Changing Talk Online (CHATO)
Pilot Study Protocol

Changing Talk Online (CHATO): A Pragmatic Trial to Reduce Behavioral Symptoms in Dementia Care (Pilot)

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Study Title

Changing Talk Online (CHATO): A Pragmatic Trial to Reduce Behavioral Symptoms in Dementia Care (Pilot)

Objectives

AIM 1. Establish acceptability and preliminary efficacy of online CHATO modules through pilot testing with NH staff.
AIM 2. Develop and pilot test the data collection tool with consultant and advisory panel input. Interviews of NH administrators and staff who participate in the pilot testing of CHATO and a process evaluation will be used to identify and develop supports for implementation and sustainability in preparation for future CHATO testing.

Design and Outcomes

The R61 will prepare for the R01 pragmatic trial by establishing feasibility of online modules and preliminary efficacy of CHATO with NH staff. The research design is a randomized clinical trial. One NH will provide initial feasibility testing. Any modifications to the modules will be made. Then six nursing homes (estimated N=150 staff) will be randomly assigned to intervention or wait-list control groups. The primary outcome will be knowledge gain for staff completing CHATO training. Additional outcomes include facility level data related to resident quality measures of behavioral and psychological symptoms of dementia (BPSD) and inappropriate use of psychotropic medications to control BPSD. Implementation strategies will be assessed by survey and leadership interviews completed by an external evaluator.

Group	Time 1	1 Month	Time 2	1 Month	Time 3
Immediate 3 NHs	Baseline assessment[1]	CHATO training[2]	Post-training assessment[3]		
Wait list 3 NHs	Baseline assessment[1]		Repeat baseline assessment[1]	CHATO training[2]	Post-training assessment[3]

[1]Pre-test knowledge, Communication rating; [2] Three modules over a one-month period;
[3] Post-test knowledge, Communication rating, Program Evaluation, Diffusion of Innovation

Interventions and Duration

Changing Talk Online (CHATO) training is a course designed to increase awareness of the importance of effective communication with older adults and to use evidence-based person-centered communication during interactions with older adults in nursing homes and other health care settings. The total program is approximately 3 hours, split into 3 modules. Each module is approximately an hour, depending on the individual user. Each NH will work with the research team for three months to plan, implement, and collect data.

Sample Size and Population

This course is designed for staff in nursing homes, independent and assisted living, and health care settings in the community that include registered nurses, nursing assistants, nursing home dieticians, direct care professionals, other administrations and support employees. All the employees at all seven nursing homes will be asked to participate. Assignment of NHs to intervention and wait-list control groups will be at random. We estimate a total sample of 150 training participants.

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1 STUDY OBJECTIVES

1.1 Primary Objective

AIM 1. Establish acceptability and preliminary efficacy of online CHATO modules through pilot testing with NH staff.

1.2 Secondary Objectives

AIM 2. Develop and pilot test the data collection tool with consultant and advisory panel input. Interviews of NH administrators and staff who participate in the pilot testing of CHATO and a process evaluation will be used to identify and develop supports for implementation and sustainability in preparation for future CHATO testing.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

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.[1] Of today's 1.4 million nursing home (NH) residents, 61% have moderate to severe dementia, and up to 90% of them exhibit behavioral and psychological symptoms of dementia (BPSD) such as physical and verbal aggression, agitation, and wandering.[2-4] These behaviors are associated with depression as well as reduced quality of life and lower survival rates in persons with dementia (PWD).[3] BPSD also stress family caregivers and precipitate NH placement.[5,6] In the NH, BPSD increase time to provide care, and NH staff, primarily Certified Nursing Assistants (CNAs) who provide most direct care, report that BPSD represent the most stressful aspect of their job.[7-9] Considering additional costs for CNA burnout and turnover, It is estimated that BPSD increase costs of dementia care by 25 to 35%.[10] With national NH rates for a semi-private room of $82,200 per year, reducing BPSD may save up to $20,000 per resident annually.[11]

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 resistiveness to care (RTC), a subset of BPSD that disrupt 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.[12] Thus, improving communication has great potential as a nonpharmacological intervention to reduce BPSD in NH care.[13]

2.2 Study Rationale

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.[14] When younger people talk with older adults, they modify their speech by simplifying, clarifying, and altering the underlying affective quality of messages.[15,16] The resulting implicit message of incompetence begins a negative feedback loop for older persons, who react with depression, withdrawal, and dependency.[14] Elderspeak is especially threatening to self-concept and personhood, critical to the wellbeing of PWD who are likely to respond with BPSD.[17,18] The Need-driven Dementia-compromised Behavior model recognizes BPSD as the expression of unmet needs of PWD.[19,20] Communication, that staff can modify to prevent BPSD, is an essential constant 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.[21,22] Alarmingly high rates persist, despite negative outcomes,[23] an FDA black box warning of increased mortality for older adults with dementia,[21] and a recent Centers for Medicare and Medicaid Services (CMS) mandate to reduce off-label prescribing of antipsychotics.[24] CMS and the National Partnership to Improve Dementia Care target reductions in psychotropic drug use as top priority.[25] Despite reductions in antipsychotic rates (one type of psychotropic medication) ranging from 3 to 12% from 2011-2016, up to 20% of NH residents received inappropriate antipsychotic medication in 2017.[26] Research demonstrates that educating direct care providers in behavioral interventions to control BPSD also reduces psychotropic drug use (antipsychotics, hypnotics, antidepressants, antianxiety, sedative, anticonvulsant and mood stabilizers),[27-29] although evidence is limited by lack of rigorous clinical trials that also evaluate approaches that influence intervention effects.[27]

Our recently completed R01 clinical trial that tested Changing Talk (CHAT) communication training (NR011455) provides preliminary data for the proposed research. CHAT decreased staff elderspeak that reduced resident RTC.[30] 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 (see Figure 1). 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.

