Pilot Pragmatic Clinical Trial to Embed Tele-Savvy into Health Care Systems

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PREFACE

The Clinical Intervention Study Protocol Template is a suggested format for clinical trials sponsored by the National Institute on Aging (NIA). Investigators are encouraged to use this format, as appropriate, when developing protocols for their studies. Large multi-site observational studies will also benefit from this protocol template.

Note that instructions and explanatory text are indicated by italics and should be replaced in your protocol with appropriate text. Section headings and template text formatted in regular type should be included in your protocol document as provided in the template.

The goal of this template is to provide a general format applicable to all single- and multicenter clinical intervention trials (e.g., drug, surgery, behavioral, nutritional, device, etc).

As you can see the version number and date are on the bottom of each page. When making changes to an approved and "final" protocol, please provide a summary of the changes, with the date, at the front of the protocol.

FULL PROTOCOL TITLE

Pilot Pragmatic Clinical Trial to Embed Tele-Savvy into Health Care Systems

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Supported by:

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Study Intervention Provided by:

Investigators

Sponsor of IND/IDE:

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PRÉCIS

Study Title

Pilot Pragmatic Clinical Trial to Embed Tele-Savvy into Health Care Systems

Objectives

Objective 1: Evaluate effectiveness and implementation of the Tele-Savvy intervention, a group-based, remotely delivered psychoeducational intervention for family and other informal caregivers of older adults with Alzheimer's disease and related dementia (ADRD). In this pilot pragmatic clinical trial, we will introduce the Tele-Savvy intervention to ADRD caregivers at two health care system sites—UConn Health and Emory Healthcare—to determine feasibility and acceptability of offering Tele-Savvy as a routinely available caregiver program at both health care systems. To evaluate effectiveness, at each study site, we will conduct three sequential 7-week Tele-Savvy programs with 10 caregivers in each program. Caregivers will be randomly assigned to participate in either the Tele-Savvy Program or a self-guided Caregiving During Crisis program. To evaluate implementation, we will use Normalization Process Theory as a guide, with the goal of understanding staff acceptability and willingness to adopt Tele-Savvy as a routinely-offered caregiver psychoeducational program.

Objective 2: Establish an identification and invitation strategy, embedded into the daily workflow of both study sites, enabling caregivers to be invited to participate in the Tele-Savvy program in a pragmatic fashion. We will use electronic health records (EHRs) to identify family members or significant others linked to patients with diagnoses of ADRD, and then verify the accuracy of these identified individuals by having clinicians confirm or disagree with these identified individuals.. These identified individuals will be invited to participate either via electronic means or by clinic staff members.

Objective 3: Demonstrate viable routine collection of caregiver outcomes data into EHRs. Collaborating with information technology and clinical personnel at both health care systems, we will implement procedures enabling routine collection of these caregiver measures and inclusion of these measures into the EHRs at both health care systems.

Design and Outcomes

This cluster randomized pragmatic clinical trial will test the effectiveness and feasibility of embedding the Tele-Savvy intervention, a psychoeducational program for family and other informal caregivers of older adults living in the community with Alzheimer's disease and related dementia (ADRD), in two health care systems/clinical sites: UConn Health in Farmington, Connecticut, and Emory Healthcare in Atlanta, Georgia. A total of 100 caregivers, 50 at each study site, will participate in this pilot study. At each site, 30 caregivers will be randomly assigned to receive the Tele-Savvy intervention, and 20 caregivers will be randomly assigned to receive the self-guided Caregiving During Crisis online program.

All 100 caregivers will complete identical self-administered questionnaires to measure the caregiver-specific outcome measures in this pilot study. Outcome measures will include caregiver mastery (primary outcome), caregiver response to specific memory and behavioral

problems, and caregiver stress. Also, we will employ process measures of participation and engagement in the interventions for caregivers in both arms of the trial, as well as implementation outcomes via surveys with clinicians and Information Technology staff at each of the two clinical sites responsible for programming electronic medical records to enable capture and storage of caregiver outcomes.

Interventions and Duration

The Tele-Savvy intervention is grounded in social learning and stress process theory. Its main goal is to produce improved caregiver mastery over the symptom management skills commonly encountered when supervising and caring at home for an older adult living with ADRD. Over the 7-week program, there are synchronous and asynchronous activities each week. The synchronous portion includes weekly scheduled videoconferences (60-80 min) that serve as an online classroom in which facilitators lead lectures and discussions and provide a venue for caregivers' interactions and sharing of their experiences. The majority of Tele-Savvy is asynchronous. Daily, caregivers access online 6- to 15-min prerecorded videos, each focused on one main learning objective.

Tele-Savvy is a psychoeducation program designed to build not only knowledge and skill but also confidence. The psychoeducation approach uses three main strategies to accomplish this goal. The first strategy is instruction, providing information that helps caregivers increase their fund of knowledge for caregiving. The second strategy involves active learning, accomplished by interactive exercises conducted during the course; for example, thinking about how, given what the caregiver now understands about the cognitive losses in dementia, to best convey information to the person living with dementia. Active learning is also accomplished by asking course participants to try these strategies during the regular course of home caregiving -- this is what we refer to as "homework" -- the real life application of what is taught in class in the home setting. The third approach involves acknowledging caregiving success through a process of reporting back on caregiving activities during the week, particularly those that involved trying out the caregiving strategies taught in class. Reporting success and observing the caregiving successes of other participants is an important means of building and reinforcing caregiver confidence and competence.

The attention control group will receive the self-guided Caregiving During Crisis program. Caregiving During Crisis is a fully online, asynchronous, professionally designed continuing education course aimed at developing the competency of informal caregivers of community-dwelling persons living with dementia to ensure the safety of that person and themselves during this time of the COVID-19 pandemic. The course, readily accessible by home computer or smartphone, describes methods of home infection control and prevention to create a Safe Home space, strategies for safely leaving and re-entering the home (e.g., to shop), additional strategies for safely allowing service personnel (e.g., home health aides or electricians) and select family members to enter the Safe Home space, and risk management strategies to frame decisions when/if COVID restrictions are relaxed or revoked.

Two-thirds of the 100 caregivers (the first 67 caregivers) enrolled in the study will be on study for 6 months, and one-third of the caregivers (the final 33 caregivers) will be on study for 3 months.

Sample Size and Population

We will enroll a total of 100 caregivers into this pilot study across the two clinical sites using a cluster randomized design. A total of 60 caregivers will be randomly assigned to receive the Tele-Savvy program in three sequential cohorts of 10 caregivers each at each site. A total of 40 caregivers will be randomly assigned to receive the attention control condition in three sequential cohorts of 6-7 caregivers at each site.

