COVER PAGE

Care.Coach Avatars for Improvement of Outcomes in Hospitalized Elders, Including Mitigation of Falls and Delirium: a Multi-Site Clinical Study

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Protocol Name:	A Protocol-Driven, Digital Conversational Agent at the Hospital Bedside to Support Nurse Teams and to Mitigate Delirium and Decrease Falls Risk
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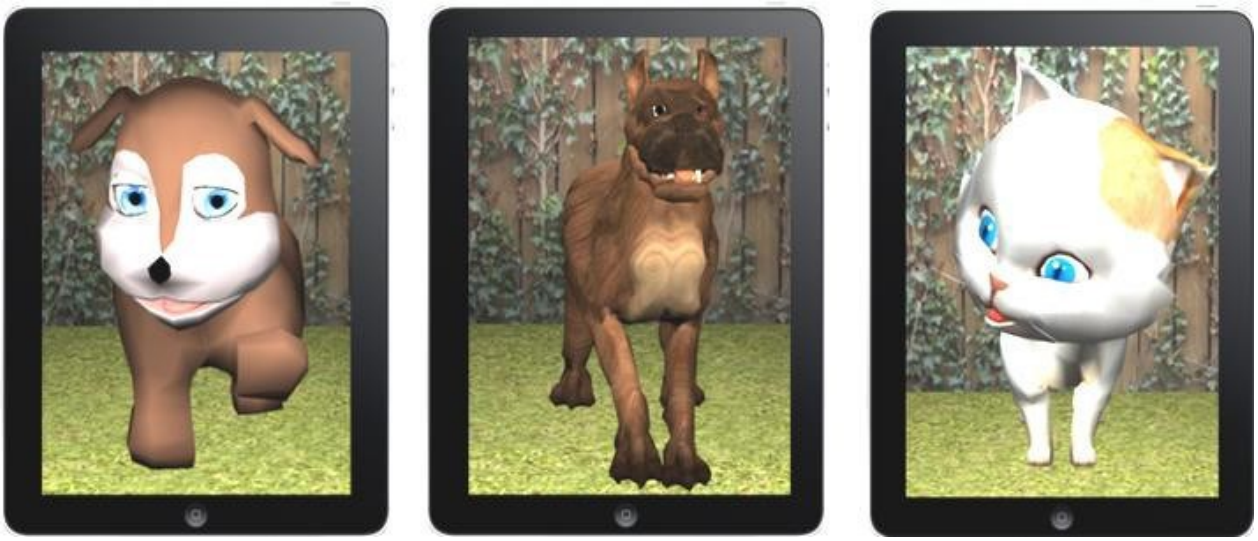
ABSTRACT

Delirium occurrence rates for hospitalized older adults range from 29-64%. Although 30-50% of delirium is preventable, it frequently goes unrecognized until acute and potentially devastating. The Hospital Elder Life Program (HELP) is a multidimensional clinical strategy that is effective in preventing delirium, but labor intensive. This randomized controlled study will test an innovative method to implement the HELP approach: a tablet-based digital avatar that can see, hear, and talk with a patient using speech-to-text technology. The avatar platform has already been validated at Jamaica Hospital in a previous study in 2016: "GeriJoy: The Use of an Avatar Virtual Service Animal to Improve Outcomes in Hospitalized Older Adults" as well as in multiple published studies to effectively provide psychosocial support to older adults across varied clinical settings. This study will focus on discerning the relative impact of implementing HELP through this technology. Participants aged 65+ will be randomly assigned to receive one of the following interventions in addition to usual care throughout their hospitalization: 1) an avatar delivering HELP protocols and socialization; or 2) no intervention beyond usual care. Participants will be assessed by the investigators upon admission to the study and reassessed upon 24-hour discharge notification using the Short Portable Mental Status Questionnaire (SPMSQ), Memorial Delirium Assessment Scale, and Short CAM (Confusion Assessment Method). Based on patient medical records of sedation, restraints and incidence of falls and delirium, pre- and post-assessment scores will be compared using paired t-tests to determine outcomes among the groups. If the avatar is effective in improving outcomes by providing HELP interventions, the number of patients who benefit from HELP could increase greatly due to technology-enabled cost efficiencies, and protocol and data collection standardization across many sites.



