Official Title:	Development and Piloting of a Family-Centered, mHealth-Enhanced Intervention to Promote Caregiving Mastery in Detection, Prevention, and Management of Delirium Superimposed on Dementia
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DEVELOPMENT AND PILOTING OF A FAMILY-CENTERED, MHEALTH-ENHANCED INTERVENTION TO PROMOTE CAREGIVING MASTERY IN DETECTION, PREVENTION, AND MANAGEMENT OF DELIRIUM SUPERIMPOSED ON DEMENTIA

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ClinicalTrials.gov Number	*NCT05630014*

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Amended: 04/15/2024

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

Table of Contents

List of Abbreviations

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DSD	Delirium Superimposed on Dementia
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
ISM	Independent Safety Monitor
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PI	Principal Investigator
PLWD	Persons Living with Dementia
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
US	United States

Protocol Summary

Title	*Development and Piloting of a Family-Centered, mHealth-Enhanced Intervention to Promote Caregiving Mastery in Detection, Prevention, and Management of Delirium Superimposed on Dementia*
Short Title	*A Pilot Study of the Aliviado DSD Caregiving Mastery Program*
Brief Summary	*Delirium superimposed on dementia (DSD) is an acute and serious condition that is common in persons living with dementia (**PLWD**). Involvement of family caregivers may aid prevention, early detection, and management of DSD. The purpose of the proposed study is two-fold. First, we will develop a family-centered, mHealth-enhanced DSD caregiving mastery program ("Aliviado DSD Caregiving Mastery Program") through a 5-week co-design workshop with 8 family caregivers (Aim 1). We will adapt/refine the existing clinician-centered DSD contents and an mHealth app from the evidence-based "Aliviado Dementia Care" program for use by family caregivers to support their day-to-day implementation of DSD detection, prevention, and management tasks in the community. Second, we will pilot test the full Aliviado DSD Caregiving Mastery Program with 30 family caregivers of PLWD at high risk for delirium, assessing feasibility, acceptability, app usability, and preliminary program impact (Aim 2).*
Phase	*Phase I (NIH Stage I)*
Objectives	*1. To adapt the existing Aliviado app for use by family caregivers* *2. Assess feasibility, acceptability, app usability, and preliminary impact of the Aliviado DSD Caregiving Mastery Program.*
Methodology	*1. Co-design workshop* *2. A single-arm, pre-post study*
Endpoint	*Primary endpoints: feasibility, acceptability, and app usability* *Secondary endpoints: caregivers' delirium knowledge, caregiving mastery, strain, depression, and burden*
Study Duration	*12 months*
Participant Duration	*10 months*
Duration of behavioral intervention	*6 weeks*
Population	*Adult family caregivers of community dwelling PLWD. "Adults" are individuals who are 18 years of age and older. "Family caregivers" are relatives or friends who provide unpaid care to PLWD.*
Study Sites	*NYU and University of Pittsburg*
Number of participants	*Aim 1: 8 family caregivers* *Aim 2: 30 primary caregivers plus 0 to 30 optional secondary caregivers* *Optional: Enrolled primary caregivers can choose to invite additional relatives or friends to participate in the Aim 2 pilot study as "secondary caregivers".*
Description of Study Intervention/Procedure	*Intervention: Aliviado DSD Caregiving Mastery Program, a family caregiver intervention consisting of mHealth-app based educational videos and articles; caregiver-administered assessment tools and care plans; and motivational push notification or text message reminders and encouragements.*
Reference Therapy	*None*
Key Procedures	*None*

Statistical Analysis	*Aim 1: Descriptive statistics to describe sample characteristics* *Aim 2: Descriptive statistics will be calculated to summarize caregiver characteristics, feasibility, acceptability, and app usability outcomes. Paired t-tests will be performed to compare (1) changes in caregiver delirium knowledge and caregiving mastery from baseline to Week 2 (immediately post training), and (2) changes in delirium knowledge, caregiving mastery, strain, depression, and burden from baseline to posttest (Week 6).*

Schematic of Study Design

Figure 1. Aim 1 Codesign Workshop

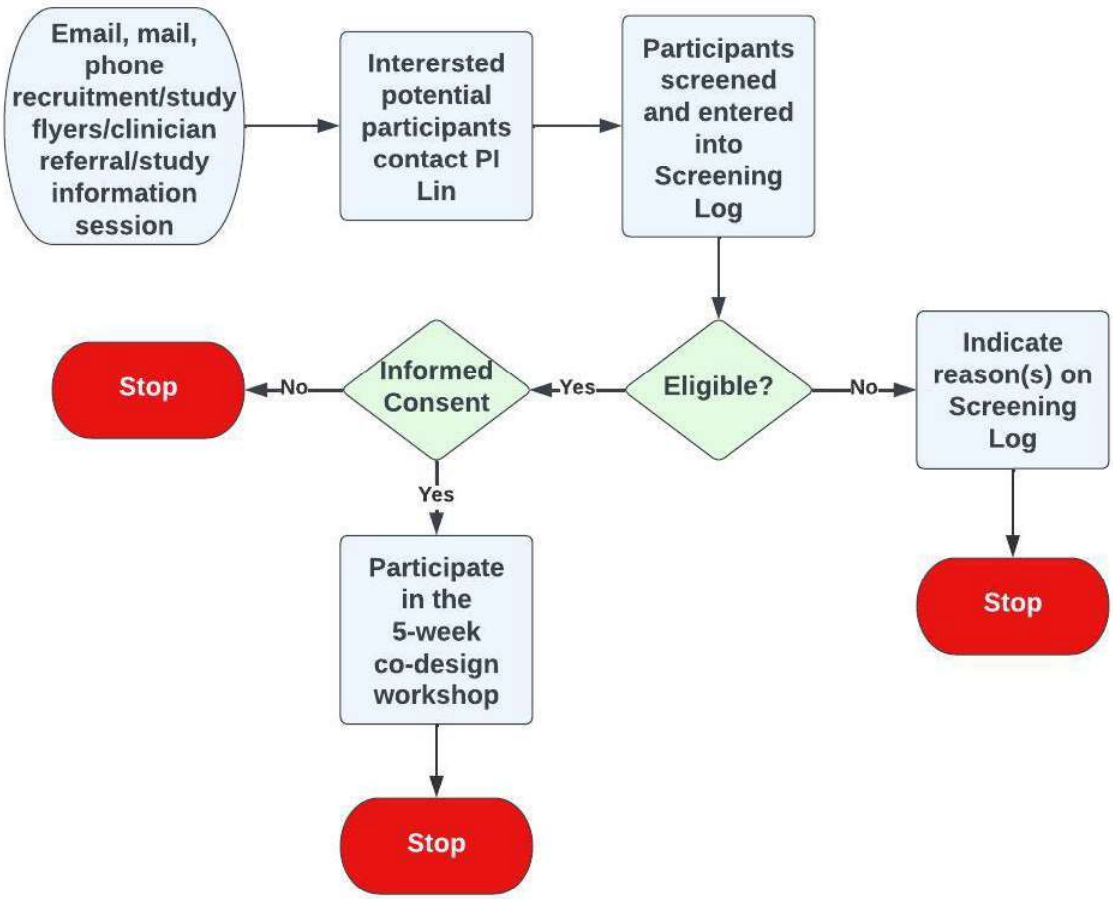
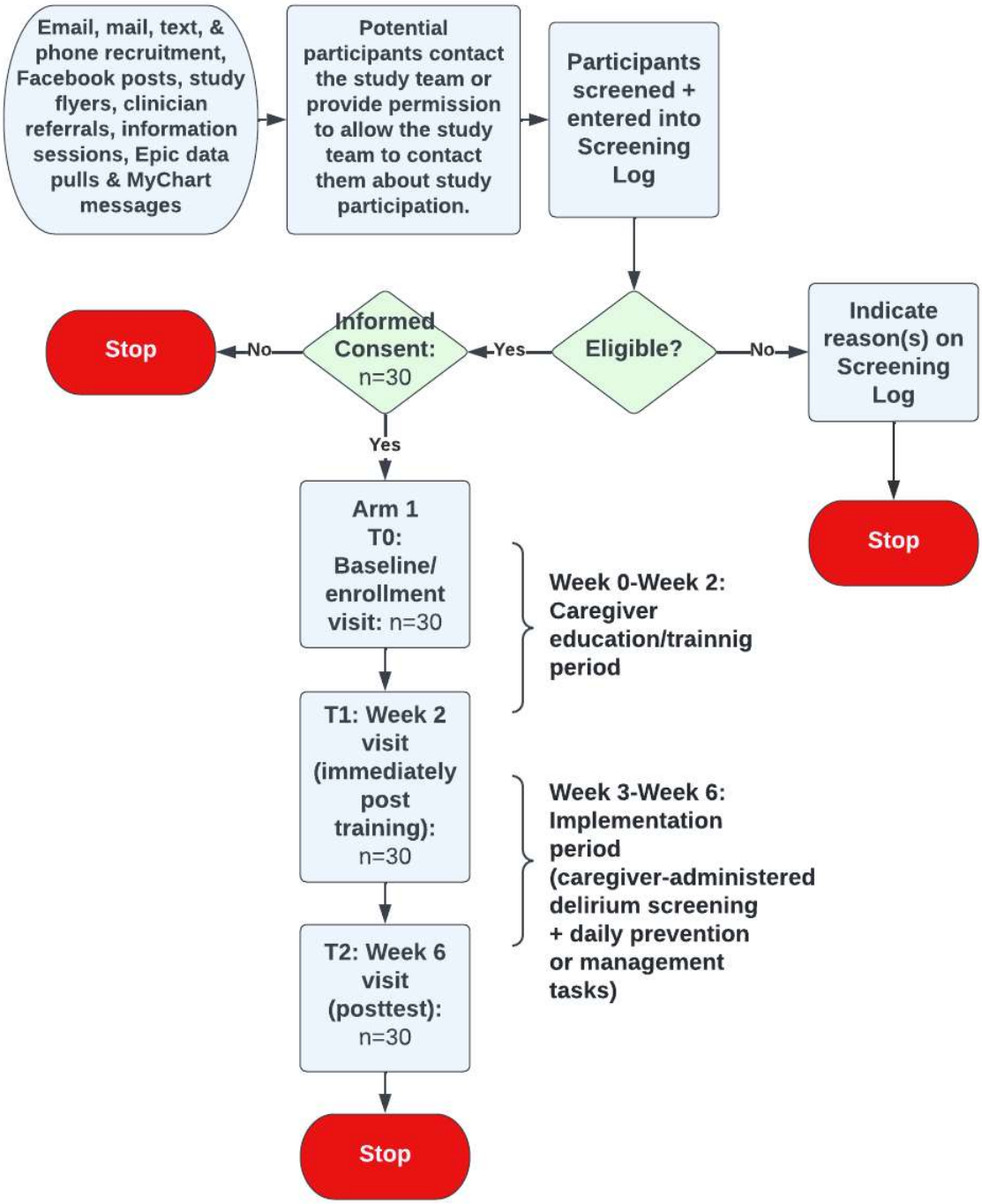


Figure 2. Aim 2 Feasibility Trial



1 Key Roles

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This proposal is selected by the Emory Roybal Center to receive funds (subaward) from the NIA grant

Table 1. Roles and Responsibilities

Name	***Address/ Phone/Email***	***Role***	***Responsibilities***
Shih-Yin Lin	*NYU Rory Meyers College of Nursing* *433 First Ave #745M* *New York, NY 10010* *(720) 883-5715 (Cell)* *SL199@nyu.edu*	*Principal investigator (PI); Contact PI; Study coordinator*	• *Identification, recruitment, screening, enrollment, and retention of participants* • *Reporting and monitoring of adverse events and serious adverse events* • *Obtaining informed consent from participants* • *Compliance with and accountability of study intervention administration* • *Submitting required documents and reports to the NYU School of Medicine IRB, NIA, Safety Officer, and Emory Roybal Center* • *Development and implementation of data collection, management, and quality control procedures* • *Ensuring compliance with human subjects regulations and policies* • *Collection of study data and follow up of participants through study completion* • *Development and maintenance of all study materials including the MOP and study forms* • *Maintenance of study binder* • *Data analysis* • *Dissemination of study findings* • *Coordination of study team meetings*
Yong K. Choi	*Department of Health Information Management* *School of Health and Rehabilitation Sciences* *University of Pittsburgh*	*Co-PI; Back-up study coordinator*	• *Identification, recruitment, screening, obtaining consent, enrollment, and retention of participants* • *Scheduling and leading Aim 1 human-centered co-design workshop* • *Development of personas, mHealth app prototypes, and other relevant study materials*

Name	Address/ Phone/Email	Role	Responsibilities
	6051B Forbes Tower, 3600 Atwood St, Pittsburgh, PA 15260 *(206) 496-2147 (Cell)* *yong.choi@pitt.edu*		• *Collection of study data and follow-up of participants* • *Data analysis* • *Communication with the app developer* • *Preliminary usability testing* • *Dissemination of study findings*
Abraham A. Brody	*NYU Rory Meyers College of Nursing 433 First Ave, Room 504, New York, NY10010* *(212) 992-7341* *Ab.Brody@nyu.edu*	*NYU collaborator/Medical monitor to adjudicate for study-relatedness of adverse events and series adverse events*	*Assist with participant recruitment, review intervention materials, serve as the adjudicator to determine whether an adverse or serious adverse event is related to the study, assist with interpretation and dissemination of research findings.*
Jason Fletcher	*NYU Rory Meyers College of Nursing 433 First Ave, Room 753, New York, NY 10010* *(212) 998-5401* *Jason.fletcher@nyu.edu*	*NYU collaborator/Statistician*	*Dr. Fletcher will assist with quantitative data analysis, interpretation, and the writeups of quantitative findings.*
Donna M. Fick	*Penn State College of Nursing 308 Nursing Sciences Building, University Park, PA 16802* *(814) 865-9325* *dmf21@psu.edu*	*External consultant – expert on delirium superimposed on dementia*	*Dr. Fick will participate in the scheduled quarterly study team meetings, review study materials, and be available for additional consultation as needed. Dr. Fick will assist the PIs in intervention development/adaptation; interpretation and dissemination of the research findings. She will not be engaged in research, as she will not interact with subjects or review identified data.*
Jennifer A Pruskowski, Pharm D, MS, BCPS, BCGP	*Assistant Professor and Director of Geriatric Pharmacy Research and Education* *Division of Geriatric Medicine, School of Medicine* *University of Pittsburgh* *(412) 692-2361* *jpruskow@pitt.edu*	*External consultant – expert on geriatric pharmacotherapy and patient education*	*Dr. Pruskowski will review intervention contents, focusing on guidance and patient education materials related to deprescribing of delirium-inducing medications; respond to participants' medication-related questions that arise throughout the study periods; and attend the study team meetings as needed. Dr. Pruskowski will also participate in publishing results of the study. She will not be engaged in research, as she will not interact with subjects or review identified data.*
Drenna Waldrop	*Nell Hodgson Woodruff School of Nursing* *Emory University* *1520 Clifton Road, NE Atlanta, GA 30322-4027* *(404) 712-9487* *drenna.waldrop@emory.edu*	*Emory University collaborator/Project mentor*	*Dr. Waldrop will provide mentorship to ensure successful completion of this project in accordance with NIA and Emory Roybal Center regulations and policies. Dr. Waldrop may also participate in publishing results of the study. She will not be engaged in research, as she will not interact with subjects or review identified data.*

2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Delirium Superimposed on Dementia (**DSD**) refers to occurrence of delirium (i.e., a serious, acute, fluctuating disturbance in attention and cognition) in persons living with dementia (**PLWD**).[1] DSD is highly prevalent in PLWD, affecting 22% to 89% of PLWD in the community and hospital settings.[1] Compared to dementia alone, those with DSD have accelerated cognitive and functional declines and higher rates of rehospitalization, institutionalization, and death.[2–4] Moreover, DSD causes substantial distress and burden to both PLWD and family caregivers[5,6]—defined here as relatives and friends that provide unpaid care.