STUDY TEAM ROSTER

Principal Investigator: **Richard H. Fortinsky, PhD**

UConn Center on Aging, University of Connecticut School of Medicine, 263 Farmington Ave., Farmington, Connecticut 06030-5215
fortinsky@uchc.edu
Main responsibilities/Key roles: responsible for successful conduct of all study tasks at both study sites, including direct supervision of study coordinator and research data base manager, and ensuring that personnel at both clinical sites perform their duties as required to successful conduct of the study.

Co-Investigator: **Karina Berg, MD**

UConn Center on Aging, University of Connecticut School of Medicine, 263 Farmington Ave., Farmington, Connecticut 06030-5215
kberg@uchc.edu
Main responsibilities/Key roles: Clinical lead at UConn Health site; responsible for facilitating use and modification of electronic health record system at this clinical site to enable recruitment of study participants (caregivers) and capture and storage of caregiver outcomes data in the electronic record system.

Co-Investigator: **Kenneth Hepburn, PhD**
Nell Hodgson Woodruff School of Nursing, Emory University, 1520 Clifton Rd., Atlanta, GA 30322
khepbur@emory.edu
Main responsibilities/Key roles: Scientific lead at Emory site, Dr. Hepburn will provide training of the Tele-Savvy facilitators at both the UConn Health (Geriatrics Associates) and Emory Healthcare (IMCC) sites, ensuring that they are certified to lead both synchronous and asynchronous components independently before the first caregiver cohort begins the program. Throughout the portion of the pilot study during which Tele-Savvy classes are held, he will provide guidance and oversight at both study sites to ensure that Tele-Savvy implementation there follows study protocol.

Co-Investigator: **Carolyn Clevenger, PhD**
carolyn.clevenger@emory.edu
Main responsibilities/Key roles: Dr. Clevenger will be responsible for coordinating project activities at the Integrated Memory Care Clinic (IMCC) at the Emory site. She will collaborate with her colleagues in identifying candidates for the Tele-Savvy trial and will oversee the work of clinic staff in facilitating the participation of selected caregivers into the trial, the gathering of caregiver outcomes data, and the transfer of caregiver data to Dr. Higgins for analysis.

Co-Investigator: **Melinda Higgins, PhD**
mkhiggi@emory.edu
Main responsibilities/Key roles: Dr. Higgins, based at Emory University, will serve as the pilot project biostatistician. She will work with the two project sites to ensure that caregiver data are

transferred securely to her and combine data into a single data base and then will take the lead in analyzing those data. She will participate in study team meetings and in manuscript writing.

PARTICIPATING STUDY SITES

List the name and address of each study site investigator, including telephone numbers and e-mail address. Use the same format as used for the Study Team roster.

Study Site #1: UConn Health (Dr. Fortinsky and Dr. Berg; please see email contact information above)

Study Site #2: Emory Healthcare (Dr. Hepburn, Dr. Clevenger, and Dr. Higgins; please see email contact information above)

1 STUDY OBJECTIVES

This study consists of three objectives, all of which are of equal importance because this is a pilot study of a pragmatic clinical trial being tested at two health care systems, also referred to as clinical sites in this protocol.

1.1 Primary Objective

Evaluate effectiveness on caregivers and implementation of Tele-Savvy to determine feasibility and acceptability of offering Tele-Savvy as a routinely available caregiver program at both health care systems. We will test the hypothesis that caregivers receiving the Tele-Savvy intervention will experience a greater improvement in caregiver mastery than the attention control group. At each health care system, we will conduct three sequential 7-week Tele-Savvy programs. Caregivers will be randomly assigned to participate in either the Tele-Savvy Program or to receive the attention control condition, a self-guided Caregiving During Crisis program. We will use Normalization Process Theory to guide our implementation evaluation, with the goal of understanding staff acceptability and willingness to adopt Tele-Savvy as a routinely-offered caregiver psychoeducational program.

1.2 Secondary Objectives

Establish an identification and invitation strategy, embedded into the daily workflow of two health care systems, enabling caregivers to be invited to participate in the Tele-Savvy program. We will use electronic health records (EHRs) to identify family members or significant others linked to patients with diagnoses of ADRD, and then verify the accuracy of these identified individuals by having clinicians confirm or disagree with these identified individuals. These identified individuals will be invited to participate either via electronic means or by clinic staff members.

Demonstrate viable routine collection of caregiver outcomes data into EHRs.
Collaborating with clinicians and information technology personnel at both health care systems, we will implement procedures enabling routine collection of these caregiver measures and inclusion of these measures into the EHRs at both health care systems.

2 BACKGROUND AND RATIONALE

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

Dementia, an umbrella term encompassing multiple causes of brain neurodegeneration that result in cognitive decline and development of behavioral and psychological symptoms, affected more than 50 million people worldwide in 2019; by 2050, this number will reach more than 150 million people.[1] In 2020, an estimated 5.8 million Americans live with ADRD, and more than 16 million informal caregivers, mostly family members (*hereafter, caregivers*), provide unpaid care to them.[2] The scope of caregiving activities varies widely, but for individual caregivers the activities often evolve in predictable fashion over the course of the dementia disease process. Caregivers must adjust to the realization that their relative or partner has a progressive neurodegenerative illness, witness cognitive and behavioral changes, gradually assume increasing responsibility for supervising and conducting instrumental and self-care related

activities of daily living, learn how to conduct medically complex tasks, coordinate services and communication with other family members, engage in advance care planning, and gatekeep the use of emergency and acute healthcare services. Caregivers of older adults with ADRD take on these responsibilities with little guidance, and many studies have shown that these caregivers provide more intense care and experience significant psychological and physical health-related consequences compared to caregivers of older adults without ADRD.[2,3]

In the COVID-19 era, these caregiving challenges have become compounded. It is widely known that community-dwelling older adults are at highest risk for severe illness and death from COVID-19 and are also likely to face longer in-home restrictions than other segments of the population. Caregivers of older adults living at home with chronic illnesses and associated disabilities face serious challenges related to these COVID-19 restrictions, such as how to keep older adults and themselves occupied and socially engaged to avoid loneliness and social isolation, and how to manage older adults' and their own health care needs by navigating the health care system. Caregivers of older adults with ADRD are at risk for increased physical and mental health problems due to loneliness and social isolation, especially if they experience unavailability of community-based services such as respite care and if they assume greater care responsibilities due to a shortage of in-home workers.[4] The caregiver population is ethnically and racially diverse, so the social determinants of health associated health disparities likely add to the complexity of challenges faced in the COVID-19 era.[5] Recent publications, principally commentaries and recommendations, have focused on the need to address caregivers of community-dwelling older adults, including those with ADRD, in the midst of the COVID-19 pandemic. Recommendations have been offered regarding the potential benefits of health care providers using technology creatively to reach caregivers at home to train them about how to avoid unnecessary hospital visits and to address accumulating needs among caregivers of older adults at home in the COVID-19 pandemic, including remote assistance using technology.[6-11]