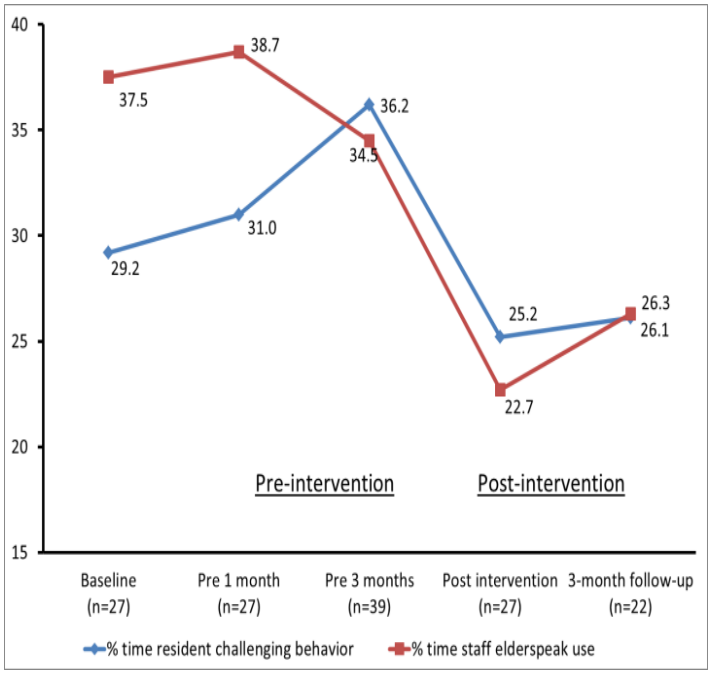

Figure 1. CHAT effects on elderspeak & RTC.

CHAT increases staff awareness of elderspeak's negative effects and guides practice of more effective communication. CHAT includes three, hour-long sessions, with replicated effects on communication in three studies among staff (N=89) and residents (N=194) in over 20 NHs.[30-32] Effect sizes ranged from η^2 = .35 to .62 for reducing elderspeak diminutives (inappropriately intimate terms of endearment) and collective "we" pronoun substitutions; effects were maintained

over 2 months. Person-centered (vs task-focused) communication also increased.[30,33] 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.[34]

To evaluate the potential impact of CHAT on psychotropic medication use, we extracted CMS 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 of antipsychotic medication use for the same time periods to control for changes that may have occurred due to the CMS mandate and other factors.[47] The state benchmark 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).[48]

Despite the success of CHAT in reducing elderspeak and RTC, we found challenges to educating NH staff that limited participation in CHAT including turnover, absenteeism, heavy workloads, and personal conflicts.[35,36 37] Each CHAT session was held multiple days and times. Still, as few as 44% of staff in one NH completed at least two of the three sessions,[30] although this rate is higher than that noted for other NH staff training programs.[38] Although successful in reducing RTC, the classroom format limits staff access and participation and feasibility for widespread dissemination. Creative, efficient approaches are needed to overcome NH staff education barriers.[39,40] We first evaluated online web conference training with multiple NHs as an alternative format for increasing access and dissemination.[41] However, engagement of individual staff was limited with this approach. To facilitate dissemination, online CHAT modules (CHATO) were developed to provide the same CHAT content with asynchronous and independent access for busy NH staff.[37]

The PI worked with an instructional designer, item writer, and media team to transition CHAT content, including 20 video clips of NH staff-resident interactions, to the online CHATO modules.[37] Scripts from the original CHAT were narrated to maintain content, integrating adult learning theories and principles for online learning, and eliminating a need for advanced literacy skills. Interactive scenario and game-based activities engage staff. For example, participants watch a video clip, select problem communication in the transcript, type their improved communication, and compare it to suggested corrections. Moderated online discussions are included in the modules that are supported on Training-Source.org, a free and publicly available learning portal.

IT functionality and content equivalency of the newly developed CHATO online modules was demonstrated by a convenient university-affiliated sample of nurses, CNAs, and students (N=9) with NH experience. They rated the online modules at 4.7 to 5.0 on a 1 to 5 scale (1 = strongly disagree to 5 = strongly agree) for increasing their knowledge, usefulness, clarity, and satisfaction. CHATO was rated as easy by 57%, while 43% found it somewhat challenging but not too difficult. All reported moderate to great improvement in recognizing and understanding ineffective communication and developing effective communication skills.[37] Pre to post test scores improved from M = 82.4% (SD 10.62) to M = 91.21% (SD 8.22). Effect sizes for pre-post changes for identifying ineffective, appropriate, and person-centered communication in a video clip were greater for CHATO participants compared to past CHAT participants (N = 217).[34,37] Although the group testing CHATO may not represent all NH staff, findings confirm that CHATO is feasible and comparable in content and effects.

