Virtual Coaching to Maximize Dementia Caregiver's Respite Time Use

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Protocol Summary

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This document was created using the ERICA Online System at the University of Utah. The document is created from study information approved by the IRB on the date listed above. Any alteration to the original content of this document may not be considered to represent the study as approved by the IRB.

Background and Introduction

SIGNIFICANCE

The challenge of providing care to a rapidly growing number of adults with Alzheimer's Disease (AD) and Alzheimer's Disease-Related Dementias (ADRD) has entered a crisis phase.1,23 There are presently 5.7 million Americans living with AD; these numbers are expected to grow to nearly 14 million by 2050.1 Currently, about 1 in 3 older adults die with AD/ADRD, and every 65 seconds someone develops the disease. Family members often provide significant amounts of care to these persons in their homes and community. Currently, there are over 42 million family caregivers in the U.S. caring for older adults in general,24 with 16.1 of these providing care for persons AD/ADRD.1 Dementia caregivers provide 18.4 billion hours of care annually, estimated at a value of $277 billion.1 Family caregivers are generally unpaid and perform instrumental and technical care, often without adequate support or training.25,26 Due to various demographic trends, the number of available caregivers is not keeping pace with the increasing numbers of those who need care.2,16,27 Our population is rapidly aging, leading to a shrinking overall "caregiver support ratio."2 The availability of family caregivers is also affected by couples having fewer children, increasing divorce rates among those age 50+, and more women and older persons who want or need to be in the workforce.28,29 On top of these demographic realities, the caregiving crisis is fueled by the physical and mental health declines, financial hardships, and personal sacrifices that caregivers experience after years of fulfilling the expectations associated with caregiving.2,30,31 In particular, those caring for someone with AD/ADRD have exceptionally high levels of daily stress,32-35 making our reliance on these particular caregivers to be even more tenable and unsustainable.36 Thus, establishing new ways to support dementia caregivers is critical for our nation's public and economic health.

Over the past couple of decades, the NIH funded two major caregiver intervention studies:37 REACH I (1996-2000),38 consisting of nine interventions to reduce AD/ADRD caregiver stress and the 5-site REACH II studies (2001-2006).39 These studies, as well as many others, have examined different types of caregiver interventions including self-care, safety, social support, emotional wellbeing, management of behavioral problems, skill training, telephone-based support, behavior modification, family therapy, computerized telephone communication, coping classes, and support groups.37,39 Most caregiver support programs, including those tested in the REACH studies, produce modest benefits for caregivers,40 but surprisingly, very few have examined the effectiveness of respite services.8,9,33,41,42 Respite is defined as formal services or informal arrangements that give caregivers time away from their caregiving duties.43 It has been identified as one of the most needed and desired services 6 and is thought to be one of the most promising ways to maintain and enhance caregiver wellbeing.13 Respite allows caregivers chances to maintain their health, social and family relationships, and other aspects of their daily lives that they neglected due to their overwhelming caregiving tasks.44 Several policy initiatives, including the 2018 Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act, document that respite is critical to managing the caregiving crisis.16,45 However, past research on the effectiveness of respite finds only moderately positive, and often inconsistent or mixed results.11,13,43,46-48 No specific type

of respite activity is most effective, as time-use during respite needs to match the caregiver's profile, culture, and caregiving circumstances.49,50 While skepticism about respite justifiably remains, we cannot afford to neglect its considerable promise, given that it is the most requested service from caregivers. From an intervention and policy standpoint, there is a need to deliver support that may make respite more effective for family caregivers, especially those AD/ADRD caregivers that are among the most burdened of all and could therefore benefit the most from effective use of respite.

Scientific Premise - An important element missing from the research on respite's effectiveness is how caregivers use their respite time. Congruence between desired and actual time use has been identified as a predictor of overall life satisfaction.51 Our previous research suggests that if caregivers are able to make respite more effective and have higher levels of respite time-use satisfaction, they will enhance their wellbeing and prevent further burnout, enabling them to continue in their role as caregivers for longer periods of time. An expert panel sponsored by ARCH (a federally-funded national respite network and resource center) recently summarized the state of research on respite and provided guidelines for future research;52 53 their recommendations included finding ways to make respite more effective. Any intervention designed to maximize the benefits of respite, or to support AD/ADRD caregivers in general, needs to be cost-effective, scalable, individually tailored to caregivers' needs, and readily available no matter where caregivers reside, such as in rural areas.48,54,55 Consistent with a recommendation of the NIH AD Research Summit in 2015,56 these goals may be best achieved by delivering interventions using widely available mobile and internet technologies.

The Phase 1 study was deemed Non Human Subjects Research.

Phase 3 will not be conducted under this IRB application.

Purpose and Objectives

Respite, defined as time away from caregiving, has been identified as the most needed and desired service for family caregivers, especially the 16 million dementia caregivers who are faced with long term and demanding caregiving circumstances. Findings on the effectiveness of respite services have been mixed –how caregivers spend their respite time seems to be a key factor behind these inconsistent findings. We have developed a novel intervention called "Time for Living & Caring" (TLC) that shows promise in improving respite time-use and maintaining caregiver wellbeing. However, it relied on trained facilitators and up to 15-20 individual home visits or phone calls with each caregiver, limiting its scalability to real world practice. The purpose of this study is to redevelop the TLC intervention, in which AD/ADRD caregivers are taught strategies to assess and identify ways to spend upcoming periods of respite time, to a fully online, self-administered virtual coaching format, and then to pilot-test the new TLC intervention for feasibility and efficacy.