2.2 Study Rationale

In the absence of effective pharmacotherapy to treat ADRD or appreciably slow symptom progression, numerous non-pharmacologic interventions designed to help persons living with ADRD and caregivers have been implemented and evaluated. Recent meta-analyses and scoping reviews of systematic reviews of these interventions have found evidence of efficacious programs, particularly on improving skill-building and psychological outcomes of caregivers of persons living with ADRD.[12-15] Tele-Savvy and its parent intervention Savvy Caregiver represent interventions designed to improve caregiver mastery through skill building, and to improve psychological outcomes such as burden.[16,17] Attention in the field of caregiver interventions has turned to replicating or adapting efficacious interventions for persons living with ADRD and their caregivers in "real world" health care and social service systems and settings. Initially, these efforts were referred to as translational studies,[18-20] whereas presently the field has moved toward efforts to implement efficacious interventions via embedded pragmatic trials.[21,22] Recently published translational studies with pragmatic trial elements found that beneficial outcomes for persons living with ADRD and/or caregivers could be achieved when efficacious interventions are incorporated into community service settings.[23,24]

Caregivers have long been recognized by researchers as critically important participants in medical visits with older adults generally, and for persons living with ADRD in particular.[25-28] Older adults report being more satisfied with outpatient medical visits when they are

accompanied by family members or other companions than when they are not. Older adults also report that physicians engage in more communication about their conditions when they are accompanied to medical visits, and these trends are strongest for older adults in the poorest health including those with cognitive impairment.[29] The vast majority of primary care practitioners recognize the value of family caregivers as participants in older patients' outpatient visits.[30] This study also found that only 19% of practitioners referred their patients to the Alzheimer's Association, compared to 30% in earlier studies.[31,32] These results strongly suggest that efficacious interventions offering meaningful benefits that cannot be easily offered in the outpatient medical setting to caregivers of older adults would be attractive to physicians and other office-based practitioners, if the linkage could be made between interventions and these types of health care settings. This is precisely what the proposed pilot study is intended to accomplish—to offer Tele-Savvy, an efficacious caregiver intervention ideally suited to the COVID-19 era because it is an online program, to caregivers of older adults living with ADRD who accompany these older adults to medical encounters at geriatric and dementia care clinics, using pragmatic procedures to identify and invite caregivers to participate.

Compilations of caregiver assessment tools have been developed and disseminated for use by health care practitioners,[33] but evidence is lacking regarding the degree to which such tools have been adopted in outpatient medical care encounters with older adults. The greatest opportunity to embed caregiver assessment tools into EHRs lies in outpatient settings in which clinicians trained in geriatric medicine treat and manage older patients. The incorporation of caregivers into the coproduction of care for such patients is embodied in geriatric fellowship curricular milestones. Training includes managing psychosocial aspects of care including interpersonal and family relationships (Milestone 23) and assessing and incorporating caregiver needs and limitations, including caregiver stress, into care management plans (Milestone 24).[34] As noted in Section C.3 below, the UConn Health site for the proposed pilot study is an outpatient setting in which geriatrics fellows receive training and, although fellows routinely meet with caregivers as part of their outpatient experiences, this pilot study would introduce the routine use of caregiver assessment tools already used as evaluation measures in the Tele-Savvy program.

3 STUDY DESIGN

A total of 100 family or other informal caregivers of older adults living with Alzheimer's disease or other dementia (ADRD) will be enrolled in this study from the outpatient clinics at two health care systems—UConn Health and Emory Healthcare—that specialize in geriatric care and care of persons with ADRD and their families. Of these 100 caregivers, 60 will be randomly assigned to participate in a 7-week Tele-Savvy program, and 40 will be randomly assigned to an attention control group that will receive an online, self-guided program called Caregiving During Crisis.

Pragmatic elements of this pilot clinical trial include use of electronic health record systems at each health care system site to identify and recruit caregivers, use of electronic patient portals to identify and invite caregivers to join the study, and the plan to incorporate caregiver-reported outcomes used in the study's outcome evaluation into the electronic health records of the persons living with ADRD/patients who receive care at the clinics.

Three Tele-Savvy programs, with 10 caregivers in each Tele-Savvy program cohort, will be held sequentially at each health care system site, for a total of 60 caregivers in 6 Tele-Savvy cohorts. Recruitment will occur in three waves, whereby caregivers will be randomly assigned at a 3:2 ratio to either Tele-Savvy or the attention control group until the first Tele-Savvy cohort is filled

(first wave), followed by the same randomization procedure until the second and third Tele-Savvy cohorts are filled.

The Tele-Savvy program, *a low-risk, psychoeducational intervention*, is grounded in social learning and stress process theory and its main goal is to produce improved caregiver mastery over the symptom management skills commonly encountered when supervising and caring at home for an older adult living with ADRD. Over the 7-week program, there are synchronous and asynchronous activities each week. The synchronous portion includes weekly scheduled videoconferences (60-80 min) that serve as an online classroom in which facilitators lead lectures and discussions and provide a venue for caregivers' interactions and sharing of their experiences. The majority of Tele-Savvy is asynchronous. Daily, caregivers access online 6- to 15-min prerecorded videos, each focused on one main learning objective. The lessons' didactic messages are delivered through expert presentations that are usually augmented by vignettes enacted by amateur actors playing a "caregiving family" in various dementia-stage-specific caregiving situations and using caregiving strategies in familiar settings. Caregivers can watch the lessons whenever and as often as they wish. The Canvas platform at Emory University houses the Tele-Savvy software that includes analytics to monitor caregivers' use of asynchronous material each week." Topics of the synchronous sessions progress from cognitive losses through caregivers' emotions, guiding behavior and decision-making skills, and family systems. Videos depicting caregiving situations follow a similar course as the more didactic videoconference topic presentations each week, ending with increasing caregiver mastery and the concept of caregiver village.