While CHAT effectively reduced RTC, the in-person classroom format required an onsite interventionist, which limits accessibility and feasibility for dissemination. A pilot test of

acceptability and preliminary efficacy of online CHATO modules is the next logical step. The pilot will prepare for a pragmatic clinical trial that will test the effects of improved staff communication (from CHATO) on resident BPSD, using available clinical Minimum Data Set (MDS) data. Effects on psychotropic medication use, measured by MDS and Nursing Home Quality Measures (NHQM) data, will also be evaluated. This research will address the gap in rigorous trials testing nonpharmacological interventions to decrease BPSD that also identify strategies to improve intervention dissemination.[27]The goal is to increase access to CHATO training, as a tool to reduce BPSD and inappropriate psychotropic medication use to improve dementia care.

3 STUDY DESIGN

The R61 will prepare for the R01 pragmatic trial by establishing feasibility of online modules and preliminary efficacy of CHATO with NH staff. The research design is a randomized clinical trial. One NH will provide initial feasibility testing. Any modifications to the modules will be made. Then 6 nursing homes (estimated N=150 staff) will be randomly assigned to intervention or wait-list control groups. The primary outcome will be knowledge gain for staff completing CHATO training. Additional outcomes include resident quality measures related to behavioral and psychological symptoms of dementia (BPSD) on both resident and facility levels and facility level data related to inappropriate use of psychotropic medications to control BPSD.

Staff Knowledge Gain. At time 1, nursing home staff in both groups will complete baseline pre-tests of knowledge and rating of communication. The immediate intervention group will then complete the online CHATO modules within a one-month period. This includes assessments of post-test knowledge, communication rating, program evaluation, and diffusion of innovation surveys at Time 2. Also, at Time 2, the wait-list control group will repeat the pre-tests of knowledge and communication rating and will then complete the CHATO online module training over a one-month period, followed by Time 3 collection of post-test knowledge, communication rating, program evaluation, and diffusion of innovation surveys. Knowledge gain and communication rating data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training. Changes in knowledge from Time 1 (baseline) to Time 2 will be compared between immediate and wait-list groups using model estimates obtained with a linear mixed model (LMM) approach to account for repeated measures and clustering within nursing homes. Next, pre- to post-training changes in knowledge will be combined for immediate and wait-list groups and also tested using LMM approach. The models will be adjusted for covariates, such as staff role (RN, LPN, CNA, other), experience, and whether the nursing home has a SCU or not.

TABLE 1. R61 Study Design

Group	Time 1	1 Month	Time 2	1 Month	Time 3
Immediate 3 NHs	Baseline assessment[1]	CHATO training[2]	Post-training assessment[3]		
Wait list 3 NHs	Baseline assessment[1]		Repeat baseline assessment[1]	CHATO training[2]	Post-training assessment[3]

[1]Pre-test knowledge, Communication rating; [2] Three modules over a one-month period;
[3] Post-test knowledge, Communication rating, Program Evaluation, Diffusion of Innovation

Resident Quality Measure Outcomes. In addition, nursing homes in both groups will provide monthly summary reports for behavioral symptom occurrence for the facility (in aggregate as well as for individual residents [deidentified]). A nursing home aggregate antipsychotic medication use report will also be collected and analyzed. The BPSD and medication reports will

be provided for the one-month period before baseline data collection and for each month thereafter until the post-training assessment of the wait-listed nursing homes is completed (a total of seven months for both groups). Resident outcomes data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training. Seven months of data will be plotted to examine changes in nursing homes and resident outcomes.

Implementation Strategies and Process Evaluation. An Implementation Toolkit for NHs and a CHATO Training Manual (See Appendices) have been created to provide support and implementation suggestions to pilot nursing homes. Several consultants provided feedback and additional resources to be included in these materials. Each NH will be given a three-month period to complete the CHATO training. One month for orientation, team development, and planning, one month to complete the three-week training, and one month for staff recognition and follow up. The CHATO Research Team will meet with the NH leadership at the beginning and end of this three-month period, manage CHATO training virtual discussion board, and provide technical assistance as necessary. The process evaluation includes an online implementation survey (See Appendices) which identifies the strategies NHs used to implement the training and includes the Artifacts of Culture survey. The survey uses the Diffusion of Innovation framework and mirrors the Implementation Toolkit. Additional process evaluation activities include: Leadership phone interviews completed by the consultants and external evaluators at LeadingAge and open-ended questions asked of direct care staff in the CHATO virtual discussion.

TABLE 2. R61 Research Timeline

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Quarter 5	Quarter 6
Planning (IRB, DSMB, Manuals, Measurement)	———	———				
Pilot CHATO Modules		———	———	———		
Analyses:						
Knowledge Gained			———	———	———	
Process Evaluation			———	———	———	
Resident Outcomes					———	———
Dissemination						———

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

NH Participating in CHATO. A NH home is eligible to participate in the study if they a) serve people with dementia, and b) have internet available for staff to complete the CHATO training, and c) are willing to complete leadership interviews and surveys. Seven NHs from Presbyterian Manor will participate in the pilot due to past relationships with organization. The nursing homes that were unable to participate in the original CHAT study will participate in the CHATO pilot.

Staff Participants. NH staff including CNAs and nurses who are permanent employees and who provide direct care at least 8 hours weekly will be invited to complete the CHATO training, available by URL link. Other personnel, such as housekeeping, dietary, and administrators may also participate. Our prior research found that a variety of staff benefit from CHAT, but we will focus on direct care nursing staff who communicate most with residents. Participation by as many staff as possible is desired to achieve facility-wide communication change. NHs will provide the staff that will take the training. Their roles and other demographics will be collected in the training module.