Specific aims/hypotheses

For hospitalized older adults, will the use of an avatar delivering HELP protocols…

1. decrease delirium incidence and severity,
2. decrease falls and falls with injury,

..more than usual care?

Background and significance

Delirium strikes more than 5 people every minute, totaling over 2.6 million people annually in the U.S. (U. S. Department of Health & Human Services, 2011). It is under-recognized, leading to inappropriate use of sedation, sitters, and even restraints in the hospital setting (Adams & Kaplow, 2013; Harding, 2010). Delirium contributes to falls, cognitive decline, disability, morbidity, and mortality, increasing health care costs over $164 billion a year (Inouye, Westendorp, & Saczynski, 2014; Labella, Merel & Phelan, 2011; Leslie & Inouye, 2011). Delirium can also initiate a "cascade of events" leading to an overall decline in function and independence (Fong, Tulebaev, & Inouye, 2009). These risks are greatest among older patients with limited English comprehension, low health literacy, and socioeconomic disadvantage (Tow, et al, 2016). Acute delirium may become chronic and have serious permanent sequelae (Fong, Tulebaev, & Inouye, 2009).

HELP is based on a geriatric assessment and integrates trained volunteers with hospital nursing staff to deliver protocols tailored to patients' individual needs. The protocols target delirium risk factors including orientation, activities, mobilization, vision, hearing, hydration, nutrition, and natural sleep. Use of the tailored protocols is tracked daily for quality assurance. HELP is used in more than 200 hospitals worldwide and prevents delirium, cognitive and functional decline, falls, sitter use, institutionalization, and reduces length of hospital stay (Inouye, Bogardus, Baker, et al., 2000; Rubin, Williams, Lescisin, et al, 2006; Rubin, Neal, Fenlon, et al., 2011). Although HELP is cost effective, it requires extensive training and monitoring of a large team of volunteers, which can deter adoption, especially in safety net facilities that serve patients at highest risk (Rubin, Neal, Fenlon, 2011; Caplan & Harper, 2007).

This study will measure the effectiveness of implementing a subset of the HELP protocols using a novel type of relational agent, which is a technological entity capable of building social relationships with patients (Wang & Osborne, 2017). The relational agent platform, called "care.coach," is provided by a California-based company founded by researchers from the Massachusetts Institute of Technology, and has been shown in multiple published studies to effectively provide psychosocial support through conversation and socialization with older adults in varied clinical settings (Machesney, Wexler, Chen & Coppola, 2014; Demiris, Thompson, Lazar & Lin, 2016; Chi, Demiris, Thompson, Lazar & Lin, 2016; Wexler, Drury& Pollak, 2016; Wexler, Drury & Pollak, 2017a; Wexler, Drury & Pollak, 2017b; Wang, Luxenberg & Morey, 2016; Chi, Sparks, Lin, Lazar & Thompson, in press). Uniquely, the relational agent is embodied as an animated animal displayed on a tablet device. This "avatar" represents a real-time fusion of human and software intelligence, powered by a live, 24x7 staff of health advocates who see, hear, and speak with each patient through the avatar, and who are guided by software algorithms to implement clinical protocols. Because the team is distributed across the world, they can cost-effectively provide unlimited compassionate psychosocial support, conversation in English and Spanish, and supervision: typically, when used for inpatient care, 1-6 hours/patient of direct attention, depending on patient need/risk, across 60-80 "check-ins" per 24 hours.

A study was conducted at JHMC in 2016 which enrolled 95 patients, of which half had a care.coach avatar. Patients were enrolled from 3 inpatient medical-surgical units. The avatar was used as a social conversational agent. The study found that patients who had the avatar experienced less delirium, less loneliness and experienced fewer falls (Wexler, Drury, Pollak, Scher, Iovino, Narducci, & Wang, in press).