Research shows that it is feasible for family members to perform delirium assessment to aid early detection[7–12] and assist with delirium prevention and management tasks to address modifiable risk factors.[13,14] **The purpose of this project** is to develop and pilot test a family-centered, mHealth-enhanced intervention program to improve caregivers' knowledge, skills, and mastery in DSD detection, prevention, and management in the community. The proposed intervention, the "Aliviado DSD Caregiving Mastery" program, will adapt existing DSD components in the clinician-focused, evidence-based "Aliviado Dementia Care" program for use by family caregivers.[15–17] "Aliviado" means "relief" in Spanish/Portuguese. The original Aliviado Dementia Care program is an agency-wide quality improvement program to optimize home-based, clinician-delivered symptom management for PLWD and their families. The existing Aliviado DSD contents include a DSD education video for aides, a clinician-initiated acute delirium care plan, a clinician-administered delirium assessment, and an acute delirium caregiver education article, all accessible via a clinician-facing Aliviado mHealth app. While these contents are a solid template for the proposed intervention, with the exception of the caregiver education article (written for both professional caregivers and family caregivers), the remaining DSD contents require adaptation for direct use by families. Moreover, to promote caregivers' self-efficacy/mastery, we include additional strategies informed by Pearlin's Stress Process Model,[18] Bandura's Social Cognitive Theory[19–22] (e.g., social support and goal setting), and Nudge Theory.[23] The proposed study aligns with Stage I of the NIH Stage Model.[24]

2.1.1 Theoretical Framework/Mechanism

The DSD Caregiving Mastery Program is informed by the Stress Process Model, Social Cognitive Theory (including the Threefold Stepwise Implementation Model[19]), and Nudge Theory. In the Stress Process Model (Figure 3): The "primary stressors" are the patient's cognitive status, problematic behaviors, and dependencies of activities of daily living, and the caregiver's felt sense of overload and relational deprivation. The "secondary stressors" are role strains and intrapsychic strains including *global mastery* and *situational competence*. This intervention program is designed to address a specific type of situational comptenence, DSD caregiving mastery. The "mediators" are coping and social support.

DSD accelerates cognitive and functional declines and can worsen behavioral issues, yet different from dementia, delirium is often preventable and reversible. Thus, the prevention and early detection tasks can help reduce the additional situational caregiving stress resulting from DSD-induced cognitive and functional declines and worse behavior symptoms at the "primary stressors" level. **The inclusion of a caregiver strain assessment and referral to community supportive services as part of this intervention helps to address the "secondary role strains"** in the Stress Process Model**.** The tailored care plan with specific DSD management strategies addresses the "mediator" of coping, while the ability to include a secondary caregiver helps to activate the "mediator" of social support. To address "secondary intrapsychic strains" in the Stress Process Model, we adopt Social Cognitive Theory-informed strategies to promote mastery and competence. For instance, training videos with successful case scenarios provide *observational learning/vicarious experience*, meanwhile increase caregivers' DSD knowledge/skills to improve *behavioral capabilities* and *competence*. Practicing delirium assessment using case vignettes as part of the caregiver training provides caregivers with *mastery experiences* in DSD detection, which contributes to increased *self-efficacy* and *mastery*. The tailored care plan facilitates *goal setting*. The additional support to help caregivers with lower self-efficacy to set incremental goals

follows the guidance in Bandura's Threefold Stepwise Implementation Model. Lastly, we use Nudge Theory-informed mobile push notifications or text messages to provide text-based *verbal persuasion*, and nudge caregivers to perform the target prevention, detection, and symptom management behaviors. (See 6.1 and Table 2 for more detail.)

Figure 3. Screenshot of Pearline's Stress Process Model

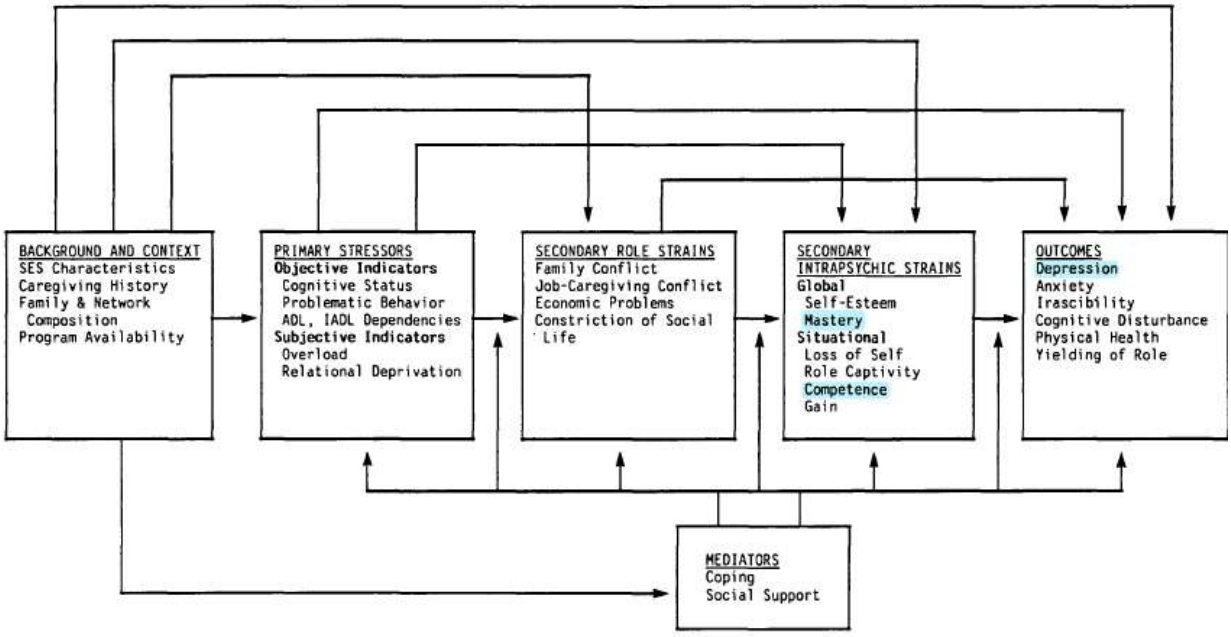

Figure 1. A conceptual model of Alzheimer's caregivers' stress. The stress process is made up of four domains: the background and context of stress; the stressors; the mediators of stress; and the outcomes or manifestations of stress.

According to the Stress Process Model, improved mastery and competence may contribute to improved caregiver outcomes such as improved depression and anxiety. Therefore, we decide to also measure caregiver depressive symptoms to find out whether improved DSD caregiving mastery and competence are related to improved depressive symptoms in caregiver participants as a group (on average).

This study does not diagnose depression nor screen for positive depression cases.

2.2 Rationale

Research shows that it is feasible for family members to perform delirium assessment to aid early detection[7–12] and assist with delirium prevention and management tasks to address modifiable risk factors.[13,14] However, most delirium/DSD interventions involving families have been developed for hospital/institutional settings[8,8,9,13,14,25,26] and have not considered different education/training needs of multiple caregivers within the same family. Moreover, although mHealth apps for dementia caregivers have burgeoned,[27,28] no DSD interventions have leveraged mHealth-based behavioral economics nudges,[23] or motivational messages and prompts, to reinforce family caregivers' implementation of DSD prevention, detection, and management tasks in the community. Thus, there is a considerable gap between what is feasible and the available interventions to support family caregivers to provide DSD care in the community.

The duration of the caregiver education/training period in the proposed intervention, the Aliviado DSD Caregiving Mastery Program, is set at 2 weeks to allow caregivers plenty of time to complete the self-paced training. The duration of the implementation period is set at 4 weeks to assess whether caregivers

can perform weekly screening in the mHealth app for at least several times without major issues. Findings from this pilot feasibility trial will reveal feasibility and acceptability of the proposed frequency of delirium assessment and intervention duration, which will inform further refinement of the Aliviado DSD Caregiving Mastery Program in preparation for a future efficacy trial.

Given that this is a pilot study to assess feasibility, acceptability, and preliminary impact of the intervention on family caregivers, all caregiver participants will receive the intervention (a single-group, pre-post design). There are no control groups nor PLWD subjects in this pilot study. After feasibility and acceptability of the intervention are established in family caregivers, we will then add control groups and enroll PLWD-caregiver dyads in future efficacy and effectiveness trials of the Aliviado DSD Caregiving Mastery Program.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

This is a minimal risk study. The intervention itself is inherently not risky as it is a family-centered, psychoeducational training program on implementation of evidence-based best practices through an mHealth app to improve family caregivers' mastery in performing DSD detection, prevention, and symptom management tasks. The greatest potential risks to family caregiver subjects are (1) a breach of confidentiality and (2) psychological distress.

Though possible, we anticipate that a breach of confidentiality is unlikely to happen because personal identifiers will only be collected and stored in the password-protected REDCap electronic consent and HIPAA authorization form, in which only authorized study team members will have access to, whereas all the other study data will be deidentified and stored in a password-protected NYU Box folder, in which access will only be granted to appropriate study team members. NYU Box is the NYU WSQ Campus approved storage of high-risk data.

When learning something new such as a new mHealth app, some caregivers can become frustrated or experience psychological distress. However, we believe psychological distress is unlikely to happen, because we will have tested our mHealth app to ensure user-friendliness. We will also proactively offer additional technical support/training sessions on how to use the study app via Aliviado Support Center (Aliviado.dsd.caregiving@nyu.edu) to caregivers who report a lower level of comfort with technology at enrollment (caregivers are free to decline this offer/additional support). If caregiver subjects experience psychological distress or become frustrated with the technology, they can contact Aliviado Support Center (Aliviado.dsd.caregiving@nyu.edu) for assistance. If participants do not feel comfortable answering depressive symptom questions or any questions in any of the study questionnaires, they have the option to select "prefer not to answer" as their response. Subjects may also experience psychological distress when answering questions about their depressive symptoms and will also have the option to select "prefer not to answer".

2.3.2 Risk of Use of Mobile Health Technology

The study mHealth app will only be used to collect study data with IRB approval. Though breach of confidentiality or loss of privacy is possible, we anticipate that either is unlikely to happen because the mHealth app is NYU-housed with IT security approval for research sensitive data and is HIPAA compliant. Data will be collected directly from individual users from the app in an encrypted process where the app is run in a Heroku shield private dynos runtime environment and the data will be stored in a Postgres database housed within a Heroku shield private space encrypted and secured environment (same type of environment that runs the NYU Langone Heath instance of the EPIC haiku app). The app does not access the user's camera or albums and does not track the user's physical activities. Any risks associated are outlined in the informed consent, as follows:

"The optional testing of the beta version of the mHealth app may also subject you to potential risks of breach of confidentiality and psychological distress. However, we anticipate that the likelihood of these potential

risks should be similar to participating in the main co-design workshop and should not exceed what you would expect from your normal day-to-day use of apps that you download from an app store." (Aim 1)

"The Aliviado mHealth app is HIPAA compliant. The use of the Aliviado mHealth app to collect study data is approved by the NYU Grossman School of Medicine. Any information that you enter the Aliviado mHealth app is considered research data. Your data will be de-identified and aggregated with data from other study participants before we perform data analysis. Your data will be processed in an encrypted process and stored within an encrypted and secured environment. Potential risks associated with the use of the study mHealth app include loss of privacy and breach of confidentiality; however, these potential risks would not exceed what you would expect from your normal day-to-day use of commercially available mobile health technology such as apps that you download from an App store." (Aim 2)

2.3.3 Risk of Use of Text Messaging

SMS text messaging will serve as an alternative to mobile push notification to provide reminders, caregiving tips, and words of encouragement to the caregiver study participants. We will obtain consent from participants to send text messages and will include information of the following risks in the consent form:

Text messages are not encrypted, posing a risk to confidentiality, as they can be intercepted or accessed by unauthorized parties, including mobile or cell phone carriers. The security for sensitive or personal information is less robust compared to encrypted emails or secured messaging services, making texts more susceptible to compromise. The reliability of text messages is dependent on mobile network carriers, and neither the research team nor carriers are liable for delays or failures in message delivery. Participants may incur charges from their mobile carriers for texts related to the study, and these costs are the participant's responsibility, not covered by the research institution. It's crucial to note that text messaging is not suitable for emergency communication; in emergencies, participants should contact emergency services directly.

The link to the privacy policy of the SMS text messaging carrier will also be provided: https://www.slicktext.com/privacypolicy.php.

2.3.4 Known Potential Benefits

Caregiver participants may experience potential benefits of improved DSD knowledge and a sense of mastery in performing DSD prevention, detection, and management tasks.

3 Objectives and Purpose

3.1 Primary Objective

The primary objective of this study is to assess feasibility, acceptability, and app usability of the Aliviado DSD Caregiving Mastery Program in a sample of family caregiver of PLWD at risk of delirium.
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3.2 Secondary Objectives (if applicable)

The secondary objective is to examine the preliminary impact of the Aliviado DSD Caregiving Mastery Program on family caregivers' delirium knowledge, caregiving mastery, strain, depression, and burden.

4 Study Design and Endpoints

4.1 Description of Study Design

We will conduct a 2-phase pilot study to develop (Aim 1) and pilot test (Aim 2) an mHealth-enhanced intervention program to promote family caregivers' detection, prevention, and management of DSD in the community (the "Aliviado DSD Caregiving Mastery program"). The first phase (Aim 1/intervention

development) is a 5-week co-design workshop, in which, 8 family caregivers will attend weekly sessions to review the proposed intervention contents and iteratively redesign the user interface of the existing, clinician-facing Aliviado mHealth app to ensure caregiver friendliness. The caregiver version of the Aliviado mHealth app will be built in between study phases, over a 6-week period, including a 4 to 5-week sprint to revise the app user interface based on caregivers' design preferences and another week of preliminary testing with 5-6 caregivers from the co-design workshop to ensure no major navigation issues or broken links before proceeding to the second phase of the study. The second phase of the study (Aim 2) is a 6-week feasibility trial of the full mHealth-enhanced Aliviado DSD Caregiving Mastery program, in which, 30 family caregivers will first complete DSD training over a 2-week period (Week 1-Week 2) and then implement a care plan of tailored DSD detection, prevention and management tasks including weekly delirium assessment in the caregiver mHealth app for another 4 weeks (Week 3-Week 6). The delirium assessment (Family Confusion Assessment Method[7]) has been developed and validated for use by families. This assessment asks family caregivers questions about the symptoms of their loved one over the past day/week/month based on their recall; no questions will be asked to the PLWD directly; no identifiers of the PLWD will be collected. The purpose of having caregiver subjects complete the weekly delirium assessment over this 4-week period (Week 3-Week 6) is to find out whether caregiver subjects can complete this assessment in the mHealth app successfully for several times on their own after watching the self-paced training videos during Week 1 and Week 2, revealing potential issues in completing this assessment, if any.The feasibility trial adopts a single-group, pre-post design. Caregiver participants will be enrolled to the feasibility trial on a rolling basis. Given that this is a feasibility study rather than an efficacy or effectiveness trial, there are no control groups and no PLWD subjects will be enrolled. Demographic information, dementia type/severity, comorbidity, and behavior symptoms of PLWD will be collected at **baseline only**, **anonymously**, to summarize the caregiving context of enrolled caregiver subjects. No PLWD outcome data will be collected in this study.

4.2 Study Endpoints

4.2.1 Primary Study Endpoints

Aim 1 co-design workshop: NA (The purpose of the co-design workshop is to understand caregiver participants' preferences of the intervention contents and app features; no intervention is implemented at this stage and no outcome data collected.)

Aim 2 feasibility trial: Because this is a pilot feasibility study instead of an efficacy or effectiveness trial, the primary study endpoints are feasibility, acceptability, and app usability:

- Feasibility is indicated by (1) successful enrollment of 30 primary caregivers and (2) 85% retention.
- Acceptability is indicated by: (1) >80% of primary caregiver participants reporting high program satisfaction and willingness to recommend this program to others; (2) >80% of primary caregiver participants completing all training videos within the target 2-week timeframe (Week 1-Week 2); and (3) >80% primary caregiver participants successfully complete the weekly delirium screening at least twice over the 4-week implementation period (Week 3-Week 6).
- App usability is assessed by a modified IBM Computer Usability Satisfaction Questionnaire[17] at Week 6 (final visit).

