ANCILLARY REVIEWS

DO NOT DELETE. Submit the completed checklist below with your protocol.

Which ancillary reviews do I need and when do I need them? Refer to HRP-309 for more information about these ancillary reviews.			
Select yes or no	**Does your study…**	*If yes…*	**Impact on IRB Review**
☐ **Yes** X **No**	Include Gillette resources, staff or locations	*Gillette Scientific review and Gillette Research Administration approval is required. Contact:* *research@gillettechildrens.com*	**Required prior to IRB submission**
☐ **Yes** **X No**	Involve Epic, or Fairview patients, staff, locations, or resources?	*The Fairview ancillary review will be assigned to your study by IRB staff* *Contact:* ancillaryreview@Fairview.org	**Approval must be received prior to IRB committee/ designated review.** **Consider seeking approval prior to IRB submission.**
☐ **Yes** **X No**	Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The regulatory ancillary review will be assigned to your study by IRB staff* *Contact: medreg@umn.edu* *See https://policy.umn.edu/research/indide*	
☐ **Yes** **X No**	Require Scientific Review? Not sure? See guidance in the Investigator Manual (HRP-103).	*ONLY REQUIRED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE*	
☐ **Yes** **X No**	Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco?	*Complete the CPRC application process.* *Contact: ccprc@umn.edu*	
☐ **Yes** **X No**	Include the use of radiation? (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	*Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee.* *Contact: barmstro@umn.edu*	**Approval from these committees must be received**

☐ **Yes** **X No**	Use the Center for Magnetic Resonance Research (CMRR) as a study location?	*Complete the CMRR pre-IRB ancillary review* *Contact: ande2445@umn.edu*	**prior to IRB approval;** **These groups each have their own application process.**
☐ **Yes** **X No**	Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents?	*STOP – Complete the Medical Template Protocol (HRP-590)*	
☐ **Yes** **X No**	Include the use of human fetal tissue, human embryos, or embryonic stem cells?	*STOP – Complete the Medical Template Protocol (HRP-590)*	
X Yes ☐ **No**	Include PHI or are you requesting a HIPAA waiver?	*If yes, HIPCO will conduct a review of this protocol.* *Contact: privacy@umn.edu*	
☐ **Yes** **X No**	Use data from CTSI Best Practices Integrated Informatics Core (BPIC) Formerly the AHC Information Exchange (AHC-IE)?	*The Information Exchange ancillary review will be assigned to your study by IRB staff* *Contact: bpic@umn.edu*	**Approval must be received prior to IRB approval.** **These groups do not have a separate application process but additional information from the study team may be required.**
☐ **Yes** **X No**	Use the Biorepository and Laboratory Services to collect tissue for research?	*STOP – Complete the Medical Template Protocol (HRP-590)* *The BLS ancillary review will be assigned to your study by IRB staff.* *Contact: Jenny Pham* *Pham0435@umn.edu*	
☐ **Yes** **X No**	Have a PI or study team member with a conflict of interest?	*The CoI ancillary review will be assigned to your study by IRB staff* *Contact: becca002@umn.edu*	
X Yes ☐ **No**	Need to be registered on clinicaltrials.gov?	*If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff* *Contact: kmmccorm@umn.edu*	
☐ **Yes** **X No**	Require registration in OnCore?	*If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff* *Contact: oncore@umn.edu*	**Does not affect IRB approval.**

PROTOCOL COVER PAGE

Protocol Title	The Residential Care Transition Module; NCT02915939
Principal Investigator/Faculty Advisor	Name: Joseph Gaugler, PhD
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	Current Academic Status (Student, Fellow, Resident): N/A
	Department: N/A
	Telephone Number: N/A
	Institutional Email Address: N/A
Scientific Assessment	I believe Scientific Assessment is not required.
Version Number/Date:	76, 2/10/2022

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
62	11.09.20	Added detail about procedures for sending Thank You Letters to participants at the end of their study completion. Also, we clarified the consent procedures so that each section of the consent form will be briefly reviewed with each potential participant to ensure comprehension.	Yes
63-64	N/A	Discarded	N/A
65	12.15.2020	Revised adverse event plan to enhance clarity. Added clarity to survey timing procedures. Edited typo on follow-up survey.	No
66	1.8.2021	Added a script for reaching out to participants in the COVID-19 supplement to participate in the semi-structured interviews.	No
67	2.10.2021	Revised email and cover letter language for the follow-up surveys for Groups B and C to clarify what the additional surveys are for. Added questions to the follow-up surveys about the COVID-19 vaccine. Added procedure, with UBACC and phone script, to screen participants who staff identify as having potential memory concerns (in response to RNI00005994).	No
68	3.05.2021	A semi-structured interview script was created for bereaved participants so that the interview script was more sensitive and applicable to participants whose care recipient has passed away. If a participant's care recipient is still living, the original script will still be used. Also, updated procedures for working remotely.	No
70	9.2.21	Added final newsletter along with COVID supplement results page and	No

		cover letter to Ethos. No changes to protocol.	
74	12.21.21	Continuing Review and Modification. A former employee (Ann Emery, carl0219@umn.edu) is receiving IRB-related updates about this project from ethos, please remove her.	No
75	1.11.22	Staff update; no protocol changes	
76	2.10.2022	Updated protocol to newest UMN IRB Social template, retaining all information included in old format. Updated study staff not at UMN per IRB guidance.	No

Table of Contents

ABBREVIATIONS/DEFINITIONS

- ADRD: Alzheimer's disease or a related dementia
- DMO: Data Monitoring Officer
- DSMP: Data and safety monitoring plan
- IRB: Institutional review board
- NH: Nursing home
- NIA: National Institute on Aging
- RCT: Randomized controlled trial
- RC: Research coordinator
- RCTM: Residential Care Transition Module
- RLTC: Residential long-term care
- SPM: Stress Process Model
- SPM-RC: Stress Process Model for Residential Care
- TC: Transition counselor
- UMN: University of Minnesota

1.0 Objectives

1.1 Purpose: This 5-year project will utilize a randomized controlled trial (RCT) to evaluate an intervention designed to help families successfully adapt to the admission of a cognitively impaired relative to a RLTC facility. The Residential Care Transition Module (RCTM) provides 6 individualized formal sessions of consultation (one-to-one and family sessions) over a 4-month period to those who have admitted a relative to a RLTC setting. The RCTM will identify individual placement stressors and enhance family caregivers' strategies for coping with them. In this RCT, family members who have admitted a cognitively impaired relative to a RLTC setting will be randomly assigned to the RCTM [(*n* = 120)] or a usual care control condition [(*n* = 120)]. A mixed methods analysis[62] will be used to pursue the following aims:

- ***Specific Aim 1***. Assess whether the RCTM yields statistically significant reductions in family members' primary subjective stress (e.g., burden) and negative mental health outcomes (depressive symptoms) in the 12 months following enrollment when compared to controls;
  - *Secondary Aim 1a.* Determine whether the RCTM results in greater increases in caregiver competence and self-efficacy when compared to controls;
  - *Secondary Aim 1b.* Ascertain whether those who receive the RCTM report greater family involvement and visits to relatives in RLTC when compared to usual care controls;
- ***Specific Aim 2***. Determine whether family members who receive the RCTM indicate statistically significant decreases in secondary role strains (perceived adjustment of the relative and the caregiver to RLTC placement) over a 12-month period when compared to control family members;
- ***Specific Aim 3***. Determine whether RCTM family members report statistically significant decreases in residential care stress (e.g., improved perceptions of staff communication or staff support; reduced upset at having a relative in residential care; reduced negative interactions with relatives or staff in the facility) when compared to family members in the usual care control group; and
- ***Specific Aim 4***. Delineate the mechanism of action of RCTM under conditions of high and low success by embedding qualitative components (up to 30 semi-structured interviews) at the conclusion of the 12-month evaluation.

The RCTM will fill an important clinical and research gap by evaluating a multidimensional intervention designed specifically for families following RLTC entry to determine whether and how this approach can help families better navigate residential care transitions of cognitively impaired relatives.[64,67-70]

Many RCTM caregivers have been caring for a relative in RLTC since the onset of the COVID-19 pandemic, and are currently reporting to us new stressors associated with COVID-19. We will systematically assess caregivers' COVID-19-related experiences and extend the originally planned collection of caregiver stress and mental health data for an additional 4-months beyond the current study period to capture changes in caregiver mental health and well-being following the onset of the pandemic. The following aims have been identified for the supplement focused on caregivers' coping with COVID-19:

Specific Aim 1. Examine COVID-19-specific experiences among RCTM participants with a care recipient currently in residential care. We will gather quantitative and qualitative data on caregivers' current COVID-19-specific experiences, including preventive practices implemented by

facilities, effects of the pandemic on communication and visiting, and concerns about the care recipient's health and well-being. We will use a parallel-convergent mixed methods design and analytic strategy, with data collected via a supplemental quantitative survey delivered at 0-, 1-, and 4- months post-pandemic-onset, as well as semi-structured interviews with 20 participants. We will also gather insights from RCTM case notes, as recent sessions with currently-enrolled participants have focused on addressing caregivers' challenges in adapting to COVID-19.

Specific Aim 2. Evaluate the influence of COVID-19 on caregiver stress and mental health trajectories for AD/ADRD caregivers. We propose to extend the currently-administered surveys of caregiver stress and mental health to collect additional assessments at 0-, 1- and 4-months. This will provide a total of up to seven waves of data per participant, with multiple assessments before and after the onset of the COVID-19 pandemic. These data will allow us to estimate nonlinear longitudinal models examining how caregiver stress and mental health have changed after the onset of the pandemic, and how specific COVID-19-related experiences intensify or buffer against changes in caregiver stress and well-being.

Specific Aim 3. Determine whether RCTM treatment group participants are more resilient to negative psychosocial effects of COVID-19. There is a need to identify supports and services to help RLTC residents and their families adapt to the novel stressors introduced by the COVID-19 pandemic. The RCTM intervention is designed to provide caregivers with coping skills that may translate to other stressful experiences and potentially protect against negative consequences of COVID-19. We will compare trajectories of caregiver stress and well-being across the treatment and control groups to determine whether the RCTM provides benefits in the context of COVID-19.

2.0 Background

2.1 Significance of Research Question/Purpose:

Emerging research on family caregiving and institutionalization has found that families do not disengage from care responsibilities following relatives' admissions to residential long-term care settings. Families instead remain involved in a spectrum of care activities ranging from instrumental activities of daily living to emotional support. Perhaps for these reasons, a number of studies have noted that caregiving stress, depression, or other key outcomes remain stable or sometimes increase following residential long-term care (RLTC) entry for certain types of caregivers. A few interventions have attempted to increase family involvement after institutionalization, but no rigorous studies have demonstrated that these interventions are effective in helping families navigate transitions to RLTC environments.

Persons with dementia rely heavily on informal (i.e., unpaid) sources of care, and this has a staggering effect on families. Currently 85% of the 5.3 million persons with Alzheimer's disease or a related dementia (ADRD) in the United States are cared for by one or more family members, and 15 million individuals provide unpaid care to persons with ADRD.[1] There is no one consistent definition of *caregiving*, but in its most global sense caregiving refers to attending to an individual's health and daily care needs.[2,3] Dementia caregiving can extend to managing the consequences of specific symptoms, such as behavioral disruptions. A well-established literature demonstrates the adverse effects of dementia care on family members, including impaired physical health,[4-6] financial strain,[7] degradation in social well-being, and increased prevalence of depression, anxiety, or other psychological symptoms.[8,9]

2.2 Preliminary Data:

R21 AG026525/RCTM Feasibility and Pilot Evaluation. The research team has collaborated to establish a strong base of preliminary research to support the evaluation of the RCTM. Specifically, preliminary work on this project was supported by R21 AG026525 to Dr. Gaugler (PI), Dr. Mittelman (Co-I), and Dr. Hepburn (Co-I);[4-6] the R21 also supported formative research to develop and test the feasibility of the RCTM. Dr. Gaugler's research team first conducted focus groups at two local RLTC facilities with families and staff (*N* = 48) to determine the need for a psychosocial program for families who have admitted their relative to RLTC and to review an outline of potential content for the RCTM intervention. The focus groups lasted approximately 2 hours each and posed 4-5 questions with follow-up probes. Each facility hosted two focus groups (one consisting of family members and another consisting of professional nursing staff). Participants were identified through flyers. These focus groups were conducted via the phone to ease participant burden. Each group of 6-10 participants was audiotaped and results were transcribed. A content analysis was conducted, and a range of themes emerged that highlighted how family needs could be addressed through consultation following RLTC placement, including family members' stress and feelings of guilt, managing the administrative paperwork related to admission, fostering positive staff relationships to advocate for a relative's needs, managing the impact of staff turnover on family involvement with and quality of care for the relative, and managing family conflict related to the placement transition. Families also indicated the need for a "go-to" person to provide psychosocial consultation, support, and education about/referral to key resources that could meet their relatives' care needs (this was a theme that also emerged in the staff focus groups, along with the difficulties of establishing positive relationships with family due to distrust, negative stereotypes regarding RLTC, and similar issues). This focus group information, along with a systematic review of existing protocols involving family member support during and after the placement transition,[42,43,46-48,75] led to the development of the RCTM intervention model and a preliminary treatment manual.