Unlike common digital assistants such as Apple's Siri that are limited by simplistic artificial intelligence and poor understanding of the speech of frail older adults, the care.coach avatar connects one human being to

another through an engaging animated dog or cat that responds to touch and demonstrates emotions appropriate to the conversation or other interaction state, e.g. through facial expressions, bodily reaction to touch, heart symbols, tears, sleeping, snoring, etc. Conversations and observations about the patient's state are automatically recorded and referenced in future interactions, providing both continuity in the growing relationship and quality control in the delivery of clinical protocols. In addition to conversation, the avatar can also display photos, play music, and read or pray with the patient. The staff undergo extensive non-medical training and for this study will also complete the HELP online training for volunteers.

The software system guiding the staff can be programmed to deliver complex sets of protocols, and has previously been used to implement coaching programs for managing multiple chronic conditions at home (Wang, Luxenberg & Morey, 2016), as well as in our prior exploratory work for preventing falls (e.g. through frequent toileting checks) and delirium (e.g. through simple re-orientation tasks) in the hospital. For this study, the system will be programmed to deliver a robust suite of adapted HELP volunteer protocols including re-orientation, vision/hearing aid checks, hydration and meal consumption encouragement, cognition and attention assessment for early delirium detection, and so on, including an automatic guidance and triage protocol for when to phone the nurses station (e.g. if a bed-bound patient is getting out of bed or tugging on IV lines). If the avatar is effective in improving outcomes by providing HELP interventions, the number of patients who benefit from HELP could increase greatly due to 1) the low cost and ease of deployment of the avatar platform, not only enabling hospitals that have yet to secure adequate budget and staff for a typical HELP program to begin seeing HELP benefits/outcomes data by deploying this technology-enabled variant, but also enabling existing HELP sites to easily expand coverage to nights and weekends, and to additional hospital units and patients, and 2) the ability of the avatar to standardize best practices and automate data collection and reporting (e.g. all survey instruments can be administered by the avatar itself), enabling large scale, highly consistent data aggregation and outcomes reporting across many such HELP sites.)

Study design: This randomized controlled trial will compare outcomes on delirium, falls, sitter utilization (1:1's) and restraints between the two study groups: HELP-protocolized avatars, and usual care. Each day of the study, enrollment of subjects will proceed with randomization of each subject between groups (the randomization primarily effects delirium data, which is assessed by subject) until there are no more available intervention devices. However, falls and other unit-level grouping are non-randomized (see below).

Sample Size: A total of 3,650 patients (avatar and usual care) are expected to be enrolled at JHMC over the course of two years, based on an estimated average length of stay of 4 days.

Study Units: Patients will be recruited from the following units at JHMC: 3S, 3N, 4S, IMCU, 5N, 6S, and Hospice. Because the hospital only collects/reports unit-by-unit quarterly falls data, we will take the following measures to ensure that falls data collected for study purposes are a valid indicator of possible intervention effect:

- There are expected to be protocol and technical adaptations made during the first quarter of the study, and the study will not begin enrolling subjects exactly at the start of a calendar quarter. Therefore, the first calendar quarter of falls data is not intended to provide useful data regarding unit-level falls outcomes, and enrollment of patients may be performed on select units by convenience.
- Starting on the first day of the first full calendar quarter, a unit-equitable enrollment protocol will be implemented in which one or more of the study units at any time may be formally designated for active subject enrollment, and such designated study units will have their enrollment numbers monitored and rounding adjusted as needed to ensure that, on average, each designated unit receives a similar number of intervention patients at any time. Which units are designated or not designated for enrollment may be changed at the start of each calendar quarter to compare the effect of the intervention and to control for annual changes in fall rates. Research assistants will not enroll any patients on units not designated for enrollment, but will continue to round currently enrolled patients until they are dis-enrolled.