4.2.2 Secondary Study Endpoints

Aim 1 co-design workshop: NA (The purpose of the co-design workshop is to understand caregiver participants' preferences of the intervention contents and app features; no intervention is implemented and no outcome data collected at this stage.)

Aim 2 feasibility trial: Secondary endpoints are caregivers' delirium knowledge, caregiving mastery, strain, depression, and burden. Secondary endpoints are chosen to confirm the theoretical underpinning of the intervention and to provide evidence to support preliminary efficacy of the intervention.

4.2.3 Exploratory Endpoints

Aim 1 co-design workshop: NA (The purpose of the co-design workshop is to understand participants' preferences; no intervention is implemented at this stage.)

Aim 2 feasibility trial: If enough secondary caregivers are enrolled in the study, we will also explore changes in their delirium knowledge and caregiving mastery outcomes.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria

Aim 1 co-design workshop: We will purposely sample 4 "dementia caregivers" and 4 "DSD caregivers". DSD caregivers refer to dementia caregivers who have additional experience caring for a relative or friend during an episode of DSD. The inclusion of caregivers with varying levels of experience and familiarity with DSD will help ensure that we co-produce an mHealth-enhanced intervention that is applicable to caregivers of diverse DSD education/caregiving needs.

a. To be eligible as a "dementia caregiver", an individual must:

- be at least 18 years old,
- be English-speaking,
- provide at least 8 hours of unpaid care weekly or live with a community-dwelling PLWD,
- self-identify as unfamiliar with DSD,
- have the capacity to consent, and
- have Internet access

b. To be eligible as a "DSD caregiver", an individual must:

- be at least 18 years old,
- be English-speaking,
- be a current or past dementia caregiver **with experience caring for a relative or friend during his/her DSD episode within the past 12 months**,
- have the capacity to consent, and
- have Internet access.

Aim 2 feasibility trial:
To be eligible to participate in the feasibility trial, an individual must meet all of the following criteria:

- Being 18 years old or older,
- English-speaking,
- Providing at least 8 hours of unpaid care per week to, or living with, a community dwelling PLWD whose Delirium Risk Assessment Score >=5,
- Having the capacity to give informed consent, and
- Having a smartphone with Internet access.

5.2 Exclusion Criteria

Aim 1 co-design workshop: Individuals who are blind or deaf will be excluded.
Aim 2 feasibility trial: same as above.

5.3 Vulnerable Subjects

NA.

5.4 Strategies for Recruitment and Retention

5.4.1 Use of DataCore/Epic Information for Recruitment Purposes

This study will identify potentially eligible subjects in NYU Langone Health EPIC. The DataCore will pull a list of all potentially eligible primary caregivers of the following three patient groups: (1) individuals who have a diagnosis of dementia, (2) individuals who have had DSD, and (3) individuals who have a diagnosis of dementia and at risk for DSD (e.g., had recent hospitalization, age 75+, etc.). Dementia diagnoses and delirium diagnoses will be confirmed using ICD-10 codes. The study team will discard these lists within 3 business days after the recruitment goal is reached. No information of these lists will be retained by the study team. If the study team decides additional data pull is needed due to slow recruitment/no response from caregivers contacted, the study team will discard the older version of the list as soon as the study team receives a newer version.

Up to three study recruitment messages will be sent via the MyChart online patient portal for the patient to share with their primary caregiver. If the phone number of the primary caregiver is available in EPIC, the study team will call the caregiver (up to three attempts) to follow up on potential study participation after sending the MyChart research message. Approved recruitment language will be used to communicate the reason of the call and the potential caregiver participant will be asked if they are interested in participating in this specific study. Should the potential caregiver subject agrees, the study team will provide the subject with information regarding the next steps for participation. Any personal identifiers of the PLWD will be discarded once caregivers have been recruited. No efforts will be made to relink this research data with PLWD

Before sending the MyChart research message, if the patient has a primary care provider on file, the study team will notify the patient's primary care provider that there are caregivers of their patients eligible to participate in this stduy using the IRB approved Aim 2 physician letter.

If a subject requests information regarding opting out of further recruitment for all research, subjects will be directed to contact research-contact-optout@nyumc.org or 1-855-777-7858.

5.4.2 Caregiver Self-Referrals

It is possible that a potentially eligible caregiver learns about this study via public platforms (e.g., ClinicalTrials.gov, Alzheimer's Association TrialMatch, etc.) or from another caregiver, and then, voluntarily calls or emails the PIs about study participation. When such self-referrals occur, the same screening/consenting procedures outlined in Section 7.3.1 in this study protocol will be followed.

5.4.3 Family Caregiver Registry

The study will leverage the regional family caregiver registry maintained by the University of Pittsburgh Center for Social & Urban Research (UCSUR) to identify potential study participants. This registry includes the names and contact information of unpaid family caregivers who have expressed interest in participating in research studies. UCSUR will send batches of recruitment emails to the family caregivers in the registry with a general study flyer and contact information. If interested, potential subjects will then directly contact the study team, and the same screening/consenting procedures outlined in Section 7.3.1 in this study protocol will be followed.

5.4.4 Clinician Referral

Clinicians at the inpatient geriatrics consult service at NYU Langone's Tisch Hospital / Kimmel Pavilion and Hospital - Brooklyn will distribute IRB-approved study flyers, as well as refer eligible caregivers who have expressed an interest in learning more about the study to the study team by emailing (1) the names of the caregiver and the patient and (2) the phone number of the caregiver to PI Lin in a secure email (SendSafe). PI Lin will verify this information against the geriatrics consult service's patient list and monitor the patient's discharge status. PI Lin will follow up with the caregiver about potential study participation only after the patient has been discharged.

5.4.5 Study Flyers (general), Facebook Recruitment, Recruitment Text Messages, and Information Sessions

A general study flyer will be used to recruit caregivers from caregiver support groups, listservs, or professional organization member forums or special interest groups (e.g., the Gerontological Society of America). With permission from local senior centers or retirement communities, study flyers will also be posted on their bulletins.

Study recruitment information will be provided to dementia organiziations/programs to distribute as Facebook posts if they have an organizational Facebook acocunt.

If a memory/aging program uses text messaging as an existing method to communicate with their program subscribers, the study team will provide the memory/aging program with an IRB-approved recruitment text message to distribute to their subscribers.

Interested caregivers will email Aliviado.dsd.caregiving@nyu.edu about study participation and the study team will perform screening to decide whether the caregiver is a dementia caregiver, a DSD caregiver, or a caregiver of an individual with dementia at risk of DSD.

With permission from caregiver support groups, the study team will also host in-person or online information sessions about the study and collect contact information of interested caregivers.

5.5 Duration of Study Participation

Aim 1 co-design workshop: Caregiver participants will be involved for approximately 6-8 weeks including screening, an enrollment visit, and participation in a 5-week co-design workshop. PLWD will not be enrolled. No PLWD will participate in the co-design workshop. All PLWD info will be based on caregiver report using an anonymous survey link sent to the caregiver subject at the end of the enrollment visit/before the first co-design session.

Aim 2 feasibility trial: approximately 8-10 weeks for each caregiver participant, including screening, baseline/enrollment visit (Week 0), a 6-week intervention period, and a posttest visit. The enrollment of caregiver participants to the Aim 2 feasibility trial is on a rolling basis. PLWD will not participate in the feasibility trial. All PLWD info will be based on caregiver report using anonymous survey links sent to the caregiver subject at the end of the enrollment visit/before the start of the caregiver intervention. Anonymous PLWD data will be collected at baseline only. No outcome data of the PLWD will be collected.

5.6 Total Number of Participants and Sites

Aim 1 co-design workshop: n=8 to 16; collaborative research between 2 academic institutions. “Collaborative” means that each institution carries out part of the research activities. Recruitment will end after 8 caregiver participants are enrolled and a waitlist of another 8 eligible caregivers are identified. We plan to maintain a waitlist of eligible caregivers in case some enrolled caregiver participants decide to leave the study early or cannot attend some of the weekly group co-design sessions due to time conflicts or other reasons. Caregivers on the waitlist will be screened for eligibility before being listed on the waitlist. If any openings of the weekly co-design sessions are available, caregivers on the waitlist will be notified by phone or email from the research team. Before attending the co-design workshop, caregivers on the waitlist will need to provide eConsent in REDCap following the same standard procedure as the enrolled participants. The Aim 1 co-design workshop is collaborative research between two sites, i.e., NYU and the University of Pittsburg. The co-design workshop will be led by the co-PI at the University of Pittsburg via **HIPAA Complaint Zoom** while data collected from the co-design workshop will be stored in the password-protected NYU REDCap or NYU Box as appropriate. Caregiver subjects will be recruited from a list of potentially eligible caregivers identified in the data pull performed by the DataCore. The screening and consenting of all caregiver subjects will be completed by the PI or the co-PI following the “Remote e-Consenting” process using “REDCap” described in the “Use of Electronic Informed Consent”

guidance document. We will create the REDCap version of the IRB-approved consent form following the NYU Health Science Library video series on eConsent.

Aim 2 feasibility trial: n=30 to 60 (30 primary caregivers + 0-30 optional secondary caregivers); single site. The enrollment goal is 30 primary caregiver participants. The 30 enrolled primary caregivers are allowed to invite additional family members or friends to participate in the study and enroll as secondary caregivers. However, the enrollment of secondary caregivers is optional, and thus, we anticipate 0 to 30 secondary caregivers will be enrolled. To ensure the study is adequately powered, we need 26 evaluable primary caregiver participants who complete the study. We will recruit additional primary caregivers if more than 4 primary caregivers drop out of the study, or the number of primary caregiver participants who complete the study has not reached 26. Single site: All participants will be screened, enrolled, and consented at the NYU Site; all data will be collected and stored in the password-protected NYU REDCap or NYU Box as appropriate. Data will be deidentified before uploading to NYU Box. Subjects will be recruited from a list of potentially eligible caregivers identified in the data pull performed by the DataCore. The screening and consenting of all caregiver subjects will be completed by the PI or an NYU research assistant trained by the PI following the "Remote e-Consenting" process using "REDCap" as described in the "Use of Electronic Informed Consent" guidance document. We will create the REDCap version of the IRB-approved consent form following the NYU Health Science Library video series on eConsent.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.7.2 Handling of Participant Withdrawals or Termination

The study team will ask participants to provide their reason(s) for termination and keep a termination log. The study team will email and call the participants for up to three times to obtain their reason(s) for termination; for Aim 2 participants, the study team will also ask participants to provide information on any adverse events/serious adverse events suspected/experienced during their study participation (this is not applicable to Aim 1 participants because Aim 1 is not an intervention study). To reduce the likelihood of participant withdrawals, the study team will clearly explain to potential caregiver participants the study procedures during screening and the consenting process, ensure accuracy of contact information of enrolled caregiver participants, query about any plans to move within the next 6 months, and allow flexibility in scheduling data collection sessions (i.e., scheduling the Aim 1 weekly codesign sessions to the day of the week most participants are availability; allowing +/- 5 days to complete each Aim 2 planned data collection session). Caregiver participants will be encouraged to contact the Aliviado Support Center at Aliviado.dsd.caregiving@nyu.edu for any questions, concerns, or technical support; questions and concerns about the study will be forwarded to the PIs; technical support will be provided by the Support Center staff.

For Aim 1 codesign workshop, we plan to maintain a waitlist of 8 caregivers in case some of the enrolled caregivers drop out of the study or are not able to complete all 5 weekly codesign sessions. Caregivers on the waitlist will be notified of openings of the weekly codesign sessions and will need to complete the standard eConsent procedure in order to attend the codesign sessions.

For Aim 2 feasibility trial, if there are more than 4 dropouts, we will continue to recruit additional caregivers until 26 primary caregivers have completed the study.

5.7.3 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to all investigators, the funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the sponsor and/or IRB.

6 Behavioral/Social Intervention

6.1 Study Behavioral or Social Intervention(s) Description

The Aliviado DSD Caregiving Mastery Program is an mHealth based family caregiver intervention to promote prevention, detection, and management of DSD in the community. The DSD Caregiving Mastery program consists of training videos; symptom management algorithms; assessments; care plans; education articles; mobile push notification or text message reminders and encouragements; and brief communication guides to empower/activate caregivers to discuss probable DSD and deprescribing of delirium-inducing medications with their loved one's healthcare providers. The communication guides are provided to caregiver subjects when they obtain a positive result using the Family Confusion Assessment Method, or when a delirium-inducing medication is identified according to the 2023 updated Beers criteria in the medication list that they provided. Caregivers will be instructed to use these guides to speak with their loved one's health care provider. The training videos will cover the purpose of theses guides, how to use theses guides, the role of family caregiver in delirium prevention, and how to peform the Family Confusion Assessment Method. Their loved one's healthcare provider will be the one to confirm or rule out delirium based on his/her clinical assessment, as well as make recommendations about what to do with the specific delirium-inducing medication based on his/her clinical judgement (continue, stop, reduce dosage, etc.). See Attachment A for the existing delirium-related contents from the existing Alivaido Dementia Care program to be adapted for use by family caregivers. See Box 1 for topics of the training videos to be developed.

Table 2. Topics Covered in the DSD Training Videos for Family Caregivers

Existing Topics in the aide training video (will be shown to the family caregivers in Aim 1 codesign workshop as an example to elicit feedback on how to redesign the video for use by family caregivers)	New topics to be added to the family caregiver version of the training videos (informed by literature review)
• What is delirium? • Symptoms of delirium • Delirium vs dementia • Delirium vs sundowning • Common causes of delirium Link to the existing aide training video.	▪ Important role families play in DSD care (▪ Assess delirium using Family Confusion Assessment Method (FAM-CAM) ▪ 3 case vignettes to practice delirium assessment using FAM-CAM ▪ Daily prevention/management ▪ Prevention/management task while your loved one is hospitalized ▪ Discuss probable DSD/de-prescribing using the tailored communication guides

Because the objective of the Aim 2 feasibility trial is to assess feasibility and acceptability of the intervention in family caregivers instead of efficacy or effectiveness of the intervention, there is no control intervention/treatment. No PLWD will be enrolled. No outcome data of PLWD will be collected. Information of PLWD will only be collected at baseline based on caregiver report in **anonymous** survey questionnaires (no personal identifiers of PLWD being collected).

6.1.1 Administration of Intervention

Caregivers will first complete self-paced training videos (~60 minutes total) over a 2-week period, followed by a 4-week usability testing period in which caregivers will administer an app version of the Family Confusion Assessment Method weekly (~5 minutes/week), perform daily prevention or management tasks specified in a tailored, caregiver-developed care plan, and receive weekly push notification reminders and encouragements. In cases where push notifications are not feasible or cannot be delivered, SMS text messaging will serve as an alternative method to convey motivational messages. This approach ensures that the motification messages related to the research study can still be reliably conveyed to participants. The DSD management algorithm identified in the literature will be simplified and presented as a series of questions to caregivers to guide tailoring of the care plan.
Caregivers can choose to complete the training videos in the mHealth app or on the Aliviado website. Caregivers will learn how to administer the Family Confusion Assessment Method through watching the self-paced training videos.

All caregivers will receive a user manual that provides (1) instructions on how to complete the training/navigate the app; and (2) a log to record questions and daily tasks completed. If a delirium assessment is positive, a tailored communication guide will be provided to facilitate caregivers' discussion of probable DSD with a healthcare provider. If delirium-inducing medications are identified, a tailored communication guide will be generated to facilitate the discussion on de-prescribing.

At enrollment, caregiver's health literacy, caregiving self-efficacy, and comfort with technology will be assessed using the BRIEF Health Literacy Screening, the Revised Scale for Caregiving Self-Efficacy and the Functional Assessment of Comfort Employing Technology Scale to tailor additional support to caregivers (caregivers can decline this offer). For instance, weekly check-in calls will be offered to caregivers with low health literacy over the 2-week training period to ensure understanding of the training material using the teach back method. For caregivers with low self-efficacy, the PI will offer a 1:1 call at the end of the 2-week training period to help caregivers set incremental goals to carry out the care plan. At enrollment, caregivers will also complete the Modified Caregiver Strain Index. Those who score >=7 will be offered referral to external support services such as NYU Alzheimer's Caregiving Program.