Resident Data. Aggregate, deidentified data for residents will be collected from participating NHs. Those with Alzheimer's disease or non-Alzheimer's dementia documented on the MDS

Active Diagnoses list will be included in the analyses.

4.2 Exclusion Criteria

NH Participating in CHATO. Assisted Living facilities or other types of facilities are excluded as well as NHs that previously participated in the CHAT study.

Staff Participants. All staff are welcome to participate in the CHATO training, no staff exclusions.

4.3 Study Enrollment Procedures

For the R61, we partnered with seven Presbyterian Manor sites to pilot the CHATO intervention. These facilities have already been screened for eligibility and/or ineligibility. Letters of agreement will be collected from each NH as well as executive leaders from Presbyterian Manors. All staff at these sites will be invited to participate and will read and accept an exempt statement prior to taking the CHATO training.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

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 [16] that describes how stereotypes of older adults as incompetent prompt younger persons (NH staff) to alter their communication with older adults (NH residents). The exaggerated 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.[16,62] 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 of effective communication.[63] 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.

CHAT and CHATO include review of actual NH video examples and practice of improved communication strategies that staff readily apply and monitor in practice, significantly reducing elderspeak in just three modules. Both CHAT and CHATO target 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.[64]

CHAT was developed step-wise and iteratively through the NIH Stage Model for Behavioral Intervention Development.[65] 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).[66]

The CHATO program is presented in three modules.[37,63] 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 interactive exercises that must be successfully completed to advance through the program, assuring delivery of content fidelity and dose of the intervention. CHATO is provided to as many staff as possible to achieve facility-wide effects of reduced elderspeak.[67]

NH sites will receive the link to the trainings in three-month intervals according to the randomization plan. The NH leadership will determine the best method of implementation for their site. The link to the training will be shared with staff and the staff will have three months to complete all three modules. The modules contain pre and posttests (scenario-based questions and rating of staff communication in video clips) to evaluate knowledge gain from CHATO. The Modified Duke Diffusion of Innovation[58] survey provides information about CHATO participant intentions to use learned skills in practice and the likelihood for translation.

During the R61, the instructional designer will assure that data for identifying each participant's NH and metrics including time spent in each module are collected for analyses.[34,37]

5.2 Handling of Study Interventions

The study intervention is the Changing Talk Online (CHATO) training. The goal of course is to increase awareness of the importance of effective communication with older adults and to use evidence-based person-centered communication during interactions with older adults in nursing homes and other health care settings. The course is designed for staff in nursing homes, independent and assistive living, and health care settings in the community that include registered nurses, nursing assistants, nursing home dieticians, direct care professionals, other administrations and support employees. The total program is approximately 3 hours, split into 3 modules. Each module is approximately an hour, depending on the individual user. Upon completion of all three modules and 70% on a posttest, a certificate of completion (3 nursing contact hours) will be awarded.

Treatment 1: CHATO Training Module 1
This module contains information on the importance, benefits, and components of effective communication. This module covers the overarching goals and objectives, the benefits and components of effective communication, communication challenges of aging, and identification of effective communication (Videos).

Learning Outcomes
- Recognize the importance of communication to older adults.
- Identify barriers to communication in care of older adults.
- Distinguish between effective and ineffective communication strategies

Treatment 2: CHATO Training Module 2
This module contains information on common communication barriers and challenges, elderspeak communication, and effective and ineffective communication strategies. It reviews benefits and components of effective communication and introduces Elizabeth Layton paintings and thought exercises. The module also covers communication barriers and nursing home communication, ignoring talk vs. task talk vs. interpersonal talk, the Communication Predicament Model and elderspeak, and the identification of elderspeak and ineffective strategies (Videos).

Learning Outcomes
- Identify elderspeak and its potential negative messages.

- Contrast effective and ineffective communication strategies.
- Revise transcripts to reduce elderspeak and ineffective communication.

Treatment 3: CHATO Training Module 3

This module contains information on common problems during communication, guidelines for improving communication, and characteristics of person-centered communication. The modules review nursing home communication, ineffective strategies, and elderspeak and discusses the Communication Enhancement Model. Affirming and effective communication and evaluating communication are practiced (Videos and Rewriting of Scripts).

Learning Outcomes

- Identify affirming communication.
- Critique communication in video recordings of nursing home staff-resident communication.
- Rewrite transcripts to reduce elderspeak and ineffective communication.

The course content is presented by Dr. Kristine Williams, RN, PhD. There are learning activities, discussion forums, list of resources, pre and posttests, and evaluations at the end of the course. The practice activities were designed to provide opportunities to apply the knowledge and skills presented in the course and a virtual discussion forum is available to share experiences and reflect with others.

5.3 Concomitant Interventions

NHs will agree not to participate in other communication education programs during study involvement. Monitoring and technical assistance will be provided to each study site to ensure adherence.

5.4 Adherence Assessment

Monitoring of user statistics including: staff demographics, time spent in the modules, completion rate and program evaluation will be done by the Instructional Designer and her staff. Technical assistance including CHATO discussion boards will be provided by the Project Director and the Learning Systems Coordinator as necessary.

