University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS

Version date: 3/25/2019

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Study Title: SPEEKO for Elderspeak: A Self-Monitoring App to Improve Communication and Reduce Behavioral Symptoms in Care for Persons with Alzheimer's Disease and Other Dementias

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I. Purpose, Background and Rationale

A. Aim and Hypotheses

A new person is diagnosed with Alzheimer's disease or other dementia every 66 seconds, and most persons with dementia (PWD) spend the late stages of dementia in nursing homes (NHs) where lack of dementia care skills and staff shortages limit quality of care.[1,2] Care of PWD in NHs is complicated by behavioral and psychological symptoms of dementia (BPSD) such as aggression, vocal outbursts, wandering, and withdrawal that occur as PWD lose cognitive and communication abilities and cannot express their unmet physical and psychosocial needs.[3,4] BPSD present to NH staff as resistiveness to care (RTC) that increases staff stress and costly time to complete care, often leading to staff turnover, injury, and inappropriate use of psychotropic medications to control BPSD. Although Center for Medicare and Medicaid Services (CMS) mandates and penalties have reduced antipsychotic medication use slightly, contraindicated use in NH residents remains a pervasive problem, causing harmful side effects and reducing the quality of life for PWD.[5]

The PI and other researchers have empirically verified that RTC occurs when NH staff use elderspeak (speech similar to baby talk) that features inappropriately intimate terms of endearment (diminutives such as "honey"), belittling pronoun substitutions that imply dependence ("we" need a bath), and harsh task-oriented commands ("sit down").[6-9] Elderspeak conveys a message of disrespect and incompetence to residents who react with withdrawal or BPSD. Our R03 study established that residents with dementia are more than twice as likely to exhibit BPSD (measured by coding RTC behavior in videos) when staff use elderspeak instead of normal adult communication.[8] Our subsequent R01 trial verified that staff reduced their use of elderspeak after attending the three-session Changing Talk (CHAT) communication training program, and that this reduced RTC.[9]

To facilitate dissemination, we developed interactive online CHAT modules (CHATO) that provide the same CHAT classroom content with the advantage of flexible and independent internet access for busy NH staff, including those in rural and small NHs.[10] Recognizing the delay and incomplete adoption and application of evidence-based skills in practice, we believe additional strategies to optimize CHATO skills implementation are indicated.[11-13] Performance-based reinforcement of skills is effective in achieving greater immediate implementation and long-term maintenance of new skills use in practice.[14] However, feasibility and costs for individualized expert feedback in NH settings are usually prohibitive and thus not widely used in practice.

This study will test feasibility and preliminary effects of an automated and performance-based feedback app that detects and reports the use of diminutives (terms of endearment such as honey, dearie, and sweetie) that are prevalent elderspeak terms linked to BPSD. The PI and colleagues developed the SPEEKO for Elderspeak app using our archived NH recordings to identify the most commonly used diminutives and then to develop algorithms

to detect them in speech.[15] Building on proof of concept established in the laboratory, we propose to demonstrate feasibility of app use at the point-of-care and will then conduct a clinical trial to test preliminary efficacy of the app for amplifying reductions in diminutives use for NH staff completing the CHATO training.

SPECIFIC AIMS:
1) **AIM 1.** Demonstrate feasibility, acceptability, and validity of the SPEEKO for Elderspeak feedback app use by staff in the NH. Five certified nursing assistants (CNAs) will use the app during NH care and provide feedback about any needed modifications. **Hypothesis:** The app will be readily used and acceptable to CNAs. Diminutive counts determined by the app will be correlated with psycholinguistic analysis, validating accuracy.

2) **AIM 2.** Test preliminary effects of an innovative self-monitoring feedback app on staff elderspeak use and compare accuracy to psycholinguistic analyses of audio-recorded staff communication. **Hypothesis:** Staff who receive immediate app feedback (N= 30 in three NHs) will have greater elderspeak reduction after completing CHATO training compared to delayed feedback controls (N= 30 in three NHs).

3) **AIM 3.** Evaluate app acceptability and costs. **Hypothesis:** Staff who use the app will find it acceptable and beneficial for their practice. Process-based costing will be used to determine costs for app use in NHs and other long-term service and support settings. Costs will be compared in relation to each group's outcomes.

B. Background and Significance

The population afflicted with Alzheimer's disease and other dementias will expand from 5 to 16 million by 2050, increasing dementia care costs from $259 billion to $1.1 trillion.[16] Of today's 1.4 million NH residents, 61% have moderate to severe dementia, and up to 90% exhibit BPSD such as physical and verbal aggression, agitation, and wandering.[3,17,18] These behaviors are associated with depression, reduced quality of life, and lower survival rates among PWD.[18] BPSD increase time to provide NH care; staff, primarily CNAs who provide most direct care, find BPSD to be the most stressful aspect of their job.[19-21] Considering staff stress, burnout, and turnover, BPSD increase costs of care by up to 35%.[22] With annual semi-private room costs of $82,200, reducing BPSD would result in significant dementia care savings.[23]

As cognitive and communication abilities decline due to dementia, NH residents become unable to convey care preferences and needs and staff communication becomes infantilizing, impersonal, and task-oriented resulting in BPSD. As verified in our research using behavioral coding and sequential analyses of video-recorded care, staff elderspeak (communication that sounds like baby talk) is linked to resident RTC, a subset of BPSD that disrupts nursing care. In our study, NH residents were more than twice as likely to be resistive to care when staff used elderspeak compared to normal communication.[8] Thus, improving communication has great potential as a nonpharmacological intervention to reduce BPSD in NH care.[24]

The Communication Predicament of Aging theory establishes the link between elderspeak and BPSD. Elderspeak derives from stereotypical views of older adults as less competent than younger persons.[25] When younger people talk with older adults, they modify their speech by simplifying, clarifying, and altering the underlying affective quality of messages.[26,27] The resulting implicit message of incompetence begins a negative feedback loop for older persons, who react with depression, withdrawal, and dependency.[25] Elderspeak is especially threatening to self-concept and personhood, critical to the well-being of PWD who are likely to respond with BPSD.[28,29] The Need-driven Dementia-compromised Behavior

model recognizes BPSD as the expression of unmet needs of PWD.[30,31] Communication that staff can modify to prevent BPSD is an essential part of the environment connecting PWD to others and affirming their self-concept.

