Protocol

Title: Mastering the Challenges of Dementia Family Caregiving in a Time of COVID-19: An Online Course

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PROTOCOL TITLE: Mastering the Challenges of Dementia Family Caregiving in a Time of COVID-19: An Online Course

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	09/03/2020	Updated honorarium to $25
2	10/19/2020	Clarifies that only Aim 2 involves human subject research Reduces number of participants in focus groups Clarifies number of focus groups versus interviews
3	07/29/2021	Updates methods of Recruitment using Emory On-Hold Services, Social Media.

Table of Contents

1. Study Summary

Study Title	Mastering the Challenges of Dementia Family Caregiving in a Time of COVID-19: An Online Course
Study Design	Two group waitlist control design
Primary Objective	Develop a prototype pandemic caregiver training and education course
Secondary Objective(s)	Conduct a waitlist-control design test of the prototype course
Research Intervention(s)/Interactions	Self-paced asynchronous online course
Study Population	Dementia Family Caregivers
Sample Size	100
Study Duration for individual participants	24 weeks
Study Specific Abbreviations/ Definitions	COVID-19: Coronavirus Disease 2019 PLWD: Person living with dementia CES-D: Center for Epidemiological Studies-Depression RMBPC: Revised Memory and Behavior Problems Checklist MPI: Multiple principal investigator
Funding Source (if any)	National Institute on Aging (pending)

2. Objectives

Aim 1: Develop a prototype pandemic caregiver training and education course. Through iterative Design Studio sessions with dementia family caregivers, program faculty, COVID-19 specialists, and other clinical experts, we will design a competency-based course curriculum that applies a psychoeducation framework to the design. Based on this process, we will storyboard and script a course with 30-35 brief video- and text-based instructional modules. After final revisions, we will produce the instructional text and videos and finalize the self-paced course to be tested in Aim 2 activities. Aim 1 activities do not constitute human subject research; they are intended solely to gather input from a variety of perspectives, including from individuals similar to those with whom the eventual program will be tested, to assist in program design.

Aim 2: Conduct a waitlist-control design test of the prototype course. We will identify a diverse set of dementia family caregivers (N=100; 1/4 African American) whom we will ask to enroll in the course to participate in formative and summative research related to it. The test will gather information about the usability and salience of the course as well as its preliminary efficacy. The course faculty and research team's observation of participants' responses to the course and the

embedded interactive exercises and the results of semi-structured interviews with a subsample of 20 participants will enable us to further refine the course.

3. Background

Family caregivers, the backbone of care for the upwards of 7 million community-dwelling individuals living with Alzheimer's disease in the U.S., provide at least 85% of the care these individuals receive,[1] at some risk to their own well-being,[9.10] and are instrumental in navigating healthcare systems. Without their care, it is almost certain that PLWD would have much higher rates of acute and emergency care use than their age-matched peers, perilous venues for them in the best of times, potentially deadly during this pandemic.[11-14] With COVID-19 restrictions, the amount of care they provide and the expertise needed to provide the care will increase. Typically, caregivers are strangers in healthcare and pandemic landscapes, but they are now called on to enact home care and safety measures and navigate an intricate, complex, and opaque system without the benefit of a compass or a translator – and largely without understanding their role in or having the skills for navigating the system. A variety of interventions, including our own, have demonstrated benefit in enhancing caregivers' caregiving capacities, with resulting positive outcomes for both caregivers and care recipients.[15-18] Only a few of these useful interventions, Tele-Savvy among them, have employed distance delivery means, thus enabling rural caregivers and others precluded by circumstance from attending in-person programs to take part in the intervention programs.[19,20]

Early findings from the synchronous/asynchronous online three-arm randomized Tele-Savvy trial provide encouraging support for this project. The online Tele-Savvy psychoeducational caregiving course we propose appears to work and caregivers do fully participate in its asynchronous component. We used multilevel mixed models to test for group, time, and group-by-time effects for each of the outcomes. Results from the first 220 participants in the baseline to six-month segment of this three-arm trial indicate that Tele-Savvy participants had statistically significant group-by-time reductions in depression and strain and statistically significant group-by-time increases in caregiver mastery, compared to those in the other two study arms. We found a significant group-by-time effect on CES-D-assessed caregiver depression ($p<.001$) with the active group showing significant decreases over time ($p<.001$). We found a significant group-by-time effect on caregiver perceived strain ($p<.001$) with the active group demonstrating significant reductions over time ($p<.001$) and the waitlist control group demonstrating significant increases ($p=.010$). Likewise, there was a significant group-by-time effect ($p=.001$) on caregivers' reactions to care recipient behaviors (RMBPC) with significant reductions over time among the active caregivers ($p=.001$). Caregiver competence likewise demonstrated a significant group-by-time effect ($p-.009$), with the active group demonstrating significant increases over time ($p<.001$). Findings regarding caregivers' mastery were comparable: a significant group-by-time effect ($p=.003$) with the active group demonstrating significant increases over time

(p<.001). Canvas-based analytics indicate that participants were highly adherent in viewing the 36 asynchronous 8-15 minute daily video lessons, spending, on average, more than 8 hours watching the videos over the course of the 43-day program.