6 STUDY PROCEDURES

6.1 Schedule of Pilot Evaluations in NHs

Assessment	Initial Leadership Meeting	Treatment CHATO Planning (1st Month)	Treatment CHATO Training (2nd Month)	Treatment CHATO Follow-up (3rd Month)	Closing Leadership Meeting	Final Data Collection
NH Agreement	X					
Staff CHATO Participation		X				
Staff Demographics			X			
Staff CHATO Knowledge Pre-Test			X			
Communication Rating Sheet Pre-Test			X			
Staff CHATO Knowledge Post-Test			X			
Communication Rating Sheet Post-Test			X			
Modified Duke Diffusion of Innovation Intention Survey			X			
Staff CHATO Evaluation			X			
Implementation Survey				X		
The Artifacts of Culture Change Tool				X		
Staff Wage Data					X	
NH Level Resident Data						X
Leadership Phone Interviews						X

6.2 Description of Evaluations

6.2.1 Screening and Randomization

Screening

For the R61, we partnered with seven Presbyterian Manor sites to pilot the CHATO intervention. These facilities have already been screened for eligibility and/or ineligibility. Letters of agreement will be collected from each NH as well as executive leaders from Presbyterian Manors. All staff at these sites will be invited to participate and will read and accept an exempt statement prior to taking the CHATO training.

Randomization

Randomization of pilot NHs will occur to prior to any data collection. Those assigned to the pilot intervention group will receive the training first while the pilot control group is waitlisted. Randomization will occur by using a random number generator.

6.2.2 Consenting and Enrollment

Consenting Procedure

The project director will meet with NH leadership and obtain the Letter of Agreement at the initial leadership meeting at the start of the NH's assigned three-month intervention period. Signed Letters of Agreement will be stored electronically on a secure KUMC server. This procedure has been approved by the KUMC IRB.

Enrollment

Enrollment in the study begins with the initial leadership meeting and a signed letter of agreement from the participating NH. During the initial meeting, we will provide leadership and overview and implementation strategies as well as links to additional resources. We will also collect a list of staff emails. The training system will send the staff a link to the CHATO training and reminder emails.

- Initial Leadership Meeting
  - Letter of Agreement
  - List of staff and their emails that will participate in CHATO training

6.2.3 Treatment: CHATO Training

The treatment schedule may vary according to the needs of each individual nursing home; however, all modules will be completed by as many staff as possible during the three-month intervention period. Technical assistance will be provided as needed.

- Treatment: CHATO Training Module 1
  - Staff Demographics
  - Communication Rating Sheet Pre-Test
  - CHATO Knowledge Pre-Test

- Treatment: CHATO Training Module 2

- Treatment: CHATO Training Module 3
  - Communication Rating Sheet Post-Test
  - CHATO Post-Test
  - Modified Duke Diffusion of Innovation Intention Survey

- CHATO Program Evaluation

6.2.4 Completion and Final Evaluation

Competition
The NH's three-month intervention period will conclude with a closing leadership meeting that will include implementation strategies, challenges and successes, overall lessons learned, collection of surveys, and staff wage data.

- By Closing Leadership Meeting
  - Implementation Survey
  - The Artifacts of Culture Change Tool
  - Staff Wage Data

If NHs need to discontinue study interventions early, circumstances and reasons will be documented. Discontinuation from the CHATO intervention is not anticipated, however, organizational confounds or special circumstances could interfere with participation rate.

Final Evaluation
Deidentified resident data will be provided by Presbyterian Manor for one-month prior to the training and one-month post. External evaluators will conduct leadership phone interviews following the closing leadership meeting. Interviews with leadership staff will provide insight into most effective implementation strategies and overall evaluation of the CHATO training process.

- Final Data Collection
  - NH Level, Deidentified Resident Data from executive management
  - Leadership Interviews by external evaluator

7 SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

This is a minimal risk pilot test of an online version of an educational program for nursing home staff that has been established as acceptable and effective. There are minimal risks for participants and participating in online continuing education is a regular job-related activity for nursing home staff. Participants may experience concern about their performance and ability to successfully complete the post-tests and about any sharing of performance-related data with their supervisor (only aggregate results that do not identify specific staff will be shared). Participants may experience frustration if they are challenged to navigate the online modules (only basic computer skills are required). Participants may experience some burden including the time and effort required to complete the online training modules, however this is limited to a 3-4 hour period.

CNA staff risks of participation include revealing CHATO training 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 data that identifies individual staff. Staff will be assured that descriptive data, CHATO performance, 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.

Another potential risk is accidental disclosure of data outside the research team. Accordingly, all data will be handled as confidential by assigning codes, not including names, from the point of archiving through data analyses. The original data files and file linking data identification codes to participants will be stored in locked secure files or on secure KUMC servers. Data access will be controlled by the research protocol.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Data Safety Monitoring Board (DSMB) will provide oversight to assure the safety of participants and integrity of the data. The members of the DSMB include a team of interdisciplinary professionals who are not a part of the research team. The DSMB members includes clinical and research experts on NH dementia care and NH staff education as well as a statistician.

The DSMB will meet twice yearly and additionally if needed at the request of the PI (due to issues arising in study conduct or major changes in study protocols)**.** The DSMB 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.

The Principal Investigator (PI) will be responsible for ensuring participants' safety daily and will monitor participant safety, evaluate progress of the study, and assure confidentiality, data management, and analysis. This includes continuous active review of research activities that will be completed with assistance of the Project Director (PD).