Psychotropic medications are often used inappropriately to control BPSD in NH residents with dementia.[32,33] Alarmingly high rates persist, despite negative outcomes,[34] an FDA black box warning of increased mortality for older adults with dementia,[32] and a recent CMS mandate to reduce off-label prescribing of antipsychotics.[35] CMS and the National Partnership to Improve Dementia Care target reductions in psychotropic drug use as top priority.[36] Despite reductions in antipsychotic rates (one type of psychotropic medication) ranging from 3 to 12% from 2011 to 2016, up to 20% of NH residents still received inappropriate antipsychotic medication in 2017.[37] Research has established that educating direct care providers in behavioral interventions can control BPSD and also reduce psychotropic drug use,[38-40] and this has been confirmed in our research.[9,41]

Our recently completed R01 clinical trial that tested Changing Talk (CHAT) communication training provides preliminary data for the proposed research. CHAT increases staff awareness of elderspeak's negative effects and guides practice in more effective communication. CHAT includes three 1-hour sessions, with replicated effects on communication in three studies among staff (N=89) and residents (N=194) in over 20 NHs.[9,42,43] Effect sizes ranged from η^2 = .35 to .62 for reducing elderspeak diminutives (inappropriately intimate terms of endearment) and collective "we" pronoun substitutions, effects that were maintained over 2 months. Person- centered (vs. task-focused) communication also increased after CHAT.[9,44] CHAT was highly rated by past participants (N=217); mean program ratings ranged from 4.5 to 4.8 on a 1(low) to 5 (high) scale.[45]

The CHAT R01 demonstrated that CHAT decreases staff elderspeak and reduces resident RTC.[9] On average, elderspeak declined from 34.6% (SD = 18.7) at baseline by 13.6 percentage points (SD = 20.00) post- intervention and 12.2 percentage points (SD=22.0) after 3 months. RTC declined from 35.7% (SD = 23.2) by 15.3 percentage points (SD = 32.4) post-intervention and 13.4 percentage points (SD=33.7) at follow-up. Linear mixed modeling determined that change in elderspeak was predicted by CHAT (b = -12.20, p = .028) and baseline elderspeak (b = -0.65, $p < .001$), while RTC change was predicted by elderspeak change (b = 0.43, $p < .001$), baseline RTC (b = -0.58, $p < .001$), resident communication disability, and comorbid illnesses.

We also extracted CMS NH Quality Measures (NHQM) data for use of antipsychotics for the 10 CHAT NHs for which data were available. We compared each NH's rates for two quarters before and two quarters after each participated in CHAT. The percentage of residents prescribed antipsychotics decreased by an average of 4.9 percentage points, from 20.7% (SD=8.5) to 15.8% (SD=9.0) after CHAT. We used state average rates for antipsychotic medication use for the same time periods to control for changes that may have occurred due to the CMS mandate and other factors.[46] State benchmarks for prescribed antipsychotics averaged 25.4% across quarters before and declined to 24.9% for quarters after CHAT, a decrease of 0.5%. The average decrease in CHAT NHs (4.9%) compared to the other state NHs (0.5%) was significant (p=0.05 for two-tailed t-test).[47]

To improve dissemination, we transitioned CHAT content to interactive online modules (CHATO) and are currently pilot testing the online version (R61AG061881) and planning a pragmatic clinical trial (R34NR017793) testing CHATO effects nationwide. Translating evidence-based best practices into practice is slow and inefficient and additional strategies are needed to support implementation.[11-13] Performance-based reinforcement of skills is effective for achieving greater immediate implementation and long-term maintenance of

staff skill use in practice.[14] However, feasibility and costs for expert individual feedback in the clinical setting are prohibitive.

C. Rationale

Our SPEEKO for elderspeak app provides immediate feedback to staff on elderspeak use at the point- of-care with the potential to engage staff in self-monitoring to increase CHATO effects. This approach combines CHAT interactive online learning with on-site feedback that is established as effective and efficient for training direct care workers and reflects staff preferences for education.[49-51] NH continuing education research has established that supervision of skills use in clinical practice is critical for long-term implementation of new practice skills by staff (typically including multiple weeks of observation and feedback).[14,52,53] Although expert on-site feedback is most effective to help staff implement new skills in practice, this is costly and usually not feasible.[14,54,55] Using available technology, the app records staff using a wearable, voice- activated recorder and promptly analyzes speech using natural language processing. The app then provides immediate and private graphic feedback and encouragement to individual staff on their use of elderspeak diminutives (terms of endearment).[56]

Hypothesized increased efficacy of CHATO training based on use of the automated feedback app will further improve training effectiveness and reduce costs. The average cost for CHAT training was $79.69 per staff attendee. We determined that an average 1% decrease in resident RTC cost $4.31 per resident, assuming average staff baseline elderspeak and each staff member caring for two residents with average RTC.[57] The new online version of CHAT (CHATO) eliminates costs for interventionist preparation, coordination, travel, and time to provide CHAT on-site on multiple days and times. Adding point-of-care reinforcement for CHAT skills use in practice has potential to increase effects of the training that may reduce RTC further. Costs for the app use will be determined in this study as a basis for estimating likelihood of adoption in long-term care settings. Repeated use of the app over time will be tested in future research to provide periodic tune-up reinforcement for NH staff. If effective, the app will be integrated into our ongoing pragmatic clinical trial testing to increase CHATO effects on behavioral symptoms in dementia care.