All caregivers can contact the NYU Meyers Aliviado Support Center for technical support; questions on how to perform assessments or specific care plan tasks will be forwarded to the PI. Caregivers' usage of the tailored additional support and the Support Center will be recorded and counted towards intervention dosage.

6.1.2 Procedures for Training Interventionalists and Monitoring Intervention Fidelity

The PI and the Aliviado Support Center will facilitate caregiver subjects' accessing the intervention. Intervention fidelity will be assessed through automatically tracking caregivers' completion of the self-paced training videos and Family Confusion Assessment Methods in the mHealth app. Fidelity of implementation of daily DSD prevention/management tasks will be assessed through reviewing caregivers' task completion log (available in the user manual provided to the caregiver).

6.1.3 Assessment of Subject Compliance with Study Intervention

Caregivers' compliance with study intervention will be assessed through reviewing caregivers' daily task completion log during the 3rd and final data collection session.

7 Study Procedures and Schedule

7.1 Study Procedures/Evaluations

7.1.1 Study Specific Procedures

Aim 1: Codesign Workshop

Screening/Informed Consent

- Screen potential subjects by inclusion and exclusion criteria until 8 family caregivers are consented (via HIPAA-compliant Zoom) and formally enrolled in the study and an additional 8 family caregivers meeting the inclusion/exclusion criteria are identified and recorded in a waitlist.

⇓

Baseline/enrollment data collection

- One 1:1 data collection session will be scheduled and completed with each co-design workshop participant at baseline/enrollment. This can be completed during the Zoom call to obtain informed consent with the caregiver participant's agreement or scheduled at a later time.

⇓

5-Week Codesign workshop

Caregiver participants will attend 5 weekly group co-design sessions (90-120 minutes/session) to discuss the following topics:

- *Session 1: family education videos*
- *Session 2: assessments and care plans*
- *Session 3: caregiver education articles and communication guides*
- *Session 4: mobile push notification or text messages to motivate/encourage caregivers*
- *Session 5: final design and features of the mHealth app; ways to best engage other family members in delirium care*

Sample materials to show caregiver subjects in the co-design sessions are provided in Attachment A.

⇓

Optional User Testing: An optional 30-minute, 1:1 user testing session will be scheduled with 5-6 volunteers from Aim 1 participants and waitlist on a first come first serve basis to test the beta version of the new caregiver mHealth app developed based on co-design workshop feedback before starting the Aim 2 pilot feasibility trial.

Aim 2: Pilot Feasibility Trial

Screening/Informed Consent

- Screen potential subjects by inclusion and exclusion criteria until 30 primary caregivers are consented and formally enrolled in the study

  - Optional: enrolled caregivers ("primary caregivers") can choose to invite additional relatives or friends to join the study as "secondary caregivers", who will also need to meet the inclusion/exclusion criteria and provide informed consent to participate in the study
- Obtain informed consent: n=30 primary caregivers + up to 30 secondary caregivers

⇓

Week 0 Baseline/Enrollment Visit, n=30 primary caregivers + up to 30 secondary caregivers

- Collect baseline caregiver demographics, health literacy, caregiving self-efficacy, comfort with technology, strain, *depressive symptoms, burden, delirium knowledge, and DSD caregiving mastery in an online survey questionnaire in REDCap; all information being collected is based on caregiver report.
- Collect caregiver reported PLWD demographics, dementia type/severity, comorbidity, behavioral symptoms, and medications using anonymous (no PLWD identifiers being collected in this study) online survey questionnaires in REDCap.

⇓

Week 1-Week 2 Intervention – Caregiver Education: n=30 primary caregivers + up to 30 secondary caregivers

- Caregivers complete self-paced educational videos on DSD and how to administer a brief delirium screener, the Family Confusion Assessment Method

⇓

Week 2 Visit (Immediately Post Training): n=30 primary caregivers + up to 30 secondary caregivers

- Collect data on caregiver participants' delirium knowledge and DSD caregiving mastery in an online REDCap survey questionnaire.

⇓

Week 3-Week 6 Intervention Implementation: n=30 primary caregivers + up to 30 secondary caregivers

- Caregivers complete weekly delirium screening using the Family Confusion Assessment Method in the study mHealth app.
- Caregivers implement a care plan consisting of delirium prevention or management tasks tailored to their loved one's delirium risk factors.

⇓

Week 6 Final Visit (n=30 primary caregivers + up to 30 secondary caregivers)

- Collect data on caregiver participants' delirium knowledge, DSD caregiving mastery, caregiver strain, depressive symptoms, burden, program satisfaction, and app usability in an online REDCap survey questionnaire.

Also see Attachment C for schedule of events.

*We will stick with CES-D to collect data on depressive symptoms. We were considering replacing it with PHQ-9 because PHQ-9 is a shorter questionnaire. We decided to still use CES-D because it does not ask about suicidal ideation. All de-identified baseline caregiver depressive symptom raw scores will only be analyzed as a group and presented as mean/sd/range (or median/interquartile range/range if not normality distributed).

If a high level of symptoms are found from CES-D, such as depressive symptoms, we will offer to refer subjects to support services that may help with these, such as the NYU Alzheimer's Caregiving Program. This information will remain confidential and will not be shared with others.

If a high level of caregiving strain is found, we will offer to refer subjects to support services that may help, such as the NYU Alzheimer's Caregiving Program, however this information will remain confidential and will not shared with others. If the depressive symptom score has increased for 15 or more points from the baseline/enrollment visit for a subject, our medical monitor, Dr. Brody, (a board-certified nurse practitioner) will call the subjects to better understand thier change in depressive symptoms; determine whether it is related to their study participation; and will refer them to mental health or emergency services as needed.

Rationale for change score: We will calculate the mean and range of the change score from baseline to posttest as a group (=all caregivers' scores lumped together).

If the upper limit of the range of the group change score is below 15, then it means that no one in the group has a substantial increase in their depression score and we will not reach out to any participants about their depressive symptoms.

If the upper limit of the range of the group change score is 15 or above (out of the 60-point CES-D scale), we will look up the participants who have a change score >=15 and notify the medical monitor.

We only care about the change score because for people who have both high baseline and high posttest scores, it just shows that their baseline symptoms have not gotten better or worse over the study period.

7.1.2 Standard of Care Study Procedures

Not applicable.

7.2 Laboratory Procedures/Evaluations

Not applicable.

7.2.1 Clinical Laboratory Evaluations

Not applicable.

7.2.2 Other Assays or Procedures

Not applicable.

7.2.3 Specimen Preparation, Handling, and Storage

Not applicable.

7.2.4 Specimen Shipment

Not applicable.

7.3 Study Schedule

All visits will be completed through phone or Via HIPAA-Compliant Zoom.

7.3.1 Screening

I. Pre-Screening Phase
   - **a.** Potential participants will call or email the PIs using the contact information provided in the recruitment email or mail.
   - **b.** PIs will take the participant's phone call or reply to the inquiry email and explain the study and answer questions. If a potential participant is interested and wishes to proceed, PIs will set up a formal screening appointment with the potential participant.

c. If the potential participant leaves a message, PIs will return their call and explain the study and answer questions within 2 business days. If the potential participant is interested and wishes to proceed, PIs will set up a formal screening appointment with the potential participant.

d. A research assistant-trained by the PI will call potential participants referred by clinicians and caregivers who do not respond to email nor mail to tell them about the study using the IRB-approved phone script and ask screening questions. The name of the interested and potentially eligible participants will be given to the PIs. PIs will then set up a formal screening appointment with each potential participant. The research assistant will send the informed consent materials electronically to the potential participant through SendSafe/REDCap to review.

II. Screening Phase

a. PIs will meet with the potential participant over the phone to explain the study procedures and answer questions.

b. PIs will begin the process of ensuring that participant meets eligibility criteria as outlined in Section 5.1. The Sour Seven questionnaire will be used to help determine whether a caregiver is a “dementia caregiver” or a “DSD caregiver” if a potential caregiver participant is unsure whether or not their loved one has had DSD within the past 12 months (“We are looking for two types of caregivers of persons with dementia. To help us better decide which category you would fit the best, we are going to ask you some additional screening questions. Thinking of the past 12 months, was there a change in your loved one's health status, such as hospitalization or a new infection? If so, do you recall observation of any of the following, right before, during, or after the hospitalization or the infection: ").

c. PIs will probe for participant’s ability to complete the duration of the study. These questions are used as indicators of potential early study dropouts. Potential caregiver participants’ response to these quesionts will not be used to exclude them from study participation.

i. Is the participant planning to move within the next 6 months?
ii. Is the participant looking for a new job?
iii. Is the participant in the military, and/or do they have a spouse in the military?

III. Consenting Phase

a. If the caregiver is eligible and wishes to participate, PIs will then schedule a follow-up Zoom call with the caregiver within a week to complete the e-Consenting process together in REDCap. If the caregiver has not received a copy of the consent form from the research assistant, then PIs will email or mail a copy of the consent form to the potential caregiver participant in advance based on the caregiver’s preference. Eligible caregivers can also choose to proceed to complete the e-Consenting process described below within the same Zoom call.

b. During the Zoom call (HIPAA compliant Zoom), PIs will open a new REDCap e-consent form in REDCap, share the screen and go over the IRB-approved REDCap e-consent and HIPAA authorization form, page by page, with the caregiver. The eConsent link will be provided as soon as available for IRB review and before use with caregiver subjects. The e-consent process informs the potential caregiver participant about the study, describes potential risks and benefits, indicates that the participation is voluntary and that he/she has the right to stop at any time. The PIs will also provide the potential caregiver participant contact information in case of medical emergency due to study participation and questions about subject rights, as well as explain who have access to study data and protected health information (PHI), how confidentiality is maintained, how the participant may receive the outcome of the study and incentives for study participation. The PI consenting the caregiver will ensure that the eligible caregiver has the opportunity to consider whether to participate and ask questions before electronically signing the consent and HIPAA authorization forms in REDCap during the Zoom call, as well as at anytime during their involvement in the research study.

If the caregiver decides to give consent, the PI consenting the caregiver will give the caregiver remote control over his/her mouse in his/her device to initial and sign the REDCap e-consent and HIPAA authorization form in REDCap. After signing electronically, the caregiver will receive an electronic copy of the signed consent and HIPAA authorization form immediately in an automatically generated email from REDCap. If a caregiver has difficulty signing the e-Consent form in REDCap using the PI's mouse via remote control, the PI will email the caregiver a link to the REDCap e-Consent form and have the caregiver open the consent form in their local device (computer, laptop, etc.) to initial and sign in REDCap. Caregivers enrolled in the feasibility study phase will have the option to include additional secondary caregivers, who will undergo the same e-Consenting process.

7.3.2 Enrollment/Baseline

Aim 1 codesign workshop: One 1:1 data collection visit will be scheduled and completed with each participant at baseline/enrollment (Week 0). The enrollment/baseline visit will be scheduled within 7 days from the time of informed consent. Participants can choose to complete the baseline/enrollment data collection in the same Zoom call in which they complete the eConsent. The following information will be collected in online REDCap survey qustionnaires:

- ✓ Demographics
- ✓ Familiarity with DSD
- ✓ Health literacy
- ✓ Comfort with technology

Aim 2 feasibility trial: One 1:1 data collection visit will be scheduled and completed with each participant at baseline/enrollment (Week 0). The enrollment/baseline visit will be scheduled after the informed consent has been obtained and based on the participant's availability. Participants can choose to complete the baseline/enrollment data collection in the same Zoom call in which they complete the eConsent. The following information will be collected in online REDCap survey questionnaires:

- ✓ Demographics
- ✓ Dementia severity
- ✓ Behavioral symptoms
- ✓ Health literacy
- ✓ Caregiving self-efficacy
- ✓ Comfort with technology
- ✓ Strain
- ✓ Depression
- ✓ Burden
- ✓ Delirium knowledge
- ✓ DSD caregiver mastery

7.3.3 Intermediate Visits

Aim 1 codesign workshop: Caregiver participants will attend 5 weekly group co-design sessions (90-120 minutes/session) to discuss the following topics. The first group co-design session will be scheduled within

a week after 8 participants have completed their baseline/enrollment visit. Each session will be video recorded along with live chat via HIPAA Compliaint Zoom.

- *Session 1: family education videos*
- *Session 2: assessments and care plans*
- *Session 3: caregiver education articles and communication guides*
- *Session 4: mobile push notification or text messages to motivate/encourage caregivers*
- *Session 5: final design and features of the mHealth app; ways to best engage other family members in delirium care*

Aim 2 feasibility trial: The second 1:1 study visit will be scheduled in Week 2 (+/-5 days) to assess changes in delirium knowledge and DSD caregiving mastery immediately after each participant has completed the self-paced training videos on DSD in online REDCap survey questionnaires.

7.3.4 Final Study Visit

Aim 1 codesign workshop: See 7.3.3 above for information about the fifth co-design session. An optional 30-minute, 1:1 user testing session will be scheduled with 5-6 volunteers from Aim 1 participants and waitlist to test the beta version of the new caregiver mHealth app developed based on co-design workshop feedback in-between the 2 study phases. The fifth co-design session and the 1:1 session will both be video recorded along with live chat via HIPAA Compliaint Zoom.

Aim 2 feasibility trial: The final 1:1 study visit will be scheduled in Week 6 (+/-5 days) to collect data on the following using online REDCap survey questionnaires:

- ✓ Caregiver strain
- ✓ Depression
- ✓ Caregiver burden
- ✓ Caregiver delirium knowledge
- ✓ DSD caregiver mastery
- ✓ Program satisfaction
- ✓ App usability

7.3.5 Withdrawal Visit

The PI or co-PI will email the subject up to 3 times and call the subject up to 3 times to obtain the reason(s) for the voluntary withdrawal. For Aim 2 participants, information on adverse events/serious adverse events suspected or experienced during their study participation will also be collected at this time. Reporting of adverse events/serious adverse events is not applicable to Aim 1 participants because the Aim 1 codesign workshop is not an interventional study.

7.3.6 Unscheduled Visit

For the Aim 1 co-design workshop, a group attendance sheet will be maintained to log attendance of the five weekly codesign sessions, along with reasons for absence. A group co-design session will be rescheduled, or a makeup session will be provided, if most of the participants are not able to attend a particular scheduled group co-design session.

For the Aim 2 feasibility trial, data collection must be completed within +/- 5 days of each planned data collection session. Reasons for incomplete sessions will be documented in REDCap.

7.4 Concomitant Medications, Treatments, and Procedures

Not applicable.

7.5 Justification for Sensitive Procedures

Not applicable.

7.5.1 Precautionary Medications, Treatments, and Procedures

Not applicable.

7.6 Prohibited Medications, Treatments, and Procedures

Not applicable.

7.7 Prophylactic Medications, Treatments, and Procedures

Not applicable.

7.8 Participant Access to Study Intervention at Study Closure

Not applicable.

8 Assessment of Safety

8.1 Specification of Safety Parameters

The following sections are only applicable to the Aim 2 feasibility trial because the Aim 1 codesign workshop is not an interventional study.

8.1.1 Definition of Adverse Events (AE)

An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. In this minimal risk study, the sole anticipated potential AE is breach of confidentiality and will be monitored for.

8.1.2 Definition of Serious Adverse Events (SAE)

Serious Adverse Event
Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

8.1.3 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

8.2 Classification of an Adverse Event

8.2.1 Severity of Event

The following guidelines will be used to describe severity of adverse events.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 Relationship to Study Intervention

The medical monitor's assessment of an AE's relationship to study intervention is part of the documentation process, but it is not a factor in determining what is or is not reported in the study. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to study intervention assessed. In a clinical trial, the study intervention must always be suspect. To help assess, the following guidelines are used. Dr. Abraham Brody will adjudicate the relatedness of AEs to the study participation.

- ***Related*** *– The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.*
- ***Not Related*** *– There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.*

8.2.3 Expectedness

Dr. Abraham Brody will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

We will follow the reporting requirements outlined in the NYU SOM IRB policies and procedures. Figure 4 and Figure 5 are screenshots of the reporting requirements.

