input. It assesses cognition in 5 domains: language, reasoning/computation, visuospatial, executive, memory, and orientation. SAGE has good interrater reliability (ICC=0.96), specificity (88-95%), sensitivity (62-95%), and negative predictive value 85%.[123-127] A score of 17 to 22 (maximum) suggests normal condition, 15- 16 suggestive of mild cognitive impairment (MCI), and ≤14 suggestive of dementia. *Frontotemporal cognitive ability*, which is associated with apathy,[107,137,138] will be assessed using two brief and well validated tools, the Trail Making Test (TMT) and Animal Naming for verbal fluency.[139] The TMT is a well established test of executive function and has two forms.[140-142] TMT-A consists of a series of numbers in circles displayed randomly on a page; the person links the numbers in sequence. TMT-B consists of numbers (1 to 13) and letters (A to L) inside circles randomly placed on a page; the person alternates in connecting ascending numbers with ascending letters. TMT is scored by time in seconds to complete, up to 5 minutes. TMT-A normal time is 29 seconds and deficient score is >78 seconds. TMT-B average score is 75 seconds and deficient score > 273 seconds. Verbal fluency tests require verbal ability and executive control processes;[139,142,143] the Animal Naming test requires naming 15 animals in 1 minute; it has good sensitivity (88%) and specificity (96%) in detecting frontotemporal dementia.[144]

Adjudication of Cognitive Impairment Classification. Because diagnosis of mild cognitive impairment or level of dementia may not be documented, we will classify the level of cognitive impairment based on the established validated instruments described above. MCI will be based on a SAGE score of 15-16. For those with SAGE scores < 15, mild dementia is an AD8< 2 and DSRD< 19; moderate dementia is an AD8>1 and DSRD between 19-36. Cut-off scores for severe dementia are SAGE<4, AD8=8 and DSRD>36. If the resident cannot be clearly classified within MCI, mild dementia or moderate dementia categories, co-investigators Scharre or Newhouse will review baseline data and determine level of cognitive impairment prior to randomization.

Activity Factors will be categorized by *domain, characteristics,* and *category*. *Domains* include physical, cognitive and/or social interactive domains; activities can have more than one domain (up to 3).[12,19,20,26,83,85,145,146] *Characteristics* refer to the type of cueing/redirection required and need for assistance initiating an activity.[146] Types of activities include physical movement/exercise, music/singing, games, puzzles, reminisce, and reading that are *categorized* as life-like or artificial, social vs. nonsocial, manipulative vs. passive, work-related vs. not work, and having a personal meaning vs. being general.[84,86] Activities will be categorized first by investigators; these will be reviewed and verified by the Activity Specialists Advisory Panel. Data will be collected each week from the participants' activity records by RAs blinded to the primary aim.

Engagement, defined as 'the act of being occupied or involved with an external stimulus,[84] will be collected

via direct observation using the Group Observational Measurement of Engagement (OME) tool;[83,84,86] used in SAR studies with older adults.[63,96,147,148] It measures engagement on five dimensions using ordinal scales: attendance duration (0-none to 6-all), attentiveness (0-none to 5-most of time), active participation (0-not at all to 4-very much), attitude (1-very negative to 7-very positive), and boredom/sleep like symptoms (0-none to 6-all the time). OME has undergone development, validation and reliability studies with interrater agreements ranging from 84% to 99% and ICC 0.78 to 0.97; construct validity with experts' evaluations have correlations ranging from 0.84 to 0.87.[83-86,149] One tool will be used for observations of participants in non-robot activities and one tool will be used specific to robot-related activities.

Once each week, trained research coordinators will observe study participants in a non-robotic group activity over the 8 weeks of study. RC will note the type of activity, environmental characteristics, and content of study participant's remarks while engaged in the activity.[84,148,149]

Environmental Characteristics can impact engagement; items addressing the environment are included in the OME tool.[84-86,149] At the weekly observational sessions, RCs will note the *number of people* in the room, background *noise level* (1-none to 5-very high), *lighting* (1-dark to 3-bright) and *time of day* (10 AM-12 PM; 1–2:30 PM, 2:30-5 PM, evening).

Human-Robot Interaction variables will be assessed for the ARIA+UC arm participants. Participants' *attitudes* at baseline will be assessed by the investigator-developed, validated RAS.[72] The RAS consists of 25 items rated on a 7-point Likert Scale. The RAS has 3 subscales that provide an aggregate 1-7 score: Performance Effort (Cronbach's alpha .86-.88), Effort Expectancy (Cronbach's alpha .80-.89), and Attitude (function and human attribute items, Cronbach's alpha=.77-.89). For each session, we will collect the following variables. *Robot type* is dichotomized as dog or humanoid. *Robot Activities* will be classified using the same schema of *domain, characteristics,* and *category* described above. *Visual attention* is measured as percent time looking toward the robotic system and percent time looking towards peers. *Verbal communication* will be collected and coded from the videotapes as duration (seconds) of positive or negative comments with others or with robot.[148] *Physiologic responses* collected from the E4 wristband include heart rate, skin temperature and electrodermal activity.