CHATO and the feedback app are readily scalable. Online CHATO modules and the portable feedback app are accessible for rural and small independent NHs and across other long-term services and support settings that frequently have unmet needs for staff education, fewer resources, less access to programs, and greater costs for training. Using technology-based resources is efficient as NHs experience more residents with dementia and needs for dementia-specific training increase.[58] This technology is suitable for other care settings (assisted living, adult day care, and home care) and may be adapted for the service sector in the future. Empowering staff to reduce BPSD may also reduce stress, job dissatisfaction, and turnover, further reducing costs and improving care continuity.[59]

II. Research Plan and Design

A. Study Objectives:
This study will demonstrate feasibility (Aim 1) and preliminary efficacy (Aim 2) of the point-of-care SPEEKO for Elderspeak feedback app in the NH setting as well as evaluate acceptability and cost (Aim 3). The goal is to increase and extend CHATO effects to further reduce BPSD and inappropriate psychotropic medication use to improve NH dementia care.

B. Study Type and Design:

Feasibility Testing (Aim 1): We will demonstrate feasibility, acceptability, and validity of the SPEEKO for Elderspeak feedback app use by staff in the NH and identify needed modifications prior to testing in Aim 2. The PI worked with the Speeko Company (see resources and letter) to develop the elderspeak feedback app. App proof of concept has been

demonstrated in the lab setting. With a preliminarily trained natural language processing detection model, diminutive accuracy testing resulted in a sensitivity (true positive rate) of 87.7% and a specificity (true negative rate) of 99.9%. The app provides immediate feedback with potential to increase CHATO effects. Recordings are analyzed by a natural language processing app that provides immediate and private feedback and encouragement to individual staff. The app detects common elderspeak terms of endearment (diminutives), identified through reanalysis of the PI's archived NH recordings.[56] Detection algorithms were also developed using the recordings to establish proof of concept. App modifications were completed to enhance recording quality and transcription accuracy and to filter noise.

Further feasibility and detection model algorithm optimization will be tested at Garden Terrace of Overland Park, a NH dedicated to dementia care. A detailed protocol and user manual will be developed, and pilot tested. Feasibility will be tested with five CNA volunteers (n=5) who will each record a 2-hour care session. These staff will record their speech during a 2-hour work session to demonstrate use of the feedback app and complete a 10-item usability scale. Potential issues (e.g., background noise, Internet and bandwidth adequacy, acceptability to residents) will be assessed. App outputs will be compared to data from transcription and psycholinguistic coding, using our established protocols, to validate app reliability for diminutive detection. The CNAs will be interviewed about use of the app, providing additional data to improve the system for Aim 2 testing. If validated, app functions may be expanded to monitor additional aspects of elderspeak (i.e., "we" pronoun substitutions).

Recording equipment: To create high fidelity recordings for optimal natural language processing, each CNA volunteer will wear a hypercardioid condenser headset microphone with unidirectional sound sensitivity. This microphone assembly is designed to pick up sound directly in front of the microphone and to reject off-axis background sounds such as from residents and staff. In addition to using microphone hardware to isolate the user's voice, the app uses digital noise gating and frequency level stabilization to limit extraneous content and to support audio quality. An iPod Touch with password encryption will be carried in the pocket of the CNA volunteer. The iPod Touch will be connected to the microphone by a standard 3.5 mm headphone jack. The battery life of the iPod Touch enables continuous use during the 2-hour recording window for each CNA.

iOS App: The iPod Touch will run an iOS app that records and processes audio in real time and utilizes voice activation frequency technology to isolate and record when a user is speaking and discard periods of silence from the recording analysis. Original back-up recordings are saved locally on the secured iPod Touch for the Project Director to access through a master password within the app to all user accounts. Together, the iPod Touch and low profile, lightweight headset microphone will provide high quality audio for maximal analytic accuracy and minimal workflow interruption or reaction by residents and staff. The initial 15 minutes of each recording session will be discarded to allow CNAs time to adjust to being recorded. Recordings will be analyzed in real time using a transcription detection model powered by Amazon Transcribe. All speech-related data are communicated using Transport Layer Security protocols to ensure end-to-end security and HIPAA compliance. Transcripts will be downloaded to the iPod Touch app that identifies and tabulates diminutives, displaying a feedback infographic at the end of the session.

Audio recording supports precise measurement of verbal communication including duration, intensity, and patterns and is less invasive than videotaping, encouraging natural communication and maintaining privacy. Recordings can be reviewed repeatedly to verify accuracy and reliability. Limitations are (1) alteration of natural speech and behavior due to the awareness of recording and (2) inability to control for environmental factors such as noise. Research has established that NH staff do not significantly modify communication if recording is presented in a nonjudgmental manner [60,61] and this was confirmed in the PI's

research.[43] The audio recording protocol is designed to measure communication in NHs [62] and health care settings;[63] it was effective in the PIs research, uses measures to limit the Hawthorne effect (i.e., minimally obtrusive recording equipment), and will record each CNA during the same time periods from day to day to assure consistency.[8,27,42-44,64,65]

Preliminary Effects Testing (Aims 2): We will test preliminary effects of app feedback on elderspeak use in audio-recorded staff communication. A cluster randomized trial will be conducted in six NHs that participate in CHATO training. We will compare the immediate and delayed-feedback control groups on elderspeak (diminutive) changes after participation in CHATO. We hypothesize that staff who receive immediate feedback will demonstrate greater reductions in use of diminutives, the most common and recognizable marker of elderspeak, compared to control group staff before they receive delayed feedback. We will validate app accuracy by comparing app results to psycholinguistic coding using our established protocols for data reduction, transcription, and coding.[8,44,66]

Six NHs will participate in audio recording of CNA communication before and after CHATO (see letters of support). These NHs will be randomly assigned to immediate feedback (n=3; recording with app feedback on elderspeak use) or control (n=3; recording with end of study feedback) groups. In each NH, 12 CNAs will be recruited using strategies successful in our past research such as announcing the research opportunity at staff meetings. Enrollment of 12 CNAs per NH allows for levels of attrition experienced in our prior studies. If fewer than 30 CNAs per group complete recordings, more NHs will be added. CNA volunteers (at least 30 per group) will record their communication in 2-hour care sessions on 1 day before and on 3 days after completing CHATO.