A feasibility study of the RCTM using the draft treatment manual as the principal guide to implementation was also conducted by the PI and Mr. Reese. Fifteen Caucasian family members (*N* = 13 daughters; age *M* = 54.53 years, *SD* = 5.29; duration of care *M* = 5.11 years, *SD* = 2.56) of cognitively impaired relatives who had placed their relatives in nursing homes or memory care units of assisted living facilities approximately a year prior to enrollment completed the RCTM intervention. Baseline/pre-RCTM and post-RCTM (4-months later) interview assessments were also completed. The small sample size precluded extensive empirical analysis. Several measures (such as perceived stress, guilt, and distress related to care recipient neuropsychiatric problems) trended downward. A content analysis of the open-ended data collected from participants as well as the TC notes revealed several mechanisms of benefit including the formation of a therapeutic relationship, provision of psycho-education related to dementia and its progression, and explorations of guilt and stigma. The results made it clear that the initial session held particular importance in that it allowed caregivers to fashion their own narrative related to the RLTC transition; repeatedly caregivers stated how surprised they were at the positive effects of telling their story in a linear and sequential manner. The TC suggested that the act of narrating the event helps to remove the sense of immediacy and allows caregivers to build up tolerance and coping skills related to RLTC.

Following feasibility testing and refinement of the treatment manual, a pilot efficacy evaluation of the RCTM intervention was conducted.[91] A randomized controlled design was used (*N* = 36; *n* = 19 in usual care control condition; *n* = 17 in the RCTM treatment condition); participants were administered a pre-RCTM baseline survey along with 4- and 8-month follow-up interviews. Participants had admitted their relatives to a RLTC an average of 141 days prior to the baseline interview. Twenty-nine caregivers were women and 17 were spousal caregivers; all were Caucasian. On average, caregivers were 62.67 years of age and had provided care an average of 51.79 months. All RCTM counseling sessions provided emotional support to participating caregivers. Twenty-six (29.6%) individual and three (33.3%) family counseling sessions addressed relatives' behaviors. Approximately 40% of all individual sessions addressed caregivers' issues with the relative's facility compared with only one family session. Bivariate analyses of sociodemographic characteristics, caregiving duration, and other context of care indices found no statistically significant differences between the RCTM treatment and control conditions. Seven care recipients had died during the 8-month follow-up; 5 prior to the 4-month interview and 2 prior to the 8-month interview. Analyses of variance found that caregivers in the RCTM treatment group indicated significantly less distress on the Neuropsychiatric Inventory-Questionnaire[92] at 4-month follow up compared to caregivers in the control group ($p < 0.05$). Caregivers in the RCTM treatment group reported less role overload at 8 months compared to usual care controls ($p < 0.05$). Due to the small pilot sample, a number of findings did not achieve statistical significance below the $p < 0.05$ threshold but trended in the expected clinical direction ($p \leq 0.10$; role overload at 4 months; Perceived Stress Scale at 4 months;[93] and Zarit Burden Inventory[94] at 8 months). Focus groups conducted following the RCTM indicated that caregivers highly valued the readily available psychosocial support following RLTC placement. Combined, the preliminary quantitative and qualitative data emphasize that the provision of skilled psychosocial support can potentially help families navigate the emotional distress and crises in the months following a cognitively impaired relative's admission to RLTC.[91]

Our prior work[22-24] established a profile of caregivers most at-risk for persistent negative outcomes in the 6 and 12 months after nursing home admission. Wives, daughters, caregivers who have challenges meeting the needs of care recipients, and caregivers with their own health needs appeared particularly susceptible to high levels of burden in the 6 months following residential long-term care (RLTC) placement. Husbands and caregivers with their own prior health impairments and emotional stressors were most likely to suffer from depression in the 12 months after a relative's RLTC entry.[23] Our research leads us to hypothesize that psychosocial interventions – particularly in the months immediately following admission – can ease the RLTC transition for caregivers and alleviate its adverse outcomes such as burden and depression.

2.3 Existing Literature: Longitudinal analyses of dementia caregiving make it clear that caregiving does not "end" with the institutionalization of a cognitively impaired relative.[10] The high prevalence of dementia among NH residents (64% of Medicare beneficiaries in NHs have ADRD and 47% of all NH residents have a formally recorded dementia diagnosis)[11] likely influences the need for ongoing family care. Family members thus remain engaged in the lives of institutionalized relatives.[12,13] While "hands-on" technical care for ambulation and transferring is often assumed by direct care workers in a NH or other types of

residential memory care settings (e.g., assisted living memory care units), family involvement continues and ranges from regular visits, to ongoing provision of more instrumental forms of direct care (such as transportation and financial management), to interaction with staff to ensure proper care delivery.[12-16] Multiple studies have found that high levels of caregiving stress or depressive symptoms continue or, in some cases, increase with institutionalization.[17-21]

Facilitating family caregivers' RLTC transition is important, because family caregiver well-being may influence their relative's quality of life once in a residential setting. Various studies have emphasized that while NHs are oriented to delivering the necessary physical care, these facilities often fall short of providing hospitable environments or encouraging individual residents to pursue the goal of a 'life worth living.'[25-29] Several studies imply that social engagement, family visits, and other types of involvement can potentially improve life satisfaction and health outcomes for NH or assisted living residents.[30-35] These findings emphasize that reducing emotional distress and negative mental health outcomes and enhancing families' overall perceptions of and relationships with staff can have positive effects on residents' outcomes.

Innovation

The RCTM is different from existing evidence-based caregiver intervention models in that it is transition-specific; unlike most other interventions the RCTM targets a key transition in the dementia caregiving trajectory and as a result is a more focused and compact protocol than other multi-component, efficacious dementia caregiver interventions. The RCTM's clinical content is specific to the needs of families attempting to adapt to the residential long-term care (RLTC) admission transition. The RCTM is further positioned as an innovative intervention when considering the state-of-the-art in transitional care management for older adults. Family caregivers often experience significant stress and upheaval when in the midst of care transitions for older relatives in need, often because of the lack of coordination between care settings.[56] Randomized controlled evaluations of transitional care support for older persons have demonstrated considerable success,[56-60] but these protocols have not been explicit about how family caregivers are included.[61] Given the approach of the RCTM, it is anticipated that this protocol will be among the first clinical interventions that adopt a family caregiver focus to facilitate successful residential transitions for older persons with cognitive impairment. The RCTM has undergone multiple phases of testing to develop a protocol that is clinically and conceptually tailored to facilitate families' management of the RLTC transition for cognitively impaired relatives.

Another innovative aspect of this proposal is the use of mixed methods to evaluate the RCTM. Specifically, we propose to use an embedded experimental mixed methods design.[62] *Mixed methods* is generally defined as the collection and analysis of both quantitative and qualitative data that link these two forms of data concurrently or sequentially.[63] Data integration can occur within the design of a single study or across multiple studies.[64] Mixed methods research is generally used: a) to better understand a research problem by converging numeric trends from quantitative data and specific details from qualitative data; and b) to obtain statistical, quantitative data from a sample and identify individuals who may expand on the empirical results through qualitative findings.[65] The proposed design combines the collection and analysis of qualitative data within a traditional randomized controlled trial design; the collection of "embedded" qualitative data in the proposed study

will occur after the randomized controlled trial.[64, p. 90] The analysis of qualitative data will enhance interpretation of empirical outcomes and will assist us in examining why and how the RCTM worked or did not for ADRD caregivers. This strategy will allow for a more in-depth exploration of the mechanisms of benefit than existing family caregiver interventions, most of which do not adopt qualitative methods to explore processes of intervention efficacy.[66] Specifically, qualitative components will provide more comprehensive information on the mechanisms and pathways that lead to benefit for family caregivers who are struggling to navigate the RLTC transition.[64,67-70]

An additional innovation in the current proposal is the utilization of a conceptual framework that is applicable to the RLTC placement transition for families. The conceptual model underlying the proposed study is the Stress Process Model for Residential Care (SPM-RC), developed by Whitlatch and colleagues[20] and based on the widely used Stress Process Model (SPM) for dementia caregiving (Pearlin et al.).[71] The SPM offers a multidimensional, theoretical framework for analyzing the occurrence of stress and outcomes in the caregiving career.[71,72] The model incorporates an appreciation for the sociodemographic context of care (e.g., background characteristics of the caregiver and care recipient), care demands (functional, cognitive, and behavioral severity of dementia), subjective stress (caregivers' emotional appraisals of and reactions to care demands), resources (formal and informal support), and caregiver well-being (physical and psychological indicators of caregivers' global well-being). The major mechanism that helps to explain exacerbated stress is proliferation:[72] as stress accumulates in primary stressor domains, this stress then "spreads" to life domains outside of the primary caregiving situation (i.e., secondary stressors) which then negatively influences global dimensions of dementia caregivers' mental or physical health. In the SPM, psychosocial or formal resources are hypothesized to stem the proliferation of stress, thereby limiting or preventing negative health outcomes.

The SPM-RC adds and refines several interconnected domains of Pearlin's SPM to result in a model that is directly pertinent to RLTC. The SPM-RC captures the possible changes in relationship processes and structures in areas such as the emotional closeness of the relative and family member and family members' perceptions of difficulty when managing relatives' emotional and mental status (an appraisal that may change and expand once a relative is admitted to a RLTC setting; primary subjective stressors). Family members' perceptions of their relative's adjustment to the RLTC setting can produce "secondary" role strains, particularly if the family member feels guilt or believes the placement decision is contrary to the wishes of the relative. With RLTC admission, an array of placement-related stressors may emerge (residential care stress). These range from establishing effective roles and relationships with direct care workers or other facility staff, attempting to remain involved in the life of the relative in order to maintain or improve quality of life, and advocating for more appropriate care should families perceive that institutional care is of deficient quality.[73,74] Personal and organizational stressors frequently interact. If family members perceive that their relative is not doing well, they may increase their engagement in advocacy, hands-on care, or other types of involvement in order to improve their relative's overall sense of well-being (family involvement and visits).[35,46,73,74] Similarly, family members' own perceptions of how they have adjusted to a relative's placement and the potentially new roles they have assumed may contribute to their stress. Finally, the model includes contextual indices related to family caregivers' interactions with and perceptions of

the RLTC setting itself. Family members' appraisals of their involvement with and the quality of interactions with staff may reflect how well family members' perceive their own – as well as their relative's – overall adjustment to the residential care setting. In this manner, the SPM-RC model incorporates placement-specific stressors to better capture the experience of RLTC for family members, including its impact on key emotional and mental health outcomes.

Prior efforts have successfully analyzed and tested the SPM-RC model (and several hypothesized relationships within it) that informs the RCTM.[20] We predict that the RCTM will act as a psychosocial resource for family members, operating on and producing beneficial outcomes in the key outcome domains identified by the SPM-RC. The RCTM topic areas are linked to stressors identified in the model, and its psychoeducational approach is designed to strengthen family caregiver self-efficacy in these same domains. As such, we hypothesize reductions in primary subjective stress and negative mental health outcomes on the part of family caregivers (Specific Aim 1); reductions in secondary role strains (Specific Aim 2); and reductions in residential care stress (Specific Aim 3). Related to the predicted outcomes, we have – innovatively, we believe – tailored our measurement strategy to capture outcomes most closely associated with RLTC placement alongside more general measures of stress and mental health. Prior research focusing on RLTC entry for dementia caregivers employ measures designed for at-home care situations (e.g., the Zarit Burden Interview).[22,23,75] Similarly, many studies of caregiver stress following RLTC placement include pre- and post-placement measurements that often do not capture challenges specific to residential care admission for caregiving families (e.g., perceptions of staff support; perceived adjustment to the RTLC transition). The inclusion of such measures in the proposed study will help to advance understanding of how individualized psychoeducational and psychosocial support can enhance family caregivers adaptation to a relative's RLTC admission. Our embedded evaluation strategy described earlier likewise addresses this gap.