Much of the "normal work" of caregiving involves guiding PLWD through days at home and in the community that are as calm, engaging, and event-free as possible, and that has been the mastery-development focus of much of MPI Hepburn's work.[21] The COVID-19 pandemic, however, brings into stark focus caregivers' need to acquire the knowledge, skills, and competence to maintain care recipients' safety and ensure their safe navigation of the healthcare system. Functioning as a public health/infection control expert and healthcare system navigator requires skills and knowledge that family members do not possess as a matter of course.

4. Study Endpoints

The key study outcomes are measures of caregiver psychological well-being and confidence in their ability to provide effective care to the PLWD. The study ends after participants complete the online course and the follow-up interviews conducted to gather these study endpoints/outcomes .

5. Study Intervention / Design

The proposed study is a two-group waitlist control design to study a psychoeducational intervention for dementia caregivers. The study has two phases: 1) course development and 2) testing.

Our overall approach to course development and testing is one that we have used successfully in MPI Hepburn's work to produce video instructional content for dementia family caregivers. End-users are engaged throughout in both developing the broad outlines of an instructional curriculum, crafting the granular elements of the curriculum (e.g., text and video content for individual lessons), and providing formative feedback on the prototype product. The approach to co-production of care that informs the sense of mastery to be developed is one that MPI Clevenger has successfully deployed in MPI Clevenger's Integrated Memory Care Clinic (IMCC),[22] Emory's patient-centered medical home for PLWD.

6. Procedures Involved

Aim 1 [Weeks 0-24]. Table 1 below outlines the activities in which we will engage to stand up the caregiver education course we will test in Aim 2. Guided by a Design Studio process, we will engage in an iterative process of curriculum development, course design, and materials production that will involve a diverse group of dementia family caregivers, our core pilot project team, other clinical and caregiver experts, and our educational design consultant. The Design Studio's process is deeply grounded in the early and frequent involvement of potential end users in product design and uses a variety of brainstorming techniques to challenge and refine an emerging product – like

this course. This process it will play an important role in developing the Aim 1 prototype pandemic caregiving course. This is a design, not a research, activity.

The Design Studio activities will be conducted in three stages using focus group methods. To facilitate group discussion by all participants, the sample size for each Design Studio session will be limited to 8-10 participants per group, an average of nine per group. Drs. Epps and Perkins (co-Investigators) will lead these discussions with one acting as moderator and the other as trained observer. The observer will assist with the process and record observations of participants' nonverbal interactions and behaviors. Design Studio sessions will last approximately 60-90 minutes and be audio-recorded and transcribed verbatim.

Table 1. Activities to be Undertaken in Aim 1

Aim 1 Activities	Project Weeks						
	0	4	8	12	16	20	24
• Project team develops preliminary course content table	----x						
• In collaboration with educational consultant, develop preliminary course design	----------x						
• Design Studio #1,	-------x						
• Course content and design revisions (team and educational consultants) some scripting	---------x						
• Design Studio #2,	------x						
• Course revisions, storyboarding, video scripting continues	----------x						
• Design Studio #3,	------x						
• Finalization, including scripting, video production, placement on Canvas platform	----------x						
• Aim 2 recruitment and consenting begins	----------						

Table 2 below represents the broad initial draft outline of the key sections and up to 36 specific topics we believe to be essential segments in the course. The outline will serve as the basis for course design activities with our instructional designers and specialists, and these together – the topic outline and rough course design – will provide the material for our first Design Studio exercise. We emphasize the draft nature of this outline. The Design Studio process emphasizes empathy with the end-user experience as the driver of end-product design.[23-27] We will use the empathize/define phases of design thinking to understand how generally to design the course and associated elements and use ideation/prototyping techniques to clarify what should be included or not included in more detail. Constructed as it has been from an "expert" perspective, the draft document likely omits significant elements of and perspectives on caregiver mastery development that will need to be incorporated into the eventual design of the proposed course.

In the first audio-recorded Design Studio exercise, to be held online if necessary, we will engage IMCC Advisors and a diverse group of other caregivers in an initial exploration of the overall objectives and the preliminary form and content of the course. After the first group, the team, led by investigators Epps and Perkins, will analyze the transcripts, using a thematic analysis approach,[28] an iterative process that will involve deconstructing text, identifying salient themes, conceptualizing relationships, and synthesizing results. Two primary coders (Epps and Perkins) will independently code the first transcript. A

secondary coder (Clevenger) will review the coding and reconcile any differences. Codes will be discussed among the entire project team to ensure concordance and reliability. This analysis will guide refinements of the course and course materials as well as development of draft text and video scripts for two topic segments.