In both NH groups, 12 CNAs will be recorded for a 2-hour shift prior to participating in CHATO training (baseline). The URL link to complete the CHATO modules will be provided for the CNAs as well as other NH staff. Staff will be expected to complete the training over a 2-week period. After completion, the 12 CNAs from each NH who are participating in the app testing will be recorded again within a week of completing training (post-CHATO time 1), then approximately 1 week later (post-CHATO time 2), and finally another week later (post-CHATO time 3). Immediate feedback NH CNAs will receive the app feedback at the end of each post- CHATO recording session, while control group NH CNAs will not receive app feedback until the end of their post-CHATO time 3 recording sessions.

Each NH will provide a letter of interest, acknowledging random assignment, committing to engage staff in CHATO training, and agreeing to provide descriptive and cost data including number and types of staff and average wages. Each NH will be approved prior to participation by the KUMC IRB. NH size and census, profit status, proportion of residents with dementia, presence of a special care unit, staffing and turnover ratios, Medicare star rating, antipsychotic prescription rate, and Medicaid case mix will be collected from Nursing Home Compare and NH reports. Medicaid case mix is a measure of resident acuity or care needs that is used to determine Medicaid reimbursement rates and has been used in research to control differences in care needs across NHs.[67,68] Participating NHs will be encouraged to engage all direct care staff, including housekeeping, dietary, and administrative staff in the training.

CHATO Training. CHATO is a direct Internet module adaptation of the CHAT program, developed by the PI and an instructional design team to include all CHAT content and interactivity. Standards for online education were used to transition to the module format. CHAT (and CHATO) have interchangeable content and are conceptually based on the Communication Predicament of Aging Theory[27] that describes how stereotypes of older adults as incompetent prompt younger persons (NH staff) to alter their communication with older adults (NH residents). The exaggeration simplification and clarification strategies of elderspeak result in speech that sounds like baby talk and is perceived as demeaning,

contributing to isolation, depression, assumption of dependency, and BPSD.[27,69] CHATO alerts NH staff to elderspeak and its negative effects, involves them in taking the older adult's perspective, and guides self-evaluation and practice in effective communication.[70] Improved communication, based on individual assessment of resident abilities, supports positive self-concept and meets socialization needs, reducing need-driven dementia-compromised behavior or BPSD.

Session Content. CHATO includes review of actual NH video examples and practice in improved communication strategies that staff readily apply and monitor in practice, significantly reducing elderspeak in just three modules. CHATO targets adult learners using applied strategies tailored to improve specific aspects of elderspeak that are described in the literature and are modifiable. Limiting content and complexity minimizes burden to staff and their NH employers and increases the likelihood of skill enactment.[71] CHAT was developed step-wise and iteratively through the NIH Stage Model for Behavioral Intervention Development.[72] Early Stage 1 development led to Stage III testing of CHAT in controlled NH (community) settings to establish efficacy. After additional Stage I modification of the original CHAT content to online module format, CHATO is now positioned for effectiveness testing (Stage IV) with NH (community) providers to maximize external validity in preparation for future implementation and dissemination research (Stage V).[73]

CHATO is presented in three modules.[10,70] Session 1 introduces effective versus ineffective communication. Participants identify communication issues in video vignettes. Session 2 focuses on identification and negative effects of elderspeak, using video-recorded examples. Session 3 includes strategies for improved communication based on assessment of each resident's abilities. Participants critique communication in videos and correct transcripts to eliminate elderspeak. Training is limited to three 1-hour sessions to assure feasibility in busy NHs. The modules include moderated discussion and interactive exercises that must be completed to advance through the program. This assures content fidelity and dose of the intervention. CHATO is provided to as many staff as possible to achieve facility-wide effects of reduced elderspeak.[74] The modules contain pre- and post-tests (scenario-based questions and rating of staff communication in video clips) to evaluate knowledge gain. The Modified Duke Diffusion of Innovation[75] survey provides information about CHATO participant intentions to use learned skills in practice and the likelihood for translation.

Audio Recordings. CNAs will be recorded for 2 hours on 1 day in the week before and 3 days in the 2 weeks after CHATO training. To ensure consistency, every attempt will be made to make post-CHATO recordings at the same time of day. CNAs will be permitted to turn the recording unit off when they do not wish to be recorded. Although this may limit validity of the recordings, it assures privacy and participation. Recordings will be time coded and take place during morning care when elderspeak and BPSD are most frequent.[44,76,77] To minimize attrition, CNAs will be recruited just prior to their NH's participation in CHATO training. *A priori* randomized order for NH participation will control for historical effects. Intention-to-treat analyses will be used. The feedback group CNAs will receive automated feedback on elderspeak use after each post-CHATO recording session. The control group will receive feedback for all recording sessions after their final (third post-CHATO recording session). The Project Director will download recordings for both groups and delete them from the iPod Touch.

Data Archiving. After each recording session, the Project Director will screen and edit recordings to delete any resident or other staff communication or other identifiers (names) so that the archived recording contains only the desired CNA participant's voice. Recordings and data will be archived in a dedicated research computer labeled with unique identifier codes. To reduce the Hawthorne effect, the initial 15 minutes of each recording session will be discarded. An estimated hour of recorded speech will be collected four times for each of

60 CNAs, providing approximately 240 hours of recordings for transcription, coding, analysis, and additional app algorithm training.