Figure 4. Defintions of Adverse Event, Unrelated and Related to the Rearch and Reporting Requirements

indicates that the research procedures caused harm to subjects or others or indicates that subjects or others are at increased risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse Event
Any physical, psychological or social harm occurring to subjects during the course of participating in research, whether or not it is related to participation in the research. An Adverse Event can be any unfavorable or unintended event that is temporally related to the research. Examples of Adverse Events include: abnormal laboratory findings, nightmares, broken wrist, upper respiratory tract infection, nausea and vomiting, and other symptoms or diseases. Although Adverse Events occur most commonly in the context of biomedical research, Adverse Events can occur in the context of social and behavioral research.

Unanticipated
An event is "Unanticipated" when its nature, frequency, specificity and severity are not expected, given the research procedures described in the protocol-related documents and characteristics of the subject population being studied, and are not accurately reflected in the informed consent document, protocol and/or investigator's brochure.

Related to the Research
An event is "Related to the research procedures" if in the opinion of the Principal Investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current subjects.

Reporting Requirements

All Unanticipated Problems, meaning those that are **serious**, **unexpected**, and **related** to the research activity, must be reported to the NYU Langone Health IRB. Not all Unanticipated Problems involve direct harm to subjects. Events can occur which are unexpected and result in new circumstances that increased the risk of harm to subjects without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the subjects, individuals the subject may come in contact with, family members, research personnel, etc.) in addition to the subjects. In each case, even if the event did not cause any detectable harm or adverse effect to subjects or others, they nevertheless represent Unanticipated Problems and should be promptly reported under this Policy.

Principal Investigators must report to the IRB as soon as possible, but in all cases within ten (10) working days of becoming aware of and/or receipt of information about any of the following:

- Adverse Events which, in the opinion of the Principal Investigator, are both unexpected and Related to the research. The IRB only requires Unanticipated Adverse Events and Serious Adverse Events that are Related to the research to be reported to the IRB.
- Unanticipated Problem Related to the research that exposes individuals other than the research subjects (e.g., investigators, research assistants, students, the public, etc.) to potential risk.
- Information that indicates a change to the risks or potential benefits of the research. For example:
  - an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than those initially presented to the IRB, or
  - a paper is published from another study that shows that the risks or potential benefits of the Principal Investigator's research may be different than initially presented to the IRB.
- A breach of confidentiality, including the loss of digital storage devices that contained research data.
- Change in subject's status during the course of their participation in a study that might affect their

Figure 5. Reporting Requirements (con.)

eligibility to remain in the study. Examples: Incarceration of a subject in a protocol not approved to enroll prisoners; pregnancy during research participation; children who reach the age of majority (in New York State, age 18) during study participation.

- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject. For clarity, the NYU Langone Health IRBs do not require reporting of unintentional or intentional changes to the IRB-approved protocol (protocol deviations) unless the deviation was made due to concerns of subject safety or rises to the level of a protocol deviation.
- Complaint of a subject or subject's family member when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.
- Protocol violation. A protocol violation refers to an accidental or unintentional change to the IRB-approved protocol that harmed subjects or others or that indicates subjects or others may be at increased risk of harm. Examples: receipt of wrong dose of study medication.
- Event that requires prompt reporting to the study sponsor.
- Sponsor-imposed suspension of the research based on risk.

If the Unanticipated Problem is a subject's death, the Principal Investigator should report such event to the IRB no later than five (5) calendar days of becoming aware, whether or not causality (relatedness to the research) has been determined.

The IRB will accept other reports when the Principal Investigator is unsure whether the event should be reported. The Principal Investigator should first contact the IRB Office by email or telephone to determine if the reporting is necessary under this Policy.

Study staff should report the above events electronically using IRB/Research Navigator. The IRB/Research Navigator submission is titled *Reportable New Information*.

If the event requires immediate intervention to prevent serious harm to subjects or others, the investigator may act accordingly to prevent harm and then must report the event within five (5) days.

Investigators must report all other possible Unanticipated Problems occurring at the local research site and non-local research sites to the IRB as soon as possible but no later than ten (10) business days from the date of the event or from the date the investigator is notified of the event.

Problems occurring within thirty (30) days after subjects' active participation or treatment must be reported according to the above schedule.

Investigators or the study team must report possible Unanticipated Problems to the IRB Office in writing using the Unanticipated Problem Reporting Form. The written report should contain the following:

- detailed information about the possible Unanticipated Problems, including relevant dates
- any corrective action, planned or already taken, to ensure that the possible Unanticipated Problems is corrected and will not occur again
- an assessment of whether any subjects or others were placed at risk as a result of the event or suffered any physical, social, or psychological harm and any plan to address these consequences
- any other relevant information
- any other information requested by the IRB Office

A report of a possible Unanticipated Problem involving risks to subjects or others will be immediately forwarded by IRB Office staff to the IRB Chair if the IRB Office staff believes that immediate intervention may be required to protect subjects or others from serious harm.

8.4 Reporting Procedures – Notifying the IRB

There are no anticipated SAE related to this minimal risk study. Any AE or SAE that is determined by the study medical monitor to be related to the study, or an unanticipated problem, will be reported following the NYU SoM IRB policies and procedures (also see Figure 4 and Figure 5).

8.4.1 Adverse Event Reporting

We recognize that some caregivers might experience psychological distress resulting from learning a new mHealth app during the feasibility trial. Therefore, we will passively monitor any psychological distress reported by caregivers. The term "passive" or "passively" refers to the reliance on voluntary caregiver report, in contrast to the study team's administration of regular screening throughout the study period to "actively" monitor any changes in psychological distress in caregiver participants.

A summary of all adverse events and serious adverse events will be reported to the NIA Program Officer and the Safety Officer on a quarterly basis.

8.4.2 Serious Adverse Event Reporting

This is a minimal risk study and we do not anticipate any serious adverse events resulting from study participation. Any unanticipated SAE that is determined to be related to this study will follow the following reporting procedure:

Unanticipated Problem Reporting

Upon notification of any Unanticipated Problems:

1. PI Lin will first notify the NYU Medical Monitor, Dr. Abraham A. Brody, within 24 hours to determine whether the unanticipated problem is related to study participation.
2. PI Lin will send out a notification email to the IRB, the Emory Roybal Center (to forward the information to the NIA Program Officer), and the Safety Officer within 48 hours of any unanticipated problem that is determined to be related to study participation.
3. PI Lin will also submit a Reportable New Information form in the Research Navigator within 5 calendar days of IRB-reportable AE/SAE/Unanticipated Problems including breaches of confidentiality.
4. Upon advisement by the IRB, NIA, and Safety Officer, PI Lin will determine the study's status and notify the Study Team.
5. PI Lin will advise the Study Team regarding screening, enrollment, and ongoing participation.

8.4.3 Reporting of Pregnancy

Not applicable.

8.5 Reporting Procedures – Notifying the Study Sponsor

Per NIA policy, all AE that are serious and unexpected should be submitted to the NIA and Safety Officer within 48 hours of the site awareness. The Safety Officer will propose AE and SAE definitions and frequency of monitoring and reporting. A copy of the data safety monitoring plan will be attached to this study protocol once it is approved by the NIA-appointed Safety Officer.

There are no specific stopping rules of the study given that this is a minimal risk study. However, the study may be terminated or suspended based on the judgement of the Safety Officer.

8.6 Study Halting Rules

Aim 1 co-design workshop: Not applicable. No intervention will be implemented during the co-design workshop. Participants will only review the proposed intervention contents for the Aim 2 feasibility trial and provide feedback for improvement/refinement. The purpose is to understand the participants' preferences.

Aim 2 Feasibility Trial: This study phase may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Safety-related temporary suspension or termination will be determined by the Safety Officer.

Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to all investigators, the funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed and satisfy the sponsor and/or IRB.

8.7 Safety Oversight

It is the responsibility of the PI to oversee the safety of the study. Any AE/SAE will first be reported to the PI and then forwarded to the local Medical Monitor, Dr. Abraham A. Brody, to adjudicate their severity and relatedness to study participation. The Medical Monitor will review all AEs on a regular basis throughout the trial and be available to advise the PI on trial related medical questions or problems. This safety monitoring will include careful assessment and appropriate reporting of AE/SAE following the approved study data and safety-monitoring plan approved by the Safety Officer. Medical monitoring will include a regular assessment of the number and type of serious adverse events. The NIA-appointed Safety Officer will review the data safety monitoring plan and the IRB-approved study protocol. Handeling of protocol deviations is detailed in Section 14.3 below.

Data safety monitoring reports will be submitted to the IRB during the annual continuing review, unlesss a shorter reporting period is required by the IRB.

- **Medical Monitor: Dr. Abraham A. Brody**
  Dr. Brody is the associate director of the Hartford Institute for Geriatric Nursing and professor in the Departments of Nursing and Medicine at NYU Grossman School of Medicine. He is a board certified geriatric and palliative nurse practitioner who is priviledged at NYU Langone to perform research monitoring as a member of the medical and dental staff. As part of his experience and expertise, including in several prior NIH funded extramural awards, Dr. Brody will perform assessments of emergent depressive or other psychological symptoms identified in participants and determine the need for referral, treatment, or emergent services.

Safety oversight will be under the direction of an NIA-approved Safety Officer, Dr. Kenneth Boockvar. The Safety Officer will evaluate cumulative participant safety data and make recommendations regarding the safety continuation of the study. The Safety Officer will define and approve all data elements needed to assess trial safety.

- **Safety Officer: Dr. Kenneth Boockvar**

Dr. Boockvar is Acting Director at JJ Peters VA Medical Center; Professor of Geriatrics and Palliative Medicine, Icahn School of Medicine at Mount Sinai; and Director of Clinical Studies, Jewish Home Lifecare. Dr. Boockvar has considerable experience conducting research and implementing geriatrics models of care with front-line health care providers, including developing, implementing, and testing interventions designed to prevent delirium. Dr. Boockvar has been the PI on projects examining care for patients with complex illness since 2000, with continuous funding since 2001, using health services and clinical research methods, both qualitative and quantitative. Currently, Dr. Boockvar is the PI on projects examining 1) medication prescribing in nursing home residents and individuals with dementia; and 2) delirium assessment and prevention in long-term nursing home residents. As a leader/core leader of the VA Center for Medication Safety in Aging, the U.S. Deprescribing Research Network, and the Mount Sinai Pepper Center, Dr. Boockvar has considerable experience reviewing and monitoring clinical trials.

9 Study Monitoring

Study site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

- The PIs will conduct centralized monitoring of all data collected for the feasibility trial; assess data quality on a weekly basis during the weekly PI meetings with 100% data verification; and generate quarterly data monitoring reports.

- The PIs will monitor all visits and study forms to:
  - Ensure maintenance of required study documents
  - Verify adherence to the study protocol
  - Monitor the quality of data collected
  - Ensure accurate reporting and documentation of all adverse events and unanticipated problems
  - Ensure the rights and safety of participants
  - Confirm that the study is conducted in accordance with GCP guidelines

- During weekly PI meetings, the PIs will review all study forms completed in the previous week to ensure:
  - Informed consent has been obtained and documented in accordance with IRB regulations
  - The information recorded on the forms is complete and accurate
  - There are no omissions in the reports of specific data elements
  - Missing visits are indicated on the forms
  - Participant disposition when exiting the study is accurately recorded
  - All errors and corrective actions will be entered into a Data Management Log and the Protocol Deviation Form as appropriate.

10 Statistical Considerations

10.1 Statistical and Analytical Plans

Statistical considerations of this study are described in the following sections. However, given that this is a small feasibility trial, no additional formal Statistical Analytical Plan will be developed.

10.2 Statistical Hypotheses

Primary hypothesis: The Aliviado DSD Caregiving Mastery Program will be feasible, acceptable and usable to family caregivers of persons living with dementia at risk for DSD.

Secondary hypothesis: The Aliviado DSD Caregiving Mastery Program will improve caregivers' delirium knowledge and DSD caregiving mastery, as well as decrease caregiver strain, depression, and burden.

10.3 Analysis Datasets

Aim 1 and Aim 2 samples will be analyzed separately.

10.4 Description of Statistical Methods

10.4.1 General Approach

Descriptive statistics will be calculated to summarize caregiver characteristics and baseline data. Continuous variables will be presented as mean and standard deviations (or median and interquartile ranges). Categorical variables will be presented as percentages.

10.4.2 Analysis of the Primary Efficacy Endpoint(s)

The primary endpoint of this study is feasibility, acceptability, and app usability. Descriptive statistics will be calculated to summarize feasibility, acceptability, and app usability outcomes. Estimates will be reported with 95% confidence intervals.

10.4.3 Analysis of the Secondary Endpoint(s)

Paired t-tests will be performed to compare changes in delirium knowledge and caregiving mastery from baseline to 2 weeks (immediately post training), and changes in delirium knowledge, caregiving mastery, caregiver strain, depression, and burden from baseline to posttest (Week 6); effect sizes (Cohen's d) will be reported for all outcomes. To maintain the familywise error rate, we will use Bonferroni-adjusted alpha to determine significance.

10.4.4 Safety Analyses

NA

10.4.5 Adherence and Retention Analyses

We will calculate the Aim 1 co-design workshop attendance rate.
Adherence to the Aim 2 intervention will be assessed by the number of delirium assessments performed, the number of videos watched, and the daily DSD prevention management tasks logged. We will also calculate the retention rate (i.e., the number of participants who complete the study divided by the number of participants enrolled).

We will conduct an exploratory analysis to assess the dose effect, using a linear mixed model to examine caregiver knowledge gains, controlling for the degree of video completion. While not sufficiently powered, this analysis will provide preliminary estimates of the impact associated with degree of participation on caregiver knowledge, and will provide informative context for the results from the unadjusted analyses. Estimates will be reported with 95% confidence intervals to convey the precision of estimates.

10.4.6 Baseline Descriptive Statistics

Descriptive statistics will be calculated for all variables collected at the baseline/enrollment visit.

10.4.7 Planned Interim Analysis

Not applicable (NA).

10.4.7.1 Efficacy Review

NA

10.4.8 Additional Sub-Group Analyses

NA

10.4.9 Multiple Comparison/Multiplicity

NA

10.4.10 Tabulation of Individual Response Data

NA

10.4.11 Exploratory Analyses

We will also track the usage of the intervention by secondary caregivers enrolled, if any. If enough secondary caregivers participate, we will also explore changes in their delirium knowledge and caregiving mastery outcomes.

10.5 Sample Size

Aim 1 co-design workshop: We aim for 5-8 participants per session based on recommendations from Smaradottir et al.[29] and our consultation with a Design Thinking expert from the Emory Roybal Center Design Studio. Accordingly, the target sample size is 8 caregivers (plus 8 on the waitlist).

Aim 2 feasibility trial: Because improvement in delirium knowledge should occur before improvement of caregiver mastery, our power calculation is based on delirium knowledge. Home health aides exposed to the current Aliviado videos demonstrated medium-to-large knowledge gains (Cohen's d = .64). We will have 80% power to detect an effect of this magnitude in 26 caregivers, using a Bonferroni adjusted significance level of $\alpha = .025$. The expected gains will likely be larger, as previous research with a similar delirium intervention using telephone-based education modules found even greater improvement at 2 weeks (Cohen's d = .86) and 2 months (d = .87) post-intervention,[30] and our projected sample of 26 will yield >99% power to detect similar effects. To allow for a 12% dropout rate and remain adequately powered, we aim to recruit 30 caregivers.

10.6 Measures to Minimize Bias

10.6.1 Enrollment/Randomization/Masking Procedures

NA

10.6.2 Evaluation of Success of Blinding

Not applicable.

10.6.3 Breaking the Study Blind/Participant Code

Not applicable.