Table 2. Preliminary Draft of COVID-19 Course Curriculum Content

Key Sections	Topics Within Sections	
Introduction	Caregiving as Skilled Work	Caregiver: Co-producer of Care
Caregiving for a Person Living with a Dementia Disorder during a Pandemic (COVID-19)	COVID-19: An introduction	Infection Control 101
	Hand washing and sanitizing	Masks and gloves? Really? When?
	When guests/workers enter the home	Going out and coming back in
	The threats of sheltering in place: isolation	Falls Prevention – avoiding the ER
	Longer days of caregiving	Care when person is in other settings
	Quality of life: threats and choices	What's the plan for the person's care?
	A crisis plan: What if you become ill?	Reliable Information, Fake News, and Scams
Navigating the Health Care System for a Person Living with a Dementia Disorder	How providers hear you	SBAR – Talk like a nurse
	Asserting your standing in the case	Prepping for telemed/out-patient visits
	Safe Use of the Emergency Department	Packing for an emergency
	When the person is hospitalized	Coordinating input from multiple providers
	Transferring back home	How to best use home care
	Getting jargon translated	Case Management: think like a Social Worker
Guiding and Managing Daily Life	The "clinical role" of the caregiver	Designing engaging tasks and activities
	Think and process like a Nurse	Care of chronic conditions
	Caregiver self-care	Using other resources

These materials will serve as the stimuli for the next audio-recorded Design Studio convened with IMCC caregiver Advisors, other caregivers, and also clinicians and Roybal Center Advisors. In this session, the revised outline will be subject to group scrutiny and suggestions. Again, team analysis of the results of the exercise will address key development questions:

- What's missing?
- Where is emphasis needed?
- What's irrelevant?
- What is/are key takeaway lesson(s)?
- Do educational methods encourage involvement and promote the specific caregiving mastery at which we are aiming?

Following analysis comparable to that employed after the first Design Studio session, we will produce a near-final course design, attending to issues of the "feel" and readability of the course, the exercises and opportunities for interactivity to be included, and the methods by which the instructor will monitor and provide feedback. We will also develop penultimate versions of course text and video asset scripts and begin production of caregiver and instructor manuals and other course materials.

These materials will provide the grist for the third Design Studio exercise, again an audio-recorded session convened primarily with caregiver participants but with some clinical and educational expert participation. We ask the same "What do you think?" questions about the content, structure, format, and mode of delivery of the course and

the proposed instructional videos (e.g., Is a lecture format acceptable? Should there be a combination of graphics and voiceover? Would some kind of embedded enactment be useful? What exercises might prompt interaction and foster mastery?).

Following an analysis comparable to those described above, the team will go into full production mode. We will work with the School of Nursing instructional design team to finalize scripting for the possibly as many as 36 segments, finalize the look, feel, and flow of the course, embed it on Canvas, a cloud-based learning management platform used by our School of Nursing, and move to the production of an accompanying caregiver manual and other associated course materials. The team will shoot the video assets – likely small (4-8 minute) mini-talks provided by our team and other experts – that will introduce and reinforce the text and pictorial content of the course. Based on previous experience, video production should take no more than 3-5 days, then editing and integrating these materials into the final course should take no more than three weeks.

Aim 2 [Weeks 16-52]. Drawing on the recruitment resources identified above, we will recruit 100 caregivers in two waves of 50 each to participate in a waitlist-control design pilot test. When 50 individuals are identified for the first wave, we will contact them, obtain their consent for participation, and, using established instruments delineated in Table 3 below to assess depression, anxiety, burden, and mastery, gather, through 30-minute phone or video interviews, baseline quantitative data on mood and caregiving competency. Once all participants in each wave have completed their baseline quantitative interviews, we will randomly assign half (25) to immediately enroll in and begin the course; we will inform the other half of the group (25) that the course will be open for their enrollment after a waiting period of approximately eight weeks, the time it will take the immediate participants to complete the course. All participants will again be interviewed at that 8-week point, following the immediate group's course completion and prior to the wait-list group's enrollment. All will be interviewed again 8 weeks later. This same pattern of data collection and random assignment will be followed with the second wave participants.

Table 3. Scales to be Used in Qualitative Interviews

Outcome Domains/Scales	Description of Validated Scales
The CES-Depression Scale[29]	21-item self-report depression scale
Stait-Trait Anxiety Inventory[30]	20-item self-report scale of positive and negative anxiety experiences
Perceived Stress[31]	16-item scale of self-reported caregiving stress
Revised Memory and Behavior Problem Checklist (RMBPC)[32]	24-item scale reporting on frequency of disturbing care recipient behaviors and severity or caregiver reactions to these behaviors.
Zarit Burden Scale[33]	22-item scale of objective and subjective caregiver burden
Caregiver Mastery Scales[34]	3 3-5 item scales of caregiver mastery of caregiving situations
Caregiver Competency Self-Assessment[35]	18-item caregiver self-assessment of perceived capacity to manage care situations

The Aim 2 baseline, midpoint, and final instrument-based interviews for all participants and audio-recorded semi-structured follow-up formative evaluation interviews with selected participants will be conducted by phone or videoconference by an interviewer trained and supervised by Co-Investigator Perkins; a protocol used in Hepburn's Tele-Savvy study will be employed to identify and respond to indications of extreme caregiver stress. Focus groups (Aim 1) will be conducted online, led by Perkins and Epps.