Clinical framework of the Residential Care Transition Module. There is a demonstrable need for supporting family members following RLTC placement. Scholars emphasize the importance of incorporating families in the provision of services and care to cognitively impaired older adults in residential care settings.[36] However, most services for families are designed for at-home caregivers,[37] and in prior intervention studies RLTC placement has been conceptualized as an outcome to be prevented or delayed. Earlier RLTC transition intervention protocols that sought to increase the frequency and quality of family involvement (e.g., reduce staff-family conflict) can be categorized into three models: group protocols that include peer-led support,[38-42] limited telephone-based counseling support to families,[43] and staff-family partnerships that attempt to clarify the family and staff roles and responsibilities in RLTC.[44-47] These various approaches have modest to weak effects in increasing family involvement, enhancing staff satisfaction, and improving resident well-being.[48] Although several pilot studies and a recently published randomized controlled trial (RCT) report on providing support to families of institutionalized relatives, these protocols either lack sufficient rigor to support their implementation or, in the case of the RCT, did not result in positive outcomes for family caregivers due in part to the clinical content, delivery, and measurement approach selected.[49,50]

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

- The parent study's primary outcomes include reductions in family members' primary subjective stress and negative mental health outcomes.
- The administrative supplement's primary outcomes include changes in caregivers' mental health and caregiving stress before and during the COVID-19 pandemic.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

- Parent study's secondary outcomes include secondary role stressors, and residential care stress. Other variables include context of care, caregiver depressive symptoms, primary objective stressors and resources.
- The administrative supplement's secondary outcomes include AD/ADRD caregivers' and care recipients' COVID-19 related experiences and resilience during COVID-19 pandemic.

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

Residential Care Transition Module (RCTM) clinical sessions are designed to be delivered during the timeframe (i.e., the months following RLTC entry) when family caregivers are most at-risk for psychosocial distress. The RCTM incorporates psychosocial and psychoeducational approaches, focusing on the identification of potential stressors associated with RLTC placement and the development of more effective individual coping strategies and enhanced caregiving self-efficacy within this new environment. As critical reviews of caregiver interventions suggest, multi-component programs that provide some combination of therapeutic/social support along with training and skills-based modules appear most likely to improve caregiving outcomes.[51,52] The RCTM is structured in similar fashion to provide individual and family counseling as well as ad hoc support in addition to knowledge and skill transfer to assist families adapt to RLTC.[48]

The RCTM includes six consultation sessions over a 4-month period conducted by a trained Transition Counselor (TC) with a primary family caregiver (self-identified as the person most responsible for providing on-going assistance to the care recipient in RLTC).[2] Other family members may also be included in the counseling sessions based on the needs expressed by and at the discretion of the primary caregiver. Typically, these additional participants would be identified before the enrollment of the primary caregiver and thus, participate in the initial screening and consent process, often completing the study surveys as well. The first 3 sessions are held weekly and the final 3 sessions are held monthly [subject to scheduling/availability]. RCTM sessions take place either via telephone or video-based conference. The sessions focus on the experiences of the caregiver, the care recipient, and (potentially) other family members following RLTC admission. Among the objectives for each session are the caregiver's acquisition of information and strategies designed to deal with unique issues, including distance caregiving. The sessions are designed to establish a therapeutic rapport with the caregiver and the family; provide a safe environment to explore stressors; examine family relational dynamics as they relate to the RLTC placement decision itself as well as the roles different family members play in the life of the caregiver and relative in RLTC; identify new modes of communication to facilitate more effective

interactions with other family members and care staff; and identify effective ways to advocate for improved quality of care for and quality of life of their relatives in RLTC. Throughout the RCTM counseling process/relationship, caregivers receive constructive feedback to help achieve their goals stated at the outset of the RCTM intervention. The duration of each session is about 45 to 150 minutes each.

The following summarizes the clinical content of the semi-structured RCTM, delivered across six sessions, each of which is prioritized and tailored according to the needs expressed by the caregiver. Each component is designed to positively influence key outcome domains of RLTC admission for family caregivers: primary subjective stress; secondary role strain; care-related distress; and depressive symptoms (see below):

Information about core questions is provided and information is tailored to respond to the needs of the caregiver and family and woven across the sessions. Among the questions often addressed include: How does RLTC placement affect the caregiver or other family members participating in the counseling session?; What are the constraints and reasons for the way dementia care is provided in RLTCs?; How can this care be optimized?; and How can the family caregiver's voice be heard when expressing the long-term care goals of the relative? Critical stressors identified during the intake interview, crisis situations, and adaptation issues are taken into account when individualizing a "curriculum" that uses conversation, presentations and online information and support.

- **Psycho-education**: Education on how dementia affects the brain and behavior, personality, and cognition is provided to explain the changes the relative is currently experiencing and may experience in the future. There is a focus on the biological basis for why these changes occur, emphasizing that they are not under the relative's control.
- **Promotion of communication**: The objective is to strengthen family members' skills in understanding other family members' perspectives and to establish positive and collaborative relationships with RLTC staff.[48] The Four Steps of Conflict Resolution and dementia-friendly activities designed to engage the PWML are included.
- **Problem solving**: Individual and family counseling sessions help caregivers divide potentially overwhelming problems into manageable components and direct the caregiver or other family members to formal/informal services available within the facility and in the outlying community (e.g., ombudsman).
- **Patient behavior management strategies**: Instruction and practice focuses on acquisition of skills and strategies to manage reactions to unpredictable behavior [as utilized in evidence-based interventions for dementia family caregivers such as the Savvy Caregiver Program as well as strategies provided by the Alzheimer's Association].[53-55]
- **Concrete planning:** Goals for care to optimize personal and socioemotional care assistance for relatives in RLTC are explored and strategies are developed to secure support for them from other family members and facility staff. These goals can also be made concrete in the facility's care plan for the relative in RLTC.[67] Follow-up allows for refinement of the care plan.
- **Making families aware:** Caregivers acquire knowledge about the rehabilitative treatments used in RLTCs to effectively manage dementia symptoms (e.g., depression, agitation, etc.) and to determine whether such treatment approaches

are available and delivered in the relatives' RLTC setting. Caregivers also learn about differences in the levels and types of care within different care settings (for example assisted living versus memory care).

- **Ad hoc counseling** is provided throughout the RCTM, which consists of ongoing, informal counseling on the telephone, or via email with the TC at the request of the family caregiver. This makes it possible for the TC to respond to the effects of the changing nature of the disease; changes in the RLTC environment, services, and policies; and crises as they occur. As needed, information/resources are provided to participants.

5.0 Procedures Involved

5.1 Study Design:

We propose to use an embedded experimental mixed methods design.[62] *Mixed methods* is generally defined as the collection and analysis of both quantitative and qualitative data that link these two forms of data concurrently or sequentially.[63] Data integration can occur within the design of a single study or across multiple studies.[64] Mixed methods research is generally used: a) to better understand a research problem by converging numeric trends from quantitative data and specific details from qualitative data; and b) to obtain statistical, quantitative data from a sample and identify individuals who may expand on the empirical results through qualitative findings.[65] The proposed design combines the collection and analysis of qualitative data within a traditional randomized controlled trial design; the collection of "embedded" qualitative data in the proposed study will occur after the randomized controlled trial.[64, p. 90] The analysis of qualitative data will enhance interpretation of empirical outcomes and will assist us in examining why and how the RCTM worked or did not for ADRD caregivers. This strategy will allow for a more in-depth exploration of the mechanisms of benefit than existing family caregiver interventions, most of which do not adopt qualitative methods to explore processes of intervention efficacy.[66] Specifically, qualitative components will provide more comprehensive information on the mechanisms and pathways that lead to benefit for family caregivers who are struggling to navigate the RLTC transition.[64,67-70]

5.2 Study Procedures:

Recruitment. At various outreach events, a Documentation of Permission form will be utilized to provide the PI and research team the ability to reach out to the potential participant about the project. Following completion of this form, a research coordinator will initiate email, telephone, or mail contact with family caregivers. Alternatively, interested research participants can reach out to the study team directly to initiate contact. During initial contacts with potential participants, the coordinator will describe the RCTM intervention, explain study procedures such as voluntary participation, randomization, and what the usual care control condition includes. A telephone and email script will be utilized. More information about recruitment can be found under section 12.0 "Recruitment Methods".

-**Study schedule: Months 3-44 (see Timeline below)**

Eligibility screening. If caregivers are interested in participating, the RC will conduct a brief screening procedure using the RCTM Screening Form, developed based on the above eligibility criteria.

-Study schedule: Months 3-44 (see Timeline below)
-Time for participants: 10-15 minutes

***Enrollment/Consent*.** Following eligibility screening, the consent process will take place. Going forward, our consent process will specifically entail: study staff reviewing highlights of each section of the consent form with the potential participant, then study staff will ask each potential participant whether they have any questions about the consent form or study details. Since we are improving our procedures, this more detailed consent process will begin after approval of the protocol (v 11.09.2020). During the parent study and the supplement, we provided potential participants an overview of the project prior to initiating the consent process, which we will continue to do.

After an overview of the project has been described, highlights of the consent form will be described and any questions from the potential participant will be answered, then a signed informed consent will be obtained from the eligible family caregiver. This consent will be offered electronically, over the phone or via mail. Online consent forms will be administered via the secure University of Minnesota Qualtrics survey application. Participants will be provided with a copy of their completed consent form. See more details on the consent process in section 22.1 “Consent process”.

-Study schedule: Months 3-44 (see Figure below)
-Time for participants: 30-45 minutes

Baseline. Following the completion of consent, the baseline survey will be administered. The survey will ask the family caregiver to complete a survey that will ask questions about the family caregiver, the person with ADRD, and the person with ADRD’s and family caregiver’s memory loss’ emotional, psychological, physical health, the caregiver’s confidence about their care situation. The survey will also ask the family caregiver about various health events that the person with ADRD may have experienced. The baseline survey can be completed via mail, telephone interview, or online (with minor verbiage edits to instructions made to facilitate online completion/tracking via Qualtrics).

-Study schedule: Months 3-44 (see Timeline below)
-Time for participants: approximately 45 minutes

Treatment/Intervention Period. Participants will be randomly assigned in a 1:1 ratio to receive either the RCTM intervention or a usual care control condition. The project biostatistician (Dr. Roth) will generate a random assignment schedule using a random number generator provided by the SAS analysis system. Treatment condition assignments generated by this program will be printed and individual caregiver assignment slips will be placed in sequentially numbered, sealed opaque envelopes. The next sealed envelope in

the sequence will be opened at the time each individual participant is randomly assigned to his or her condition. The randomization schedule will be stratified by family member relationship (spouse vs. non-spouse) and time since the relative's admission (3 months or less vs. over three months) to ensure balance on these important predictors of caregiver outcomes. Cases will be randomized within variable-sized blocks that range from 6 to 10 participants. No research staff or investigator interacting with potential participants will have access to the random assignment schedule, and, because of the variable block sizes and the sealed assignment envelopes, no person with participant contact will be able to determine the next treatment assignment in the sequence. These procedures accomplish both random treatment assignment and treatment allocation concealment throughout the trial, and are consistent with the recommendations of the CONSORT statement (see **http://www.consort-statement.org/**). The RC will inform the ADRD caregiver of their randomization status as soon as possible following completion of the baseline interviews.

-Study schedule: Months 3-44 (see Figure below)
-Time for participants: approximately 10 minutes

Usual Care. The usual care control group proposed here is similar to those we have used in our prior studies[91,95-97] to adjust for the social engagement provided to the RCTM treatment condition. As summarized above, the TC will provide quarterly contact calls. If caregivers in the control group initiate contact with the TC for care needs, the TC will provide information and referral support. Based on our prior experience, ADRD caregivers in an attention control group will often seek information and psychosocial support during quarterly contact calls; in order to balance ethics with the integrity of the randomized control design, the TC will provide information and referral (e.g., local phone numbers of the Alzheimer's Association or an Area Agency on Aging). The TC will collect data on the duration, frequency, and content of each quarterly contact call.

-Study schedule: Months 3-56 (see Figure below)
-Time for participants: approximately 15 minutes for each follow-up contact call

For those ADRD caregivers who are assigned to the RCTM treatment condition, the semi-structured RCTM intervention (described above) will be administered.

-Study schedule: Months 4-55 (see Figure and Timeline below)
-Time for participants: from 45-150 minutes per session

5.3 **Follow-Up:**

Follow-up for the parent was planned through Month 55, resulting in about a 53-month data collection period. Following the completion of the RCTM disposition form, blinded research assistants will administer follow-up surveys to enrolled caregivers at 4 months, 8 months, and 12-month time-points. Unless the research team is aware that the participant is bereaved, staff send (or call in attempt to complete) the disposition survey 7 days (+/- 7 days) prior to the date the next follow-up survey is scheduled to be sent. If no response is received, staff send reminders (or call) as needed. As needed, the disposition and follow-up

survey may be sent together per study procedures. The follow-up survey is scheduled to be sent 4 months (+/- 7 days) following the receipt of the previous survey or within 7 days of receiving the disposition status. If the date a survey is scheduled to be sent falls on a weekend/holiday, the survey send date is moved to the next business day (and the survey is sent +/- 7 days from that date). Participants are given several reminders to facilitate survey completion. *[Please note: Survey time-points are calculated following the date of receipt of the previous survey (or if the previous survey was not returned, surveys time-points are calculated using the appropriate time interval following the receipt date of the prior survey). Based on this, if participants are not prompt in survey completion, subsequent surveys are pushed back accordingly.]* In addition to the 4, 8, and 12-month surveys, additional surveys may be sent if the participant is participating in surveys related to the COVID supplement. These supplemental survey time points are calculated according to the protocol-based survey schedule (i.e. 1, 3 months) following the sent or receipt date of the previous survey as described above. Data will be collected regarding any caregiver status changes or bereavements. Surveys will continue to be administered whether the person with ADRD moves to another setting or passes away. A modified survey will be administered if the person with ADRD passes away during the course of the study. For participants still enrolled in the RCTM study in May 2020, additional COVID-19 related questions will be included in follow-up surveys.