The PI will be responsible for submitting necessary reports (including minutes of annual and any additional DSMB meetings) to the funder. The PI will provide timely reporting of a) any unanticipated problems or unexpected adverse or 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 DSMB and if applicable the action plan for response, and d) notice of any actions taken by the IRB or regulatory bodies regarding the research and any responses to those actions.

To assure data control and safety for participants, each research team member will be trained and supervised by the site PI and/or PD, including instruction in all research activities, data handling, and in reporting subject complaints or other behaviors indicating a negative response to participation in the study immediately to the PI. Research team staff will be supervised during direct interactions with research study participants and provided with feedback.

All data identifiers will be removed for secured computer storage; a code will be assigned to each subject for data storage and the key linking the code number to subject identification will be kept secure by each site PI. All data will be deidentified prior to dissemination outside the research team.

7.3 Adverse Events and Serious Adverse Events

The OHRP Unanticipated Problem and AE Guidance definitions will be used for this study. Adverse Events (AE) will be documented on the Adverse Event Form and unanticipated events that are not adverse events will be recorded on the Unanticipated Problem form. Adverse events and unanticipated problems (Ups) will be reported to the IRB, DSMB and NIH Program Officer

as required. The PI will evaluate each AE for severity, whether it was expected or unexpected, and will determine relationship to participation in the study.

A Serious Adverse Event (SAE) occurs when an unanticipated event which may result in death, life threatening or places participant at risk of death, requires of prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, or otherwise is judged to represent a significant hazard. SAE are not expected in this minimal risk exempt pilot study, however, the Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis and will monitor participant safety.

7.4 Reporting Procedures

When SAEs occur that are unanticipated and are related to the intervention, they will be reported to the NIA Program Officer and to the DSMB Chair or designee, within 48 hours of the research team's knowledge.

Ups involving risks to study participants or others will be reported to the NIA program officer within 48 hours unless they are also SAEs

7.5 Follow-up for Adverse Events

A summary of all SAEs will be reported to the NIA Program Officer and to the DSMB quarterly.

7.6 Safety Monitoring

The DSMB will initially review and approve the written study protocol; data collection and storage protocols, intervention materials, informed consent procedures, and the plan for data and safety monitoring. Any outside agreements with vendors and subcontractors will be reviewed. The DSMB 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).

The DSMB will meet twice annually, either in-person or by teleconference call to review study progress, data quality, and participants safety. Safety reports are sent to the SO if necessary twice a year and will include a detailed analysis of study progress, data and safety issues. The content of the data and safety monitoring report will include: (e.g., study status, participant descriptive information, safety information, study quality). Blinded reports will be produced for open sessions and unblinded reports for closed sessions.

8 INTERVENTION DISCONTINUATION

This is a low risk study consisting of pilot testing an educational intervention. Thus, it is difficult to anticipate specific, a-priori stopping rules. If the research team, IRB, NIA program officer, and/or DSMB identify a pattern to these events, an interim analysis of safety data will be conducted to inform a decision for premature stoppage of study. Since this is a low-risk, short (six-month) pilot test of an educational intervention, no interim analyses on the primary study outcomes are planned.

9 STATISTICAL CONSIDERATIONS

9.1 General Design and Outcomes

Primary Objective

AIM 1. Establish acceptability and preliminary efficacy of online CHATO modules through pilot testing with NH staff.

Staff Outcomes: Knowledge gain and communication rating data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training.

Resident Outcomes: The BPSD and medication reports will be provided for the one-month period before baseline data collection and for each month thereafter until the post-training assessment of the wait-listed nursing homes is completed (a total of seven months for both groups). Resident outcomes data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training.

Secondary Objectives

AIM 2. Develop and pilot test the data collection tool with consultant input. Interviews of NH administrators and staff who participate in the pilot testing of CHATO and a process evaluation will be used to identify and develop supports for implementation and sustainability in preparation for future CHATO testing.

Implementation Outcomes: We will analyze NH strategies used to engage staff in CHATO (approach, motivation, incentives). Strategies will be described, categorized, and correlated with participation rates. A survey for CHATO group NHs, will describe how CHATO was implemented and concurrent activities that may have influenced BPSD and psychotropic use rates. The Artifacts of Culture Change Tool will describe the NH care environment and practices, leadership and workplace practices, staffing outcomes, and occupancy.[100] In addition, a simple cost-effectiveness analysis (CEA) for the cost associated with hypothesized BPSD reductions will be calculated.

9.2 Sample Size and Randomization

Seven NHs will be used to pilot the CHATO intervention during the R61. One nursing home will be used to test overall feasibility. The additional six will be randomized into three intervention and three waitlist controls using a random number generator. We estimate a CHATO training sample size of 150 participants.

9.3 Interim analyses and Stopping Rules

This is a low risk study consisting of pilot testing an educational intervention. Thus, it is difficult to anticipate specific, a-priori stopping rules. If the research team, IRB, NIA program officer, and/or DSMB identify a pattern to these events, an interim analysis of safety data will be conducted to inform a decision for premature stoppage of study. Since this is a low-risk pilot test of an educational intervention, no interim analyses on the primary study outcomes are planned.