Three sources of information will enable us to move forward with the preparation of a revised course. The interactive elements of the course (discussion board, exercises and reflections) and the course instructor's observations will enable us to gauge caregivers' understanding of, reactions to, and apparent benefit from individual segments of the course. The Canvas platform allows us to monitor caregivers' course behaviors (e.g., time spent on segments, repeated viewing of segments, extent of participation in interactive components). This information may point to the relative importance of segments as well as the usability of interactive components. The post-course qualitative interviews with caregivers will provide extensive information about topic matter and the usability and acceptability of course material and overall course design. Data from these sources will begin to flow from the point of the gathering of baseline data from the first wave of participants (approximately week 22) and will continue through the qualitative interviews with course participants (approximately week 48). MPI Clevenger will lead the team's efforts to distill these data strands into practical course revision design activities with the instructional design consultant team to map the steps needed to produce a final course version by project's end.

7. Data and Specimen Banking

De-identified interview-gathered questionnaire data regarding caregivers' psychological well-being and self-asessment of competency will be stored in REDCap for analysis. De-identified transcriptions of audio-recorded Aim 2 open-ended qualitative interviews will be stored on Emory's instance of Box, accessible only to the study investigators. All study participants will be assigned ID numbers. The file linking identities to IDs will be stored separately on the PI's encrypted work computer. De-identified transcriptions of audio-recorded Aim 1 design sessions will also be stored on Emory's instance of Box, accessible only to the study investigators.

The final dataset will include standardized measures of caregiver well-being and competence and will be stored in PI Clevenger's office in the Emory University Nell Hodgson Woodruff School of Nursing in Atlanta, Georgia. Data from this study will be available to qualified researchers through a data sharing agreement that is fully consistent with NIH data sharing policies and applicable laws and regulations as well as official policies and practices established by the Roybal Center at Emory. Although these data will be de-identified prior to release for sharing, there remains a possibility of deductive disclosure of participants with unusual characteristics. Therefore, this data sharing agreement will require: 1) a commitment only to use the data for research purposes and not to identify any individual participant; 2) a commitment to securing the data using appropriate computer technology; and 3) a commitment to destroy or return the data after analyses are completed.

8. Sharing of Results with Participants

Results of each Design Studio will be shared with participants as each iteration of the course is developed. At study's end, we will prepare a lay report detailing the results of the study and distribute this report to study participants.

9. Study Timelines

For those caregivers engaged in the Aim 1 portion of the study, this will be a one-time involvement, lasting only during their participation in one of the Design Studio exercises. This will take approximately 1-2 hours

For any caregiver engaged in the Aim 2 wait-list control trial of the prototype developed in Aim 1, participation will last approximately 5 months.

We expect Aim 1 recruitment and enrollment to occupy a span of approximately 5 months, and Aim 2 recruitment and enrollment – which will begin while we are still engaged in Aim 1 activities – is expected to span about 5 months, from project month 4-9.

The study as a whole will take one year. Aim 1 activities will be complete by the end of the fifth month; Aim 2 activities will be completed by project's end.

10. Subject Population

We will seek to enroll family members (or friends) who self-identify as a principal caregiver and the principal companion of a community-dwelling PLWD during healthcare encounters. We will provide verbal and written instructions in how to access and use the course, provide a schedule for their completion of the course over the next 6-8 weeks, and mail out course materials. At the end point of each wave, we will purposively select 10 caregivers to participate in semi-structured interviews (total n=20) based on varying caregiver characteristics and findings from baseline quantitative data (e.g., stress levels, gender, race/ethnicity). Interviews will last approximately 45 minutes and will ask questions about the overall contribution of the course to their own perceived sense of competence as caregivers and healthcare navigators during the pandemic. We will also seek their responses to the course (Acceptable? Usable? Relevant? Enough? Too much? What's missing? How to improve?). We will provide $25 gift cards for participation in each baseline focus group and post-intervention semi-structured interview.

Caregivers would be excluded if their loved one is institutionalized or receiving hospice services or there are plans to do so within the next three months. Participants must also be able to read and speak English and be able to access the online course materials.

11. Vulnerable Populations

The study does not include individuals who lack decision-making capacity or may be susceptible to undue influence or coercion.

12. Local Number of Participants

We plan to recruit 30 participants in phase 1 of the study, designing the course, and 100 participants in phase 2, testing the course. All participants will be recruited from networks in Georgia.

13. Recruitment Methods

Core pilot team members can draw on their multiple involvements as recruitment sources for a diverse group of caregiver to address Aims 1 and 2. MPI Clevenger's IMCC has patient panel of >600 and a very active Family Advisory Board that has been integrally involved in the development and vetting of all aspects of the IMCC. The statewide Georgia Memory Net serves >300 dementia families, many in rural Georgia (Hepburn). Emory's NIA-supported Alzheimer's Disease Research Center (Hepburn, Co-I) maintains a large registry of caregivers willing to be contacted. Core team members' ongoing work with African American church communities (Epps), MCI empowerment activities (Hepburn), and MPI Hepburn's near-completed Tele-Savvy project can further ensure successful recruitment from program completers (25% African American).

Direct care providers (physicians, nurse practitioners) *will not* recruit participants.

Recruitment and Recruitment Materials for Aim 1 Design Studio Activities.

Caregivers who engage in the Design Studio process of developing the Caregiving During Crisis are not taking part in the research study. We will use the personal and organizational contacts described in the paragraph above to identify participants. For example, we expect to draw on advisory board members from the IMCC and MCI empowerment center, as well as community advisors to the Emory Roybal Center to take part in these design activities. Invitations will be made through phone calls and emails directly to these individuals.