Outcomes. The primary outcome of ***Apathy*** will be measured on the Apathy Evaluation Scale-Clinician (AES-C) described above via interviews at baseline, Week 4 and Week 8. ***Cognition*** is a secondary outcome and focused solely on frontotemporal cognitive ability because of its strong association with apathy. We will measure cognition at baseline, Week 4, and Week 8 using the Trail Making Tests (A and B) and Animal Naming test. We will also measure the NPI-NH at Week 4 and Week 8 to adjust for neuropsychiatric changes as needed.

Ensuring Data Fidelity. Research staff will be trained by the investigator team using a standardized training approach via pre-recorded video in assessing apathy, depression and cognition from co-I's Scharre and Newhouse. A standardized data collection protocol and manual will be used. To minimize drift and maintain intra-site agreement, the Research Coordinators will conduct twice yearly in-person meetings to conduct inter-rater reliability checks with one another. In turn, RCs will conduct monthly inter-rater reliability checks with Research Assistants who are collecting the Outcome Measures; retraining will be conducted if inter-rater agreement <90%.

Sample Size/Power. Sample size is determined to have sufficient power to detect ARIA effect on apathy (primary outcome). Using mixed-effects linear modeling for repeated measures, 188 participants (94/arm) are needed to have 80% power to detect an effect size of 0.5 for between-group comparisons in the change of apathy from baseline. The effect size of 0.5 is corresponding to 5 points difference in apathy score, assuming a common standard deviation of 10 based on published studies.[20,63,99,150,151] We assumed 1) a first-order autoregressive correlation structure among the repeated apathy measures at three time points, 2) with-subject correlation of 0.7, and 3) attrition rate of 10% based on our pilot studies.[70-72,74,75] Our power analysis also applied Bonferroni method to adjust for two between-group comparisons of main interest (Week 4 vs. baseline, Week 8 vs. baseline) to maintain an overall Type-I error rate of <0.05. The same study power also applies to cognitive function (secondary outcome).

Statistical Analysis. Congruent with the RCT nature of the study design, we will conduct intent-to-treat analysis. Descriptive statistics will be used to examine variable distribution, identify outliers, summarize sample characteristics, and check the balance of two study arms (ARIA+UC vs. UC) in baseline

characteristics. Trend plot will be used to visually illustrate the change in each outcome over time (baseline, Week 4, and Week 8). All outcome variables are continuous, including **apathy (primary outcome)** as measured by AES-C score and **cognition (secondary outcome)** as measured by time in seconds to complete TMT (A and B) and number of animals named in 1 minute in the Animal Naming test.

To examine **the effect of ARIA on apathy**, we will use mixed-effects linear modeling for repeated measures to model apathy as a function of fixed-effects of intervention (ARIA+UC vs. UC), time, and intervention by time interaction, adjusting for **covariates** (e.g., biological sex, baseline cognitive function, and any unbalanced baseline measures). Subject-specific random intercepts with first-order autocorrelation will be also included in the model to adjust for within-subject clustering from repeated measures. The overall effect of ARIA on apathy is supported by a significant intervention by time interaction. From the model, we will also test the effect of ARIA on apathy at each time point by deriving between-group contrast estimates to compare ARIA+UC vs. UC in the change of apathy from baseline at Week 4 and Week 8. Bonferroni adjustment will be applied to the two between group comparisons (Week 4 and Week 8) to avoid inflated Type 1 error. The same analytic approach will be used to examine the effects of ARIA on each executive measure of cognition (TMT-A, TMT-B, and Animal Naming test; the secondary outcomes).

For the exploratory sub-aim on **cognitive function as a moderator** for the effect of SAR type (humanoid or animal) on apathy, we will first use mean plots to visually illustrate the change of apathy over time by sequence of SAR type (humanoid first or animal first) and level of cognitive function (MCI, mild dementia and moderate dementia). Next, mixed-effects linear modeling will be used to model apathy as a function of fixed-effects of sequence, time, level of cognitive function, and their two-way and three-way interactions. Again, we will adjust for confounders (e.g., biological sex, race/ethnicity) as fixed-effect covariates in the model and include subject- and site-specific random-effects to adjust for within-subject clustering from repeated measures and within-site clustering from cluster randomization. From the model, we will derive contrast estimates to compare the change of apathy from baseline at Week 4 and Week 8 across SAR type and cognitive function level. Due to the exploratory nature of this sub-aim, we will not rely on statistical significance of the comparisons. Instead, we will report point estimates, effect sizes, and their 95% confidence intervals. These estimates along with clinical significance will guide results interpretation.