Note: Depending on the survey type and time-point, the due date for surveys administered to primary caregivers that enrolled with other family members is either calculated separately or is dependent upon the receipt of the other family members' surveys. Specifically, due dates for treatment fidelity surveys and routine 4-month surveys are calculated based upon the receipt of the previous survey time-point by all family members; other surveys are calculated based upon the receipt of that individual's survey only.

We will take several steps to address attrition bias. If ADRD caregivers wish to withdraw from the RCTM treatment group, but agree to continue with follow-up interviews/surveys, we will continue routine data collection without counseling.

Several steps will enhance study retention. Baseline and follow-up surveys are administered in a format that is convenient to ADRD caregivers (online, telephone, or mail survey/questionnaire formats). Baseline interviews are anticipated to take no more than 60 minutes; follow-up interviews are expected to take approximately 45 minutes. Quarterly follow-up calls by the TC to all participants will ask "how things are going" and will offer the opportunity for controls to feel connected to the overall study. Following completion of the final 12-month assessment, participants receive a call from one of the TCs. A handwritten note from the study team to thank each participant for their study participation will be sent out to enrolled participants after their last survey or semi-structured interview. These thank you letters will not be sent if a participant withdraws from the study. If a participant did not return all surveys as scheduled, a thank you card will be sent near the projected date of their last study survey. If a participant is enrolled in the study supplement, a thank you letter will be sent after their last survey or interview is completed. Bi-annual project newsletter will be sent to all participants. We will also pay participants $25 following the completion of each baseline, 4-, 8-, and 12-month and final qualitative interview (if selected). Payments will be made using a pre-paid debit card, using the Greenphire ClinCard system.

-Study schedule: Months 3-56 (see Timeline below for general guide)
-Time for participants: 45 minutes

Treatment fidelity. To guarantee accuracy of treatment delivery, Mr. Reese and Dr. Gaugler developed a detailed RCTM treatment manual based on the extensive preliminary work detailed above. The treatment manual will ensure consistent implementation of the RCTM in the proposed project. The manual is an ongoing reference that provides a step-by-step timeframe of delivery activities. The manual will eventually serve as a training tool for future TCs and help enhance the consistency of RCTM clinical approach and strategy.

Throughout delivery of the RCTM, the TC will maintain a detailed contact log and notes to document the frequency, duration, and clinical content of each RCTM session; this will serve as a means to assess treatment receipt as recommended by Burgio et al.[98] and others and will allow the research team to track administration of the RCTM. This will also assist in documenting any deviations from the multi-session protocol of the RCTM and the reasons for them. Also, as recommended by investigators of other evidence-based, ADRD caregiver interventions (e.g., REACH),[98] feedback from caregivers themselves in the RCTM treatment condition can further ascertain treatment receipt. Specifically, caregivers' perceptions of the RCTM will be assessed using close-ended items from a 22-item online or mail survey that will ask caregivers to rate their experiences with various facets of the TC's psychosocial counseling. This checklist will be administered at each follow-up to caregivers who are randomly assigned to receive the RCTM intervention.

Strategies to assess treatment enactment will determine how participants apply the counseling content to their everyday care situations. Multiple open-ended questions will be included on the 22-item checklist described above to all caregivers in the RCTM treatment condition at the 4-, 8-, and 12-month interview intervals. Surveys are sent within 7 days of their scheduled send date (send dates falling on a weekend/holiday are moved to the next business day and administered +/- 7 days from that time). Participants are given several reminders to facilitate survey completion as needed. *[Note: Survey time-points are calculated 4 months following receipt of previous treatment fidelity survey (or 4 months following the sent date of the previous survey, if the previous survey was not returned). Based on this, if participants are not prompt in survey completion, subsequent surveys are pushed back accordingly. In order to maintain blinding of staff involved in administering the routine follow-up surveys, the treatment fidelity surveys are administered separately from the routine follow up surveys and thus the timing of these surveys are calculated without regard to receipt of the routine follow up survey.]*

The open-ended responses will provide qualitative data as to the reasons why family caregivers felt the counseling recommendations of the RCTM were or were not appropriate, whether the recommendations were helpful, which elements of the RCTM caregivers used and how effective they found them, and what barriers or facilitators exist when implementing the TC's recommendations.

Post-evaluation semi-structured interviews. Up to 30 semi-structured interviews with ADRD caregivers receiving the RCTM treatment condition will take place. The interviews will

occur within a 3-month period following the completion of the caregiver's final 12-month follow-up survey. Caregivers are selected for an interview based on their RCTM Review Checklist (i.e. treatment receipt perception) scores. The research coordinator calculates the treatment fidelity scores for those that have completed their 4, 8, and 12-month Checklist. The TCs and PI will select a sample of participants with average Checklist scores between 4 and 5 (i.e. RCTM met their needs) and those with average Checklist scores 4 and below. In addition to the selection of higher and lower average Checklist scores, a stratified purposive sampling approach will be applied. As applicable, the PI and TCs will purposively identify caregivers of varying kin relationship (spouse vs. adult child), length of stay in the residential care setting, caregiver gender, and racial or ethnic background. The open-ended responses of the semi-structured interviews will provide in-depth information on the reasons why and how dementia caregivers felt the RCTM counseling sessions reduced or exacerbated ADRD caregivers' strain and facilitated or hindered adaptation to the residential care transition. Interviews will be conducted via telephone and digitally recorded. Audio recordings will be transcribed by a professional transcription service into a Microsoft Word file which will then be uploaded to nVivo10 for subsequent analysis. If the participant does not give permission for interview to be recorded, interviewer will ask permission to take notes. If permission is granted, interviewer will proceed with the interview taking notes only. If participant does not grant permission for interviewer to record or take notes but still wants to be interviewed, interviewer will proceed with interview but data from interview will not be analyzed.

5.4 **Study Procedures for COVID-19 Administrative Supplement:**

The four key components of the additional data collection (depicted in Figure 1) are:

1. additional follow-up surveys that will assess caregivers' COVID-19-related experiences and track their stress and mental health after the onset of the pandemic;
2. the addition of supplemental COVID-19-related questions to planned surveys for participants still currently enrolled in the RCTM study;
3. 20 additional semi-structured interviews to investigate caregivers' COVID-19 related experiences and challenges; and
4. extraction of relevant qualitative data regarding participants' COVID-19 responses from RCTM case notes and open-ended surveys, as currently-enrolled participants have spontaneously begun discussing pandemic-related concerns in the context of these ongoing components of the parent study.

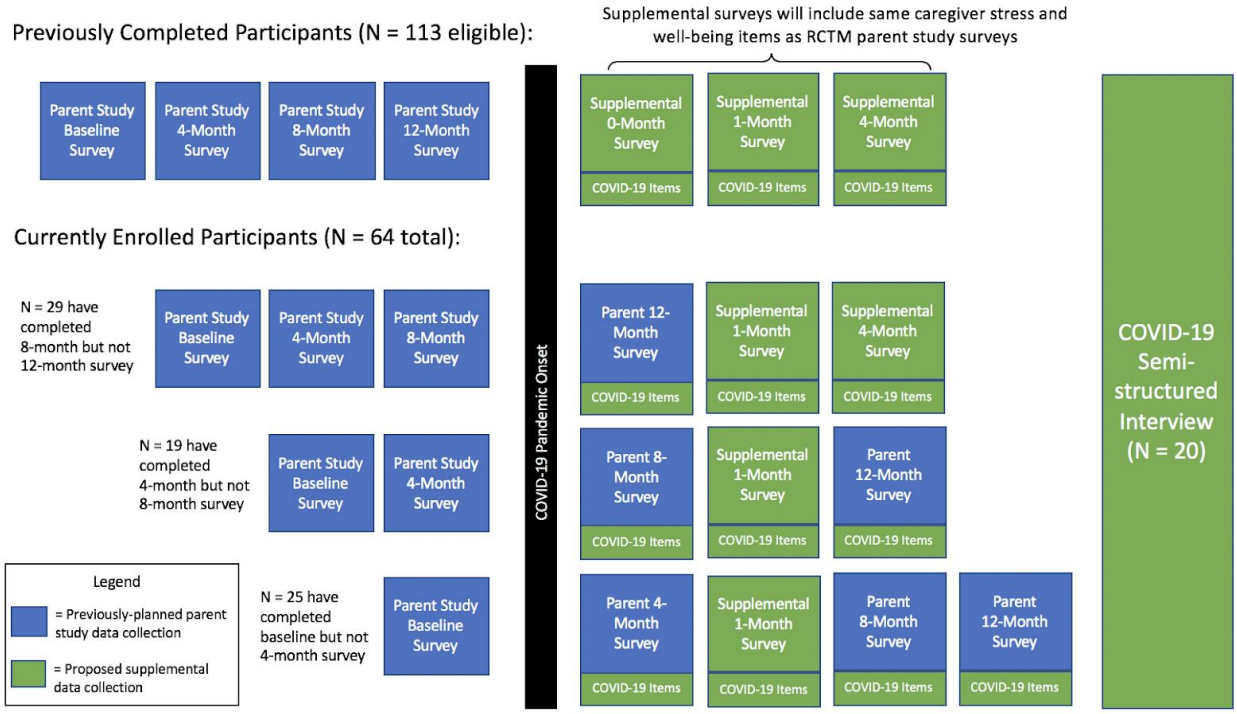

Figure 1. Data collection schedule for planed parent study and proposed supplemental study.

The sample for this supplement will be drawn from participants in the original RCTM parent study. Because participants are at varying stages of completing the parent study, we have devised a data collection schedule that accommodates participants' heterogeneous starting points (see Figure 1). This schedule integrates the proposed additional surveys into the ongoing data collection schedule for the parent study, aligning the supplemental surveys with currently-planned measurement occasions to the extent possible. The proposed schedule allows for at least three assessments of caregivers' stress, well-being, and COVID-19-specific experiences after the onset of the pandemic, which will facilitate the planned longitudinal modeling. For post-COVID-19-onset survey assessments, we propose measurement intervals of 0, 1, and 4 months in order to capture caregivers' responses to the rapidly-changing conditions that are occurring early in the pandemic period, as well as longer-term adjustment across several months.

We will aim for a total of at least 100 participants to complete the post-COVID-19-onset assessments. This sample size will allow for robust longitudinal modeling. We anticipate the sample will include the participants who remain currently enrolled in the study, plus eligible caregivers who had previously completed the full parent RCTM study. The recruitment and retention procedures used in the parent study have been highly successful, with survey completion rates of over 98% at each wave. We anticipate that the strong rapport built through previous engagement with the RCTM study will help us to re-engage a substantial portion of the original sample and maintain strong retention among the currently-enrolled participants.

Caregivers who are eligible to take part in the supplemental assessments will receive an invitation to complete additional surveys, which will provide information about the supplemental study aims and procedures. Those who are interested in participating will then provide informed consent to participate in the additional data collection efforts. The surveys will be administered according to

the same procedures that were used in the parent study. As in the parent RCTM study, participants may choose to complete the supplemental surveys either online, by mail, or by phone. We will offer caregivers $25 to thank them for participating in each survey.

We will also select a purposive sample of approximately 20 participants (split evenly among the treatment and control group) to invite for a semi-structured interview to investigate their COVID-19 and long-term care related experiences in-depth. Participants will be selected based on their responses to the COVID-19 specific items in the survey, aiming for diversity in terms of experiences navigating pandemic-related changes. For example, we will seek to recruit participants who have reported a high degree and a low degree of perceived preparedness from their care recipient's RLTC, participants who have chosen to remove their care recipient from RLTC as well as those whose care recipient has remained in RLTC, and participants living in areas with higher and lower disease exposure. Semi-structured interviews will be conducted by phone, audio-recorded, and transcribed for analysis. Participants will also receive $25 for taking part in the semi-structured interview.

Administrative Supplement Data & Measures
The supplemental surveys administered after the onset of the COVID-19 pandemic will include two main sections. The first section will consist of the same measures of caregiver stress and well-being that are included in the main RCTM follow-up surveys. These assessments will allow us to model trajectories of change in caregiver stress and well-being before and after the onset of the pandemic.

The second section of the supplemental surveys will consist of a questionnaire focused specifically on AD/ADRD caregivers' and care recipients' COVID-19 related experiences. We developed items for the COVID-19 questionnaire through discussion with the RCTM research team, review of emerging literature on COVID-19 and long-term care, and recent counseling session notes with currently-enrolled RCTM participants. The following measures assess key contextual factors and decisions related to COVID-19 that may affect caregivers' and care recipients' experiences.