Aim 1 is to modify, adapt, and refine the existing intervention modules. This phase of the project utilizes a community-engaged design process where stakeholders (i.e., current or

former caregivers, diverse community leaders, respite providers) will work alongside the research, technical, and creative teams to develop and provide feedback on the TLC design, features, and prototypes.

Aim 2 is to conduct a pilot test with dementia caregivers who are currently using respite. This phase uses a full powered pilot sample (n=120) and a randomized waitlist control experimental design where participants are exposed to the redeveloped TLC intervention for 8 weeks and will provide assessments of daily respite use, respite time-use satisfaction, and wellbeing. These pilot data will be used to assess feasibility and to explore hypotheses regarding the potential efficacy of the intervention, as well as the mechanism (i.e., time-use satisfaction) underlying the intervention's effect on wellbeing. Wellbeing is measured with two primary outcome of anxiety and caregiver burden, both thought to be closely related and responsive to intervention's purpose.

Aim 3 is intended to explore future implementation of the redeveloped TLC intervention with respite providers. This provides yet another layer of the tool's feasibility. We will host webinars to demonstrate the features and functionality of the TLC intervention as well as to preview pilot study results from Aim 2, then ask providers for feedback on their likelihood of implementation and barriers to using TLC with their clients.

Together, these three aims represent a comprehensive approach to Stage 1 research activities, with the overall goal of developing an intervention that is scalable to real world applications. Throughout all stages of the proposed project, our team is committed to community-engaged research practices, where community partners will provide input and connect us with potential research participants. Given this pragmatic yet scientifically rigorous approach, the results have the potential to guide and accelerate the eventual implementation of the TLC intervention to community and health care practice.

This application relates specifically to Phase 2 of the project, which specifically addresses Aim 2 where human subjects will be recruited and enrolled.

Study Population

Age of Participants: Over 18 years of age

Sample Size:

At Utah:	150
All Centers:	150

Inclusion Criteria:

Inclusion criteria:

AD/ADRD caregivers who are currently using or interested in using respite, such as home-care respite providers or adult daycare providers, or informally provided by family members or friends.

The caregiver must:

1) be the primary caregiver,

2) live in the same house with the care recipient,

3) have access to and/or interest in using respite at least once a week for a minimum of 4 hours,

4) be providing care to a family member with Alzheimer's disease or dementia,

5) be English speaking, and

6) be age 18 or over.

We will recruit a total of 150 caregivers with purposive selection of caregivers to ensure that we are getting a diverse sample of caregivers (i.e., males and females, racial and ethnic diversity, rural and urban residence, early and late-stage dementia caregivers).

Exclusion Criteria:

- Not a primary caregiver
- Not living in the same house with the care recipient
- No access and/or interest in using respite at least once a week for a minimum of 4 hours
- <18 years of age
- Non-English speaking
- Not providing care to a family member with Alzheimer's disease or dementia

Design

Randomized Trial

Complete up to 140 brief daily time-use measures.

Study Procedures

Recruitment/Participant Identification Process:

Recruitment will rely primarily on our team's relationships with a number of community partnerships - for example, Community Faces of Utah, Utah Coalition of Caregiver Support, the Utah Telehealth Network, and the Alzheimer's Association (see letters of support) -- who will provide referrals to the TLC study team. These organizations have agreed to collaborate

with the investigators, by passing along information and recruitment fliers about the TLC study. These groups will pass names of potentially eligible caregivers to the TLC research staff (if participant agrees to this transfer of information); or individuals identified by each community partner will reach out to the TLC research staff on their own after receiving a promotional flyer or business card. Potential participants will only be contacted by the TLC study team if they have given their permission to the community partner for their names and contact information to be given to the TLC study team for this contact. Most eligible participants will contact the TLC study team on their own, after receiving a flyer and information about the study from a community partner.

Other community-based recruitment strategies include:

- Advertising in community-based senior-oriented publications, such as Simply Seniors.

- Distribution of a promotional flyer or study information via websites, social media, newsletters, personal contacts, and other listservs that might reach ADRD caregivers in the community (see updated flyer in attachments). Potentially eligible participants who see the promotional flyer and are interested in participating will reach out to TLC study team to learn more about the study. TLC project coordinator and RAs will respond to each inquiry within 72 hours and begin the informed consent and enrollment process with each.

We will also use the CHAAD database to identify potentially eligible participants for the TLC study (CHAAD database is formerly called the CACIR database, created and maintained by Dr. Norman Foster, Professor of Neurology & Director, Center for Alzheimer's Care and Imaging Research). The CHAAD database contains information on up to 9,000 patients seen in the CACIR/Cognitive Disorders Clinic since 2008. Dr. Foster and his team have agreed to identify a subset of caregivers (defined as the primary or lead care-partner of a patient seen in the CACIR clinic) from the CHAAD database. All persons included in the database have agreed to be contacted for research purposes. We will mail an initial "opt-out" letter to the identified care-partners describing the TLC study and giving them the option to 'opt out' of further contact from the TLC study (see 'opt-out' letter in attachments). After waiting two-weeks from the date of anticipated delivery of the 'opt out' letters, the TLC project coordinator or RA will initiate contact with any caregiver who did not opt-out to tell them more about the study and go through the informed consent process for those who are interested in participating.