11 Source Documents and Access to Source Data/Documents

All data collected for this study will be maintained in an electronic format. All e-Consent and HIPAA documents will be collected and stored on the password-protected REDCap system with 2 factor-authentication. All surveys will be collected through online NYU REDCap survey quesionanires, cleaned, deidentified, and uploaded to a secure folder in PI Lin's password-protected NYU Box research space with

2 factor-authentication. Where there are unanticipated problems, adverse events or serious adverse events, the corresponding report forms will be filled out and maintained in REDCap. Protocol deviation forms will be filled out and maintained in a secure folder within PI Lin's NYU Box research space for reporting purposes. PI Lin will be responsible for creating and maintaining an electronic study binder in REDCap. During weekly meetings, PI Lin and PI Choi will review all forms completed in the previous week to ensure accuracy, as well as edit/update the forms as needed. All corrections made will be recorded in a Data Management Log in a secure folder within PI Lin's NYU Box research space and be updated and maintained by both PIs.

12 Quality Assurance and Quality Control

Validation checks will be set up for all items in all electronic study forms and surveys. Survey data will be downloaded in csv or Excel format, deidentified, and cleaned in STATA and/or R on a weekly basis, uploaded to a secure folder within PI Lin's NYU Box research space and then be reviewed during the weekly PI meeting to ensure accuracy. Descriptive statistics and graphs will be used to identify outliers and unusual values.

During the weekly PI meetings, the PIs will review the REDCap dashboard and verify that all forms are complete and on schedule; reasons for incomplete or delays in completion will be recorded in REDCap (and the Protocol Deviation Form if applicable). Any potential data entry errors will be discussed and corrected during the weekly PI meeting. All corrections made will be recorded in the Data Management Log. If needed, the PIs will reach out to participants to confirm their information accuracy.

Recordings from the co-design workshop (audio, video, live chat) will be encrypted and labeled only with a code number, which will be kept in a password-protected REDCap folder only accessible by the Principal Investigator and the co-Principal Investigator. Recordings will then be transcribed, deidentified and uploaded to a secure folder in PI Lin's NYU Box research space with two factor authentication for later data analysis. PIs will verify accuracy of the transcripts and the original recordings may be consulted as needed.

13 Ethics/Protection of Human Subjects

13.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

13.3 Informed Consent Process

13.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to participating in any study activities.

13.3.2 Consent Procedures and Documentation

All informed consent will be completed following the HIPAA compliant, remote e-Consenting method approved by NYU Langone Health. A potential caregiver participant will first be screened remotely through a telephone call with PIs (or be pre-screened by a research assistant during a recruitment call and then formally screened by the PIs via phone) to confirm eligibility. If the caregiver is eligible and wishes to participate, PIs will then schedule a follow-up Zoom call (via HIPAA compliant Zoom) with the caregiver to complete the e-Consenting process together in REDCap. A copy of the consent form will be emailed or mailed to the potential caregiver subject in advance to review before the consenting Zoom call. During the HIPAA compliant Zoom call, PIs will share the screen and go over the IRB-approved REDCap e-consent and HIPAA authorization form, page by page, with the caregiver. The e-consent process informs the potential caregiver participant about the study, describes potential risks and benefits, indicates that the participation is voluntary and that he/she has the right to stop at any time. PIs will also provide the potential caregiver participant contact information in case of medical emergency due to study participation and questions about subject rights, as well as explain who have access to study data and protected health information, how confidentiality is maintained, how the participant may receive the outcome of the study and incentives for study participation.

PIs will ensure that the eligible caregiver has the opportunity to consider whether to participate and ask questions before electronically signing the consent and HIPAA authorization form in REDCap during the Zoom call, as well as at anytime during their involvement in the research study. If the caregiver decides to give consent, PIs will give the caregiver remote control over the mouse of the PI's device to initial and sign the REDCap e-consent and HIPAA authorization form in REDCap. After signing electronically, the caregiver will receive an electronic copy of the signed consent and HIPAA authorization form immediately in an automatically generated email from REDCap. If caregivers have difficulty signing through remoate control over the PI's mouse, then a link to the REDCap e-consent form will be emailed to the caregiver to sign and initial in REDCap, Caregivers enrolled in the feasibility study phase will have the option to include additional secondary caregivers, who will undergo the same e-Consenting process. Electronic informed consent and HIPAA authorization documents with subject information will be collected, stored, and maintained on the password-protected REDCap system with 2 factor-authentication. Only authorized study team members will have access to the consent and HIPAA authorization forms stored in REDCap.

13.3.3 Waiver of Authorization/Consent

The following is applicable to Aim 2 feasibility trial only:

The study team will obtain a waiver of authorization/consent to view the patient's discharge status in EPIC to determine whether and when to contact the potential caregiver participants referred by the inpatient geriatrics consult teams (see **5.4.4 Clinician Referral**). According to feedback from the inpatient geriatric consult team, caregivers are too overwhelmed to consider study participation when their loved one is still in the hospital. The referral clinician suggests that the study team reaches out to caregivers only after their loved one is discharged. Because the referral clinician cannot predict the discharge date and location in advance and suggests that after they have made the referral, the study team monitors the patient's discharge status in EPIC to determine whether and when to follow up with their caregiver about study participation.

13.4 Posting of Clinical Trial Consent Form

Not applicable.

13.5 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, or representatives of the IRB may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored in REDCap for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be deidentified and stored in a password-protected NYU Box folder. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by the study team will be secured and password protected.

13.5.1 Research Use of Stored Human Samples, Specimens, or Data

Data collected from this study will be deidentified and shared following NIH's data sharing policy as appropriate.

13.6 Future Use of Stored Specimens

NA.

14 Data Handling and Record Keeping

14.1 Data Collection and Management Responsibilities

A research assistant trained by the PI will conduct phone recruitment and log phone screening/recruitment results in REDCap (e.g., interested/declined/did not answer). The PIs will collect the rest of the study data and will be responsible for managing and validating of all study data.

14.1.1 Data Collection in REDCap Online Survye Questinonaires

PIs will complete measures specified in Table 3 and Table 4 in REDCap online survey qeustionnaires based on caregiver report.

Table 3. Aim 1 Measures (In the Form of Online REDCap Survey Quesionnaires)

Variable	Measure	Administration Time (mins)[a]
Caregiver and care recipient demographics information	Demographic quesionnaires developed by the study team.	5
DSD exposure	Did your provide care to or visit your loved one when he/she had a delirium episode within the past 12 months? (Yes/No)	<1
Health literacy	BRIEF Health Literacy Screening (4 items)	2
Comfort with technology	Functional Assessment of Currently Employed Technology Scale (10 items)	3

Table 4. Aim 2 Measures (in the Form of Online REDCap Qustionniares)

Variable	**Measure**	**Administration Time (mins)**	**Timeline[a]**		
			Baseline/ enrollment (Week 0)	Immediately post training (Week 2)	Posttest (Week 6)
Caregiver and care recipient demographics information	Demographic questiobnaires developed by the study team	5	Yes	-	-
Health literacy	BRIEF Health Literacy Screening (4 items)	2	Yes	-	-
Comfort with technology	Functional Assessment of Currently Employed Technology Scale (10 items)	3	Yes	-	-
Dementia Severity	Quick Dementia Rating System (10 items)	4	Yes	-	-
Behavioral and psychological symptoms of dementia	Neuropsychiatric Inventory Questionnaire (12 items)	5	Yes	-	-
Caregiver strain	Modified Caregiver Strain Index (13 items)	5	Yes	-	Yes
Caregiver Depression	Center for Epidemiological Studies Depression Scale (20 items)	4	Yes	-	Yes
Caregiver Burden	Short Form Zarit Burden Interview (12 items)	3	Yes	-	Yes
General caregiving self-efficacy	Revised Scale for Caregiving Self-Efficacy (15 items)	3	Yes	-	Yes
DSD Caregiving Mastery	A DSD Competence Scale modified from Pearline's Competence Scale with	5	Yes	Yes	Yes

	additional items developed by the Aliviado team to assess confidence and completion of DSD prevention, detection, and management tasks (14 items)				
Caregiver Delirium Knowledge	Caregiver Delirium Knowledge Questionnaire (19 items)	5	Yes	Yes	Yes
Program satisfaction	13 Likert-type questions to assessment program satisfaction and willingness to recommend the program plus one optional open-ended question to provide additional feedback (14 items total)	3-5	-	-	Yes
Usability	A modified IBM Computer Usability Satisfaction Questionnaire developed by the Aliviado team (24 Likert-type questions + 3 optional open-ended questions to provide additional feedback)	5-10	-	-	Yes

14.1.2 Data Collection Tools – Mobile Health Technology

Products and Devices

The Aliviado mHealth app is NYU-housed and will only be used to collect study data with IRB approval and if the subject has agreed to all applicable Terms of Service. The Aliviaod mHealth app does not include location tracking services. The app will not track participants' geographic location or physical activities. Time logged in to the app, number of care plans and assessments completed, number of videos watched, etc. will be automatically tracked by the Aliviado app (app usage).

14.2 Study Records Retention

All study records will be maintained for at least three years after the conclusion of final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained. All identifiers will be destroyed 3 years after the end of the study. Deidentified data may be uploaded to the NYU data repository or an external data repository if required by the NIH/NIA.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or MOP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the PI to not deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the subject. The PI will submit an amendment request to the IRB and receive written approval prior to the implementation of any change to the protocol.

It is the responsibility of the study site to use continuous vigilance to identify and report deviations within 2 working days (48 hours) of identification of the protocol deviation, or within 2 working days (48 hours) of the scheduled protocol-required activity. All deviations must be addressed in study source documents.

The PI will report protocol deviations that impact participant safety within 48 hours of occurrence to the study Medical Monitor (Dr. Ab Brody), IRB, NIA Program Officer (via Emory Roybal Center for Caregiving Mastery), and the Safety Officer. All other deviations will be reported as part of the quarterly Data Safety and Monitoring Report to the NIA/Emory Roybal Center for Caregiving Mastery and the Safety Officer. The PI will maintain a log of all protocol deviations and causes, develop mitigation measures within 7 days of any protocol deviations/violations, and notify the whole study team of such measures to ensure no further issues.

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

- Enrollment of an ineligible participant
- Failure to obtain Informed Consent
- Visits or procedures conducted outside of the protocol specified window
- Failure to keep IRB approval up to date
- Follow-up visit at a time point different from that specified in the protocol

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

14.4 Publication and Data Sharing Policy

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy, and the Section 801 of the Food and Drug Administration Amendments Act of 2007, requires that all clinical trials be registered in a public trials registry such as ClinicalTrials.gov, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIH IC grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

This pilot study will be registered on the ClinicalTrials.gov and the publication and authorship policies will follow the Aliviado Health Team Authorship Guidelines (See Attahcment B). The Aliviado Health Team Authorship Guidelines are consistent with the ICMJE authorship recommendations.

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

15 Study Finances

15.1 Funding Source

This study is financed through a subaward (A684268) of the NIA-funded, Emory Roybal Center for Dementia Caregiving Mastery pilot program (5P30AG064200-04).

15.2 Costs to the Participant

There are no costs to the participants.

15.3 Participant Reimbursements or Payments

Aim 1 co-design workshop: Caregiver subjects will receive a $90 gift card at the end of each co-design session completed (total of $450 if all sessions are completed).

Aim 2 feasibility trial: Primary caregiver participants will receive a $25 gift card for completing the first data collection session (enrollment/baseline), another $25 gift card for completing the second data collection session (Week 2/immediately post training) and a $50 gift card for completing the posttest data collection session (Week 6). Secondary caregivers referred to the study by an enrolled primary caregiver will not receive any payments after each data collection session but will be entered into a raffle of one $100 gift card at the end of the study.

16 Study Administration

16.1 Study Leadership

The study will be co-led by the PI Lin and PI Choi. PI Lin and PI Choi will provide oversight of the entire project including subject recruitment; data collection, analysis, and management; and dissemination of the study findings. PI Choi will be responsible for leading the Aim 1 co-design workshop. PI Lin will be responsible for leading the Aim 2 feasibility trial. PI Lin will serve as contact PI and assume fiscal and administrative management including communication between PIs and other research team members, hosting quarterly research team meetings (additional meetings will be scheduled as needed), communication with the Roybal Center, NIA, Safety Officer, and NYU School of Medicine IRB, and timely submission of the biannual progress reports and other required documents.

17 Conflict of Interest Policy

The study will manage actual or perceived conflicts of interest following NYU Langone Health's *Policy on Conflicts of Interest in Research and Other Sponsored Programs.* Under this Policy, individuals participating in research and other sponsored programs must disclose all financial interests that reasonably appear to be related to the individual's responsibilities at NYU Langone Health and to the specific project. NYU Langone Health, through its Conflicts of Interest Management Unit (CIMU), will then review and evaluate such disclosures, determine if a conflict of interest exists, and determine whether such conflict can be managed or must be eliminated in order to permit the researcher to engage in the project.

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19 Attachments

- Attachment A: Materials to be Refined/Re-designed with Caregivers (Aim 1 Co-Design Workshop)
- Attachment B: Publication Policy
- Attachment C: Schedule of Events
- Attachment D: Sample push notification/SMS text messages

Attachment A: Materials to be Refined/Re-designed with Caregivers (Aim 1 Co-Design Workshop)

1. Existing Aliviado Home Health/Hospice Aide Educational Video on Delirium: Caregiver subjects will watch the aide version and discuss what they like/dislike about the video and how to modify the video contents for use by family caregivers. Caregiver subjects will also review and provide feedback on the proposed content areas/topics for the family caregivers provided below (e.g., Are there any additional topic areas that we should also include in the family caregiver training videos?).

   Link to the video:
https://drive.google.com/file/d/1mSdguwBNL6phJ0fQI-qfkOuE8hI5rDBm/view?usp=share_link

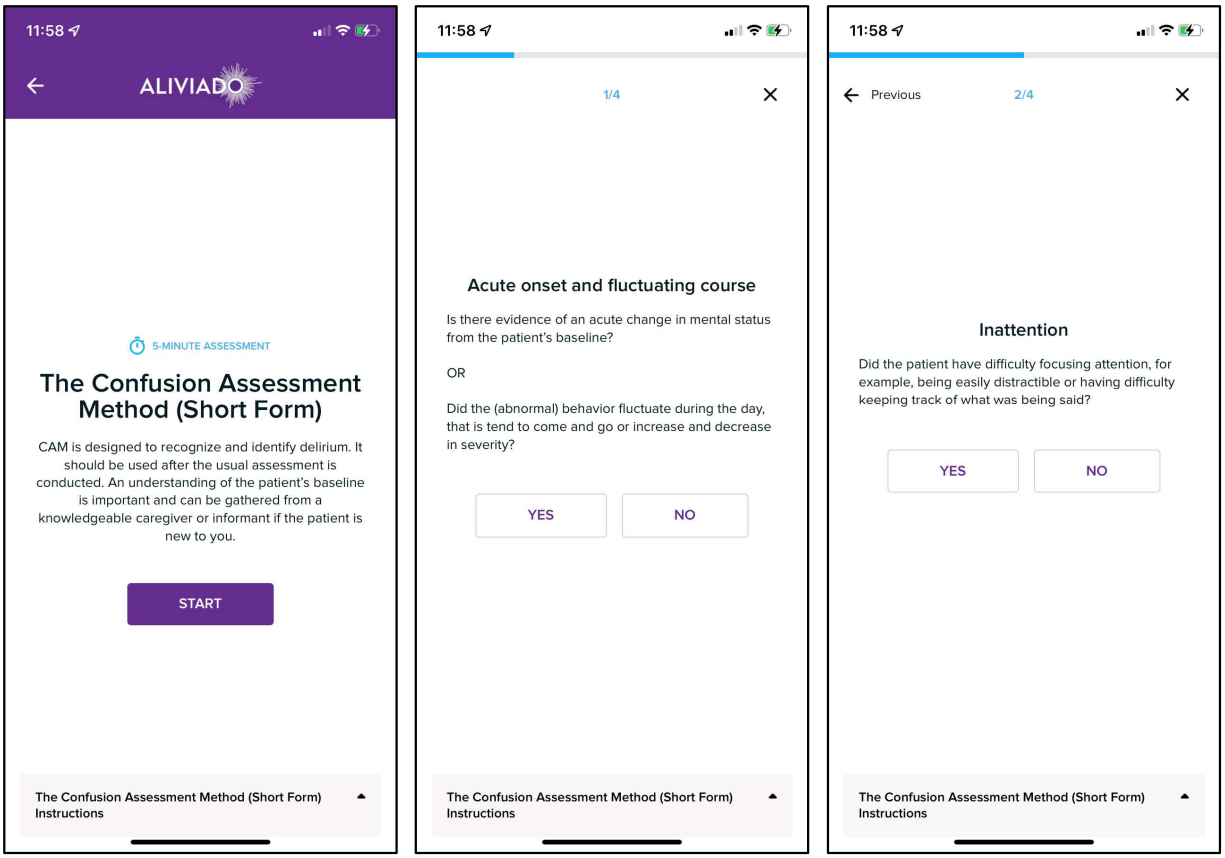
Proposed contents of DSD training videos for family caregivers (~ 60 min)