- *Care recipient's residential status.* The questionnaire will assess whether the care recipient is still living in an RLTC facility, the approximate capacity of the RLTC, and whether the care recipient has roommates.
- *RLTC measures to mitigate COVID-19.* Participants will complete a checklist of possible measures that their care recipient's RLTC facility may have taken to prevent the spread of COVID-19 or mitigate its effects on residents (e.g., limiting visitors, canceling group activities, facilitating video or phone contact with family members).
- *Care recipient's health status.* Participants will report whether their care recipient has a known COVID-19 diagnosis, has experienced symptoms of COVID-19, and has any pre-existing health conditions that may contribute to heightened risk of serious infection.
- *RLTC COVID-19 status.* Items will assess whether the RLTC facility has known positive COVID-19 cases and the facility's plans for management of COVID-19 cases.
- *Caregiver's health, employment, and family status.* Caregivers will be asked whether they have been diagnosed with COVID-19, or are experiencing symptoms. They will also be asked about their employment status, and responsibilities for caring for other family members aside from the care recipient.
- *Perceptions of RLTC crisis management.* This portion of the questionnaire will ask caregivers to evaluate the RLTC facility's handling of the situation, in terms of

preparedness, communication, effectiveness of preventive measures, and efforts to help residents remain engaged.

- *Caregiver-Care recipient communication*. Participants will report the methods they have used to remain in contact with their care recipient, the frequency of contact, and the effects of any changes in contact on the caregiving relationship.
- *Staying or leaving RLTC.* Caregivers will be asked if they have decided to move their care recipient out of RLTC and the reasons for their decision.

We developed a semi-structured interview protocol for in-depth evaluation of participants' experiences related to COVID-19 and long-term care. The semi-structured interview protocol will ask participants first about their overall experience of the COVID-19 pandemic as it relates to their caregiving role, starting with the onset of the pandemic and describing up to the present. Participants will then be asked a series of probing questions to explore the challenges that have emerged and the coping strategies caregivers have used. Interview questions will prompt participants to discuss any COVID-19-specific practices that their care recipient's RLTC has implemented and how these practices have affected the caregiver and care recipient. Participants who received support from the RCTM Transition Counselor through the pandemic period will also be asked how the RCTM was or was not helpful in coping with COVID-19. Interview questions will be modified by caregiver bereavement status to be conscientious of more difficult topics for participants whose care recipient has passed away.

Relevant qualitative data will also be extracted from counseling case notes and open-ended survey questions.

5.5 Individually Identifiable Health Information: A HIPAA waiver was requested for participants' study involvement with study approval.

6.0 Data Banking

6.1 Storage and Access: Any datasets generated and/or analyzed S:\Public_Health_Center-on-Aging_Gaugler\Smartwatch Memory Aid\Protocol & MOP\current protocol and published or placed in a data repository will be de-identified.

6.2 Data: See 6.1.

6.3 Release/Sharing: All information obtained from the participants will remain strictly confidential and will not be released except at the express written request of the study participant [unless permitted by law or regulatory oversight].

7.0 Sharing of Results with Participants

7.1 When manuscripts are published, the findings will be distributed to all research participants. Main outcome papers that address the study aims will not be disseminated until all data collection procedures are completed. However, analyses of treatment receipt, perceived utility, important aspects of intervention delivery, and other descriptive analyses have and will be disseminated prior to the main outcome papers. The project team aims to minimize the length of time between final data collection procedures and dissemination of final outcome papers to appropriate peer-reviewed journals. We anticipate a timeframe of 6 months between final data collection and peer-reviewed article submissions of RCTM outcomes.

8.0 Study Duration

8.1 ADRD caregivers will participate in the parent study for about 12-months; the total project duration is 5 years (06/01/2016 - 05/31/2021). This will be extended for the COVID-19 administrative supplement for one year beyond the originally planned timeline. A project timeline is below:

Project Timeline

	Months 1-3	Months 4-12	Months 13-55	Months 56-60	Months 60-62
Data management processes	●	○	○	○	○
Hiring and training of research coordinator and 2 research assistants	●	○	○	○	○
Monthly research team meetings/Project management	●	●	●	●	●
Recruitment of ADRD caregivers [(*n* = 240)]	●	●	●		
Re-enrollment of previous RCTM participants (up to N = 113) to take part in supplemental COVID-19 surveys					●
Administration of Residential Care Transition Module counseling sessions		●	●	○	
Baseline, 4-, 8-, and 12-month data collection		●	●	○	
Treatment fidelity/process evaluation		●	●	●	
Embedded semi-structured interviews, post evaluation			●	●	●
RCT longitudinal analysis; Analysis of post-RCT embedded component			●	●	
Dissemination			○	●	●

NOTE: ADRD = Alzheimer's disease or a related dementia; RCT = randomized controlled trial;
LEGEND: ● = primary focus; ○ = ongoing but less intensive

9.0 Study Population

9.1 Inclusion Criteria: Eligibility criteria include family caregivers who consider themselves the most involved in visiting and providing assistance to the person with memory loss (or who share the primary caregiving role equally). For the caregiver to participate, the care recipient must be residing in a RLTC setting (e.g. assisted living, nursing home, memory care, or other residential long-term care setting) and have received a physician's diagnosis of ADRD. Family caregivers must be English speaking, 21 years of age or older, and not participating in any other one-to-one psychosocial consultation specifically for caregiving (support group participation is not a deterrent to enrollment, nor is general counseling not specific to caregiving). Family caregivers on psychotropic medications, such as anti-depressants or anti-psychotics, will be eligible if they have remained on a stable dosage for the last 3 months.

The sample for the administrative supplement focused on COVID-19 will be drawn from participants in the original RCTM parent study. Caregivers who have already completed the study and who have not previously reported bereavement, as well as those caregivers who remain currently enrolled in the parent study, will be invited to take part in the proposed supplemental assessments. Among previously-completed participants, those whose care recipient is still alive will be eligible to re-enroll. Among currently-enrolled participants, any who are not bereaved, or who are bereaved but have been continuing to participate in

bereavement-modified surveys, will be eligible to participate in supplemental surveys. Both control and treatment group participants will be eligible. Previously-completed caregivers whose care recipient has already passed away will not be eligible to enroll in the supplement.

9.2 Exclusion Criteria: Caregivers are not eligible to participate if they do not meet the inclusion criteria above.

9.3 Screening: If caregivers are interested in participating, the RC will conduct a brief screening procedure using the RCTM Screening Form, developed on the above eligibility criteria.

Previously completed participants who are interested in participating in the additional survey(s) for the COVID-focused supplement will complete a brief screening survey prior to re-enrollment, including items assessing bereavement

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be primary focus of the research (targeted), included but not the focus of the research or excluded from participation in the study.
Children	Excluded
Pregnant women/fetuses/neonates	included but not the focus
Prisoners	Excluded
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	included but not the focus; see Sections 10.2 and 22.6 for descriptions and safeguards
Non-English speakers	Excluded
Those unable to read (illiterate)	Excluded
Employees of the researcher	Excluded
Students of the researcher	Excluded

Undervalued or disenfranchised social group	included but not the focus
Active members of the military (service members), DoD personnel (including civilian employees)	included but not the focus
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	included but not the focus
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	included but not the focus
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Excluded
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded

10.2 Additional Safeguards: N/A

All participants in the above table that are listed as “included but not the focus” could be included in the study by chance. However, these vulnerable groups are not sought out during recruitment and we do not ask potential participants if they belong to one of the above groups or not. Thus, extra safeguards are not put in place to protect these groups since we would not know if they were included in the research or not. Given our study population of interest, it is unlikely for participants to be a part of the groups listed as “included but not the focus,” besides adults lacking the capacity to consent or have a diminished capacity to consent which is addressed below.

Due to the nature of the project and its risk, a specific capacity to consent assessment is not included with consent. Participants are reminded that all study procedures are voluntary and they can withdraw at any time. We do not anticipate any individuals from the above noted groups to have increased risk from participating in the proposed research, such as an increased risk of coercion, etc. Thus, our standard protocol practices (i.e. data security, confidentiality procedures, etc.) provide reasonable protections to these potentially vulnerable participants (including those listed above and any others who may meet inclusion criteria to enroll). For specific procedures for those with potential memory impairment noted during the study, see section 22.6.

10.3 If research includes potential for direct benefit to participant, provide rationale for any exclusions indicated in the table above:

Some individuals in the above vulnerable groups are excluded because they are not our population of interest or because participating in such research would potentially be risky for them.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

- Parent study: 240 primary caregivers
- Administrative supplement: 100 caregivers

12.0 Recruitment Methods

12.1 Recruitment Process: At various outreach events, a Documentation of Permission form will be utilized to provide the PI and research team the ability to reach out to the potential participant about the project. Following completion of this form, a research coordinator will initiate email, telephone, or mail contact with family caregivers.

Alternatively, interested research participants can reach out to the study team directly to initiate contact. During initial contacts with potential participants, the coordinator will describe the RCTM intervention, explain study procedures such as voluntary participation, randomization, and what the usual care control condition includes. A telephone and email script will be utilized.

Participants for the supplement will be drawn from participants in the original RCTM parent study. Caregivers who are eligible to take part in the supplemental assessments will receive an invitation to complete additional surveys, which will provide information about the supplemental study aims and procedures.

12.2 Source of Participants: Dr. Gaugler has created a University of Minnesota Caregiver Registry that includes family and professional caregivers who have participated in his free annual community education conference, “Caring for a Person with Memory Loss” (CPWML). Approximately 200-350 persons attend each CPWML conference. Attendees are invited to complete a brief form which enrolls them in the Registry and gives Dr. Gaugler and his research staff permission to contact and invite them to participate in his studies. We will periodically send project recruitment materials to members of the caregiver registry. Specifically, a research coordinator will initiate email, telephone, or mail contact with family

caregivers on the University of Minnesota Caregiver Registry or with others recruited by the PI or the TC. Professional care providers on the Registry will also be asked to identify potential ADRD family caregivers for recruitment purposes. During initial contacts with potential participants, the coordinator will describe the RCTM intervention, explain study procedures such as voluntary participation, randomization, and what the usual care control condition includes. If caregivers are interested in participating, the research coordinator will initiate a brief screening procedure applying the inclusion criteria above. Caregivers will be offered the opportunity to ask questions about the study procedures, and informed consent will be obtained.

Dr. Gaugler is a member of the Minnesota Care Options Network. To supplement Registry-based recruitment efforts, we will ask 'facility liaisons' (e.g., administrator, director of nursing, or director of social services) to assist with recruitment efforts. Initially, facility liaisons will be asked to advertise monthly presentations that will be conducted by the University of Minnesota evaluation team (Dr. Gaugler, the TC, or research coordinators). These presentations will introduce the RCTM to interested family members. Following each presentation, the evaluation team will circulate a sign-up sheet for those interested in participating in the project. In addition, facility liaisons can post flyers in select areas of facilities that are frequented by residents and family members and/or distribute announcements in the facility newsletter and web page. Finally, facility liaisons will be asked to contact eligible family members to share information about the RCTM and ask family members' permission for Dr. Gaugler, the TC, or research coordinators to contact them to discuss participation in the project.

We will also ask direct care providers in the Registry to identify ADRD caregivers of diverse ethnic or racial origin and geographic location who are not in the Registry. These recruitment efforts will be facilitated by the Minnesota Board on Aging (MBA) and the Minnesota-North Dakota Alzheimer's Association regional office (see Letters of Support). The MBA will help us promote this study through Area Agencies on Aging, many of which serve ethnic and racially diverse older adults as well rural ADRD caregivers. To further facilitate these efforts, the PI will conduct a number of free, community presentations about the RCTM throughout the Minneapolis/St. Paul and outlying rural areas seeking to recruit underrepresented ADRD caregivers.

IRB-approved information sheets, flyers, and study materials will be shared at various community events, including events such as Minnesota's Farm Fest and the Minnesota State Fair.

In addition to the above methods of recruitment, we will also recruit in such a way where interested parties can reach out to our research team directly, such as e-letters sent out by the Alzheimer's Disease Education and Referral program of the National Institute on Aging. Additional recruitment is conducted through the following IRB-approved advertisements: a radio announcement, periodic newspaper advertisements in local circulars in various states; project listings on CTSI StudyFinder and Clinicaltrials.gov; the University of Minnesota School of Public Health website; Banner Health's Alzheimer's Prevention Registry (including a study listing, geotargeted e-mails, Facebook posts), and via Facebook advertisements. A Families and LTC Facebook business page has been created and will be used to manage the ad

placement. The goal of recruiting via these various recruitment modalities is to broaden our study population.

For the COVID-19 administrative supplement, participants will be recruited from among current and previous participants in the parent RCTM study.