INFORMED CONSENT & ENROLLMENT: Regardless of which method a potential participant is referred to the TLC study team, the Project Director and/or RA will conduct a call to screen eligibility and obtain verbal consent from any potentially eligible and interested caregiver. A home visit and/or teleconference (video or audio) will then be set up to provide an initial orientation for the research participant, as well as to assess the capabilities of their personal technology and internet access. Participants who consent to participate and who have the technological capabilities to participate will be enrolled in the study.

To facilitate recruitment of the full sample, we will utilize all of these recruitment efforts until we meet our enrollment targets; not all participants have to start the study at the same time.

Informed Consent:

Description of location(s) where consent will be obtained:

Consent will be obtained verbally via home visit and/or teleconference (audio or video). Participants will therefore be in their homes and/or other location from which they can participate in a teleconference (audio or video).

Description of the consent process(es), including the timing of consent:

Once caregivers are identified to be potentially eligible for participation, (with their permission) they will be put in touch with project staff who will contact them to arrange informed consent and (if consented) enrollment into the study. During the consent process the potential participant will be informed of the overall purpose of the study, what participation would entail in terms of intervention participation and data collection, the randomization process (including they could be randomized into a wait-list control condition), potential risks, potential benefits (to self and society) and how they will be reimbursed for their time. They will also be informed that their participation would be entirely voluntary and that they could drop out at any time, and that their withdrawal or limited participation will not affect the respite services they are currently receiving or any services that they might be eligible for in the future. They will be informed that all their information will be confidential and secured. Participants will be given opportunity to ask questions about the study and participant expectations, and then asked to provide verbal consent during that teleconference call (video or audio). If the potential participant desires, they will be given additional time to decide if they want to participate and then contacted 2-3 days later to learn of their decision. All consent will be obtained verbally. Upon receiving verbal consent, Project Director and/or RA will send a copy of the formal consent document to the participant by email. The consent form contains 24-hour phone numbers (including the Institutional Review Board) the participants may call if they have concerns or questions regarding their participation. A record of verbal consent and documentation of email delivery of the formal consent form will be recorded in REDCap.

Procedures:

Consenting and enrollment. During Phase 2, *which is the only phase of the overall project that has been deemed human subjects research,* caregivers will be recruited to participate with the assistance of the community partners (Community Faces of Utah, Utah Coalition of Caregiver Support, and the Utah Telehealth Network) who agreed to collaborate with the investigators. These groups will pass names of potentially eligible caregivers to the research staff. The Project Director and/or RA will then conduct a follow-up call (audio or video) to screen eligibility, describe the project, and obtain verbal consent. Upon receiving verbal consent, Project Director and/or RA will email the participant a full consent document for their records (see documents and attachments).

A home visit and/or teleconference (audio or video) will subsequently be set up to provide an initial orientation for the research participant, as well as to assess the capabilities of their personal technology and internet access. Since this is a pilot test, we would like participants to use their own technology if possible, since it will provide us with information about the usability and feasibility of the intervention as accessed on a number of different types of devices, browsers, and networks. However, if needed, the project will provide a netbook

and/or high-speed internet service to those persons who do not have reliable access to these technologies.

Intervention Description & Random assignment to group #1 or group #2 - The TLC intervention is designed to be a fully self-administered 16-week program, where participants engage with online tools at least once a week. The online TLC intervention will guide participants through goal setting and goal attainment processes to more effectively use their respite time. They will use a digital calendar to schedule, plan, and review the respite time they had each week. Throughout the intervention period, they will receive personalized weekly prompts (via email or text, based on their preferences) giving them instructions and reminders about how to schedule, plan, and review their respite needs. There will be a hotline that caregivers can use to contact a project staff member should they encounter any unanticipated problems or new barriers. The TLC online intervention also includes resource pages to foster success as well as provide information useful to family caregivers

Upon consent, participants will be randomly assigned to Group #1 or Group #2. The study design is akin to a waitlist control design, with group #1 (treatment group) receiving 8 weeks of intervention followed by 8 weeks of continued use of TLC intervention tools, and group #2 (waitlist group) doing respite as usual for 8 weeks, followed by 8 weeks of more intensive coaching from the TLC intervention. Both group #1 and #2 will fill out daily/weekly reviews of their respite use throughout the calendar functions of the TLC intervention tools during the 16-week intervention period, as well as monthly questionnaires at baseline/enrollment, week 4, week 8, week 12, week 16, and week 20.

Note: when we created the online, self-administered version of the TLC intervention, we merged all data collection instruments with intervention prompts into a single online delivery package, so both group #1 and group #2 receive access to the TLC study tools from day 1 and end their access at the end of week 20. This has altered the traditional "waitlist" (i.e., no contact) condition associated with group #2. Both group #1 and group #2 receive the same instructions and orientation to the study on day 1. The groups differ only in the amount and type of "virtual coaching" (instructions and prompts from the TLC website) they receive at week 1 and week 9. Group #1 receives more intensive coaching at week 1, with an encouragement to continue doing it on their own at week 9. Group #2 receives less intensive coaching at week 1, with a more intensive coaching instructions presented to them at week 9.