Sample inclusion and exclusion criteria: All patients over age 65 on the pilot units who can provide informed consent or who have a proxy who can provide informed consent will be assessed by the investigators. Those who consent will be randomly assigned to one of the two treatment conditions unless they meet any of the exclusion criteria: a.) aggression or combativeness with intent to harm self or others, b.) alcohol or drug withdrawal, c.) severe hearing impairment and simultaneous severe vision impairment, despite assistive devices, d.) cannot verbalize fluently in either Spanish or English, e). on 1:1;if a study subject is put on 1:1 during the duration of the study, he/she will be unenrolled from the study, f) expected to be discharged within the next 24 hours.

Instruments

Pre- and post-intervention:

1. Short Portable Mental Status Questionnaire
2. Short CAM (Confusion Assessment Method) – also conducted during each daily round
3. Memorial Delirium Assessment Scale – if CAM screens positive

Statistical analyses: Demographic variables including age, gender, education, race/ethnicity, and living arrangements will be collected to determine equivalency of study groups. Pre-and post-assessment scores will be compared using paired t-tests to compare means at baseline and at hospital discharge within each group, and between groups. All data will be analyzed using the Statistical Package for Social Sciences software (SPSS, Inc. Chicago, IL). Statistical significance will be defined as $p \leq 0.05$.

Additional Information

Photos of Avatar

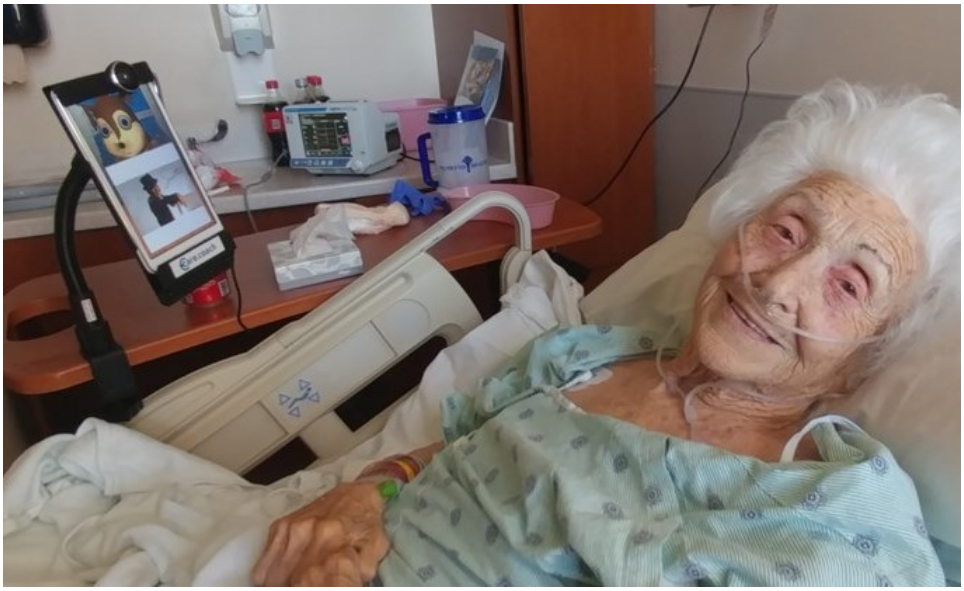


Figure D.8.1: A hospitalized older adult in South Carolina enjoys the company of an avatar as it plays music and shows a photo. A “fisheye lens” mounted to the top of the avatar device enables wide-angle visual monitoring, to enable appropriate reaction by the avatar to not only the patient’s facial and body language cues, but also any dangerous unassisted transfers, tugging on IV lines, etc. To help with re-orientation, the window behind the avatar reflects the actual weather report, and the lighting of the avatar’s environment reflects day or night status. A video showing the patient talking to the avatar and singing along is available at https://www.youtube.com/watch?v=WfWjazOmKUk