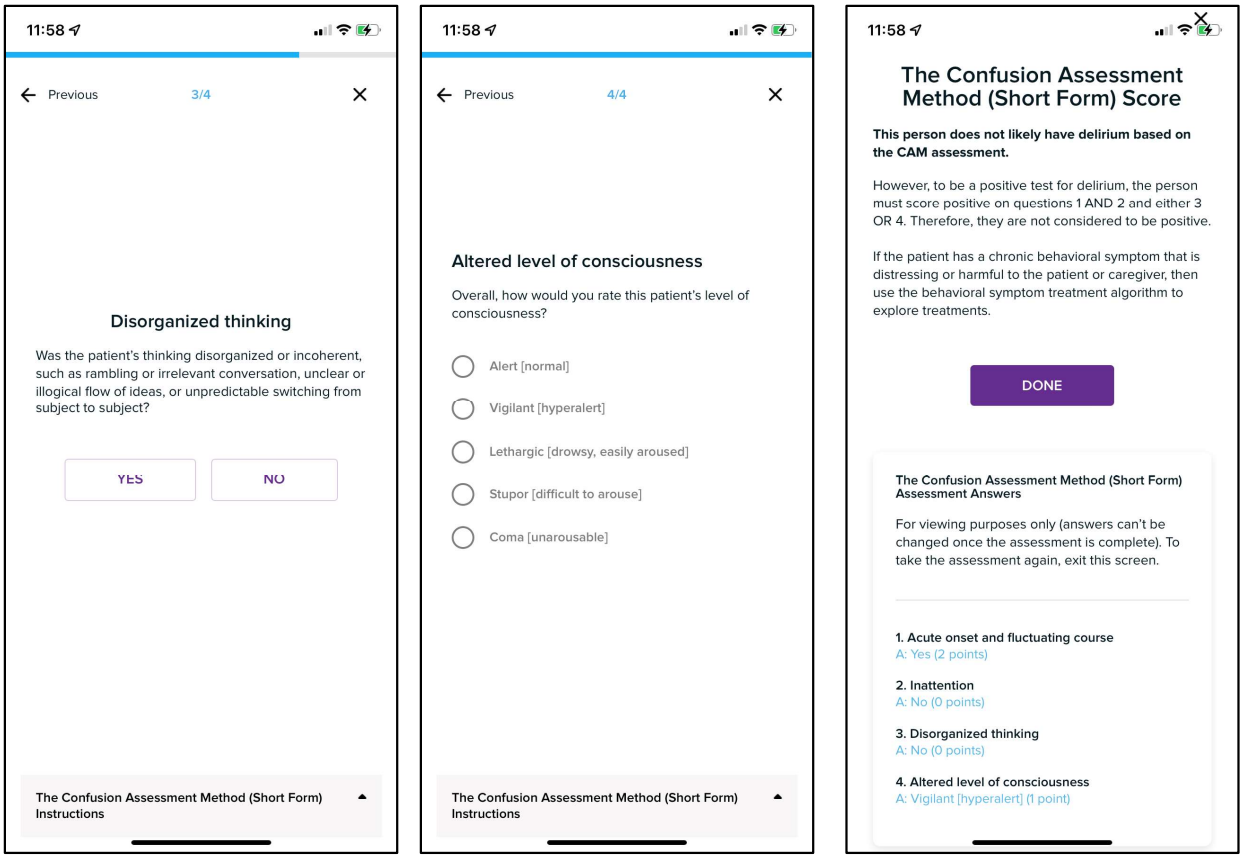
Existing topics in the aide training video (7 min total, as shown in the link above)
- What is delirium?
- Symptoms of delirium
- Delirium vs dementia
- Delirium vs sundowning
- Common causes of delirium

New topics added (informed by literature review)
- Important role families play in DSD care (5 min)
- Assess delirium using Family Confusion Assessment Method (FAM-CAM) (10 min)
- 3 case vignettes to practice delirium assessment using FAM-CAM (7 min each; 21 min total)
- Daily prevention/management (10 min)
- Prevention/management task while your loved one is hospitalized (5 min)
- Discuss probable DSD/de-prescribing using the tailored communication guides (5 min)

2. Delirium Assessment Tools

    a. Confusion Assessment Method (CAM) - Short Form: Caregiver subjects will provide feedback on the layout/visual presentation of the clinician version of the delirium assessment currently in use in the Aliviado app.





b. Family Confusion Assessment Method (FAM-CAM): Caregiver subjects will review the pdf version of the family-administered version of the delirium assessment. Caregiver subjects will provide feedback on the clarity of each assessment item in the instrument. If there is a confusing item, we will explain how to correctly interpret the specific item in the caregiver training video to be developed for the Aim 2 feasibility trial. Caregiver subjects will also provide feedback on how they want this instrument to be displayed in the app.

https://americandeliriumsociety.org/wp-content/uploads/2021/08/FAM-CAM_English.pdf

c. The Sour Seven: This is a newer validated caregiver-administered delirium assessment. The Sour Seven has fewer items than the FAM-CAM. We will show this assessment instrument to the caregiver subjects to see if they have a preference between FAM-CAM and the Sour Seven. We will also ask caregiver subjects what they think of the wording of each item in the Sour Seven. If the Sour Seven is preferred, we will also include this assessment in the caregiver training video to be developed and discuss how they want this to be displayed in the app.

The Sour Seven: Delirium Detection Questionnaire for Caregivers

The Sour Seven: A questionnaire designed for caregivers to screen for delirium (acute confusion) in seniors, including those with dementia (chronic confusion), that requires no training, no prior knowledge of the person, no questions posed to the person, is independent of language, based on seven simple observations of the person during caregiving.

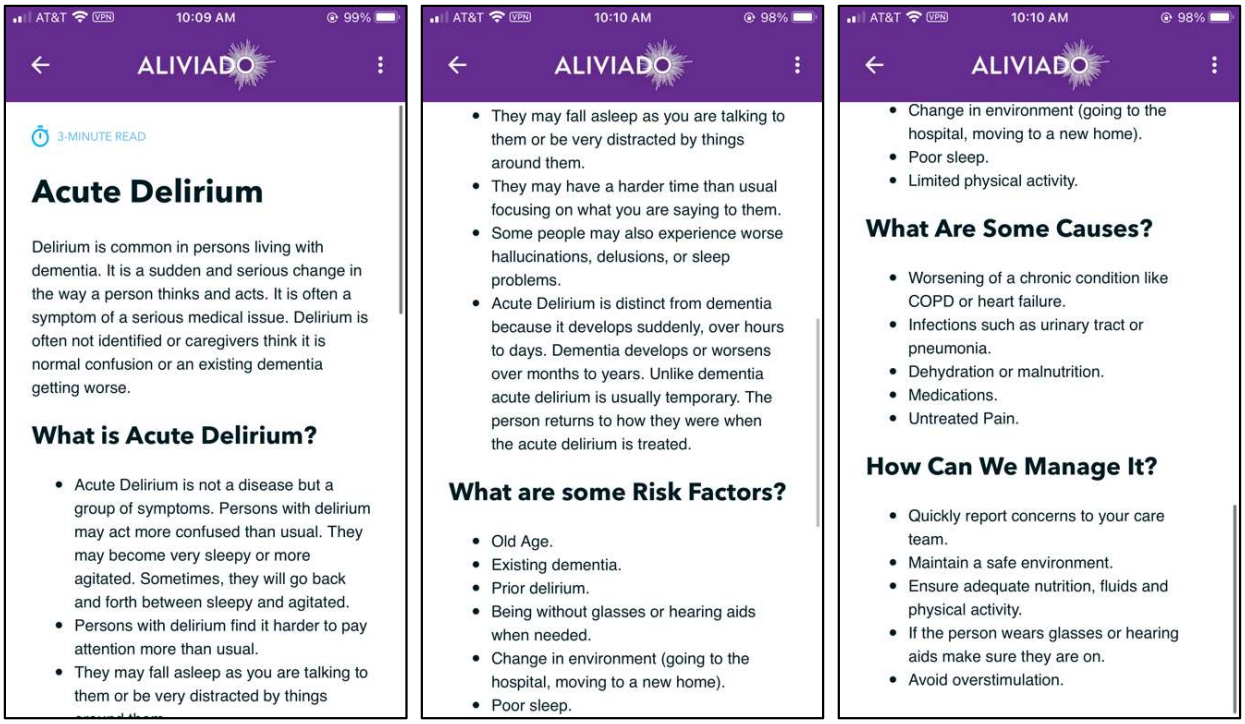
During your interaction with the person today, have you observed any of the following? Circle the corresponding value in the answer boxes.	**YES**	**NO**
1. Altered level of awareness to the environment in any way different than being normally awake.	3	0
2. Reduced attentiveness; inability to focus on you during the interaction.	4	0
3. Fluctuation in awareness and attentiveness, such as drifting in and out during an interaction or through the day.	3	0
4. Disordered thinking; the response (whether verbal or action) is unrelated to the question or request.	3	0
5. Disorganized behaviour; purposeless, irrational, under-responsive or over-responsive to requests.	2	0
6. Unexplained impaired eating or drinking (excluding appetite); unable to perform the actions to feed oneself.	2	0
7. Unexplained difficulty with mobility or movement.	1	0
Score		

Score	Predictive Value	Description
4	89%	**possible delirium**: evaluate potential medical causes, meds/substances
9	100%	**delirium**: immediate medical evaluation required

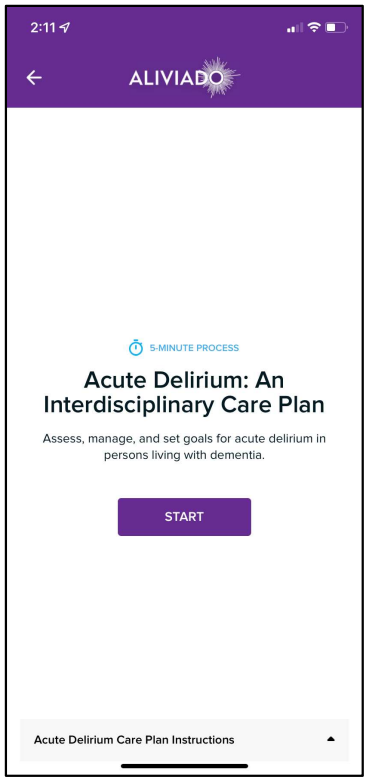
3. Caregiver Education Article

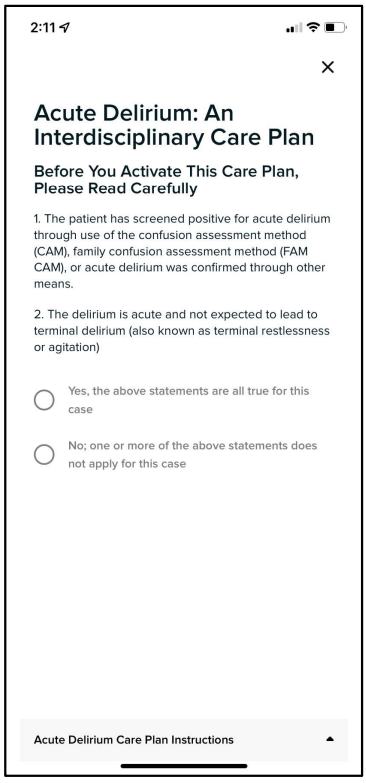
    a. Caregiver Education Sheet on Delirium (paper/pdf): This existing education sheet was developed for both professional and family caregivers. We will ask caregiver subjects if anything needs to be changed.

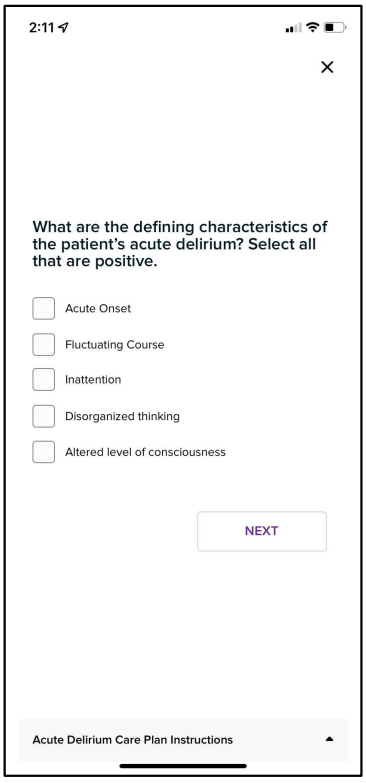
b. Caregiver Education Article on Delirium: This is the app version of the caregiver education sheet on delirium currently in use in the Aliviado app. We will ask caregiver subjects if they think anything needs to be changed.

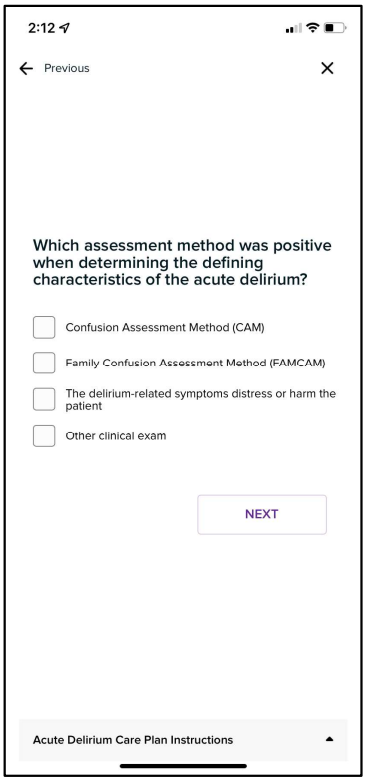


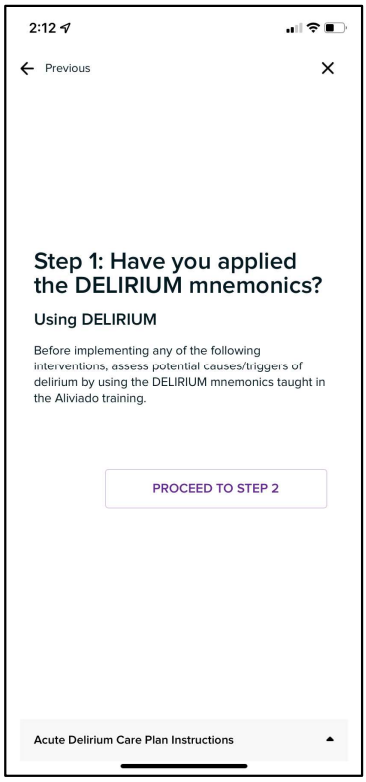
4. Caregiver Plan (clinician version): Caregiver subjects will design a care plan template for family caregivers focusing on non-pharm interventions.