Recruitment and Recruitment Materials for the Aim 2 Randomized Control Trial.

We plan to draw on the contacts available to each of the study investigators and to the broader networks with which they are affiliated (e.g., the national Alzheimer's Disease Centers and Roybal Centers) to provide information to potential participants. Potential subjects will be contacted by email if they have indicated their willingness to receive information about studies that might be of possible interest.

We will advertise online, through Social media, such as Twitter, Facebook and Instagram, and through Emory Healthcare on-hold message services. We will ask organizations in our network to use their normal methods of communication (e.g., their newsletters) provide a link to the study announcement which will be posted on our Roybal Center website (emorycaregiving.org). These announcements and scripts are attached to this application in the Recruitment Materials section.

Eligibility Determination

Screening will be conducted by distance means (phone or videoconference) by investigators Clevenger or Hepburn or Roybal Program Manager Reed.

- Is the potential subject providing care for a family member or friend? If so:
  - Does that person have a confirmed diagnosis of dementia?
  - Is the person living in the community?
  - Is the caregiver co-residing with the person?
  - Is the caregiver the main caregiver for the person?
- Does the caregiver have a computer with internet access?
- Can the person read and understand English?

The screening calls or videoconferences will not be recorded. No identifying information about the screening calls, including the person's IP address, will be recorded.

Payments to Participants.

We will provide $25.00 gift cards (e.g., Visa cards) to participants for each interview in which they take part. All trial participants will be asked to take part in a baseline interview and then subsequent interviews 3 and 5 months later. About 20% will be asked to take part in focus groups prior to their enrollment in the course, and about 20% will be asked to take part in semi-structured interviews following course completion. Thus, the maximum payment for any participant would be $100.00

14. Withdrawal of Participants

Aim 2 study participants may request, verbally or via course message or email, to withdraw from the study at any time. Likewise, the study team may also withdraw a participant if their caregiving situation changes (e.g., if the person for whom they are providing care is institutionalized or dies).

15. Risks to Participants

We believe that caregivers taking part in the trial of the Caregiving During Crisis program will be exposed to very low risks. The two main risks are of transient emotional distress and breach of confidentiality. These are described below.

Transient emotional distress. As persons providing care to a person living with dementia and doing so under the strains of the threat and restrictions of a pandemic, subjects in this study are already very likely to be experiencing a higher than normal level of stress and distress. The content of the course will draw their attention to their situation in ways that might make them more acutely aware of their distress or cause them to lower the defenses they might have

erected to fend off the distress. Likewise, the subject matter raised and the questions posed in the research interviews, the focus groups, and semi-structured interviews may also call attention to distressing matters and situations.

Based on our research experience with similar study subjects and the same questions and methods, we judge the occurrence of such distress to be relatively infrequent (perhaps in 25% of cases), of low magnitude (perhaps a 2 on a scale of 10, where 10 is the highest), of very brief duration, and fully reversible. The research interviewer will be trained to recognize such events and to provide ways to back away from and calm them. The participating investigators who would conduct the focus groups or semi-structured interviews are experienced in working with dementia caregivers and in managing such transient events in ways that permit the caregiver to work through them in a brief, respectful, and calming manner.

We can see no procedures in the study that might produce currently unforeseeable risks, and we can see no procedures that might put others at risk who are not in the study.

Threats to Confidentiality.

The Aim 2 study will gather personal information on all participants (name, email, address, etc.). This information will not be attached to any research study file. A unique ID number will be assigned to each participant, and all research documents pertaining to that participant (the data stored in REDCap or the transcriptions of the focus groups and individual interviews) will only be stored using that ID number. The file with baseline personal information and the file that links personal identifiers to ID numbers will be stored separately in the Emory encrypted computer in PI Clevenger's office. Any later sharing of data from the study will be done according to an NIH-compliant data and resource sharing agreement, and those data will be completely de-identified.

16. Potential Benefits to Participants

Although we are careful not to assert this to potential study participants, we believe the program will provide them with knowledge and skills that will help them to better negotiate the additional dementia caregiving challenges they face during this time of Coronavirus pandemic – and in possible future crises.

In terms of a knowledge contribution to the field: If this trial demonstrates positive preliminary efficacy in reducing caregiver distress and enhancing caregiver mastery, it will add to the evidence that a psychoeducational approach (developing skills, knowledge, and competence through an active and interactive learning strategy) is effective with this important population. This study's approach is aligned with other work by the investigators and with investigators supported by the Emory Roybal Center for Dementia Caregiving Mastery and with clinical practice at the IMCC that developing caregiver competence reduces caregiver distress.

In terms of the caregiver knowledge that would be strengthened: the program aims to increase caregivers' knowledge about ways to manage day-to-day life with a person living with dementia, knowledge about infection control practices to minimize risk of viral infection; and knowledge about navigating the healthcare system.

As noted in #13, above, participants will receive a $25.00 gift card (e.g., Visa card) for each research interview, focus group, and/or semi-structured interview in which they take part.