Self-administered questionnaires and daily ecological momentary assessments (EMAs). Participants in both conditions will complete self-administered questionnaires at baseline, and then every 4 weeks thereafter (for a total of 6 questionnaires, spread across 20 weeks). All questionnaires will be distributed electronically via email. Responses will automatically be recorded in a secure REDCap data base.

Participants are also asked to complete daily ecological momentary assessments (EMAs), in which they indicate if they used respite that day, and if so, their experienced and evaluative satisfaction with respite time-use. The daily EMAs will take about 1-2 minutes to complete as they are only 3 items (respite used [yes/no], and two items each measuring experienced and evaluative time-use satisfaction). The caregivers will be prompted weekly to complete their EMAs. Note: as mentioned above, all EMA data collection has been

integrated into the online version of the TLC intervention tools through a digital calendar, combining the TLC intervention with the collection of daily EMA.

Each questionnaire will take about 10-45 minutes to complete. The baseline and final questionnaire are significantly longer than the monthly questionnaires (i.e., 10 minutes versus 45 minutes). Questionnaires will include standardized fixed-choice and open-ended survey questions related to :

- demographic indicators
- caregiving context, and
- caregiver health and well-being (i.e., burden, anxiety, positive affect, global health).

The final questionnaire includes additional measures related to the participants' use of the TLC intervention tools. We will assess their perceptions of feasibility, usability, and acceptability of the online version of the TLC intervention. Other feasibility indicators such as login behavior, intervention protocol completion, and dosage will be imported in real-time directly from google analytics into the secure REDCap data base.

Procedures performed for research purposes only:

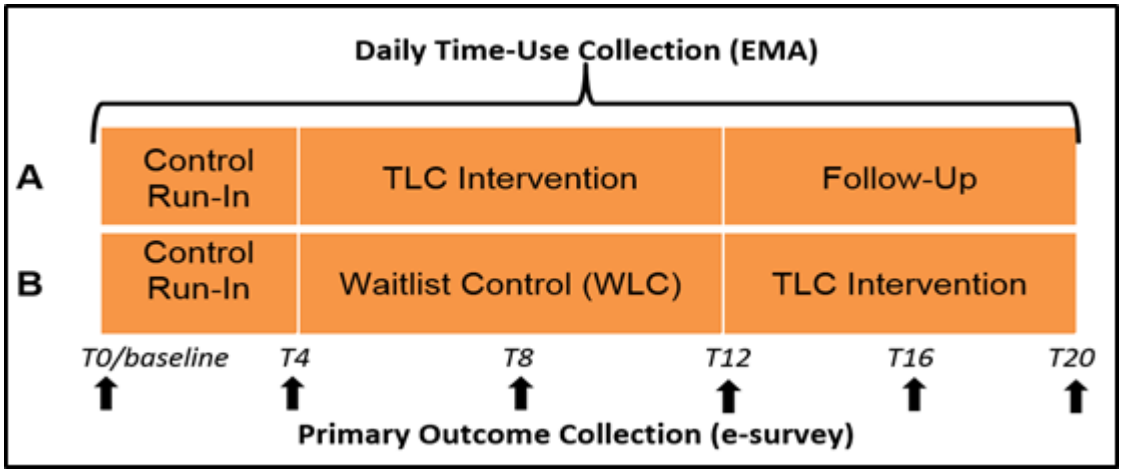
Statistical Methods, Data Analysis and Interpretation

STATISTICAL DESIGN & POWER

The overall project has three specific aims. This application relates to Aim 2, where which entails human subjects research.

Aim 2: Conduct a hypothesis driven pilot test of the TLC intervention with dementia caregivers

Statistical Design & Power - Aim 2



The purpose of Phase 2 is to conduct a fully-powered pilot study to measure feasibility and efficacy of the TLC intervention with a sample of dementia caregivers (n=120). This section describes the planned analyses to assess efficacy of the TLC intervention.

Study Design

Because this is part of early-stage intervention development activities (Stage 1), we have designed a clinical trial to pilot-test feasibility as well as efficacy of the redeveloped TLC intervention. We propose to use a waitlist control cohort design, using a fully powered sample to provide the most rigorous analysis possible. The waitlist design allows all participants to receive the intervention. As shown here in the figure, partcipants will be randomized to one of two sequences. After baseline data collection and an initial orientation/control period for the first 4 weeks, Group A will have 8 weeks of TLC intervention, then 8 weeks of follow-up. Group B will have 8 weeks of waitlist control, and then TLC intervention for 8 weeks, beginning at week 12. We will use ecological momentary assessment (EMA) during the entire 20-week study period to capture daily time-use trends for any respite periods received (n=140 daily reports, max). EMA aims to minimize recall bias and maximize ecological validity. Primary outcomes data will be collected via electroncially administered surveys at baseline (T0) and every 4 weeks thereafter (T4, T8, T12, T16, T20), for a total of 6 assessments.This randomized, prospective, and longitudinal design

allows each participant to serve as its own control and offers opportunities to assess both within- and between-group differences over time (Group A vs. B).