The attention control group will receive the self-guided Caregiving During Crisis program. Caregiving During Crisis is a fully online, asynchronous, professionally designed continuing education course aimed at developing the competency of informal caregivers of community-dwelling persons living with dementia to ensure the safety of that person and themselves during this time of the COVID-19 pandemic. The course, readily accessible by home computer or smartphone, describes methods of home infection control and prevention to create a Safe Home space, strategies for safely leaving and re-entering the home (e.g., to shop), additional strategies for safely allowing service personnel (e.g., home health aides or electricians) and select family members to enter the Safe Home space, and risk management strategies to frame decisions when/if COVID restrictions are relaxed or revoked.

Evaluation of the Tele-Savvy program is based on three outcomes: caregiver mastery, perceived stress, and reactions to behavioral and psychological symptom expressed by the person living with ADRD. Identical outcomes will be measured in the attention control group as in the Tele-Savvy program cohorts, at the same time points: pre-randomization; 3 months post-randomization for all; and 6 months post-randomization for 40 of the 60 Tele-Savvy caregivers (those in the first two program cohorts at each site) and 26 of the 40 caregivers in the attention control group. Also, we will employ process measures of participation and engagement in the interventions for caregivers in both arms of the trial.

We also will conduct an implementation evaluation guided by Normalization Process Theory to learn how well the Tele-Savvy intervention was accepted and perceived as a feasible ongoing caregiver educational program offered by the health care system clinics by caregivers and clinic staff, and to learn how successfully caregiver outcome data were embedded within the electronic health record system as planned.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

Participants must meet all of the inclusion criteria to participate in this study. Individuals will be eligible if they are: age 18 or older; identified by EHR systems and confirmed by a health care provider as a family member or unpaid significant other who provides care at home for an older adult (age 65 or older) living with ADRD; English speaking; able to understand study procedures and comply with them for the entire length of the study; and have access to appropriate video and audio technology to be able to participate in a Tele-Savvy program, or to be able to access the Caregiving During Crisis self-guided program.

4.2 Exclusion Criteria

All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation. Exclusion criteria: unwilling to be randomized to receive either Tele-Savvy or Caregiving During Crisis; and plans to admit the person living with ADRD to a nursing home on a long-term basis within 6 months of randomization.

4.3 Study Enrollment Procedures

A total of 100 caregivers will be enrolled in this pilot study, 50 caregivers from the Integrated Memory Care Clinic at Emory Healthcare, and 50 caregivers from Geriatrics Associates, the outpatient geriatric care center at UConn Health. At both study sites, caregivers will be identified in Electronic Health Records (EHRs) of patients age 65 or older with a diagnosis of Alzheimer's disease or other dementia (ADRD) as individuals to contact for patient care matters and who are known to clinicians and clinic staff to accompany patients to outpatient medical appointments. Caregivers of patients with ADRD identified through EHRs will be confirmed by clinicians as appropriate family/other informal caregivers, and after clinician confirmation caregivers will be provided information about an opportunity to opt-in or out to receive potentially one of two caregiver programs – Tele-Savvy or Caregiving During Crisis. This information will be provided either by telephone, email, or letter by clinic staff members or by an electronically-generated invitation from the EHR system. As a pragmatic approach, we will explain to caregivers that we are testing two programs we are considering making more generally available through the health care system, and that they will be assigned by chance to one or the other. Additionally, the information sheet will serve as the document to explain eligibility criteria so that caregivers can determine if they are eligible to participate. If caregivers have questions at this point, they will be instructed to contact an administrative staff member at each of the two participating study sites.

A report will be generated in the EHR at each study site for review by the study team to document when caregivers choose to opt out of study participation upon receiving the invitation. Anonymity of caregivers who opt out will be maintained, and only a count of the number of opt outs will be reported in any dissemination of study results.

Participation in the programs is completely voluntary. Caregivers will be provided information and will have the opportunity to opt-in or out and cancel stop their participation at any time. Because of this, and the intention of this study to examine whether the Tele-Savvy program can effectively be rolled out in a real-world health care setting, we request a waiver of informed

consent for research purposes under the Revised Common Rule. We provide justifications for the request in section 6.2.

Recruitment will proceed in 3 waves at each site, with caregivers in each wave randomly assigned either to a Tele-Savvy program or an attention control program called Caregiving During Crisis. The recruitment goal at each site in each wave is to enroll 10 caregivers for a Tele-Savvy program cohort and 6-7 caregivers to receive the Caregiving During Crisis self-guided program.

The study biostatistician will be responsible for generating randomization strings for each study site during each wave of recruitment, and for making the randomization strings available electronically in a secure location for access by the study coordinator.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

The Tele-Savvy program, *a low-risk, psychoeducational, group-based intervention*, is grounded in social learning and stress process theory and its main goal is to produce improved caregiver mastery over the symptom management skills commonly encountered when supervising and caring at home for an older adult living with ADRD. Over the 7-week program, there are synchronous and asynchronous activities each week. The synchronous portion includes weekly scheduled videoconferences (60-80 min) that serve as an online classroom in which facilitators lead lectures and discussions and provide a venue for caregivers' interactions and sharing of their experiences. The majority of Tele-Savvy is asynchronous. Daily, caregivers access online 6- to 15-min prerecorded videos, each focused on one main learning objective. The lessons' didactic messages are delivered through expert presentations that are usually augmented by vignettes enacted by amateur actors playing a "caregiving family" in various dementia-stage-specific caregiving situations and using caregiving strategies in familiar settings. Caregivers can watch the lessons whenever and as often as they wish. The Canvas platform at Emory University houses the Tele-Savvy software that includes analytics to monitor caregivers' use of asynchronous material each week. Topics of the synchronous sessions progress from cognitive losses through caregivers' emotions, guiding behavior and decision-making skills, and family systems. Videos depicting caregiving situations follow a similar course as the more didactic videoconference topic presentations each week, ending with increasing caregiver mastery and the concept of caregiver village.

The attention control group will receive the self-guided Caregiving During Crisis program. Caregiving During Crisis is a fully online, asynchronous, professionally designed continuing education course aimed at developing the competency of informal caregivers of community-dwelling persons living with dementia to ensure the safety of that person and themselves during this time of the COVID-19 pandemic. The course, readily accessible by home computer or smartphone, describes methods of home infection control and prevention to create a Safe Home space, strategies for safely leaving and re-entering the home (e.g., to shop), additional strategies for safely allowing service personnel (e.g., home health aides or electricians) and select family members to enter the Safe Home space, and risk management strategies to frame decisions when/if COVID restrictions are relaxed or revoked.