17. Data Analysis, Management and Confidentiality

Quantitative data will be entered at the time of each Aim 2 interview directly into the dedicated project tablet computer and saved on Emory's secure REDCap platform. All data entry screens are set up in REDCap and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported weekly and analyzed for data cleaning and verification. Upon completion of each cohort data-gathering point, all data will be merged for scale computation, aggregation, and analysis. We will use NVIVO 12 software to store and manage all qualitative data and to facilitate data analysis.

For quantitative analysis, we will test for group, time, and group-by-time effects for each of the outcomes (caregiver anxiety, depression, burden, stress, and mastery). In preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of all data. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). Preliminary analyses will examine baseline differences among completers and non-completers and by study arm (immediate/delayed) as a randomization check using 2-group comparison tests (t-tests and non-parametric equivalent tests for continuous variables (normally or non-normally distributed) and Chi-Square tests for categorical variables). The association of predisposing factors (demographics, Caregiving history, relationship and care recipient status at baseline) with changes in outcomes over time will be examined to identify significant covariates. Where significant associations with baseline measures are detected, these potential confounders will be controlled for in subsequent analyses using covariate model adjustments.

We will use repeated measures analysis to test 2 time by 2 group intervention (Immediate Participation in wave1 + immediate participation in wave 2) vs waitlist control (wave 1 + wave 2) change from baseline to post intervention at 8 weeks elapsed. Given final expected sample sizes of 45 subjects in each group (assuming 10% attrition), we will be powered at 80% with a 5% level of significance to detect moderate-to-large effect sizes for the group (f=0.297), time (f=0.300), and group-by-time (f=0.300) effects. To examine intervention effects over time for the combined intervention groups (Immediate wave 1 (week 16-24) + Immediate wave 2 (week 24-32) + waitlist wave 1 participants after course participation (week 24-32)), we will use repeated measures mainly focused on pre-to-post intervention effects for the 3 groups combined, however a group effect will be tested to ensure that the WLC1 had no placebo carryover effect that altered their "baseline at 24 weeks" from the other 2 groups. Given the

sample sizes of 25 subjects in each of these 3 groups, we will be powered at 80% with a 5% level of significance to detect moderate-to-large effect sizes for the group (f=0.381), time (f=0.381), and group-by-time (f=0.381) effects.

To address Aim 2 formative questions, Co-Investigator Perkins will lead the team in a thematic analysis[28] of the transcribed baseline focus group and post-intervention semi-structured interviews. We hope to pursue three lines of inquiry in this analysis that will be crucial for the next steps in our work: (1) In what ways might the overall concept of caregiver as healthcare navigator be sharpened? (2) In what ways might the delivery mechanism of the course be enhanced to improve caregiver learning (e.g., more interactivity)? (3) In what ways might individual components of the course be enhanced to improve caregiver learning (e.g., different formats; additional videos)? We expect that these analyses will provide compelling evidence for the feasibility, acceptability, and usability of the course.

18. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

Protection of Privacy Interests.

There are very few threats to participants' privacy interests involved in the study, and below we describe how we will minimize and manage those threats:

- Except in the focus groups in which we will ask 20% of subjects to take part, there is no direct contact between and among study subjects. Participation in these focus groups is entirely voluntary; no identification is provided about participants to other participants, and participants can choose to take part without video.
- The only personal information to be obtained will be gathered in baseline interviews; we have described above the measures we will take to remove identifiers from the data stored in REDCap
- The research interviewer will be trained by investigator Hepburn in techniques designed to make participants feel at ease with the questions being asked in the research interviews. Training will involve simulated research interviews conducted with project investigators by the research interviewer in which the interviewer will be expected to react effectively to situations in which the interviewee exhibits signs of feeling discomforted or intruded upon.
- The focus groups and semi-structured interviews will be conducted by study investigators, all of whom are experienced in interacting with caregivers and helping them to feel at ease in situations that might feel intrusive or distressing.

The only member of the research team who will have access to sources of private information about the participants will be PI Clevenger; no other team member will have or be granted access to that information.

As noted above in #15, all confidential data will be separated from REDCap files and transcripts, all of which will use ID numbers, and the confidential material will be stored

separately in PI Clevenger's Emory encrypted computer. None of the data from the study will be entered into participant's medical records.

We will follow NIH policies in retaining and destroying identified study information. Audio-recordings will be destroyed at study's end.

19. Economic Burden to Participants

Participants are asked to contribute their time to the study but no cost to participants is be expected.

20. Consent Process

The consent process will occur through distance means, by phone or videoconference, in the following manner:

1. Appointment-Making. A potential subject will contact, by phone or email, one of the three study team members identified on the project recruitment document (Clevenger, Hepburn, and Reed). If the contact is by email, a return email or phone call (if the person provides a number) will be made in order to set the time for a longer call.

2. Consent Call. This call initiates the consent process

- In this call, following a brief description of the study, the study team member will establish the eligibility of the person for the study (see # 13, above)
- If the person is eligible, the team member will more fully describe the study, study procedures (what is being asked), and study risks and protections; at each point, we will ask if the person has questions or if we can provide additional information
- To ensure understanding, we will ask potential subjects to describe back what they understand the study to be about and what they will be expected to do
- At the end of the call, we will determine if the person wishes to voluntarily consent to participation in the trial. If so, we will describe the next steps.

We anticipate these conversations will take approximately 30 minutes.