Measures

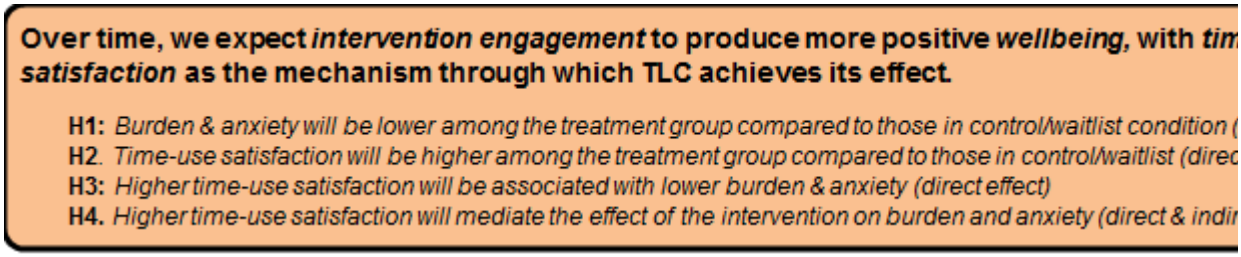
The primary outcome is wellbeing, measured with two standardized scales indicating "caregiver burden" and "anxiety." The mechanism driving the intervention effect is theorized to be related to respite time-use and time-use satisfaction. This construct is measured with "experienced" and "evaluative" time-use measures.

Analysis

The analysis to test for efficacy will specifically look at treatment x time interaction that combines both vertical (between individuals at given timepoints) as well as horizontal (evolution within individual over time) comparisons. We will utilize a multilevel model that consists of level 1 (within person) and level 2 (between person). Thus, the overall composite two level Multi-Level Mixed effects Model (MLM) is defined as follows with the first set of brackets representing fixed effects and second set random effects:

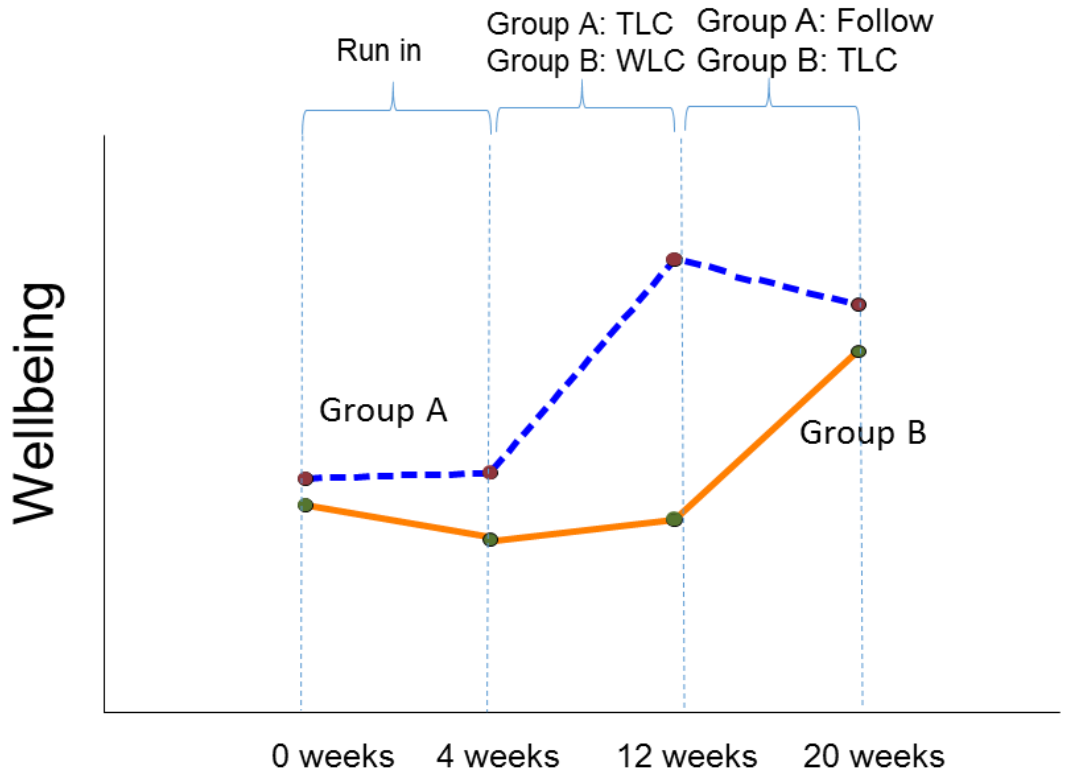
$$Yij = [\beta 0 + \beta 1Tj + \beta 2Xij] + [\zeta 0i + \zeta 1iTij + \varepsilon ij] \qquad \text{[equation 1]}$$

where Yij is the outcome measure (Caregiver Burden and Anxiety) for participant (i) at time (j) where j is an indicator for time (baseline, 4 weeks, 8 weeks, 12 weeks, 16 weeks and 20 weeks). β0 is the population mean level of the outcome measure prior to the TLC intervention, β1 fixed effect for time independent of intervention, Xij is the intervention status (pre-TLC or Post-TLC/Follow-up) at timepoint j, and β2 is the intervention treatment effect. Random effects include individual-level intercept (ζ0i), individual-level slope of change over time (ζ1iTij), and εij for residual error of each outcome measure. Our hypotheses for Aim 2 are summarized here:



H1: Burden & anxiety will be lower among the treatment group compared to those in control/waitlist condition (direct effect)

Figure 2: Anticipated results for Wellbeing with TLC



Our primary outcome will test the hypothesis that there will be significant change in "caregiver burden" or "anxiety" immediately post intervention. Figure 2 shows the anticipated results with no change during the run-in period, increase in wellbeing in Group A during the intervention but not WLC. Group B then shows increased wellbeing during TLC, with Group A maintaining or slight decrease in "caregiver burden" or "anxiety" over time. With the planned 120 participants (60 per group), we will be able to detect small to medium effect sizes on the two outcomes with greater than 90% Power (see below). Intent-to-treat analyses (ITT) will be performed on non-completers using a terminal score for both "caregiver burden" and "anxiety" scores.