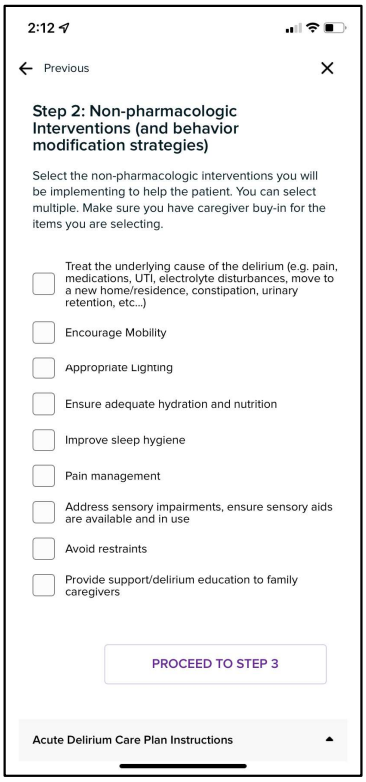

2:11
ALIVIADO
5-MINUTE PROCESS
Acute Delirium: An Interdisciplinary Care Plan
Assess, manage, and set goals for acute delirium in persons living with dementia.
START
Acute Delirium Care Plan Instructions

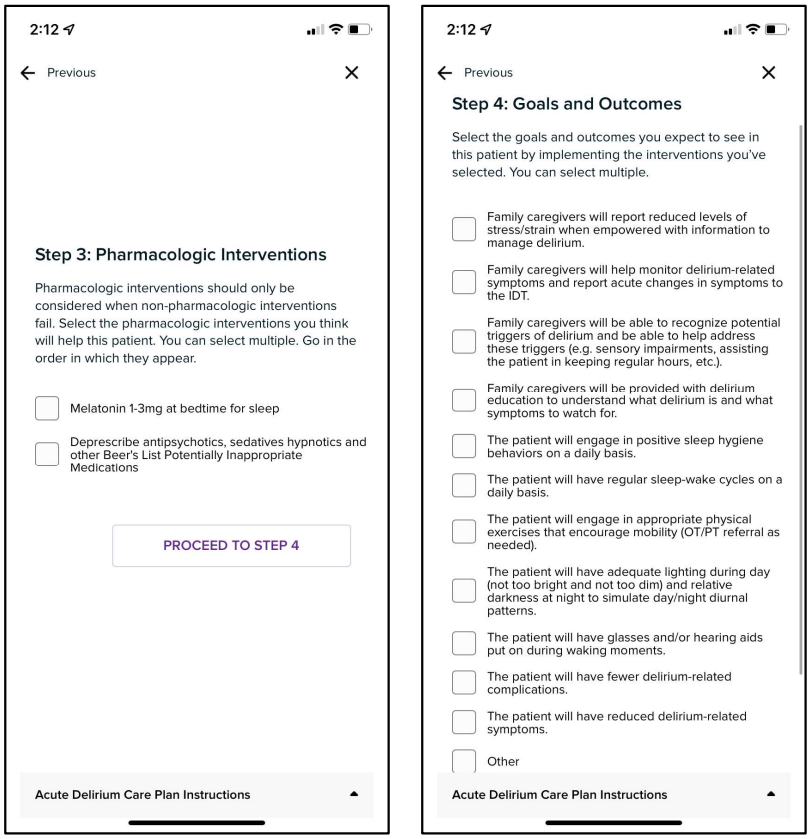

2:11
Acute Delirium: An Interdisciplinary Care Plan
Before You Activate This Care Plan, Please Read Carefully
1. The patient has screened positive for acute delirium through use of the confusion assessment method (CAM), family confusion assessment method (FAM CAM), or acute delirium was confirmed through other means.
2. The delirium is acute and not expected to lead to terminal delirium (also known as terminal restlessness or agitation)
Yes, the above statements are all true for this case
No; one or more of the above statements does not apply for this case
Acute Delirium Care Plan Instructions


2:11
What are the defining characteristics of the patient's acute delirium? Select all that are positive.
Acute Onset
Fluctuating Course
Inattention
Disorganized thinking
Altered level of consciousness
NEXT
Acute Delirium Care Plan Instructions

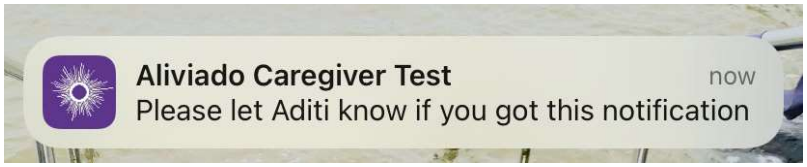

2:12
Previous
Which assessment method was positive when determining the defining characteristics of the acute delirium?
Confusion Assessment Method (CAM)
Family Confusion Assessment Method (FAMCAM)
The delirium-related symptoms distress or harm the patient
Other clinical exam
NEXT
Acute Delirium Care Plan Instructions


2:12
Previous
Step 1: Have you applied the DELIRIUM mnemonics?
Using DELIRIUM
Before implementing any of the following interventions, assess potential causes/triggers of delirium by using the DELIRIUM mnemonics taught in the Aliviado training.
PROCEED TO STEP 2
Acute Delirium Care Plan Instructions


2:12
Previous
Step 2: Non-pharmacologic Interventions (and behavior modification strategies)
Select the non-pharmacologic interventions you will be implementing to help the patient. You can select multiple. Make sure you have caregiver buy-in for the items you are selecting.
Treat the underlying cause of the delirium (e.g. pain, medications, UTI, electrolyte disturbances, move to a new home/residence, constipation, urinary retention, etc...)
Encourage Mobility
Appropriate Lighting
Ensure adequate hydration and nutrition
Improve sleep hygiene
Pain management
Address sensory impairments, ensure sensory aids are available and in use
Avoid restraints
Provide support/delirium education to family caregivers
PROCEED TO STEP 3
Acute Delirium Care Plan Instructions



5. Mobile push notification. The screenshot below shows our test push notification. The push notification messages to send to Aim 2 caregiver subjects will be developed according to feedback from the Aim 1 co-design workshop. In cases where push notifications are not feasible or cannot be delivered, SMS text messaging will serve as an alternative method to convey motivational messages to caregiver subjects.



6. Sample communication guides:

The communication guides will be revised according to caregiver feedback. We will also ask caregiver subjects if they would prefer to receive this information in the app and if so, how this information should be displayed.

i. Probable Delirium

Communication Guide: Probable Delirium

[I am/This caregiver is] in a research study to learn how to recognize symptoms of delirium and apply non-pharmacological strategies to reduce the risk of delirium or manage related symptoms in [my/their] loved one with dementia. [I am/The caregiver is] encouraged to practice using the Family Confusion Assessment Method (FAM-CAM), a valid, informant-administered delirium assessment instrument, to screen for potential delirium. According to the FAM-CAM, [my spouse/my partner/my parent/my friend/my relative/your patient] has an acute change in status and likely has delirium. [He/she] demonstrates the following delirium symptoms:

- Symptom A
- Symptom B
- Symptom C

(If applicable] [I have/This caregiver has] developed a care plan with the following recommended non-pharmacological strategies based on [my/their] loved one's delirium risk factors:

- Strategy A
- Strategy B
- Strategy C

When the FAM-CAM is positive, a formal clinical assessment performed by the patient's medical provider is required to diagnose or rule out delirium. [Therefore, I would like you to examine my loved one's condition.]

Note. Please call 911 if there is a medical emergency. If you have any questions or concerns about this information guide, please contact the Aliviado Support Center at Aliviado.dsd.caregiving@nyu.edu and we will forward your questions/concerns to an appriate Aliviado team member to respond within 2 business days in a secure email. Please do not include any personal identifiers of the patient (name, date of birth, medical record number, etc.) in your email to the Aliviado Support Center. If you or your provider needs to call about the study, you can find the PIs' phone numbers in the consent form.

ii. Deprescribing

Communication Guide: Deprescribing

A review of your loved one's medications might suggest that the following medication(s) may increase your loved one's risk for delirium. **You might want to discuss it further with your loved one's health care provider. You must NOT make any changes to your loved one's medications without first consulting your loved one's healthcare provider.**

- [Medication X]

Some medications that used to work well may not have the same benefits, or can even become harmful, as one gets older. This is because older bodies respond to and process medications differently. Moreover, when an individual takes multiple medications, they may interact with one another, and the side effects can add up.

Please note that the Aliviado DSD Caregiving Mastery Program focuses on prevention (risk reduction), early detection, and non-pharmacological management of delirium symptoms. We provide this medication review because certain medications tend to cause or worsen delirium in older adults. **The content of this guide is for informational purposes only and is not medical advice. Any medical and medication-related decisions should be made between you, your loved one, and your loved one's healthcare provider.**

Questions that you may want to ask in discussion with your loved one's healthcare provider:

- What matters most to you and your loved one?
- What condition does [Medication X] treat in your loved one?
- Is the condition treated by [Medication X] still ongoing?
- What options do you have if the condition is still ongoing and require treatments?
- What can you expect if [Medication X] is reduced or stopped in your loved one?
- Are there any risks if [Medication X] is reduced or stopped in your loved one?
- How do you feel about these options?

The content of this communication guide has been reviewed by the study team's geriatric pharmacotherapy consultant. Please call 911 if there is a medical emergency. If you have any questions or concerns about the information provided in this guide, please contact the Aliviado Support Center at Aliviado.dsd.caregiving@nyu.edu and we will forward your questions/concerns to an appropriate study team member to respond within 2 business days in a secure email. Please do NOT include any personal identifiers of [your loved one/the patient], such as name, date of birth, medical record number, etc., in your email to the Aliviado Support Center. If you or your provider needs to call the study PIs, you can find the PIs' phone nubmers in the consent form.

Attachment B: Publication Policy

Aliviado Health
Team Authorship Guidelines

Authorship of Manuscripts*
Aliviado Health research team members should participate in the writing of papers according to the guidelines of the International Committee of Medical Journal Editors (ICMJE; see below). Those who participate in conception and design, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors.

Provision of study material or patients; collection and assembly of data; provision of administrative, technical, or logistic support; and obtaining funding do not necessarily merit authorship but should be considered on a case-by-case basis, especially when other contributions are included.

Honorary authorship may be considered.
The PI(s) will oversee the assignment of authorship to ensure that recognition of authorship is distributed fairly among study investigators and team members and not dominated by any one individual.

Authorship

a. Order of authorship shall be agreed upon, by team members planned to be involved in developing a manuscript based on their proposed contribution prior to beginning the drafting process. The PI(s) will review and approve this order.

b. All persons eligible for authorship according to the guidelines of the ICJME will be listed on the journal title page with the designation that these authors are writing on behalf of the study investigators, indicated by including the tag line “and the XXXX Investigators” at the end of the author list.

b. For journals that limit the number of journal title page authors, manuscripts will be authored under the byline “The XXXX Investigators.” In this case the Writing Group will be listed in the appendix in the order as approved by the PI(s).

c. Persons who have contributed to the completion of the study, but do not meet criteria for authorship, will be listed in the Acknowledgements Section in alphabetical order by site.

d. If individuals do not provide their proposed contribution to the manuscript or are not timely in completing their contribution, the PI(s) at their discretion may change authorship order or remove from authorship if the individual no longer meets ICJME criteria.

Adjudication of Disagreements

a. Disagreements regarding authorship, which cannot be resolved by the team, will be resolved by the PI(s).

Funding Statements

Funding acknowledgment need to be included on all presentations and publications. Please see the language below:

o Funding Acknowledgement: This work was (partially) supported through a XXX Institute Award (Award #)

*Guidelines apply to all manuscripts, posters, oral presentations, and abstracts.
All manuscripts, posters, oral presentations, and abstracts must be vetted by the PI(s) prior to submission:
• At least one week prior for posters and oral presentations
• At least one month prior for manuscripts

The PI(s) must be notified of all accepted manuscripts, posters, oral presentations, or abstracts.

Writing Group Policies
In order to ensure that all team members have the opportunity to participate and be recognized in the Aliviado Health papers, writing groups will usually include appropriate investigators, staff and students. Investigators interested in being part of a writing group should submit comments and/or suggestions during the proposal development. Writing Group membership should be established before submitting the final proposal.
Usually the manuscript proposer will be designated as the Writing Group Facilitator and first author of the paper. They will receive written notification of all Writing Group members and their responsibilities as facilitator (see below).

The Writing Group Facilitator is responsible for all phases of manuscript preparation, from conception through publication. These responsibilities include:

a. Preparation of outlines, the identification of data analyses needed, and submission of interim status reports to the Writing Group;
b. Assignment of tasks to Writing Group members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;
c. Preparation and circulation of drafts for approval by each member of the Writing Group before submission of a Penultimate Draft to the PI(s) before submission to a journal;
d. Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript;
e. Choice of a journal to which the manuscript will be submitted in consultation with the Principle Investigator;
f. Correspondence with coauthor and journal editors.

The Writing Group Facilitator should contact each member of the Writing Group to discuss the outline of the paper, data analysis plan, and the responsibilities and assignments for each member. Members of the Writing Group are responsible for performance of tasks assigned by the Facilitator within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript. If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she may be removed from the Writing Group.

ICMJE Authorship Guidelines
The International Committee of Medical Journal Editors has recommended the following

criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

a. Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
b. When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.
c. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
d. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
e. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information. Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. The order of authorship on the byline should be a joint decision of the coauthors. Authors should be prepared to explain the order in which authors are listed.

Source: www.icmje.org

Attachment C: *Schedule of Events*

Aim 1/Phase 1 Codesign Workshop

Assessment	*Screening Visit*	*Enrollment Visit (Week 0)*	*Group Session 1*	*Group Session 2*	*Group Session 3*	*Group Session 4*	*Group Session 5*	*Optional preliminary usability testing*
Informed Consent Form	✓							
Demographics	✓	✓						
DSD Exposure/Familiarity with DSD	✓							
Health literacy		✓						
Comfort with Technology		✓						
Email session materials and reminder to confirm attendance (3 days before)			✓	✓	✓	✓	✓	✓
Email reminder to confirm attendance (the day before)			✓	✓	✓	✓	✓	✓
Inform waitlist caregivers of codesign session openings (Yes; NA, there are no openings)			✓	✓	✓	✓	✓	
Phone reminder (>=3hrs before the session)			✓	✓	✓	✓	✓	✓
Take Attendance			✓	✓	✓	✓	✓	
Review Session Agenda/ Objectives and Ground Rules			✓	✓	✓	✓	✓	✓
Obtain Permission for Audio/Video Recording			✓	✓	✓	✓	✓	✓
Gift Card			✓	✓	✓	✓	✓	
Brief Post Session Survey			✓	✓	✓	✓	✓	

Note. Screening and Enrollment may happen during the same visit if the caregiver is eligible and wants to proceed with data collection.

Assessment	*Screening visit*	*Enrollment Visit (Week 0)*	*Visit 2*	*Visit 3*
Informed Consent Form	✓			
Demographics	✓	✓		
Health Literacy		✓		
Comfort with Technology		✓		
Dementia Severity		✓		
Behavioral and Psychological Symptoms of Dementia		✓		
Caregiver Strain		✓		✓
Caregiver Depression		✓		✓
Caregiver Burden		✓		✓
Caregiving Self-Efficacy		✓		✓
Caregiver Delirium Knowledge		✓	✓	✓
DSD Caregiving Mastery		✓	✓	✓
Program Satisfaction				✓
App Usability				✓

Note. Screening and Enrollment may happen during the same visit if the caregiver is eligible and wants to proceed with data collection.
DSD=delirium superimposed on dementia

Attachement D: Sample Push Notification/SMS Text Messages

- Welcome to Aliviado Dementia Care! Access the Learning Center here and start your training today!
- Check out our tools to help you be a better advocate for your family member or friends with dementia!
- Click here to get some help to begin your online training in the Aliviado Dementia Care Delirium Expert Program for Family and Friends!
- Keep up the great work! You've made it through at least the first two videos. Let's make it through at least Video X this week.
- Remember to catch up on the online training videos! Take the next 5 minutes of your time to complete Video X.
- Assessing delirium symptoms systematically can lead to improved care. Assess the symptoms with FAM-CAM or SOUR-SEVEN today!
- You're really moving! Take the next 10 minutes of your time to get through one more video this week.
- We're starting week 2 of the Aliviado Dementia Care Delirium Expert Program for Family and Friends! Remember to complete the remaining videos.
- Let's get a few more videos done this week. At least through Video X. Soon you'll be an Aliviado Dementia Care Delirium Caregiving Expert!
- 🎉 🎉 🎉 Great job completing your Aliviado training! Make sure to save a copy of your certificate of completion and apply what you've learned with your family member or friend.
- Recognizing delirium symptoms can be challenging. Use FAM-CAM to assess and support your family member or friend.
- Check out our tools to help you be a better advocate for your family member or friend with dementia. Click to find them in the Aliviado app!
- Have you implemented any Aliviado care plans?
- What Aliviado assessment tools have you used?