3. Consent Documentation.

- If the person indicates agreement to participate, we will inform him or her that we will be sending, by mail or email (at the person's preference) the consent document (two copies if mailed) that will include all of the information discussed in the Consent Call.
- When the person receives the consent document s/he will be asked to either sign the document and mail it back to us or to sign and scan the signature page and email that page back to us.
- We will make it clear both in the Consent Call and in our mailed or emailed transmission of the consent document, that we are available to answer any additional questions s/he might have before completing the consent process.

- We will also make clear, in the Consent Call and the consent documentation process that we are available throughout the study to address any questions or concerns the person might have about the study or participating in it.

The interval between the Consent Call and Consent Documentation process could be a matter of hours, if email is the vehicle of transmission, to days (if mail is used). This interval should allow sufficient time for participant reflection about consent – as well as the generation of additional questions the person might have about participation.

There is nothing in the recruitment or consent process that could lend itself to pressure potential participants, either through coercion or undue influence, into participation, and the compensation offered for participation is modest, at best.

21. Setting

As noted in #13, above, recruitment of participants will leverage the study investigator team's networks of dementia care practices throughout the state of Georgia as well as national Alzheimer's Disease Center and Roybal Center networks. Recruitment will occur entirely online. The Recruitment document will be posted on the Emory Roybal Center's website (see above).

The Caregiving During Crisis course will be entirely online, delivered via a secure Canvas platform.

Research interviews, focus groups, and semi-structured interviews will be conducted on Emory's encrypted version of Zoom

The project will not have a community advisory board.

22. Resources Available

The research is being conducted as an administrative supplement to Emory's Roybal Center for Caregiving Mastery; as such, it will have administrative support through the Center. It is, as described above, also being conducted within the context of the study team members' several involvements in local, state, and national engagements, all of which are directly related to issues of dementia care and the support and development of the capacity of family caregivers to provide effective care to community-dwelling persons living with Alzheimer's disease and related disorders.

Recruitment of 100 study participants seems very feasible. Within the immediate reach of the study team there are at least 1,000 eligible caregivers, and our extended reach, especially through the NIA-supported network of Alzheimer's Disease Centers (with a number of which we have worked closely) there are many thousands more.

The administrative supplement adds effort in the Roybal Center to both investigators Clevenger and Hepburn, and it provides time for investigator Epps.

All study personnel are currently working from home, but in a phase 3 or 4 relaxation of restrictions situation, the Center has designated space in the School of Nursing, and all investigators have private offices and Emory encrypted computers. Under both scenarios, the facilities are appropriate for conducting this fully online study.

We have described above the measures we will take to ensure that any transient emotional distress participants might experience can and will be handled at the time of occurrence, and we do not foresee the need for any additional psychological resources. The study does not involve procedures that might require medical resources.

This is a small study with only an interviewer and Center Program Manager involved beyond the investigators. The procedure for training the interviewer was described above. The PI will train the Program in the conduct of the Eligibility procedure and the Consent Call, should she be the team member to handle either or both of these.

23. References

1. Alzheimer's Association (2020). 2020 Alzheimer's disease facts and figures. Accessed online: https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf.

2. Hepburn K, Lewis M, Tornatore J, Sherman CW, Bremer KL. The Savvy Caregiver program: the demonstrated effectiveness of a transportable dementia caregiver psychoeducation program. J Gerontol Nurs. 2007;33(3):30-36.

3. Kally, Z, Cote SD, Gonzalez J, Villarruel M, Cherry DL, Howland S, Higgins M, Connolly L, Hepburn K. The Savvy Caregiver Program: Impact of an evidence-based intervention on the well-being of ethnically diverse caregivers. The Journal of Gerontological Social Work, Published on-line Oct. 30, 2013.

4. Brewster, G. S., Epps, F., Dye, C. E., Hepburn, K., Higgins, M. K., & Parker, M. L. (2019). The Effect of the “Great Village” on Psychological Outcomes, Burden, and Mastery in African American Caregivers of Persons Living With Dementia. Journal of Applied Gerontology, 0733464819874574. doi:10.1177/0733464819874574

5. Kovaleva MA, Bilsborough E, Griffiths P, Nocera J, Higgins M, Epps F, Kilgore K, Lindauer A, Morhardt D, Shah RC, Hepburn K. Testing Tele-Savvy: Protocol for a randomized controlled trial. Research in Nursing & Health, 2018; 41 (2), 107-120 doi: 10.1002/nur.21859. Epub 2018 Feb 5. PMID: 29399825

6. Kovaleva M, Blevins L, Griffiths PC, Hepburn K. An online program for caregivers of persons living with dementia: lessons learned. Journal of Applied Gerontology. 2017 1:733464817705958. doi: 10.1177/0733464817705958. [Epub ahead of print]

7. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev. 1977 Mar 1977;84(2):191-215.

8. Folkman S. Positive psychological states and coping with severe stress. Soc Sci Med. 1997 Oct 1997;45(8):1207-1221.

9. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. JAMA. 1999;282(23):2215-2219.

10. Schulz R, Sherwood PR. Physical and mental health effects of family caregiving. Am J Nurs. 2008;108(9 Suppl):23-27; quiz 27.