H2: Time-use satisfaction will be higher among the treatment group compared to those in control/waitlist (direct effect)

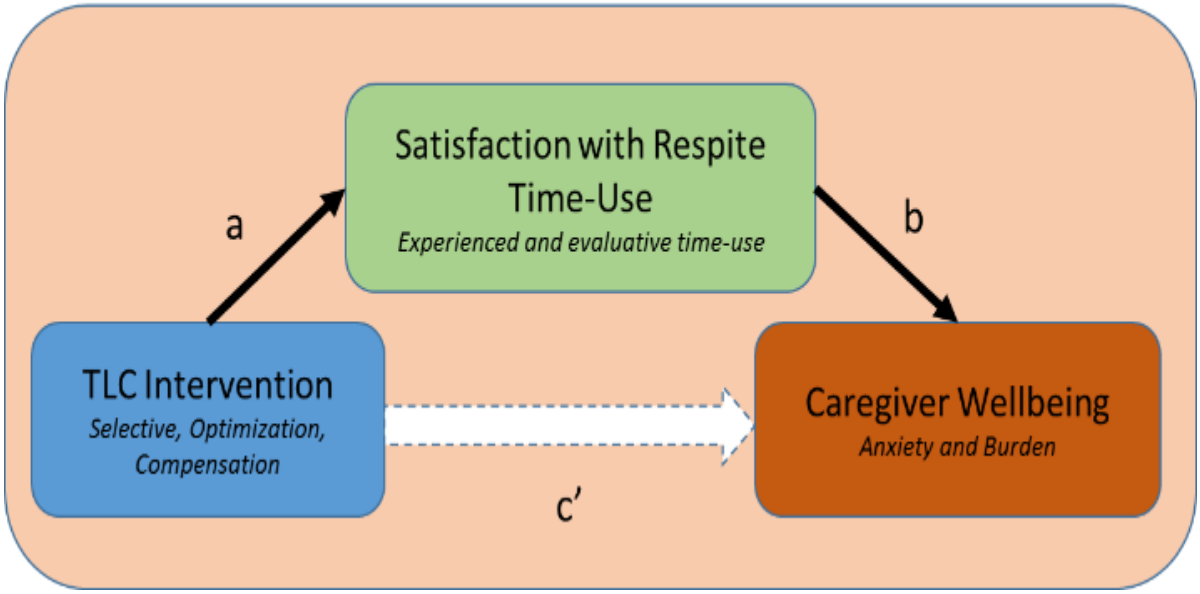
Time-use satisfaction data will be collected daily using EMA, of short questions. First, did you have respite today? Then, if yes, how satisfied are you with your respite time-use? (1-

5) Did the respite time make you feel more positive/negative about your role as a caregiver? (1-5). These two items measure "experienced" and "evaluative" time-use measures, respectively, which have been theorized to be associated with the wellbeing outcomes (anxiety & caregiver burden). Aggregated averages of these two measures will be computed for specific time-periods (i.e., across the four-week interval spanning the primary data collection timepoints). The same MLM will test significance of time x intervention interaction on mean Time-use satisfaction following TLC intervention compared to WLC.

H3: Higher time-use satisfaction will be associated with lower burden & anxiety (direct effect)

Using the same MLM framework, we will examine if aggregate Time-Use Satisfaction (predictor) is associated with lower "caregiver burden" and "anxiety." As an exploratory aim we will examine Time (β1) immediately post intervention through follow up to determine maintenance, attenuation, or no change in Group A outcomes after TLC for wellbeing (anxiety & caregiver burden) and time-use satisfaction (experienced & evaluative time-use).

Figure 3: Time-use mediates TLC impact on Well Being



H4: Higher time-use satisfaction will mediate the effect of the intervention on burden and anxiety (direct & indirect effects)

Figure 3 displays our overall mediation model, whereby TLC intervention improves wellbeing by increasing Respite Time-Use Satisfaction. We hypothesize that "satisfaction with respite time-use" is the factor that links respite use with wellbeing outcomes such that TLC intervention leads to improvements in respite quality that in turn produces better outcomes over time.

Mediation analysis will be conducted as previously outlined for cross-sectional as longitudinal models.149, 138, 139 In its simplest form, mediation is represented by three linear equations

Mediator (Time-Use) = i1 + aX + e1 (2)

Y (Wellbeing) = i2 + cX + e2 [without mediator](3)

Y (Wellbeing) = i3 + c'X + bM + e2 [with mediator] (4)

When substituting the Mediator M in equation 3 the indirect pathway by which the TLC intervention impacts wellbeing through time-use is represented by the product of coefficients a*b. If significant, then mediation is present. If the direct pathway c in equation 3 becomes non-significant in equation 4 (c') when conditioning on the indirect pathway, then M is said to fully mediate the relationship between TLC and wellbeing. Importantly, in the models we will control for individual values of the wellbeing outcomes obtained before the start of the TLC intervention. The indirect pathway will be tested using the Sobel test that divides product-of-coefficients a*b by the first-order delta-method standard error of the indirect effect. This value is compared against a standard normal distribution to test for significance.148 We will also consider additional statistical mediation tests that account for non-normality of the product of coefficients and/or bootstrapping methods for more accurate estimates.121