9.4 Data Analyses

SAS software[71] will be used for all analyses. Initial analysis will calculate descriptive statistics at

all data collection points. Outliers will be investigated for accuracy and possible entry errors. Graphic representation of data and correlations among variables will be examined. Patterns and site effects of missing data will be examined in relation to variables of interest.[72]

Knowledge gain and communication rating data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training. Changes in knowledge from Time 1 (baseline) to Time 2 will be compared between immediate and wait-listed groups using model estimates obtained with a linear mixed model (LMM) approach to account for repeated measures and clustering within nursing homes. Next, pre- to post-training changes in knowledge will be combined for immediate and wait-list groups and also tested using LMM approach. The models will be adjusted for covariates, such as staff role (RN, LPN, CNA, other), experience, and whether the nursing home has a SCU or not. Distributions of residuals will be evaluated for normality and variance homogeneity and variables will be transformed as needed or statistical analyses for non-normal data will be utilized.

The BPSD and medication reports will be provided for the one-month period before baseline data collection and for each month thereafter until the post-training assessment of the wait-listed nursing homes is completed (a total of seven months for both groups). Resident outcomes data will be compared between the intervention and wait-list control groups and within nursing homes before and after the CHATO training. Seven months of data will be plotted to examine changes in nursing homes and resident outcomes.

We will analyze NH strategies used to engage staff in CHATO (approach, motivation, incentives). Strategies will be described, categorized, and correlated with participation rates. A survey for CHATO group NHs, will describe how CHATO was implemented and concurrent activities that may have influenced BPSD and psychotropic use rates. The Artifacts of Culture Change Tool will describe the NH care environment and practices, leadership and workplace practices, staffing outcomes, and occupancy.[100] In addition, a simple cost-effectiveness analysis (CEA) for the cost associated with hypothesized BPSD reductions will be calculated.

Scores for each engagement strategy category will be calculated, summarized using means and standard deviations, and correlated with participation rates. Strategy categories (approach, motivation, incentives) will be summarized using frequencies and percentages and examined in relation to participation rates using ANOVA or Kruskal-Wallis test, depending on the distribution of participation rates. Participation rates will be calculated using data from the NHs (eligible staff) and from the modules (CHATO participants). Data describing CHATO participant time spent on each module and completion rates, all collected by the learning system, will also be analyzed. We will also evaluate NH attrition and within-NH dropout/completion rates for CHATO participants. We will also evaluate CEA differences for the three typical NH scenarios.[56]

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Data will be collected according to Table 4. The data itself will be collected via the Moodle learning system managed by the Instructional Designer or RedCAP managed by the Project Director. The person responsible for collection will send data to the data manager for data cleaning and analysis. The data manager is the individual designated for managing data files and for assuring confidentiality. She will provide data directly to the DSMB and Program Officer upon request. She will serve as the data coordinator for the study.

TABLE 4. Data Collection Forms, Method of Collection, and Person Responsible.

Data Collection Form	Method of Collection	Person Responsible
NH Agreement/Letter of Support	NH Leadership/Word	Project Director
Staff CHATO Participation	NH Leadership/Excel	Project Director
Staff Demographics	CHATO Training/Moodle	Instructional Designer
Staff CHATO Knowledge Pre-Test	CHATO Training/Moodle	Instructional Designer
Communication Rating Sheet Pre-Test	CHATO Training/Moodle	Instructional Designer
Staff CHATO Knowledge Post-Test	CHATO Training/Moodle	Instructional Designer
Communication Rating Sheet Post-Test	CHATO Training/Moodle	Instructional Designer
Modified Duke Diffusion of Innovation Intention Survey	CHATO Training/Moodle	Instructional Designer
Staff CHATO Evaluation	CHATO Training/Moodle	Instructional Designer
Implementation Survey	NH Leadership/RedCAP	Project Director
The Artifacts of Culture Change Tool	NH Leadership/RedCAP	Project Director
Staff Wage Data	NH Leadership/RedCAP	Project Director
NH Level Resident Data	NH Executives/Internal Data System	Project Director
Leadership Phone Interviews	NH Leadership/Phone Interview	LeadingAge Evaluators

10.2 Data Management

The participating nursing homes will not be responsible for collecting any data onsite. They will provide a NH Agreement, identify staff taking the training, take the Implementation Survey and The Artifacts of Culture Change Tool, and provide staff wage data. NH Chain Executives will provide NH level deidentified resident data.

Data will be collected in RedCAP and the Moodle learning system and provided to the data manager for data monitoring, cleaning, and analysis. Data will be stored on the collection platform and on secure servers at the University of Kansas Medical Center and/or the University of Iowa.

TABLE 5. Data Collection Forms Description

Data Collection Form	Description
NH Agreement	A signed letter of agreement from the participating NH indicating participation in the research.
Staff CHATO Participation	List of participating staff and their email address where they can receive the link to the CHATO training.
Staff Demographics	Participants' age, sex, race, ethnicity, NH employer, role, education, and length of time in current NH and health care role.
Staff CHATO Knowledge Pre-Test/Post-Test	Two forms (Forms A and B) measuring knowledge gained from training.
Communication Rating Sheet Pre-Test/Post-Test	Participant watches a video and answers questions which tests their ability to visually and audibly identify effective vs ineffective communication strategies and recognize elderspeak vs. person-centered care.
Modified Duke Diffusion of Innovation Intention Survey	Participants rates the training intervention on four scales: complexity and compatibility, observability/image, organizational support, and intention to use.
Staff CHATO Evaluation	Program evaluation of the CHATO training.
Implementation Survey	Measures approach, motivation, and incentives used to implement CHATO.
The Artifacts of Culture Change Tool	Measures NH care environment and practices, leadership and workplace practices, staffing outcomes, and occupancy.
Staff Wage Data	Wages per hour by NH role.
NH Level Resident Data	Resident behavioral and medication data.
Leadership Phone Interviews	Qualitative data regarding implementation strategies, lessons learned, and overall evaluation of the CHATO pilot from the NH leadership perspective.