Psycholinguistic Coding. RAs will transcribe all recordings (for both groups) and will use brackets to code diminutives using our established operational definitions and protocols.[10,43,45,56,78] To assure reliability, as used in our past studies, RAs will be trained on a practice sample until achieving 90% agreement for utterance segmentation and coding. A second trained coder will independently code 10% of the actual study transcripts. Additional training will be provided if agreement falls below 85%. Systematic Analysis of Language Transcripts (SALT)[79] will be used to tabulate frequencies for each code. Data will be entered in an electronic spreadsheet using unique identifier codes and stored on a secure computer. RAs will not have access to the key connecting codes with identifying information and will be blind to group assignment and assessment time points.

Acceptability and Cost Testing (Aim 3): CNAs testing the app will complete the System Usability Scale (SUS), a validated 10-item industry standard survey to rate (1) use of the microphone, recorder, and app; (2) acceptability and work compatibility; (3) feedback infographic; and (4) interest in self-monitoring. We hypothesize that staff who use the app will find it acceptable and beneficial for their practice. As in our prior studies, we will use process-based costing to determine average costs for using the SPEEKO for Elderspeak feedback app, comparing costs relative to any difference determined for reductions in diminutive use in the immediate and delayed feedback groups.[80,81] Evaluation of acceptability and costs are key factors in consideration of ongoing plans for app dissemination in NHs and across other long-term services and support settings.

C. **Sample size, statistical methods, and power calculation**
Aim 1: We will demonstrate feasibility, acceptability, and validity of the SPEEKO for Elderspeak feedback app with detection model algorithm optimization with a diminutive accuracy testing benchmark of 80% or higher. App outputs will be compared to data from transcription and psycholinguistic coding, using our established protocols, to validate app reliability for diminutive detection. Also, an analysis of a CNA-completed, 10-item usability scale (The System Usability Scale) with an acceptability benchmark of 50% or higher.

Aim 2: Linear Mixed Models (LMMs) or Generalized LMMs, depending on the distribution of each outcome, will be developed to determine the impact of group assignment (feedback or no feedback) on use of elderspeak diminutives. Baseline diminutive use, group (feedback vs. no feedback), recording session (pre- and post CHATO sessions 1, 2, and 3), and interaction between intervention and session will be fitted as fixed effects. To account for clustering, each NH will be fitted as a random effect. To account for correlation due to repeated measurements, an appropriate covariance pattern will be determined from data. CNA and resident sex and CNA knowledge gain will be tested as covariates. Aim 2 will estimate variability, effect sizes, and intracluster correlation for a future larger-scale study. Sample sizes of as few as 30 in each group, or 10 CNAs on average in each NH, will achieve 80% power to detect a difference between the group means of 0.74 to 0.76 standard deviations, assuming the intracluster correlation coefficient ranging from 0.001 to 0.01 and coefficient of covariation among cluster sizes of 0.25. A two-tailed t-test was used with a significant level of 0.05 and the degrees of freedom based on the number of subjects.

Aim 3: We will use process-based costing to determine average costs for using the SPEEKO for Elderspeak feedback app, comparing costs relative to any difference determined for reductions in diminutive use in the immediate and delayed feedback groups.[80,81]

D. **Subject Criteria (See Vulnerable Populations appendix, if applicable):**
1. Inclusion criteria: We will recruit CNAs who are age 18 or older, permanent employees, and fluent in English to participate. Descriptive information (age, sex, race, ethnicity, role, experience) will be used to identify CNA covariate factors predicting communication

change. CNAs will be compensated a $25 gift card after each recording session and $50 to complete the CHATO training (all three modules and pass the posttest). CNA staff who have the least preparation but provide most direct care may benefit the most from feedback on their communication provided in a private and nonthreatening manner. Volunteers who self-select may not be representative of all CNA staff. However, CNAs who are willing to make recordings and receive feedback will provide information about app feasibility, acceptability, and preliminary effects.

2. Exclusion criteria: CNAs younger than 18 or CNAs who are not fluent in English.
3. Withdrawal/Termination criteria: The volunteer CNAs may withdraw at any time.

E. Specific methods and techniques used throughout the study

1. **Laboratory tests:** N/A
2. **Study Procedures:** Staff Training, CNA audio recordings (prior to training and 3 times post training), and surveys post training and post recording.
3. **Timeline:**

Timeline of Research Activities	Year 1 (months)	Year 2 (months)
	1 2 3 4 5 6 7 8 9 10 11 12	1 2 3 4 5 6 7 8 9 10 11 12

• Hire & train team, prepare manuals/protocols, IRB approval
 • App demonstration/modification
 • CHATO training and feedback app testing)
 • Analyses & Dissemination:
  ○ Transcription/coding
  ○ Cost & surveys		

F. Risk/benefit assessment:

1. **Social/Economic risk:** The primary risk is accidental disclosure of audio recordings or other data outside the research team. Accordingly, all audio and other data will be handled as confidential by assigning codes, not including names, from the point of archiving through data analyses. The original audio and other data files and file linking data identification codes to participants will be stored in locked secure files. Data access will be strictly controlled by the research protocol. To protect staff from use of study data in performance evaluations, NH administrators will not have access to recordings or other data that may be connected to individual staff or neighborhoods.

2. **Psychological risk:** CNA staff risks of participation include anxiety at being recorded, but this is minimal. An additional risk is disclosure of recordings of their communication revealing performance, and survey responses to supervisory staff and administrators who may use this information for performance evaluations. Thus, NH administrators will not have access to recorded or other data that identifies individual staff or neighborhoods. Staff will be assured that recordings, descriptive data, and survey responses will not be shared with administrators, supervisory staff, or other staff. In addition, recordings that may be used for future training materials or presentations will not identify the CNA or their NH employer. No appreciable risk of physical, psychological, social, legal or other harm to staff participants is expected. No information about past, present, or future physical or mental health or payment of health care benefits (HIPAA protected information) will be collected. Any recordings or other data suggesting physical or mental harm or illegal behaviors will be reported to the NH administration and state authorities following mandated reporting guidelines.