5.2 Handling of Study Interventions

Trained Tele-Savvy facilitators are used to lead all synchronous sessions, and an intervention manual is provided for both the facilitator and the caregivers participating in each program. Facilitators must complete a training program, and the facilitators for this pilot study at both sites program will have successfully completed the training before they begin leading the first program in this study. Facilitators also complete a checklist of objectives covered in each program session to help monitor treatment fidelity.

The Tele-Savvy program will be offered on a secure Emory University School of Nursing Canvas platform. The security of this platform has been demonstrated in a multi-site efficacy clinical trial, so there is little likelihood of its being penetrated in a way that might release individual's private information. Results and publications that come from the evaluation of this project will not identify caregivers by name or other PHI identifiers.

Caregivers assigned to the attention control condition, Caregiving During Crisis, will receive online instruction on how to use the self-guided intervention. This self-guided, online, asynchronous program will be accessible on the secure Emory University School of Nursing Canvas. Individual caregivers will access this program as often as they wish, using a secure password. Results and publications that come from the evaluation of this project will not identify caregivers by name or other PHI identifiers.

Because this is a pragmatic clinical trial, no members of the study team will be masked.

5.3 Concomitant Interventions

Not applicable to this study.

5.4 Adherence Assessment

Tele-Savvy facilitators will be responsible for documenting attendance by caregivers at each synchronous session, which will be reviewed to determine caregiver adherence to the synchronous component of the intervention. The secure Tele-Savvy online platform located at Emory University will record each time a caregiver accesses educational and skill-building material for the asynchronous component of the intervention. Caregivers will be issued user identification numbers and passwords for both security purposes, and so that their adherence to the asynchronous material can be documented and retrieved by approved study staff to determine their adherence. Attendance in 4 or more of the 7 synchronous sessions will be operationally defined as adherent, and adherence to asynchronous components will be measured as high-medium-low tertiles.

6 STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Baseline, Enrollment, Randomization:	3 months post-randomization (+ 2 weeks)	6 months post-randomization (+ 2 weeks)
Inclusion/Exclusion Criteria	X		
Enrollment/Randomization	X		
Demographics	X		
Caregiver mastery	X	X	X
Reactions to behavioral and psychological symptoms	X	X	X
Caregiver stress	X	X	X
Adverse Events	X	X	X

6.2 Description of Evaluations

Descriptions for the Schedule of Evaluations define what is to be done at each study period and include special considerations or instructions for evaluations.

This section should include definitions of the row headings in the Schedule of Evaluations and any special instructions. All of the items listed on the Schedule of Evaluations should be described in this section.

6.2.1 Screening Evaluation

Opt-in/Opt-out Procedure

Participation in the programs (Tele-Savvy or the control program) is completely voluntary. Caregivers will be provided information and will have the opportunity to opt-in or opt-out. Because of this, and the intention of this study to examine whether it can be effectively be rolled out in a real-world health care setting, we request a waiver of informed consent for research purposes under the Revised Common Rule and provide the following justifications:

(i) The research involves no more than minimal risk to the subjects:

The research presents no more than minimal risk of harm or discomfort to subjects beyond those ordinarily encountered in daily life or during routine clinical exams or tests. Participation in the programs (Tele-Savvy or the control program) is completely voluntary. Caregivers will be provided information and will have the opportunity to opt-in or opt-out.

Tele-Savvy is a low risk *psychoeducational, group-based program*, grounded in social learning and stress process theory and its main goal is to produce improved caregiver mastery over the symptom management skills commonly encountered when supervising and caring at home for an older adult living with ADRD. Offering the Tele-Savvy program as proposed in this pilot study is similar to standard approaches used by health systems to invite patients to participate in health education programs. Caregiving During Crisis program, used for the control group, is a fully online, asynchronous, professionally designed continuing education course aimed at developing the competency of informal caregivers of community-dwelling persons living with dementia to ensure the safety of that person and themselves during this time of the COVID-19 pandemic. Caregivers might experience distress while completing self-administered questionnaires, which ask about their experiences as caregivers and their emotional health and well-being. During the Tele-Savvy online classes, it is possible that caregivers will experience sadness, anxiety, anger, and other emotions during the process of sharing the ADRD journey that their spouses, parents, or other relatives/care recipients have traveled, as well as their own caregiving responsibilities. They also might become fatigued during the online classes as well as during the times between classes when they are viewing educational videos or doing their homework. These are common stressors not outside of what they may ordinarily experience and they are free to stop participation in the programs at any time.

(ii) The research could not practicably be carried out without the requested waiver or alteration:

Inclusion of research informed consent would affect the scientific validity of studying a new process of implementing an efficacious intervention—the Tele-Savvy Program—for the underserved target population of family caregivers of older adults living with dementia in the two health systems participating in this pilot study. Offering the Tele-Savvy program as proposed in this pilot study is similar to standard approaches used by health systems to invite patients to participate in health education programs. One of the study sites, Emory, already offers the program as part of its standard practice.

(iii) The research involves using identifiable private information that could not practicably be carried out without using such information in an identifiable format:

Identifiable private information is required in order to contact caregivers and follow them over time. See section 11.3 below about how we will maintain participant confidentiality. Additionally a HIPAA waiver will be requested for the purpose of collecting PHI as it relates to the practicability of contacting caregivers and tracking them in the correct medical records of patients. Caregiver PHI will be collected for the sole purpose of ensuring that caregiver data are stored in the correct EMR record, that of the patient for whom they are a caregiver.

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects:

Caregivers will be provided with an information sheet that describes their participation in the research study and will have the option to Opt-in to participate or Opt-out. If they choose to participate or not, it will not adversely affect the rights and welfare of either their loved ones care or their own.

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

As part of this pragmatic trial, we will share results of the pilot study with relevant clinicians and clinical service administrators at both the UConn Health and Emory Healthcare systems. We also will provide a brief synopsis of study results written in lay language that the health care systems will be able to share with caregivers who participate in the study.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

Once caregiver eligibility has been established, a caregiver will be defined as enrolled in this study.