10.3 Quality Assurance

10.3.1 Training

The PI will conduct an annual review of research team member compliance with IRB required training and certification. The PI or PD 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.

10.3.2 Quality Control Committee

The DSMB responsibilities are to: review the research protocol, informed consent documents and plans for data safety and monitoring; advise the NIA on the readiness of the study staff to initiate recruitment; evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome; consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial; review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator; protect the safety of the study participants; report to NIA on the safety and progress of the trial; make recommendations to the NIA, the Principal Investigator, and, if required, to the Food and Drug Administration (FDA) concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study; if appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis and have the approval of the DSMB; ensure the confidentiality of the study data and the results of monitoring; and, assist the NIA by commenting on any problems with study conduct, enrollment, sample size and/or data collection.

The DSMB Members include:

Dr. James Powers, Vanderbilt University, is a Geriatrician with relevant background in Quality Improvement, Medication Safety, and Long-Term Care.

Dr. Kimberly Van Haitsma, Penn State University, is a Clinical Geropsychologist with extensive clinical experience, expertise in nursing home staff training, and improving dementia care. She also brings extensive pragmatic clinical trial expertise.

Dr. Daniel Bontempo, Texas Tech University, is a statistician with substantive social science expertise as a consultant as well as in multivariate and multilevel modeling methodology.

10.3.3 Metrics

Accurate data entry and export will be evaluated prior to the start of the pilot study. The research team will create accounts and log in as participants, provide dummy descriptive data, and complete the modules (including assessments). Results will be exported from the Moodle platform and reviewed to assure that all data are captured in the proper format and that the exported data reflect the entered data. Accuracy will be reevaluated after the first nursing home completes the pilot study.

10.3.4 Protocol Deviations

A protocol deviation for this study will be defined by the DSMB and is outlined below. All protocol deviations will be recorded in the Protocol Deviations Log and reported to the DSMB quarterly. Only protocol deviations that impact participant safety will be reported within 24 hours of occurrence if possible, or as soon as they are discovered. A log for recording protocol deviations will be used.

Protocol deviations/violations include, but are not limited to, the following:

- Randomization of an ineligible participant
- Failure to obtain Informed Consent
- Enrollment of a participant into another study
- Failure to keep IRB approval up to date
- Wrong treatment administered to participant

Variations in how individual nursing home implement the CHATO training will also be monitored. Any implementation protocol deviations for the 7 pilot homes will be recorded by the instructional designer and/or project director.

10.3.5 Monitoring

The instructional designer and her staff will monitor the Moodle system. The project director will monitor RedCAP. All monitoring will be done in conjunction with the data manager and statistician. All coordination of research activities will be monitored by the PI. Review of these systems will be done daily during the pilot to ensure the training and any data collection are being completed as determined by the protocol.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

Approval of the Kansas University Medical Center (KUMC) Institutional Review Board (IRB) for the protection of human subjects was obtained on February 5, 2019. The KUMC IRB will act as the one IRB for this study with agreement from the IRB at the University of Iowa sub award site.

Research personnel will abide by all tenets of the University confidentiality policies as well as the Privacy Protection for Research. All research staff will remain current in the NIH required Human Subjects protections and HIPAA certifications. KUMC partners with the Collaborative Institutional Training Initiative at the University of Miami (CITI) to provide Human Research Protection training and other types of training to our research community. This tutorial training is available on line for all research team members and will be completed by all research team personnel. Consultants will be required to submit proof of Human Subjects Protections and HIPAA training from their respective institutions or may complete the CITI program.

11.2 Informed Consent Forms

A letter of agreement will be obtained from nursing homes (NHs) who participate in the study. The KUMC IRB will act as their IRB and the letter of agreement to participate from an authorized administrator will be submitted to the KUMC IRB for approval. Staff read an exempt statement prior to taking the first module of the CHATO training.

11.3 Participant Confidentiality

All data will be handled as confidential by assigning codes, not including names, from the point of archiving through data analyses. The original data files and file linking data identification codes to participants will be stored in locked secure files. Data access will be controlled by the research protocol. Any data suggesting physical or mental harm or illegal behaviors will be reported to the NH administration and state authorities following mandated reporting guidelines. No information about past, present, or future physical or mental health or payment of health care benefits (HIPAA protected information) will be collected.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

This study will include NH staff. In addition, NH resident data from the MDS will be used to evaluate study outcomes. Of particular 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 are not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

13 PUBLICATION OF RESEARCH FINDINGS

Any presentation, abstract, or manuscript will be made available for review by the sponsor prior to submission.

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15 APPENDIX

15.1 Changing Talk Online (CHATO) Implementation Toolkit

15.2 Changing Talk Online (CHATO) Training Overview

15.3 CHATO Implemenation Strategies Survey

15.3.1 Artifacts of Culture Change Survey

15.4 CHATO Leadership Inverviews