3. **Potential benefit of participating in the study**
   a. Participation in this study may benefit NH staff participants who may gain knowledge about communication with older adults with dementia from the CHATO training program that may improve their job performance and secondarily, increase their job efficacy and satisfaction.
   b. Residents in the NH may benefit from improved and more respectful nursing staff communication (resulting from the CHATO training) that could improve the NH environment and their mood and reactions to care. The potential benefit of the

knowledge gain to improve future care for persons with dementia and staff, outweighs the minimal risks.

    c. The CHAT intervention has been established as effective in reducing NH staff elderspeak use, that is linked to increased BPSD and inappropriate antipsychotic medication use. NHs that participated in the CHAT communication training program demonstrated reductions in elderspeak use and in BPSD and antipsychotic medication use. To increase access to training, CHAT has been transformed from a traditional classroom format into interactive online modules (CHATO) and an automated app has been developed to provide individual staff feedback to staff at the point of care on their use of elderspeak diminutives. Use of the app has potential to increase the effects of the CHAT training through reinforcement. The goal is to further improve and sustain effects of communication training in nursing staff that will reduce BPSD and inappropriate use of psychoactive medications. This nonpharmacological approach uses available technology to improve dementia care and aligns with the top priority goal of the National Partnership to Improve Dementia Care. As the number of persons diagnosed with dementia triples in the next 30 years, empowering care providers to provide high quality care for individuals with dementia is of critical importance.

G. **Location where study will be performed:** The study will be coordinated and managed from the KU School of Nursing. All study records will be kept on secure computers and servers managed by KUMC. Garden Terrace of Overland Park, a nursing home that has participated in our past studies, will be the site for initial clinical demonstration of the app. Dr. Coleman will then work with six nursing homes in rural Colorado, where she resides, to test the app effects with six volunteer nursing home communities. The communities are on the Western Slope in the cities of Delta, Olathe, Montrose, Paonia, and Grand Junction, CO.

H. **Collaboration (with another institution, if applicable):** N/A

I. **Single IRB Review for a Multi-site study (if applicable):** N/A

J. **Community-Based Participatory Research (if applicable):** N/A

K. **Personnel who will conduct the study, including:**
    1. Indicate, by title, who will be present during study procedure(s): **Project Director**
    2. Primary responsibility for the following activities, for example:
        a. Determining eligibility: **Project Director**
        b. Obtaining informed consent: **Project Director**
        c. Providing on-going information to the study sponsor and the IRB: **PI & Project Director**
        d. Maintaining participant's research records: **Project Director**
        e. Completing physical examination: N/A
        f. Taking vital signs, height, weight: N/A
        g. Drawing / collecting laboratory specimens: N/A
        h. Performing / conducting tests, procedures, interventions, questionnaires: **PI & Project Director**
        i. Completing study data forms: **Project Director**
        j. Managing study database: **Project Director**

L. **Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan**
    1. **Responsible parties:** The **Principal Investigator (PI)** will be responsible for overall assurance and monitoring of safety of participants and integrity of data in conduct of both phases of the proposed study. This includes continuous active review of research activities that will be completed with assistance of the Project Director. The PI will be

responsible for submitting necessary reports (including minutes of annual and any additional SMC meetings) to the National Institute on Aging (NIA). The PI will provide timely reporting to NIA of a) any unanticipated problems or unexpected serious adverse events that are determined to be related to the study protocol, b) IRB-approved revisions to the study protocol that indicate a change in risk for participants, c) a summary of recommendations made by the SMC and if applicable the action plan for response, and) notice of any actions taken by the IRB or regulatory bodies regarding the research and any responses to those actions.

In addition, an expert **Safety Monitoring Committee (SMC)** will provide oversight to assure the safety of participants and integrity of the data. The members of the SMC include a team of interdisciplinary professionals who are not a part of the research team. Per direction of the NIA program officer responsible for this FOA, members of the committee will be identified upon funding of the study. It is anticipated that the SMC members include clinical and research experts on NH dementia care and NH staff education as well as a statistician.

2. **Data/events/frequency of review:** The **SMC** will initially review and approve the written study protocol, data collection and storage protocols, intervention materials, informed consent procedures, and this plan for data and safety monitoring. Any outside agreements with vendors and subcontractors will be reviewed. The SMC will also review the general reporting guidelines based on the study procedures approved by IRB. Reporting rules will be established taking into consideration the population under study and anticipated adverse outcomes (reflected in the human subjects consent documents). Prior to study implementation, the SMC will identify pre-specified stopping rules that will be employed if significant benefits or risks have developed, if trial management issues prevent successful completion, or if compelling ethical concerns arise. The PI and other research team members as delegated will conduct an audit at least annually including review of a random sample of at least 3 CNAs who participate in CHATO training and participate in audio recording for compliance with study protocols including informed consent documents, data storage documentation and deidentification of data. The SMC will meet annually and additionally if needed at the request of the PI (due to issues arising in study conduct or major changes in study protocols)**.** The SMC will review reports of the research team concerning data quality and timeliness, adherence to study protocols, participant recruitment and accrual, and consenting procedures. The research team (under the direction of the PI) will report accrual, retention figures, and all adverse and other events and outcomes.

3. **Types of analyses to be performed:** At the end of the first year, the research team will generate summary analyses of results for primary outcomes. The annual SMC meeting will include evaluation of these interim data analyses to evaluate the need for revising or stopping the study.