12.3 Identification of Potential Participants: Please see above.

12.4 Recruitment Materials: Please see above.

12.5 Payment:

Participants will be paid $25 following the completion of each baseline, 4-, 8-, and 12-month and final qualitative interview (if selected). These same payments are provided for the administrative supplement. Payments will be made using a pre-paid debit card, using the Greenphire Clincard system.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances:

Staff may become aware of participants who have potential memory concerns through study interactions, such as phone calls by the interventionist or research coordinator. When this type of participant is identified, the research coordinator will call the participant and determine if they are able to consent to participation. To do so, a brief summary of the consent form will be read to the participant, then the research coordinator will administer the UBACC (UCSD Brief Assessment of Capacity to Consent). ***Please see details in section 22.6- "Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent"*** for more information on administering the UBACC. If the participant scores under 14.5, then we will withdraw them from the study and therefore not ask them to complete any additional surveys. Participants in the treatment group who do not pass the capacity to consent screener will be offered the opportunity to continue contact with the study interventionist, if they desire, even if they are withdrawn from the study. This will ensure continued support for any participants who had planned to continue their contact with the counselor, but are no longer eligible to participate in surveys. We will report participants who are withdrawn for this reason along with their UBACC scores to the IRB as an RNI within 5 business days of the capacity to consent call with the participant. This data will also be reported in the annual data reports on participant safety as part of the data safety monitoring plan (see plan below).

13.2 Withdrawal Procedures:
In instances where ADRD caregivers wish to withdraw from the study, we will attempt to determine the reason for study withdrawal and conduct necessary documentation (RNI, tracking forms, etc.). Withdrawn participants will not be contacted for further data collection.

13.3 Termination Procedures:
There is no intention to terminate any participant's participation in the research study, however if this were to occur, the procedures that would be carried out would be similar to those if the participant requested to withdraw, or was lost to follow up. Data from participants who were terminated would be used up until the point of their termination.

14.0 Risks to Participants

14.1 Foreseeable Risks:

Since the study involves no invasive procedures, there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver. However, the research team has considerable experience providing psychosocial support to dementia caregivers on various protocols and serious psychological risks are unlikely to occur based on this experience. The potential social or legal risks for the participants relate only to possible violations of confidentiality. Given the procedures outlined below, such risks are highly unlikely.

The experience of the research team and the exclusion of caregivers with serious psychiatric illness will minimize the possibility of psychological risks. The unlikelihood of such problems is evident from the absence of any clinically significant problems during the past 13 years that the research team has operated various protocols related to dementia caregiving intervention research. The research coordinator and research assistant will be trained to interview in ways that are non-threatening, friendly, and respectful. We will emphasize to all participants that they do not have to complete any question they do not want to answer, and that the interview may be terminated at any time according to their wishes. We will stress to ADRD caregivers that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota, long-term care facility, or other entities.

In the event a caregiver does become upset during the interview process, the research coordinator or research assistant will contact Dr. Gaugler, who will be available for consultation. If a caregiver is in crisis because of their care situation or some other reason, research staff will be instructed to consult with Dr. Gaugler. With the caregiver's permission, we will then contact the appropriate resource person in an external agency (e.g., the Alzheimer's Association). Based on the research team's experience working with their caregiving families, we expect very few or no such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, Adult Protective Services will be notified to protect the rights of persons with dementia and their families.

All information obtained from the participants will remain strictly confidential and will not be released except at the express written request of the study participant. All electronic data will be maintained in Qualtrics, the Secure Computing Environment, secure Academic Health Center project folder, and in Box. All data on Dr. Gaugler's computer in D351 Mayo Building and the research staff's computers (also located in D351 Mayo Building) are encrypted and protected by strong passwords only accessible to Dr. Gaugler and the research team.

Research data will be maintained on the Academic Health Center secure project folder for approximately 2-3 years which is the time anticipated it will take to disseminate any and all research papers or presentations from these data. Similarly, paper forms of the data will be

located in a locked file cabinet in D351 Mayo Building only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

14.2 Reproduction Risks: N/A

14.3 Risks to Others: N/A

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

There are no expected benefits from participation, but participants who receive the intervention may feel better about navigating the transition of your loved one into residential care. See above for details related to compensation.

17.0 Statistical Considerations

17.1 Data Analysis Plan:

Analysis of Specific Aims 1-3

Data available at baseline, 4 months, 8 months, and 12 months will allow for individual growth curve models that examine change in ADRD caregiver outcomes.[103,104] Multilevel analysis approaches are available that support growth curve modeling. In this context, growth curve modeling is an example of a 2-stage modeling process consisting of 1) a within-subjects model across time, and 2) a between-subjects model that incorporates caregiver and person with ADRD covariates.[105,106] The primary independent variable in the proposed investigation consists of an indicator variable for random assignment into the RCTM treatment condition or the attention care control. [SAS (version 9.4) Proc Mixed[107]] will be used to conduct these analyses, as it supports multilevel and growth curve modeling procedures.

Our proposed analyses will provide in-depth tests of Specific Aims 1 to 3 (i.e., rates of change in primary subjective stress, secondary role strains, residential care stress, and caregiver depressive symptoms) over a 12-month period. In one set of outcome evaluations, the baseline value will be included as a covariate, and time will be "centered" at 4-months post-baseline. This scales the intercept effect to be a main effect of RCTM group assignment and allows the RCTM treatment and the attention control groups to have different 4-, 8-, and 12-month change trajectories, or an RCTM treatment*time interaction effect. After establishing that the individual growth parameter estimates have significant variance around the mean trajectories of change in key dependent variables, an RCTM treatment vs. control group indicator will be added as the key independent variable to predict intercepts and rates of change in outcomes. Additional analyses will determine if covariates (e.g., context of care indicators, primary objective stressors, and resources) significantly vary across the RCTM treatment and control groups at baseline and over time via growth curve modeling procedures. If statistically significant variations between the RCTM treatment and control groups are found, initial status and rate of change parameters for these covariates will be included in all tests to provide further statistical control.

Secondary Analyses

In addition to analyses of secondary Aims 1a and 1b (which will mirror the Specific Aims 1-3 analyses described above), empirical treatment fidelity data on variations in use of RCTM (e.g., frequency and duration of counseling sessions) will be included in growth curve models as a series of post-hoc Specific Aims 1, 2, and 3 analyses. These analyses will explore the effects of variations in RCTM utilization on the outcomes hypothesized above. [A series of mediational models will also be tested examining some of the hypothesized pathways of the SPM-RC as described in the conceptualization of the proposed project (e.g., whether RCTM assignment mediates the empirical relationships between care-related stressors and more global psychological and emotional outcomes on the part of family caregivers). As detailed by Selig and Preacher and other methodologists, mediational models appropriate for longitudinal data will be utilized.[108] These analyses will explore the empirical mechanisms that explain RCTM's efficacy or lack thereof.]

Specific Aim 4 Analyses

Specific Aim 4 analyses will primarily focus on thematic content analysis of open-ended data to examine RCTM utility and mechanisms of benefit. Systematic reading and rereading of qualitative content and hand coding of a significant proportion of this content is necessary in order to develop an understanding of meanings in their conversational or observational contexts.[109,110] Specifically, the PI, Dr. Garcia (Co-Investigator) and the research assistants will independently develop coding categories together with descriptors (via hand-coding and NVivo) and will develop a shared coding scheme that will reflect the primary categories of the transcription. Through repetition of this procedure, a consensus perspective on appropriate coding categories and themes will be modified and developed. These themes will provide insights as to the RCTM's implementation and use (i.e., treatment fidelity/process evaluation) and mechanisms of benefit (i.e., semi-structured interview embedded component).

Grounded theory techniques described by Morse[111] and Strauss and Corbin[109] will guide the analyses of qualitative data in the treatment fidelity/process evaluation procedures and Specific Aim 4. These approaches allow participants to construct meanings, perceptions, and behaviors from their own vantage points. All open-ended data collected will be first read by the PI, Dr. Garcia, and the research assistants to identify textual elements that emerge repeatedly (i.e., codes); these codes will then be clustered into larger categories that are later used to construct major thematic elements from the text (with the use of nVivo 10[112] analytic software).

During weekly meetings in the analysis phase of the proposed project, the PI, Dr. Garcia, and the research assistants will discuss their own identified codes to reach a consensus about specific codes, categories, and themes that emerge from the qualitative data (these decisions will be noted in an audit trail). In addition, patterns that link particular themes will be identified and discussed in successive meetings between the PI, Dr. Garcia, and the research assistants to identify more complex processes of RCTM use or RCTM's pathways to benefit. During monthly team meetings, the development of codes, categories, and themes will be reviewed with the other Co-Investigators to yield any additional input into these project components. The multiple team meetings and discussions will allow for an exploration of alternative interpretations of the qualitative data and will also provide a

check regarding the quality and richness of the data collected during the embedded mixed methods components. [Moreover, member checking[113,114] will take place where transcripts in addition to emergent thematic findings from the qualitative data are presented to participants themselves to ensure that we interpret open-ended responses and the meanings derived from these data appropriately.]

Additional mixed methods analyses[63,64] will take place to complete Specific Aim 4. The thematic codes and categories of the post-RCT embedded component will be cross-tabulated with the empirical data from the RCT to determine whether the findings diverge, converge, or highlight pathways toward additional questions and analysis.[64] Findings that diverge will be treated as "interpretive opportunities" to either demonstrate that no true discrepancy in efficacy exists or to propose the phenomenon that explains the apparent discrepancy.[115] Specifically, empirical outcome data of the RCT will be sorted according to the qualitative themes that emerge across the two subgroups of the embedded semi-structured interview component (e.g., increased or decreased rates of change in care-related strain). This integration will provide empirical context for ADRD caregivers' statements regarding why the RCTM is perceived to work or not, respectively.[64,116] The comparative, mixed method analysis approach may also suggest that those who reported greater increases in subjective stress during RCTM use may indicate certain themes more often or may use RCTM differently than ADRD caregivers who report greater decreases in care-related strain.

The post-intervention interviews will help explain mechanisms of benefit based on the questions of "why" and "how" that are implicit in qualitative data. While empirical analyses such as mediational models might provide some suggestion as to why the RCTM exerts benefits, utilizing qualitative data is a more comprehensive approach by allowing intervention participants to describe, in their own words and experiences with the RCTM, why the psychosocial support provided helped families adapt to the RLTC transition. Such an approach may also identify domains untapped in empirical measurement. This certainly occurred in the pilot evaluation of RCTM efficacy,[117] and is largely why a mixed methods design for this larger-scale evaluation was selected. Also, the qualitative data that emerge from the post-RCTM interviews may suggest additional secondary analyses of the empirical data that could test possible mediators or path analyses (see above). In this regard, the mixed methods approach is advantageous for the proposed project.

Planned Interim Analyses
Not applicable; if these are done, they will be conducted at the 4-, 8-, and 12-month intervals; given how the qualitative data component of the mixed methods research design is structured, these findings will not be fully available until the final months of the 5-year project.

Analysis Plan for COVID-19 Administrative Supplement

We will aim for a total of at least 100 participants to complete the post-COVID-19-onset assessments. This sample size will allow for robust longitudinal modeling. A sample size of 20 is appropriate for exploratory semi-structured interviews to examine the potential effects of COVID-19 on caregivers with a relative in long-term care.

For our first aim (examining COVID-19-related experiences among caregivers with a care recipient in RLTC), we will use a parallel-convergent mixed methods design to integrate qualitative and quantitative data about participants' COVID-19-specific experiences. We will calculate descriptive statistics for the measures of COVID-19-specific experiences, and use appropriate correlational methods to examine the relationship between key COVID-19 experiences (e.g., having a confirmed positive case in the relative's RLTC facility; removing a relative from the RLTC facility; perceptions of the RLTC's crisis response effectiveness) and caregivers' stress and mental health. In addition, we will use thematic analysis techniques developed by Braun and Clarke to investigate themes from semi-structured interviews and open-ended survey responses relating to caregivers' challenges and coping responses to COVID-19. These open-ended responses will provide insights regarding novel challenges that are currently emerging for caregivers, and reveal which issues are perceived as most important and urgent from caregivers' perspectives. All open-ended data will be read by the PI and the coding team to identify preliminary patterns within the text (i.e., codes). These codes will be refined through an iterative process of weekly discussion and adjustment of the coding scheme. Decisions will be noted in an audit trail to enhance transparency of the coding process. Codes will be clustered into broader overarching themes that reflect key insights. Additional mixed methods analyses will involve cross-tabulating the thematic codes with the quantitative data on caregivers' COVID-19 experiences, RCTM treatment group assignment, and caregiving stress to determine whether the findings diverge, converge, or highlight additional directions to explore. This comparative, mixed methods analysis approach may suggest how and why caregivers are able to cope with COVID-19 related challenges.