Baseline Assessments

All baseline assessments will be completed by caregivers. These self-administered assessment tools will be sent electronically to caregivers via secure email from each of the two participating clinical sites once they are enrolled in the study. Instructions will be provided to caregivers about

how to complete and return baseline assessments, either via return secure email or by uploading them to the secure EHR portal. Baseline assessment tools will include:

- Demographics: age, sex, race, ethnicity, relationship to older adult with ADRD (e.g., spouse, significant other, daughter), co-residence with older adult with ADRD, employment status, and number of hours per week providing care to person with ADRD
- Caregiver mastery: measured using a 4-item self-perceived caregiving competence scale[53]
- Caregiver reactions to memory and behavior problems: 24-item scale capturing caregiver reactions to 24 memory and behavior problems[54]
- Perceived Stress Scale: 14-item measure of the degree to which situations in one's life are appraised as stressful[55]

Randomization

The administrative study coordinator will electronically access the appropriate study site's randomization string (strings will be generated by the study biostatistician, see Section 4.3) after a caregiver returns completed baseline assessment forms. Randomization results will reveal whether the caregiver is assigned to the Tele-Savvy program or to the attention control group. Randomization will be performed within business 3 days of receipt of completed baseline assessment forms. The administrative study coordinator will then notify the Tele-Savvy facilitator at each study site of the randomization result, and the facilitator will notify caregivers about the treatment group to which they are assigned. The statistician will provide the randomization scheme (random sorting using 10% maximum allowable deviation using PASS 2020 software[56]), which will be applied after the baseline assessment. For the Tele-Savvy intervention, because 10 caregivers at each site must be assembled in order to convene a cohort, a window of up to 3 weeks will be allowed between randomization of a caregiver to that treatment group and initiation of the intervention. For the attention control group, caregivers will be permitted to access the Caregiving During Crisis program anytime beginning 3 days after randomization.

6.2.3 Follow-up Visits

Follow-up assessments will be sent electronically to caregivers for self-completion within the windows specified in the Table in Section 6.1. Identical assessments as completed at baseline (except Demographics) will be completed at the follow-up assessment points.

6.2.4 Completion/Final Evaluation

Potential reasons for early termination include unexpected serious illness or death of caregiver, voluntary withdrawal from the study by the caregiver, long-term nursing home admission of the older adults with ADRD, and death of the older adult with ADRD. Caregivers who terminate due to reasons other than death will be asked to complete follow-up assessments as appropriate to the time at which they terminate within their 6 months in the study. This follow-up assessment request will be sent electronically by the administrative study coordinator.

7 SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

Risks to study participants are primarily psychological in nature. They might experience distress while completing self-administered questionnaires, which ask about their experiences as caregivers and their emotional health and well-being. During the Tele-Savvy online classes, it is possible that caregivers will experience sadness, anxiety, anger, and other emotions during the process of sharing the ADRD journey that their spouses, parents, or other relatives/care recipients have traveled, as well as their own caregiving responsibilities. They also might become fatigued during the online classes as well as during the times between classes when they are viewing educational videos or doing their homework.

Protection against risks from self-administered questionnaires: Caregivers will be instructed to contact the Tele-Savvy facilitator and/or the study site clinician (Co-investigator Dr. Berg at UConn Health and Co-investigator Dr. Clevenger at Emory Healthcare), if they have concerns about questionnaire items causing distress or other psychological reactions. The facilitator and/or study site clinician will send administrative study coordinator the follow-up outcome status of these contacts for recording for study regulatory and reporting purposes.

Risks from participating in the Tele-Savvy program: The principal risk to participation is that the content and process may be emotionally-charged for participants and dealing with these materials may cause transient discomfort. However, it is remotely possible that such discomfort might persist and be observed by the facilitators to be serious in nature. Both facilitators are Licensed Clinical Social Workers with extensive experience working with distressed caregivers and are capable of assessing the seriousness of participants' discomfort. In such cases, facilitators will be instructed to note their observation to a participant and offer to refer him or her to the services of the clinicians on the study team if caregivers wish to speak with a clinician (Co-investigator Dr. Berg at UConn Health and Co-investigator Dr. Clevenger at Emory Healthcare). More generally, throughout the 7-week program, facilitators will introduce community-based resources and supports should caregivers feel distressed.

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

All instances of psychological distress necessitating contact of clinicians on the study team will be recorded on case report forms by the study coordinator and will follow DSMB or Safety Officer and Institutional Review Board (IRB) of record guidelines for reporting.

7.3 Adverse Events and Serious Adverse Events

AE Definition: AE is any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

AEs for this study include: As noted above, the only expected AEs with possibly deleterious outcomes for this study are risks of transient emotional upset experienced during completion of study questionnaires and/or in processing their caregiving situation during the course of participating in the group-based online course.

SAE Definition: SAEs consist of any adverse event that results in death; is life threatening or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; is another condition which investigators judge to represent significant hazard

SAEs for this pilot study include:

No serious adverse events are expected. This is a very low risk study, principally involving participants being asked to complete an online program designed to enhance their caregiving self-efficacy and mastery when completing complex care tasks, and complete self-administered questionnaires.

7.3.1 Reporting Procedures

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. In addition, the NIA-appointed Safety Officer will oversee all data and safety monitoring activities for this study. The Safety Officer will act in an advisory capacity to the NIA Director to monitor participant safety, to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects.

Severity of Event

Mild: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

Moderate: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning

Severe: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

Expectedness

- **Unexpected** - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.
- **Expected** - event is known to be associated with the intervention or condition under study.

Unexpected events will be subject to expedited reporting requirements as described in the NIA Guidance on Clinical Trials and in Section 1.2.3, below.

Relatedness

- **Definitely Related**: The adverse event is clearly related to the investigational agent/procedure – i.e. an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to

the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.

- **Possibly Related**: An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.
- **Not Related**: The adverse event is clearly not related to the investigational agent/procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

7.3.2 Follow-up for Adverse Events

The study will adhere to the reporting requirements for AEs and SAEs stipulated in the NIA Adverse Event and Serious Adverse Event Guidelines as outlined below.

Process for identifying AEs and SAEs:

Facilitators of the Tele-Savvy programs in Connecticut and Georgia will receive training in AEs and SAEs and reporting procedures as part of their Tele-Savvy training. Within 24 hours of learning about any AEs or SAEs, facilitators will contact the study coordinator at UConn Health (Ms. Pascoe), who will complete a study form for collection of AE and SAE information. The study coordinator will report SAEs within 24 hours of learning about them to the PI (Dr. Fortinsky), will submit unexpected SAEs within 24 hours of learning about these events to the parties specified in the following section of this DSMP, and will submit all other SAEs to the parties noted in the following section on a quarterly basis, unless otherwise requested by the the NIA-appointed Safety Officer. All AEs and SAEs will be discussed during weekly study team meetings that will include key personnel from both sites and the study coordinator.