4. **Safety-related triggers that would cause the PI to stop or alter the study**:
   a. **Adverse occurrences** (untoward or unfavorable medical occurrences in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research study, whether or not considered related to the subject's participation in the research) will be identified by all research team members and promptly reported to the PI (and recorded on an adverse occurrence report sheet). The PI will review all reports to determine whether the event is 1) unexpected, 2) is related or potentially related to the research study participation and 3) suggests that the research places subjects or others at a greater risk of harm related to the research than was previously known or recognized[88]. If these three conditions exist, the occurrence will be considered an adverse event and will be immediately reported to the IRB on the appropriate form and to the SMC for review[89]. The SMC will review all adverse occurrence reports (including those that do not meet criteria for adverse events) at annual meetings. Because the NH staff participants are participating in a

behavioral intervention and some staff will passively record care sessions, there is minimal risk of adverse events in this study. NH residents who staff interact with are not likely to be adversely affected by changes in staff communication after the CHATO training. Through these reviews of adverse events and occurrences, the SMC will consider whether cumulative data indicates the need to change the research design, to modify information presented to participants, or to terminate the project. It is anticipated that the committee may decide that due to minimal risk in this behavioral intervention study, there is not a risk for severe adverse events that would require a-priori stopping rules (this decision will be reviewed at least annually by the SMC)[2]. Any action taken to suspend or terminate the project will be reported to the respective IRB, the NIH Office of Sponsored Projects, and the program director at NIA. New, scientific developments outside the study that may impact participant safety, or the ethics of the study are considered in making these determinations.

b. **New Developments:** The PI and SMC will monitor media, professional presentations, and scientific literature for breaking scientific developments regarding new developments, safety, and ethics that could impact the study. These will be reviewed at each annual SMC meeting. The SMC will evaluate the final study manuscripts and final reports to assure results are fairly presented and conclusions are appropriate.

III. Subject Participation

A. Recruitment:
1. Recruitment will be conducted at the 7 nursing homes involved in the study. The feasibility nursing home is in Kansas City, KS and the 6 nursing homes in the clinical trial are on the Western Slope of Colorado. All the staff at the nursing homes will be invited to participate in the CHATO training and 12 CNAs at each nursing home will be recruited to evaluate the feedback app effects.
2. The PI and Project Director will work directly with the leadership and staff at the nursing homes to recruit voluntary participants. Presentations at staff meetings will be conducted to inform direct care staff at the nursing homes of the training, app, and research. An information sheet about the project will be provide to staff. The project director will meet with interested CNAs to further explain research, answer questions, and gain consent.

B. Screening Interview/questionnaire: CNAs who participate in audio recording will be at least 18 years old (have legal right to provide consent), speak fluent English, and be permanently employed in the NH. The Project Director will meet with interested CNAs and confirm they meet the eligibility criteria.

C. Informed consent process and timing of obtaining of consent
1. Only trained research team members who have completed the NIH-approved Human Subjects' protection certification will obtain informed consents. The research team will give subjects detailed and comprehensive information about the study and obtain their written consent. The consenting process will be a private conversation between the research team member and the interested CNAs in the nursing home. Written information will be provided to the CNAs and time will be allowed for thoughtful decision-making prior to consent. Consent includes the standard elements: a study description, the potential risks, benefits and options for non-participation. Permission will be obtained to use data (including audio recordings) for secondary data analysis, use in scholarly presentations, and for training caregivers. Signed consent for administrators and CNAs participating in recording will be obtained and kept in a locked file in the study office.
2. The consent process will be CNA-driven to avoid coercion and the voluntary nature of participation will be stated upfront. Due to the time commitment and extra effort of CNAs participating in the audio recordings, they will be paid a $50 incentive to acknowledge their efforts and to encourage ongoing participation in each recording session. This small

financial token will be awarded after completing the recording sessions before and after CHATO completion to acknowledge participation and is not large enough to be construed as coercive [7,8]. Use of small financial incentive is reasonable to convey respect to research participants in exchange for their time and associated burden and has been found to enhance participation [9].

3. To guarantee confidentiality, a unique code number that has no connection to identification of subjects will be assigned to all staff and resident data. A list that links the assigned code number to the subjects' identifying information will be kept by the PI in a secure file and not disclosed to research assistants or others. Descriptive information for CNA participants recording participants will include age, gender, race and ethnicity, years of education, and experience working in long term care. No protected health information (PHI) will be collected from NH staff.

    D. Alternatives to Participation: All staff at the nursing homes will have access to the CHATO training and participation in the audio recording is voluntary.

    E. Costs to Subjects: N/A

    F. How new information will be conveyed to the study subject and how it will be documented: Any new information will be conveyed to participants or nursing home leadership by direct conversation (in-person or via Zoom Conferencing) or by email.

    G. Payment, including a prorated plan for payment: CNAs who participate in audio recordings will receive a $50 incentive after completing the study (1 recording session before CHATO training and 3 recording sessions after CHATO).

    H. Payment for a research-related injury: N/A – Participants will consent to being audio recorded while providing regular care to nursing home residents, no research-related injury is anticipated.

IV. Data Collection and Protection

    A. Data Management and Security: The PI and research team will review all data to assure that any of the following demographic information has been removed (participant name, age, address, long term care facility name and location, dates, phone and fax numbers, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, and certificate or license numbers). It is not anticipated that the following identifiers will be present, but if present, these identifiers will also be removed (vehicle identifiers and serial numbers, device identifiers and serial numbers, web universal resource locators, internet protocol address numbers, and finger prints). A unique code number that has no connection to the identifying information will be assigned to each recording and demographic and survey data. The list that links the assigned code number to the subjects' identifying information will be kept by the PI and only disclosed as needed.

The research team will maintain one copy of the deidentified staff data archived in a computer solely dedicated to the study with information protections procedures in place specific to the data/communications internet computer environment. One backup copy of the data will be made in case of computer malfunction. This backup copy on CD, DVD, or external hard drive, will be kept in a double locked storage area. Other staff data will also be securely maintained in deidentified, secured files. Only selected research personnel will have access to this data. All research team members will be informed that study materials are not to be discussed or placed on the internet, so that incidental disclosure does not occur. Data will be maintained in a double locked file for seven years after this study is completed and then destroyed (at least 3 years after the final expenditure report submission). No identifiable data will be sent outside of KUMC.