For our second aim (evaluating the effects of COVID-19 on caregiver stress), we will use latent growth curve modeling to estimate trajectories of change in caregiver stress over time. Latent growth curve modeling is a structural modeling approach to longitudinal analysis that can accommodate individually-varying measurement occasions. With up to seven waves of data per participant, we will be able to estimate nonlinear growth trajectories. We will examine change in caregivers' primary subjective stress, residential care stress, and depressive symptoms, and will center our longitudinal analyses around March 13, 2020, the date when COVID-19 was declared a national emergency in the United States.

For our third aim (determining whether RCTM treatment group participants are more resilient to negative psychosocial effects of COVID-19), we will incorporate a time-invariant covariate reflecting treatment or control group membership into the latent growth curve models for caregiver outcomes. This will allow us to compare the trajectories for the treatment and control groups to determine whether the RCTM intervention affected change in caregiver stress and mental health before and after the onset of the pandemic. We will also conduct sensitivity analyses that incorporate measures of treatment group participants' contact with the RCTM counselor after the onset of the COVID-19 pandemic, to distinguish the effects of current support via RCTM from the potential protective effects of having completed the intervention prior to the pandemic.

Statistical analyses used will include calculation of frequencies, bivariate correlations, t-tests, and chi-square tests in order to describe participants' COVID-19-related experiences.

Latent growth curve modeling will be used to estimate trajectories of caregiver mental health and well-being before and after the onset of the pandemic.

17.2 Power Analysis:

Determination of Sample Size
Intensive longitudinal analysis procedures (multilevel regression analyses of outcome and growth curve modeling) will be utilized to capitalize on the randomized controlled design and the multiple waves of data to be collected. The number of ADRD caregivers to be enrolled to address study hypotheses was determined using power analysis procedures that take into account the hierarchical analytic design of the study.[99] In this framework, the researcher identifies the Type I error rate (e.g., $p < .05$) to differentiate between a null and alternative test hypothesis, a suitable level of statistical power (.80 is considered an excellent power value), and the expected difference between the two study groups in order to determine the number of ADRD caregivers to enroll into the project. [We sought a sample size that would be sufficient to detect a group difference of 0.50 standard deviation units and modest effect sizes that we identified in our preliminary efficacy trial. This is considered to be a "medium" effect size[100] and is a reasonable benchmark to evaluate the efficacy of a behavioral intervention in comparison to a usual care control condition. We also used a Bonferroni adjusted Type I error rate of .0125 (.05/4) to accommodate up to 4 primary outcome variables (primary subjective stress; secondary role strain; residential care stress; caregiver depressive symptoms), and we allowed for a conservative 10% loss to follow-up. With these specifications, an enrolled sample size of 240 ADRD caregivers (120 in each group) was sufficient to provide adequate statistical power. After attrition, this sample size will give us .87 power to detect a 0.50 effect size and .80 power to detect a slightly smaller effect size of 0.46 standard deviation units. This effect size could apply to covariate-adjusted mean differences at a particular follow-up point, or two linear slope differences of change across time between the intervention and control conditions.]

As noted in various recommendations for mixed methods sampling, 30-40 participants is considered an adequate sample size for semi-structured interview protocols as proposed here.[101,102] As "sample size" in qualitative research is based more on the richness and depth of open-ended data collected, it is possible to achieve the goals of the post-randomized controlled evaluation embedded component with a smaller number of semi-structured interviews. Given the expected number of ADRD caregivers in the RCTM treatment condition, we decided on 30 semi-structured interviews to ensure the richness of the qualitative data collected.

17.3 Statistical Analysis: Please see data analysis plan.

17.4 Data Integrity: Several steps will be taken to ensure data quality. The psychometric properties of the study measures are generally well-established; however, additional steps will be taken to ensure the reliability and validity of the study measures. For example, internal reliability will be established with Cronbach's alpha (α) estimates for each measure and subscale. These procedures will help to establish the psychometric qualities of each tool beyond their utilization in prior study. Each outcome variable will be examined to determine if skewness exists or outliers are present. Normal probability plots and histograms of each

dependent variable will be analyzed; this step is necessary because individual outcome variables must have near-normal distributions in order to be included in subsequent models. If the outcome variables are not normally distributed, the original variables can be subjected to algebraic transformations or other standard transformation techniques to meet model assumptions.

18.0 Health Information and Privacy Compliance

18.1 Select which of the following is applicable to your research:

X My research does not require access to individual health information and therefore assert HIPAA does not apply.

☐ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

X I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe:

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed. N/A

18.4 Approximate number of records required for review: N/A

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

X Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants. When participants consent to participating in the research, they are asked whether or not they agree to communicate with the research team via unencrypted email. If a participant does not agree to communicate this way, the team can send encrypted emails to participants. Participants also agree to telephone-based counseling, depending on randomization, and completing surveys either via hard copy or via secure Qualtrics survey platform.

Access to participants

Our research team is not permitted to access medical records. Any private information that the research team is allowed to have access to will need to be provided by the participant. This includes, but is not limited to, survey responses, semi-structured interview responses, and contact information.

18.6 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store☐ Analyze ☐ Share

☐ In REDCap (recap.ahc.umn.edu)

☐ Store☐ Analyze ☐ Share

X In Qualtrics (qualtrics.umn.edu)

X Store ☐ Analyze X Share

☐ In OnCore (oncore.umn.edu)

☐ Store☐ Analyze ☐ Share

X In the University's Box Secure Storage (box.umn.edu)

X Store ☐ Analyze X Share

X In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

S:\Public_Health_Center-on-Aging_Gaugler\The Residential Care Transition Module

IT Support Contact: Troy Karkula, karku003@umn.edu

X Store X Analyze X Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☐ Other.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.7 Consultants. Vendors. Third Parties.

John Hopkins University will have responsibility for data analysis. Additionally, Production Transcripts is a professional transcription service that will be used to transcribe audio recordings of qualitative interviews. Audio recordings will be securely uploaded to their secure website and the transcripts will be securely shared with the research team once completed.

18.8 Links to identifiable data:
Individualized links are generated via Qualtrics and saved on the server. Links are destroyed at the end of data collection.

18.9 Sharing of Data with Research Team Members. Data will be shared via Box, Qualtrics and the secure server. See 19.1 "Data Security".

18.10 Storage of Documents: All electronic data will be maintained on a University of Minnesota secure server folder and a Box folder. Paper forms of the data will be located in a locked file cabinet in D351 Mayo Memorial Building (Dr. Gaugler's research office) only accessible to the research team. The office containing the files is also locked. Unless the data are being filed or accessed, these cabinets will remain locked.

18.11 Disposal of Documents: Per University of Minnesota and the School of Public Health security guidelines, participant data will be maintained on the secure project folder for approximately 2-3 years which is the time anticipated it will take to disseminate any and all research papers or presentations from these data. Baseline, follow-up, or disposition surveys inputted into Qualtrics databases that contained a participant's identifier (name)

for tracking will be de-identified upon study completion. De-identified records will be kept indefinitely, in order to encourage data sharing submitted to the National Institute on Aging.

19.0 Confidentiality

19.1 Data Security:

Who Will Manage the Study Data
Dr. Gaugler (the PI), Dr. Mitchell (the administrative supplement PI), the TCs, the research coordinators, and graduate research assistants will have primary responsibility for managing all study data. Research assistants who work under the supervision of Dr. Gaugler in the Families and LTC Projects at the University of Minnesota may also enter, clean, and assist the PI and other RCTM team members to manage data as appropriate during the course of the project.

Dr. Gaugler's team uses VPN and Remote Desktop Connection to access study data. They are not to download, view, or save any project-related data on their personal laptops or any mobile data storage device. Staff working remotely will continue use of these secure environments as needed. Note: University staff calling from personal lines outside of the University will block their personal numbers when able, and note they are calling from a personal line and request a callback to a work-based telephone number, or alternatively use a google voice account.

Confidentiality Assurance and Data Management
Names and contact information are included in study tracking documents for the purposes of interview reminders and completion of the various data collection procedures. However, data used for analysis will be de-identified according to standard procedures. Procedures for data collection and storage are described above.

As mentioned above, baseline, follow-up, or disposition surveys inputted into Qualtrics databases that contained a participant's identifier (name) for tracking will be de-identified upon study completion. De-identified records will be kept indefinitely, in order to encourage data sharing submitted to the National Institute on Aging.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

Dr. Gaugler (the PI) and the research coordinators will have primary responsibility for managing all study data. Research assistants who work under the supervision of Dr. Gaugler in the Families and LTC Projects at the University of Minnesota may also enter, clean, and assist the PI and research coordinators manage data as appropriate during the course of the project.

Prior to University of Minnesota Institutional Review Board (IRB) submission, Dr. Gaugler will identify a Data Monitoring Officer (DMO) at the University of Minnesota. The DMO will be a senior faculty member with experience conducting clinical trials.

Review process. Dr. Gaugler and the DMO will review data monitoring and safety activities annually during the 5-year project period. The responsibility of Dr. Gaugler (who also has oversight for the data management and analysis of the project) will include the production of an administrative report that will highlight study accrual. In addition, Dr. Gaugler will provide information on any deviations from the approved protocol (e.g., deviations in adhering to study eligibility criteria), error rates, and any other issues related to the progress of the study. The DMO will review the administrative report to ensure ongoing quality control, and will work with Dr. Gaugler if necessary to identify individual cases to ascertain any deviations in the approved study protocol. Following this review, the administrative report will be presented to the National Institute on Aging (NIA). In instances of adverse events (see Data Safety Monitoring Plan), the DMO, the NIA project officer, and the University of Minnesota IRB will be notified per below specifications.

The administrative reports will include the following:

1. Table of contents
2. Narrative/trial summary
    a. Summary of main findings
    b. Discussion of issues or problems
    c. Report preparation procedures
3. Study description
    a. Project organizational chart, personnel
    b. Brief statement of purpose of trial
    c. Projected timetable and schedule
4. Study administration
    a. Recruitment and participant status
        i. Table 1: Enrollment by year or month of study
        ii. Figure 1: Comparison of target to actual enrollment by month
    b. Forms status
        i. Status of forms (e.g., consent, completing of screener, baseline assessment battery, etc.)

Data Report.

Dr. Gaugler will also prepare interim analysis reports for review with the DMO. These interim analysis reports will include the following:

1. Recruitment and participant status
    a. Table 2: Targeted/Planned Enrollment Table
    b. Table 3: Demographic and key baseline characteristics by group
2. Safety assessment for all participants
    a. Table 4: Treatment duration for all participants
    b. Table 5: Adverse events by participant
    c. Table 6: Serious adverse events by participant
    d. Table 7: Participant deaths
    e. Table 8: Participants without capacity to consent during follow-up

Reports from the DMO (largely taken from National Institute of Allergy and Infectious Diseases guidelines).

At the conclusion of each annual review, the DMO will discuss her/his recommendations and findings with Dr. Gaugler. If necessary, the DMO will also issue a written summary report that identifies key issues in the administrative, safety, and data reports and provides overall safety assessment and recommendations. Any rationale for recommendations will be included where appropriate. The report will not include confidential information. Following dissemination of this report to Dr. Gaugler, Dr. Gaugler will provide the report to NIA and the Co-Investigators for review.

The DMO will notify Dr. Gaugler of any findings of a serious nature or recommendations to discontinue all or part of the intervention. Dr. Gaugler will then immediately inform the project officer at NIA of this recommendation.

20.2 Data Safety Monitoring.

A data monitoring safety plan (DMSP) that includes a data safety and monitoring officer is proposed to provide additional oversight of the research protocol and adverse event reporting, if necessary.

The main activities of the DMSP will be as follows (taken from National Institute of Allergy and Infectious Diseases guidelines):

1. Review of interim and cumulative data for any evidence of study-related adverse events (AEs);
2. Review of interim/cumulative data for evidence of efficacy of the intervention;
3. Review of data quality, completeness, and timeliness;
4. Review the adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;
5. Review adherence to the protocol;
6. Review factors that might affect the study outcome or compromise the confidentiality of the data (such as protocol violations, unmasking, etc.); and
7. Identification of factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

Safety reports. In addition to producing administrative reports on an annual basis to the DMO, Dr. Gaugler will generate annual safety reports that will list adverse events, serious events, unexpected events, events related to or associated with the intervention, and the potential causality of the intervention to the event for each participant. If the research team becomes aware of an adverse event or unanticipated problem occurring while a participant is enrolled in the study (from consent through the participant's final data collection), the event will be documented and/or reported per the protocol below. Events will be documented/reported as adverse events per the protocol if they meet one of the following criteria: a participant alerts study staff of a new or worsening health problem that causes the participant to 1) be unable to perform their daily routine, 2) seek medical care (provider visit, hospitalization, residential care placement, etc.), or 3) take a new medication. Conditions existing prior to study enrollment that have not worsened/changed will not be considered adverse events and will not be documented/reported. Per the University of Minnesota IRB guidelines, all events or information that indicates a new or increased risk, or a safety issue, will be promptly reported.