Adverse event reporting schedule:

Although no SAEs are expected due to the very low risk of the Tele-Savvy interventions, we will adhere to the following reporting schedule:

- All **adverse events that are both serious** (SAE) **and unexpected** (i.e., have not been previously reported for the study's intervention) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the NIA-appointed Safety Officer of the study's knowledge of SAE.
- The summary of all other SAEs will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the Safety Officer quarterly, unless otherwise requested by the Safety Officer.

- All deaths will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the Safety Officer within 24 hours of study's knowledge of death.
- AEs will be reported per IRB policies and also to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the Safety Officer at minimum every 6 months, or at a frequency requested by NIA and/or Safety Officer.

7.4 Safety Monitoring

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. In addition, the NIA-appointed Safety Officerwill oversee all data and safety monitoring activities for this study. The Safety Officer will act in an advisory capacity to the NIA Director to monitor participant safety, to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects.

8 INTERVENTION DISCONTINUATION

We do not anticipate discontinuing this study because the intervention has been tested in an efficacy trial that was successfully completed.

Caregivers may withdraw voluntarily from participation in the study at any time and for any reason. We will continuing to follow them, with their permission, even if the study intervention is discontinued. If modifications are required to the planned follow-up schedule due to temporary or permanent discontinuation of caregivers from the intervention, we will document accordingly and make every effort to complete one or both follow-up assessment points.

Replacement of subjects who discontinue will not be done in this study.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Statistical hypothesis: Caregivers who participate in the Tele-Savvy intervention will experience greater improvement in *caregiver mastery* between baseline and 3 month follow-up compared to caregivers who receive the self-guided, online Caregiving During Crisis program.

Secondary hypotheses: Caregivers who participate in the Tele-Savvy intervention will experience greater improvement in *reactions to behavioral and psychological symptoms of ADRD and in caregiver stress* between baseline and 3 month follow-up compared to caregivers who receive the self-guided, online Caregiving During Crisis program.

In this pilot pragmatic clinical trial, our primary goal is to successfully enroll caregivers invited to participate in this study by clinical sites in health care systems within the daily workflow of clinical activities. Within the one-year time frame allowed for this pilot study, we determined that we could enroll, at each of the two clinical sites, 3 sequential Tele-Savvy programs. We further determined that we could introduce an attention control condition and randomly assign caregivers to receive Tele-Savvy or the control condition in waves, each wave representing a

caregivers participating in a distinct Tele-Savvy program and a comparison group of caregivers receiving the Caregiving During Crisis program.

9.2 Sample Size and Randomization

9.2.1 Treatment Assignment Procedures

Three Tele-Savvy programs, with 10 caregivers in each Tele-Savvy program cohort, will be held sequentially at each health care system site, for a total of 60 caregivers in 6 Tele-Savvy cohorts. Recruitment will occur in three waves, whereby caregivers will be randomly assigned at a 3:2 ratio to either Tele-Savvy or the attention control group until the first Tele-Savvy cohort is filled (first wave), followed by the same randomization procedure until the second and third Tele-Savvy cohorts are filled.

9.3 Interim analyses and Stopping Rules

No interim analyses are planned.

9.4 Outcomes

9.4.1 Primary outcome

The primary outcome will be *caregiver mastery* of skills required to adequately fulfill the roles of being a dementia family caregiver. This primary outcome is consistent with the Social Learning theory[42,43] underlying the Tele-Savvy intervention and with the content and learning dynamics of Tele Savvy sessions. Caregiver mastery will be measured using the mastery items from the measure developed by Pearlin and colleagues[53]; this measure was used as the primary outcome in the Tele-Savvy efficacy study.[47] This outcome will be measured at study baseline for each caregiver (pre-randomization), 3 months post-randomization for all caregivers, and 6 months post-randomization for caregivers in the first and second waves.

9.4.2 Secondary outcomes

Secondary outcomes, also used in the Tele-Savvy efficacy study, will include *caregiver reactions* to behavioral and psychological symptoms expressed by persons living with dementia, using the Revised Memory and Behavior Problem Checklist, caregiver reactions scale,[54] and *perceived stress* using the global measure of perceived stress measure.[55]

9.5 Data Analyses

The proposed sample size is for 60 caregivers randomized to a Tele-Savvy group and 40 caregivers randomized to an attention control group with data collection at 2 primary time points (baseline and 3 months (post treatment)). This design is adequately powered at 80% power and 5% level of significance to detect medium effect sizes for the group effect (Cohen's f=0.285), within subject time effect (f=0.282) and group-by-time treatment effect (f=0.282) using repeated measures analysis of variance (RM-ANOVA).[57,58] This expected effect size is supported by previously measured improvements in caregiver mastery from the "Testing Tele-Savvy" study, NIH R01AG054079. We also intend to collect an additional follow-up time point at 6 months as a measure of sustainability of the treatment for approximately 2/3 of the participants (40 in Tele-

Savvy and 26 in attention control). For this smaller sample with a third time point we will be able to detect larger effects sizes (f=0.350 for group, f=0.388 for the time and group-by-time effects). In the "Testing Tele-Savvy" study, an effect size of f=0.46 was recorded for caregiver mastery improvements in active Tele-Savvy program participants. All data will be reviewed for completeness prior to analysis. All survey instruments will be scored and reliability computed prior to analysis. All measures will be assessed for normality and modeling assumptions with mathematical transformation applied as necessary prior to analysis. Multilevel mixed linear models (MLM) will be performed to utilize all data collected at each time point for all caregivers to assess changes in measures over time adjusting for attrition as needed. MLM will also adjust for the non-independence of the data collected across time nested within each subject. Post hoc pairwise comparisons between time points within subjects will be performed using Sidak error rate adjustments to control for multiple comparisons error rate inflation. Cohort number and clinical site will also be evaluated to see if any additional clustering effects are noted within each cohort or at each clinical site. Additionally, after performing an intent-to-treat (ITT) analysis, a follow-up analysis will also be conducted to see what if any additional effects were seen for subjects who were adherent versus those who weren't, looking at the number of sessions attended for potential dose effect. The demographics of the subjects will also be evaluated as potential covariates for the statistical models. All statistical tests will be performed at 5% level of significance, with 95% confidence intervals reported for all effect sizes.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Self-Administered Questionnaires: These questionnaires are attached to the CIRBI application form. All study caregivers will be assigned ID numbers at enrollment, which will be used as identifiers on self-administered questionnaires. Caregivers will receive questionnaires via secure email and/or by password-protected portals at each site. Files linking study ID numbers to subjects' identities will be kept in a separate password-protected file stored on a secure server, with access monitored by study personnel at the UConn Health site and the Emory Healthcare site.