1. **SPEEKO App:** The iPod Touch will run an iOS app that records and processes audio in real time and utilizes voice activation frequency technology to isolate and record when a user is speaking and discard periods of silence from the recording analysis. Original back-up recordings are saved locally on the secured iPod Touch for the Project Director to access through a master password within the app to all user accounts. All speech-related data are communicated using Transport Layer Security protocols to ensure end-to-end security and HIPAA compliance. The Project Director will download recordings for both groups and delete them from the iPod Touch.
2. **Audio Data:** All audio will be handled as confidential by assigning codes, not including names, from the point of archiving through data analyses. The original audio and file linking data identification codes to participants will be stored in locked secure files. Data access will be strictly controlled by the research protocol.

B. **Sample / Specimen Collection:** N/A
C. **Tissue Banking Considerations:** N/A

D. **Procedures to protect subject confidentiality**: The primary risk to participant confidentiality is accidental disclosure of audio recordings or other data outside the research team. Accordingly, all audio and other data will be handled as confidential by assigning codes, not including names, from the point of archiving through data analyses. The original audio and other data files and file linking data identification codes to participants will be stored in locked secure files. Data access will be strictly controlled by the research protocol. Any recordings or other data suggesting physical or mental harm or illegal behaviors will be reported to the NH administration and state authorities following mandated reporting guidelines. CNA staff risks of participation include anxiety at being recorded, but this is minimal. An additional risk is disclosure of recordings of their communication revealing performance, and survey responses to supervisory staff and administrators who may use this information for performance evaluations. Thus, NH administrators will not have access to recorded or other data that identifies individual staff or neighborhoods. Staff will be assured that recordings, descriptive data, and survey responses will not be shared with administrators, supervisory staff, or other staff. In addition, recordings that may be used for future training materials or presentations will not identify the CNA or their NH employer. No appreciable risk of physical, psychological, social, legal or other harm to staff participants is expected. No information about past, present, or future physical or mental health or payment of health care benefits (HIPAA protected information) will be collected. These procedures were utilized in the PI's R03 and R01 studies that analyzed video recordings from dementia care.
E. **Quality Assurance / Monitoring**
1. The PI and other research team members as delegated will conduct an audit at least annually including review of a random sample of at least 3 CNAs who participate in CHATO training and participate in audio recording for compliance with study protocols including informed consent documents, data storage documentation and deidentification of data. The PI will conduct an annual review of research team member compliance with IRB required training and certification. The PI or delegate will train and supervise research team members in recruitment and consenting procedures, data collection, provision of intervention, and data analysis and coding on a quarterly basis. Specific procedures to assure fidelity and compliance with the protocol are included in the research plan.

2. The **SMC** will initially review and approve the written study protocol, data collection and storage protocols, intervention materials, informed consent procedures, and this plan for data and safety monitoring. Any outside agreements with vendors and subcontractors will be reviewed. The SMC will also review the general reporting guidelines based on the study procedures approved by IRB. Reporting rules will be established taking into consideration the population under study and anticipated

adverse outcomes (reflected in the human subjects consent documents). Prior to study implementation, the SMC will identify pre-specified stopping rules that will be employed if significant benefits or risks have developed, if trial management issues prevent successful completion, or if compelling ethical concerns arise.

V.   Data Analysis and Reporting
A. Statistical and Data Analysis:
1. **AIM 1.** Demonstrate feasibility, acceptability, and validity of the SPEEKO for Elderspeak feedback app use by staff in the NH. Five certified nursing assistants (CNAs) will use the app during NH care and provide feedback about any needed modifications. **Analysis:** A 10-item usability scale. Success will be determined by a cumulative score of 80% or more.

2. **AIM 2.** Test preliminary effects of an innovative self-monitoring feedback app on staff elderspeak use and compare accuracy to psycholinguistic analyses of audio-recorded staff communication. **Statistical Analysis:** Linear Mixed Models (LMMs) or Generalized LMMs, depending on the distribution of each outcome, will be developed to determine the impact of group assignment (feedback or no feedback) on use of elderspeak diminutives.

3. **AIM 3.** Evaluate app acceptability and costs. **Analysis:** Process-based costing to determine average costs for using the SPEEKO for Elderspeak feedback app, comparing costs relative to any difference determined for reductions in diminutive use in the immediate and delayed feedback groups.

B. Outcome:
1. **AIM 1 Expected Outcome:** The app will be readily used and acceptable to CNAs. Diminutive counts determined by the app will be correlated with psycholinguistic analysis, validating accuracy.

2. **AIM 2 Expected Outcome:** Staff who receive immediate app feedback (N= 30 in three NHs) will have greater elderspeak reduction after completing CHATO training compared to delayed feedback controls (N= 30 in three NHs).

3. **AIM 3 Expected Outcome:** Staff who use the app will find it acceptable and beneficial for their practice. Process-based costing will be used to determine costs for app use in NHs and other long-term service and support settings. Costs will be compared in relation to each group's outcomes.

C. Study results to participants:
Audio recording feedback via the app will be provided either immediately after recording (treatment group) or at the end of the study (control group). Nursing homes will receive CHATO participation rate feedback.
D. Publication Plan:
The PI will develop an appropriate plan for publication of research results based on the study aims and results.

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APPENDIX I: VULNERABLE POPULATIONS

I. **Cognitively or decisionally impaired individuals**: This study will include **NH staff who work with a vulnerable population of older adults including persons with dementia**. Of importance to these populations is the protection of privacy and confidentiality of materials that might be used for performance evaluations or released to unauthorized parties. This is a minimal risk study because protections and protocols limit the probability and magnitude of harm or discomfort from participation. Harm and discomfort is not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

II. **Children**: N/A

III. **Pregnant women:** N/A

IV. **Prisoners:** N/A

V. **Students and/or Employees**: N/A