Although not stated as distinct hypotheses, we will conduct additional exploratory analyses to further explain for whom and how the intervention achieves its effect. These analyses will be guided by the following questions: Do variations in the receipt of the intervention modify these relationships? For example, do participants that report higher intervention feasibility (i.e., higher satisfaction and usability of the tool) or higher dosage (i.e, they accessed more of the intervention's features) show stronger treatment effects? This will be assessed by replacing the dichotomous intervention variable X (TLC vs. WLC) in equation 1 with measures indicating dosage or perceived feasibility. Similarly, we will explore whether individual characteristics or circumstances modify the relationship between intervention, time-use satisfaction, and wellbeing over time. Here, we will use biologic variables of gender and age as well as measures that capture changes in the context of the caregiving relationship as both control variables and interaction. Finally, we will explore whether treatment effects maintain, attenuate, or no-change once the intervention period ends. This will be assessed using a repeated-measures design using Group A's data from immediately post-intervention through the 8-week follow-up period.

Power and Sample Size

We assume clinically relevant small to medium effect sizes in the main outcomes of interest corresponding to 4-6.5 mean change on the total "caregiver burden" outcome and 1.0-1.4 mean change on the "anxiety" outcome. Power and sensitivity analysis were computed in GPower using RMANOVA finding a total sample of 116 would be sufficient to achieve

power of greater than 90% to detect these effect sizes. Therefore, we will aim to have a final sample size of 120 (60 in each sequence) with a 25% over-recruitment to account for study attrition providing a total sample size of 150.

Sample size and sensitivity analyses for mediation analyses are based on empirical estimates conducted by Fritz and MacKinnon (2007).121 Assuming medium effects for each of the two parts of the indirect pathways (i.e. TLC->Time-use and Time-use->Wellbeing) in Figure 3, a sample size of 75-120 will provide greater than 80% Power (Sobel148 medium-medium effects) at p=0.05.

Missing Data

We will explore missing data patterns in SPSS using the Missing Value Analysis tool. We will specify the pattern fixed effects and interactions utilizing Little's test for Missing Completely at Random. In keeping with an intent-to-treat standard and assuming maximum likelihood estimation, we will use all available data for analyses. It is not necessary to eliminate observations from participants who subsequently drop out, nor is it necessary to impute individual observations. Both practices can bias estimation and distort variability. The maximum likelihood estimates given the observed data points are the values most likely to have generated the complete ensemble of observed sample data under the assumed model. Systematic missingness (as determined by missing data patterns) may be included in our mixed effects model. Potentially non-ignorable missing data will be investigated using multiple imputation sensitivity analyses under a diverse set of covariate predictors. To minimize loss of scale scores due to missing items in a computed scale, we will prorate the respondent's score based on available items. If a respondent is missing more than 30% of the items in a computed score for the primary outcome variables, we will code the scale score as missing.

Note: feasibility is another primary outcome of the pilot test. Feasibility-related analyses are discussed at the end of this document, since the focus on feasibility and the analytic strategies to measure feasibility are shared across Aims 1, 2, and 3.

Feasibility

All three aims of the overall project have a shared goal of evaluating some aspect of the intervention's feasibility. This is not a hypothesis driven analysis, other than we expect that the TLC intervention to be feasible, from the perspective of both caregiver and provider. Our goal is to gather rich data to describe how the intervention is or is not feasible, and how it might be improved in later steps toward eventual implementation.

To guide the feasibility-related analyses, we plan to use the five dimensions of the widely-accepted and NIH-endorsed RE-AIM framework (Reach, Efficacy, Adoption, Implementation,

Maintenance).141-145 RE-AIM provides a systematic and standardized way to think about feasibility, and to improve the sustainable adoption and implementation of evidence-based interventions. To assess for overall feasibility, the Investigators (PI Utz & Co-I Caserta) will systematically archive whether the intervention achieves RE-AIM metrics during each phase of the project. Some of these measures are quantifiable and will be evaluated using statistics (primarily descriptive statistics); others will rely on qualitative metrics.

First, we present an overview of the feasibility indicators we plan to use in the study, along with descriptive benchmarks that would indicate high levels of feasibility on any given item (Figure 4). Second, we present an overview of the RE-AIM framework, noting which types of data and/or analyses from the proposed study will be used to illustrate each of the five dimensions of RE-AIM (Figure 5). These frameworks provide a structure and systematical methodology for us to consider as we explore and analyze the quantitative and qualitative measures of feasibility across the three phases of the study.