10.2 Data Management

All quantitative data from self-administered caregiver questionnaires will be stored in a REDCap database at the UConn Health site, and in a TONIC database at the Emory Healthcare site. Data from individual caregivers will be de-identified and stored using ID numbers. Each site will be responsible for maintaining in a password-protected file and server the document linking subject names and de-identified ID numbers. The clinical data manager at the UConn Health site (Ms. Ohlheiser) and co-investigator Dr. Clevenger at the Emory Healthcare site will be responsible for the protection of their respective site's data files. Transfer of de-identified study data files to the study Biostatistician at Emory School of Nursing (Dr. Higgins) will occur using secure file transfer software at each of the study sites. Dr. Higgins will be responsible for conducting all quantitative data analyses.

Additionally, consistent with Objective 3 of this pragmatic clinical trial, we intend to implement procedures at both study sites whereby caregiver questionnaire results will be uploaded into electronic health record (EHR) systems. This is an innovative data management feature that has

the goal of enabling routine collection of these caregiver measures and inclusion of these measures into the EHRs at both health care systems. The clinical data manager at the UConn Health site (Ms. Ohlheiser) and co-investigator Dr. Clevenger at the Emory Healthcare site will be responsible for leading efforts to work with information technology staff at their sites to enable transfer of caregiver outcome measures to their respective EHR systems in such a way that these data are linked to the electronic records of the patients with ADRD who receive care by clinicians at these study sites.

10.3 Quality Assurance

10.3.1 Training

Dr. Fortinsky will be responsible for training the administrative study coordinator and the data management team based at UConn Health in all aspects of the study related to coordination and data-related tasks. Dr. Hepburn will be responsible for training facilitators to deliver the Tele-Savvy intervention, for ensuring that the Caregiving During Crisis program is accessible to caregivers assigned to the attention control condition, and that the software for both interventions is working properly to monitor and document access to the software on the secure server at Emory University. Dr. Berg and Dr. Clevenger will be responsible for oversight of the clinical study sites at UConn Health and Emory Healthcare, respectively, to ensure that pragmatic trial processes implemented to identify and invite caregivers to join the study are operating smoothly and consistently throughout the study.

10.3.2 Quality Control Committee

Drs. Fortinsky, Hepburn, Berg, and Clevenger will form the quality control committee and will meet no less frequently than biweekly throughout the study period. They will be responsible for reviewing enrollment reports, adverse event reports, and protocol deviations at each meeting, and will work together to resolve potential problems related to recruitment and retention of caregivers at both study sites, as well as to patterns of adverse events requiring attention and resolution. The study coordinator will prepare enrollment, adverse event, and protocol deviation reports for each meeting of this committee. This Committee also will be responsible for determining policies and procedures governing publication and other dissemination activities related to results from this study.

10.3.3 Metrics

Ms. Ohlheiser at the UConn Health site and Dr. Clevenger at the Emory Healthcare site will be responsible for monitoring the quality and completeness of self-administered questionnaires sent by study caregivers at each time point. Errors encountered will be forwarded to the study coordinator who will contact caregivers to resolve any data-related concerns regarding outcome measures. The study coordinator also will be available to answer questions from caregivers about the self-administered questionnaire items.

10.3.4 Protocol Deviations

Case report forms will be used to document protocol deviations. Tele-Savvy facilitators will be trained by Dr. Hepburn to document any protocol deviations related to the intervention, and the study coordinator will be trained to document any protocol deviations related to the study design. Protocol deviations will be reviewed at meetings of the quality control committee as noted in Section 10.3.2.

10.3.5 Monitoring

Site monitoring will be conducted by the IMPACT Collaboratory as noted in Section 7.3.1.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

11.2 Informed Consent Forms

Participation in the programs (Tele-Savvy or the control program) is completely voluntary. Caregivers will be provided with a study information sheet and will have the opportunity to opt-in. Because of this, and the intention of this study to examine whether it can be effectively be rolled out in a real-world health care setting, we request a waiver of informed consent for research purposes under the Revised Common Rule and provided justifications for our request in section 6.3.

11.3 Participant Confidentiality

Data safety and protection procedures and policies are in place at both study sites to ensure confidentiality of research data. All study participants' names and locations will be coded and there will be no way to identify caregivers enrolled in the study in any published reports or data.

Self-Administered Questionnaires: All study subjects will be assigned ID numbers at enrollment, which will be used as identifiers on self-administered questionnaires. Caregivers will receive questionnaires via secure email and/or by password-protected portals at each site. Files linking study ID numbers to subjects' identities will be kept in a separate password-protected file stored on a secure server, with access monitored by the clinical data manager at the UConn Health site and co-investigator Dr. Clevenger at the Emory Healthcare site. All quantitative data from self-administered caregiver questionnaires will be stored in a REDCap database at the UConn Health site, and in a TONIC database at the Emory Healthcare site. Data from individual caregivers will be de-identified and stored using ID numbers. The clinical data manager at the UConn Health site and co-investigator Dr. Clevenger at the Emory Healthcare site also will be responsible for the protection of their respective site's data files. Transfer of de-identified study data files to the study Biostatistician at Emory School of Nursing (Dr. Higgins) will occur using secure file transfer software at each of the sites. Dr. Higgins will be responsible for conducting all quantitative data analyses.

Electronic Health Records (EHRs): Internal policies and procedures governing data confidentiality and patient anonymity at both study sites will be followed to utilize EHRs for identifying potential study participants. Also, as noted in Section 10.2, working with site information technology personnel at both health care systems, we will implement procedures enabling routine collection of these caregiver measures and inclusion of these measures into the EHRs at both health care systems.

At both study sites, all paper records will be kept in locked file cabinets in locked rooms. All computer entry and networking programs will be done using de-identified IDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB and the NIA-appointed Safety Officer.

11.4 Study Discontinuation

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

12 ETHICAL CONSIDERATIONS

Investigators and clinical trials staff involved in oversight, conduct, or management of this study have been trained in good clinical practice (GCP).

13 COMMITTEES

Please see Section 10.3.2 for a description of the Quality Control Committee for this study.

14 PUBLICATION OF RESEARCH FINDINGS

Publication and other dissemination activities related to results of this trial will be governed by the policies and procedures developed by the Quality Control Committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

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16 **SUPPLEMENTS/APPENDICES**

Not applicable.