Missing Data. We expect an attrition rate of <10% due to the short duration (8 weeks) of the study. Nevertheless, we will carefully examine the pattern of the missing data. Mixed-effects regression allows for missing at random. If missing at random is indicated, we will repeat the analyses before and after appropriate multiple imputation. Pattern-mixture modeling will be used if missing not at random exists. Sensitivity analysis will be performed to examine the robustness of study findings before and after multiple imputation or from pattern-mixture modeling.

Aim 3: To identify barriers and facilitators to SAR implementation across sites to address future scalability and sustainability (Months 18-42).

Introduction and Rationale. Our preliminary studies at three sites and others' observations demonstrate there are organizational factors, physical environment, staffing characteristics, staff attitudes and older adults' attitudes that can impact the implementation of robotic technology in LTC settings.[63,152-157] Although CMS mandates activity programs for residents, sites vary in the content, delivery and personnel.[158,159] For each site, we will collect information on site-specific contextual factors and obtain feedback from multiple stakeholders (i.e., older residents, families, staff). Information will provide direction for future SAR refinement as well as enable targeting implementation strategies to meet specific local contextual factors.

Design. A qualitative approach will be implemented that includes field notes, semi-structured interviews and focus groups as described below. Our approach in ascertaining barriers and facilitators is guided by the Consolidated Framework for Implementation Research (CFIR) domains and tools:[160-162] SAR characteristics (e.g., complexity, cost), outer setting (e.g., resident needs and preferences), inner setting (e.g., compatibility with existing workflow), individual characteristics (e.g., knowledge, attitude), and process (e.g., scheduling, rollout).

Setting and Sample. Each site recruited for Aim 2 will be included. The sample will consist of key stakeholders: study participants, their family members who observed at least one SAR session with the participant, and LTC staff involved in any way with the SAR implementation.

Data Collection. Semi-structured interviews: All interviews will be conducted and audiorecorded by a member of the research team using a semi-structured interview guide that covers the CFIR domains.[162] We will ask participants their perceptions of the SAR itself, the activities, the positive and negative aspects of the session and suggestions for improvement. We will solicit staff perspectives related to the impact of SAR acitvities on workflow and level of confidence in implementing the SARs. Focus groups: At the completion of the sessions, we will conduct two focus groups at each site, one with the residents/family members and one with staff. Using semi-structured, open-ended questions, we will ask residents/family members about the suitability of the SARs, responses to the SARs and suggestions for improvement. We will ask staff focus groups their perceptions of residents' and families' reaction to the SARs, the impact of the SAR on participants' apathy and engagement and, importantly, staff confidence in operation the SARs. We will conduct focus groups in a neutral, on-site conference room using a dual moderator design.[163] One researcher will moderate the session and run the digital recorder; the other researcher will record notes, relevant cues and body language. Field Notes: RCs and investigators will complete field notes after each visit/session. Field notes will be organized using the CFIR codebook template that is pre-populated with CFIR domains and constructs.[162]

Data Analysis. An independent transcription service will transcribe recordings verbatim. ATLAS.ti software will be used to help manage the interview content and analysis. Two investigators will separately analyze the material, applying the first coding guided by the CFIR domains to similar themes.[163,164] Analytic conflicts will be resolved by consensus of the team. Together, through a joint and iterative process, investigators will categorize codes into final themes. Validation will be obtained through member checking with the participants as well as triangulation through the use of 2 analysts. Using the CFIR Rating Rules,[162] investigators will rate the influence of the factor that facilitates or hinders implementation.

Family LAR Informed Consent

For older adults who are unable to provide informed consent, the family LAR will provide informed consent. Besides in-person informed consent process, an option for electronic informed consent or mailed informed consent will be provided for those unable to meet in person (e.g., live out of state).

The steps to electronic consenting are as follows:

a. Family LAR will access the Informed Consent to Participate in Research via REDCap link provided by the study personnel via email.
b. The consent link will have the informed consent document.
c. A zoom meeting will be scheduled and the research staff will review the informed consent document through screen share and answer any questions.
d. The family LAR will then be instructed to open up their email with the REDCap link to the informed consent document. At the end of the document, the family LAR will provide an electronic signature in the REDCap document, using a predetermined password to verify their identity.

For those who have no access to electronic connection, the steps for a mailed informed consent are as follows:

a. Two informed consent documents will be mailed to the family LAR with a stamped return addressed envelope.
b. A telephone meeting will be conducted with the family LAR and research staff.
c. The research staff will review the informed consent document with the family LAR and answer any questions.
d. The family LAR will be instructed to sign one of the forms and return it in the stamped envelope. The family LAR will keep one copy for themselves.

Documentation of Consent. An Informed Consent Checklist form will be used for all participants. All research staff will complete the elements of the checklist for every participant during the first Zoom

meeting. Elements include a check that the consent is in REDCap, the consent form is completed in full, and the RA verifying that the consent form was completed. The Informed Consent Checklist Form will be kept in the participants' electronic file folders in REDCap.

II. Bibliography

Include a reference list of literature cited to support the protocol statement.

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