11. Clevenger, CK, Chu, TA, Yang, Z, Hepburn, KW (2012). Clinical care of persons with dementia in the emergency department: a review of the literature and agenda for research. Journal of the American Geriatric Society; 60(0): 1742-48.

12. Godard-Sebillotte C, Le Berre M, Schuster T, Trottier M, Vedel I. Impact of health service interventions on acute hospital use in community-dwelling persons with dementia: asystematic literature review and meta-analysis. PLoS One. 2019 Jun 21;14(6):e0218426. doi: 10.1371/journal.pone.0218426. eCollection 2019.

13. Hunt LJ, Coombs LA, Stephens CE. Emergency Department Use by Community-Dwelling Individuals With Dementia in the United States: An Integrative Review. J Gerontol Nurs. 2018 Mar 1;44(3):23-30. doi: 10.3928/00989134-20171206-01. Epub 2018 Jan 23.

14. Stephan A, Bieber A, Hopper L, Joyce R, Irving K, Zanetti O, Portolani E, Kerpershoek L, Verhey F, de Vugt M5, Wolfs C, Eriksen S, Røsvik J, Marques MJ, Gonçalves-Pereira M, Sjölund BM, Jelley H1, Woods B10, Meyer G1; Actifcare Consortium. Barriers and facilitators to the access to and use of formal dementia care: findings of a focus group study with people with dementia, informal carers and health and social care professionals in eight European countries. BMC Geriatr. 2018 Jun 4;18(1):131. doi: 10.1186/s12877-018-0816-1

15. Hepburn K, Tornatore J, Center B, Ostwald SW. Dementia family caregiver training: Affecting beliefs about caregiving and caregiver outcomes. Journal of the American Geriatrics Society, 2001;49(4):450-457

16. Gallagher-Thompson D, Coon DW. Evidence-based psychological treatments for distress in family caregivers of older adults. Psychol Aging. 2007;22(1):37-51.

17. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. Gerontologist. 2002;42(3):356-372.

18. Pinquart M, Sorensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects? Int Psychogeriatr. 2006;18(4):577-595.

19. Kim H. Understanding Internet Use Among Dementia Caregivers: Results of Secondary Data Analysis Using the US Caregiver Survey Data. Interact J Med Res. 2015;4(1):e1.

20. Bossen AL, Kim H, Williams KN, Steinhoff AE, Strieker M. Emerging roles for telemedicine and smart technologies in dementia care. Smart Homecare Technol Telehealth. 2015;3:49-57. Epub 2015 Mar 22.

21. Hepburn K, Tornatore J, Center B, Ostwald SW. Dementia family caregiver training: Affecting beliefs about caregiving and caregiver outcomes. Journal of the American Geriatrics Society, 2001;49(4):450-457.

22. Clevenger CK, Cellar J, Kovaleva M, Medders L, Hepburn K. Integrated Memory Care Clinic: Design, Implementation, and Initial Results. J Am Geriatr Soc. 2018 Dec;66(12):2401-2407. doi: 0.1111/jgs.15528. Epub 2018 Aug 23. PMID: 30136290

23. van de Grift, T., Kroeze, R, Design Thinking as a Tool for Interdisciplinary Education in Health Care, Academic Medicine, 2016, 91 (9): 1234-1238.

24. Przybilla, L; Klinker, K., Wiesche, M., and Krcmar, H., A Human-Centric Approach to Digital Innovation Projects in Health Care: Learnings from Applying Design Thinking, PACIS 2018 Proceedings. 226.

25. Swanson C., Widmer M. Transforming Health Education to Catalyze a Global Paradigm Shift: Systems Thinking, Complexity, and Design Thinking. In: Sturmberg J. (eds) Putting Systems and Complexity Sciences Into Practice, 2018; 119-131

26. Badwan, B., Bothara, R., Latijnhouwers, M., Smithies, A. and Sandars, J. The importance of design thinking in medical education, Medical Teacher, 2018; 40 (4), 425-426.

27. Scholten H, Granic I Use of the Principles of Design Thinking to Address Limitations of Digital Mental Health Interventions for Youth: Viewpoint J Med Internet Res 2019;21(1):e11528

28. Guest G, MacQueen KM, Namey EE. Applied thematic analysis. Thousand Oaks, CA: Sage; 2011.

29. Radloff S. The CES-D Scale: A self-report depression scale for research in the general population. Applied Psychological Measurement. 1977(1):385-401.

30. Spielberger CD, Vagg PR. Psychometric properties of the STAI: a reply to Ramanaiah, Franzen, and Schill. J Pers Assess. 1984;48(1):95-97.

31. Cohen S, Kamarck, T, Mermelstein, R. A global measure of perceived stress. Journal of Health and Social Behavior 1983;24:386-96.

32. Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: the revised memory and behavior problems checklist. Psychol Aging. 1992;7(4):622-631.

33. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. Gerontologist. 1980;20(6):649-655.

34. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. Gerontologist. 1990;30(5):583-594.

35. Steffen A, McKibbin, C, Zeiss, AM, Gallagher-Thompson, D, Bandura, A. The revised scale for caregiving self-efficacy: reliability and validity studies. Journal of Gerontology B Psychological Science and Social Science 2002;57:74-86.