Taken from earlier National Institutes of Mental Health policy on Data and Safety Monitoring in Clinical Trials, the definition of each event is as follows:

Adverse event. Any untoward medical occurrence in a patient or clinical investigation participant which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the participants' involvement in research, whether or not considered related to participation in the research.

Serious adverse event. Any adverse experience that results in any of the following outcomes: death, a life threatening experience, inpatient hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse experience when based upon appropriate medical judgment, and they may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Unexpected. Any adverse experience, the specificity or severity of which is not consistent with the risk information described in the [protocol or consent documents].

Related to (or associated with) the intervention. There is a reasonable possibility that the experience may have been caused by the intervention.

Causality. A reasonable possibility that the product is etiologically related to the adverse event. Causality assessment includes, for example, assessment of temporal relationships, dechallenge/rechallenge information, association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, plausibility, etc.

Survey responses regarding health information will not be considered adverse events, unless otherwise communicated to the study staff. [Note: Medical events or emergencies of a non-participant will not be considered/documented as adverse events]. Regardless of the classification of an event (adverse event versus serious adverse event), only those events determined to be potentially related to the participant's involvement in research will be reported to IRB promptly. All other adverse events reported to study staff by participants will be recorded and reported annually via routine reports. Any participant deaths will also be promptly reported, regardless of the cause.

In the instance of an adverse event, Dr. Gaugler and/or the study team will classify whether the event is unexpected, adverse, or seriously adverse, whether the event is unexpected or related to the intervention, and what potentially caused the event. Per the protocol, Dr. Gaugler will review the data routinely and will alert both the DMO as well as NIA as needed if these events occur.

All AEs (following consent) will be collected on an adverse event form, in electronic format. AEs experienced by a participant during a study procedure (i.e. intervention/survey) and are considered potentially related to the participant's involvement in research will be reported within 5 days of discovery to the University of Minnesota IRB (per the University's IRB procedures) and annually to the NIA, DMO, and IRB in data monitoring reports.

AEs that occur outside of the context of a study procedure (i.e. intervention/survey), as well as those that are determined to be not related to the participant's involvement in the study, will be

documented via the team's electronic AE form and included in the annual report (to be shared with IRB, DMO, and NIA Program Officer).

SAEs that are unanticipated and related to the intervention will be reported to the IRB, NIA Program Officer, and to the DMO within 48 hours of our team's knowledge of SAE. The summary of all other SAEs (i.e. those determined not related to study involvement) will be included in the annual report (to be shared with IRB, DMO, and NIA Program Officer).

Deaths determined not-related to the study will be reported to the IRB within 5 days of the team's knowledge of the participant's death, and reported to the Safety Officer and NIA Program Officer via routine annual reports. Though unlikely, if a participant's death during the project enrollment has a possible relationship to the study, it will be reported in expedited fashion (within 24 hours of the team's knowledge of a participant's death) to the University of Minnesota IRB, the NIA Program Officer, and to the DMO. A written SAE report will be submitted soon thereafter.

No adverse events are expected to be related to study involvement. However, due to the nature of our study population, possible adverse events (i.e. general medical events and/or emergencies) may occur during the time a participant is enrolled in the study. These events will be documented and/or reported according to the protocol.

Dr. Gaugler will present the safety report to the DMO to ensure that there are no negative effects of the treatment. The DMO will review the safety reports annually to ensure that the proper procedure was followed and to identify any potential trends in the data. Dr. Gaugler will present the safety reports to NIA if adverse events occur.

Relationships between the Proposed Data Monitoring and Safety Plan and the IRB
We will notify the University of Minnesota IRB of our data monitoring and safety plan. If the University of Minnesota IRB requests it, we will provide feedback to the IRB of these data monitoring activities on an annual basis (in addition to the annual progress reported required by the University of Minnesota IRB). A brief summary report will be sent to the IRB documenting that a review of the data took place on a given date and will outline the DMO's review of any adverse or unanticipated events. Any requests for modification in the protocol will also be forwarded to the University of Minnesota's IRB.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: N/A

21.2 Contract Language: N/A

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

Following eligibility screening, the consent process will take place. Going forward, our consent process will specifically entail: study staff reviewing highlights of each section of the consent form with the potential participant, then study staff will ask each potential participant whether they have any questions about the consent form or study details. Since we are improving our procedures, this more detailed consent process will begin after

approval of the protocol (v 11.09.2020). During the parent study and the supplement, we provided potential participants an overview of the project prior to initiating the consent process, which we will continue to do.

After an overview of the project has been described, highlights of the consent form will be described and any questions from the potential participant will be answered, then a signed informed consent will be obtained from the eligible family caregiver. This consent will be offered electronically, over the phone or via mail. Online consent forms will be administered via the secure University of Minnesota Qualtrics survey application. Participants will be provided with a copy of their completed consent form.

Due to the COVID-19 pandemic, hard copy records of signed consent forms will not be maintained at D351 Mayo. However, records of signed consent forms will be saved on the University of Minnesota secure server. For this reason, staff are unable to sign online consent forms.

The modality of consent will determine who signs the consent form, as detailed below:

- Online consent form: only the participant signs
- Phone (verbal) consent form: only the staff member signs
- Mail consent form: both the participant and the staff member sign

The online and verbal consent forms in Qualtrics will only display the appropriate signature blocks according to the modality. As before, once consent is obtained, participants will be emailed or mailed a copy of their completed consent form.

For the COVID-19 administrative supplement, participants will be recruited from among current and previous participants in the parent RCTM study.

Previously-enrolled participants: For caregivers who have previously completed the 12-month parent RCTM survey, research staff will reach out by phone, email, or mail to invite caregivers to re-enroll in the study to complete three additional surveys. We will describe the contents and timing of these additional surveys, and invite caregivers to participate. Previously completed participants who are interested in participating in the additional survey(s) for the COVID-focused supplement will complete a brief screening survey prior to re-enrollment, including items assessing bereavement. Caregivers who are eligible and agree to re-enroll will provide informed consent, and will receive the additional surveys according to the same procedures used for the parent study surveys.

Semi-structured interviews: We will select a purposive sample of approximately 20 participants (split evenly among the treatment and control group) to invite for a semi-structured interview to investigate their COVID-19 and long-term care related experiences in-depth. Participants will be selected based on their responses to the COVID-19 specific items in the survey, aiming for diversity in terms of experiences navigating pandemic-related changes. For example, we will seek to recruit participants who have reported a high degree and a low degree of perceived preparedness from their care recipient's RLTC, participants who have chosen to remove their care recipient from RLTC as well as those whose care recipient has remained in RLTC, and participants living in areas with higher and lower disease exposure. We will reach out to the selected participants to provide information about the interview and invite them to participate. Those who are interested will provide

informed consent for the interview and will be scheduled for the interview at a time convenient to them.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

As mentioned, for the COVID-19 administrative supplement, participants will be recruited from among current and previous participants in the parent RCTM study.

Currently-enrolled participants: We will invite caregivers who remain currently-enrolled in the parent study to extend their participation with additional surveys. Research staff will reach out by phone, email, or mail to describe the contents of the additional surveys and the timing of these additional assessments, and to invite participants to participate. Caregivers will receive an information sheet describing the additional surveys, as well as the original RCTM consent form if they have questions. Those who agree to take part in the additional surveys will then receive the additional surveys according to the same procedures used for the parent study surveys. We request a waiver of documentation of consent for these participants, as they are still currently enrolled in the parent RCTM study, and the additional surveys they will be invited to complete present no more than minimal risk.

22.4 Non-English Speaking Participants: N/A

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

Although we do not purposively recruit cognitively impaired adults, due to the longevity of the study, staff may become aware of participants who have potential memory concerns through study interactions such as phone calls by the interventionist or research coordinator. When this type of participant is identified, the research coordinator will call the participant and determine if they are able to consent to participation. To do so, a brief summary of the consent form will be read to the participant, then the research coordinator will administer the UBACC (UCSD Brief Assessment of Capacity to Consent). In accordance with the UBACC administration instructions, if a participant does not correctly answer an item, the interventionist or research coordinator may repeat and discuss information from the consent form relevant to that item, and then repeat the item for up to three trials. A score of 14.5 or higher indicates the participant has the capacity to consent. If a participant scores 14.5 or higher, they will be eligible to continue on with the study as planned. If the participant scores under 14.5, then we will withdraw them from the study and therefore not ask them to complete any additional surveys. Participants in the treatment group who do not pass the capacity to consent screener will be offered the opportunity to continue contact with the study interventionist, if they desire, even if they are withdrawn from the study. This will ensure continued support for any participants who had planned to continue their contact with the counselor, but are no longer eligible to participate in surveys. We will report participants who are withdrawn for this reason along with their UBACC scores to the IRB as an RNI within 5 business days of the capacity to consent call with the participant. This data will also be reported in the annual data reports on participant

safety as part of the data safety monitoring plan (see plan below). We will only assess participants with possible memory problems since the study was determined by the IRB to pose no greater than minimal risk to the participants, and though capacity was not formally assessed at initial consent, all participants were assumed to have the capacity to consent at study onset.

22.7 Adults Unable to Consent: N/A

23.0 Setting

23.1 Research Sites:

Our research will be conducted at the University of Minnesota, School of Public Health, Division of Health Policy and Management, D351 Mayo Memorial Building, 420 Delaware Street S.E. Minneapolis, MN 55455. Please refer to section 12.2 "Source of Participants" for information on recruitment sources.

Collaborating Sites
Johns Hopkins University, New York University Langone Medical Center, Emory University, and the Benjamin Rose Institute on Aging are all collaborating sites; while Johns Hopkins will have responsibility for data analysis, the University of Minnesota site will oversee all study procedures, data collection, and management.

The PI (Dr. Gaugler), the Co-Is (Drs. Mittelman, Hepburn, Whitlatch, and [Roth]) and the TC (Mark Reese, MA, PC, LMFT) have extensive experience developing, implementing, and evaluating interventions for family caregivers of persons with ADRD. Dr. Mittelman is the PI of the NYUCI[76-81] and Dr. Hepburn is the PI of the Savvy Caregiver.[53-55,82,83]

Both the NYUCI and Savvy Caregiver are recognized as evidence-based, high quality psychosocial and psychoeducational programs (respectively) and are in widespread translation across the United States. Dr. Whitlatch also has considerable expertise designing and evaluating interventions for dementia family caregivers; she also developed the SPM-RC which is the conceptual basis of the proposed evaluation.[20,84,85] [Dr. Roth is a noted expert in applied research methods and longitudinal analyses of family caregiving.][86-88]
Dr. Gaugler, Dr. Mittelman, [and Dr. Roth] implemented and evaluated outcome trajectories prior to and following RLTC in an analysis of Dr. Mittelman's long-running, randomized controlled evaluation of the NYUCI.[75,89,90] The results offered some of the first high quality evidence of the benefits of enhanced counseling in the years prior to and following institutionalization for caregivers of people with AD. The RCTM is designed to build on these earlier randomized controlled trials with a focus on adaptation to the RLTC placement transition.

[The Co-Is will provide guidance to the PI as to the utility and implementation of RCTM; offer their expertise regarding data collection; assist in interpretation of quantitative and qualitative data; and collaborate on all dissemination efforts. Specifically, the Co-Is will evaluate the TC contact logs as well as qualitative data collection during and following the RCTM evaluation to develop codes/themes that characterize TC's processes; to achieve the mixed methods goals of the proposed evaluation, these insights could later be used to investigate whether certain types of counseling contact influences the various outcomes to be analyzed in the randomized controlled evaluation. The Co-Is will also take the lead in

preparing a "final" dissemination product of the RCTM to facilitate potential implementation and translation of the RCTM. Finally, the Co-Is will review protocol adherence, participant enrollment and attrition patterns, and any adverse events that might occur as part of the data monitoring and safety plan. The Co-Is will meet via tele- or web conference to discuss the project at periodic enrollment milestones.]

23.2 International Research: N/A

23.3 Community Based Participatory Research: N/A

24.0 Multi-Site Research: N/A

25.0 Coordinating Center Research: N/A

26.0 Resources Available

26.1 Resources Available:

As part of his academic appointment in The School of Public Health, Dr. Gaugler will have the necessary time to devote to the proposed project. The teaching load is flexible and based on external support for Dr. Gaugler's research time. Service expectations include standard membership on School of Public Health and university committees. Due to the advantageous research environment provided by The School of Public Health, Dr. Gaugler can devote a majority of his time to research projects.

Dr. Gaugler's secure suite in the Mayo Building includes his own office, three other connected office spaces, a meeting room, and a file area. Dr. Gaugler's office suites are equipped with secure computers (including the necessary statistical software), printers (including one color), web cameras, telephone access, and ample secure file space to conduct the proposed study. The computers have LAN access. Dr. Gaugler's suite is a private location to conduct research participant interviews when needed as well as collect and manage any related human subjects research data.

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