Figure 4. Quantifiable Feasibility Indicators and Benchmarks

Research Feasibility	Benchmark
Length of time to identify potential participants (by recruitment sources)	12 months
Consent/Enrollment Rate vs. those eligible	≥ 50%
Enrollment rate (participants/month)	≥ 12/month
Research design-related dropout rate	≤ 10%
Data collection completion rates (Primary data points and EMAs)	≥ 80%

Feasibility	Benchmark
Access to computer & internet	≥ 90%
Length of time to finalize web page design for testing	24 months
Length of time to hire and train hotline/chat line staff	3 months
System fail rate (e.g., system crashes, down server)	≤ 5%
Dosage (# of log-ins)	At least 1/week
Completion of intervention protocol per log-in (assessment, goal-setting, action plan)	≥ 90%
Intervention-related drop-out rate	≤ 10%

Acceptability	Benchmark
Caregiver positive or negative appraisal of intervention	≥ 90% positive
Caregiver confidence that tool will help make better use of respite time (1=low; 5=high)	Mean ≥ 4
Consider using tool in the future (yes/no)	≥ 90% yes
Would recommend to other respite users to help them plan their respite time (yes/no)	≥ 90% yes

Usability	Benchmark
On a scale of 1 to 5, how clear were the instructions on the introductory video?	Mean ≥ 4
On a scale of 1 to 5, how easy was it to complete the time-use assessment?	Mean ≥ 4
On a scale of 1 to 5, how easy was it to go through the goal-setting steps?	Mean ≥ 4
On a scale of 1 to 5, how easy was it to complete an action plan to meet your goal(s)?	Mean ≥ 4
Overall, on a scale of 1 to 5 how easy was the virtual coach to use?	Mean ≥ 4
How easy was the layout on the screen to follow on a scale of 1 to 5?	Mean ≥ 4
To what extent was the information presented clear and concise on a scale of 1 to 5	Mean ≥ 4
To what extent did having a chatline make the tool more useful on a scale of 1 to 5?	Mean ≥ 4
To what extent was the chat line easy to use on a scale of 1 to 5?	Mean ≥ 4
How helpful was the information from the chat line staff on a scale of 1 to 5?	Mean ≥ 4
On a scale of 1-5, how useful were the links to other resources?	Mean ≥ 4

Implementation/Feasibility (from provider perspective)	Benchmark
On a scale of 1 to 5, how likely would you consider using this application as part of your service delivery?	Mean ≥ 4
On a scale of 1 to 5, to what extent do you believe your caregiving clients would be interested in using this virtual time-use coaching tool?	Mean ≥ 4

What features of the virtual coach did you like most? Are there any features of the virtual coach you did not like? On a scale of 1-5, rank each feature of the intervention on its usefulness for your clients?	Mean > 4
In what ways would you incorporate it into how you deliver respite services? What would make you more likely to incorporate this application as part of your service package? What barriers do you believe exist that might make you less likely to incorporate this as part of your service package?	Qualitative examples
What do you think would make your clients more likely to use this tool?	Qualitative examples

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Figure 5. RE-AIM Dimensions, Suggested Questions for Evaluating Intervention, and Proposed Study

Dimension	Suggested Questions	Proposed Study
Reach	What percent of potentially eligible participants a) were excluded, b) took part and c) how representative were they?	Tracking and analysis of recruitment and eligibility data
Efficacy or Effectiveness	What impact did the intervention have on a) all participants who began the program; b) on process intermediate, and primary outcomes; and c) on both positive and negative (unintended), outcomes including quality of life?	Hypothesis-driven statistical analyses identifying direct and indirect effects of the intervention's efficacy (Aim 2)
Adoption	What percent of settings and intervention agents within these settings a) were excluded, b) participated and c) how representative were they?	Comparison of provider sample characteristics (Aim 3) to population of respite providers

Implementation	To what extent were the various intervention components delivered as intended, especially when conducted by different (nonresearch) staff members in applied settings?	Qualitative themes describing provider comments about barriers and likelihood of implementation (Aim 3)
Maintenance	What were the long-term effects (minimum of 6-12 months following intervention)?	Initial maintenance or attenuation of intervention efficacy (after 2 months) will be assessed by exploratory analysis comparing post-intervention wellbeing to follow-up wellbeing (Aim 2)
	What was the attrition rate; were drop-outs representative; and how did attrition impact conclusions about effectiveness?	Attrition rates will be calculated and described; missing data will be explored as a potential moderator of intervention efficacy (Aim 2)
	To what extent were different intervention components continued or institutionalized? How was the original program modified?	Stakeholders (Aim 1), caregivers (Aim 2), and providers (Aim 3) will all provide information on how the intervention might be further modified.

Table adapted from: www.re-aim.org

Table 1: Amendments submitted and approved by IRB throughout study

Amendments	**Date**	**Description**
Adding RA	9/2/2019	Adding new study personnel
Changing Staff on Project	2/18/2019	Adding new study personnel

Adding Study Personnel & Changes to Design/Procedures	5/13/2020	1. Adding new study personnel 2. Inclusion/exclusion - wording change 3. Screening eligibility - wording change 4. Waiver of consent documentation - to accommodate verbal consent for phone-based recruitment 5. Participant compensation - adjusting amount paid for participation 6. Updated survey documents - wording change 7. Misc. updates to study protocols and descriptions to reflect how the intervention and data collection are integrated into a single online portal
New URL for Study	6/25/2020	Created a study website - adding URL to promotional materials
Adding Staff & Finalized Surveys	9/4/2020	Adding study personnel & uploading finalized t16 & t20 surveys
Updating Recruitment Strategies	12/18/2020	Updated recruitment flyer & adding a new recruitment strategy - using an existing database from a cognitive disorders clinic
Adding Study Personnel	2/26/2021	Adding new study personnel
Adding Study Personnel	5/29/2021	Adding new study personnel
Adding Study Personnel	4/17/2023	Adding new study personnel
Adding Study Personnel	8/30/2023	Adding new study personnel