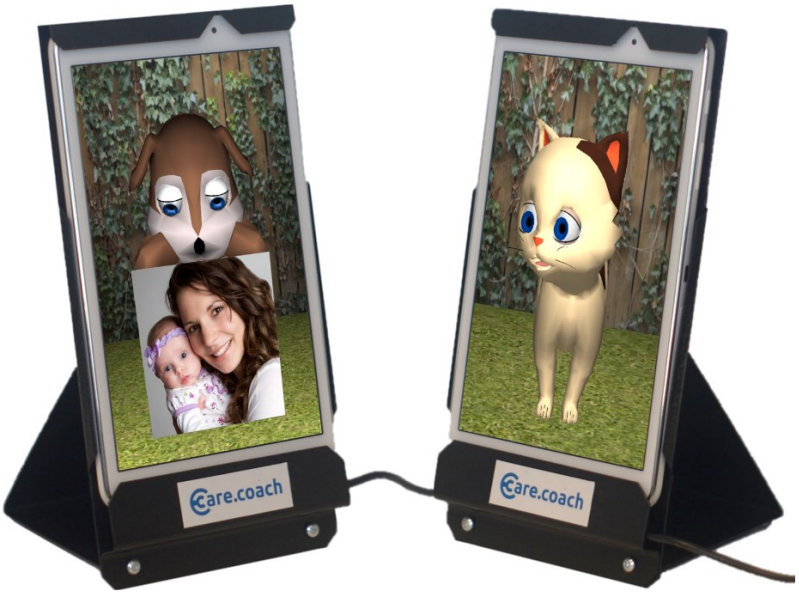


Figure D.8.2: The avatar is available in dog or cat form, depending on patient preference. Patients name their avatar as further personalization. On the left, the dog avatar is showing a photo from a web-based Family Portal, which helps with engagement and reminiscence.

Avatar Staff Training

The health advocates who staff the avatar system must each complete the following screening mechanisms and training certifications (or their equivalent as deemed by care.coach, as specific training courses and providers become outdated/available from time-to-time), through several online learning platforms, over the course of approximately 65 hours:

1. care.coach psychometric, technical, skills-based & face-to-face interview assessment
2. InfoCubic international background check
3. Registered Nurses' Association of Ontario delirium, dementia and depression course
4. National Institutes of Health privacy & ethics course for human subjects research
5. Partners Healthcare basic motivational interviewing class
6. care.coach technology, patient support, information security, and job shadowing training

The qualification process is very stringent, and the proportion of health advocate job applicants who successfully complete all the required certifications and are hired is only about 1%. Health advocates also receive ongoing training and professional development after hiring, including programs such as the Alzheimer's Association dementia care course (essentiALZ®).

For the proposed project, each health advocate will also complete the HELP volunteer training, and a one-hour module using resources from the American Delirium Society and American Nurses Association .

Clarification Regarding Data and Safety Monitoring Plan (DSMP)

In reference to the DSMP, under the physical risk mitigation section, the spirit and effectiveness of the described mitigation techniques will be preserved, but as of December 28, 2018, we are aware of the following minor technical and practical issues that affect the details of implementing the described mitigation techniques:

- The voice recording that plays automatically when a device is unplugged is standardized to say that the device is an important healthcare tool that needs to be kept plugged in to power, but the comment about "the device must be sanitized before placing it back into its designated storage cabinet" may instead be implemented with the following variations:
    - The reminder to sanitize the device may be performed by the avatar itself as part of the dis-enrollment and/or enrollment protocol, combined with a visual reminder on a label on each device.
    - For many technical and practical reasons, the avatar is now designed to stay online, plugged in to power even while on standby between patients. So instead of going back to a storage cabinet it will go to a charging area in Dr. Wexler's office, and a visual reminder about this will be placed on a label on each device.
- Due to potential technical limitations of the EHR/Epic integration the practical nature of the varied data in each patient record, we may not be able to rely on specific Epic data for each patient to indicate suitability for self-ambulation protocols, and we may never be able to push/write to the patient record. Therefore, the spirit of the risk mitigation techniques may be alternatively implemented as follows:
    - Instead of relying on Epic data, we may rely on nursing judgement when the avatar is verbally told to place the patient on a self-ambulation encouragement protocol.
    - Instead of confirming the assignment of a self-ambulation protocol to a patient through an Epic integration, we may phone call the nursing station to confirm.

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