Official Study Title: Learning Skills Together Pilot Study

NCT number: NCT04428034

IRB Approval Date: 06/03/20

Unique Protocol ID: HSC20200410E

Form B-3
Exempt Research Request
General Information Sheet

Using this form – To check the checkboxes, click once on the box. To enter text in the text boxes, click once on the gray box and then type your response. *If you are a Mac user and/or are having trouble using this form, try this alternate version of the form.*

UTHSCSA IRB Tracking Number	HSC20200410E

Section 1 – For **Exempt Research**, the research must fall within at least one Exemption Category found in items 1-6 below AND all of the following must be true. The research:

- The research is minimal risk.
- If the research involves children as participants it does NOT include:
- Interacting with children; OR
- If the research involves prisoners as participants, it must only include them as part of a broader subject population that only incidentally includes prisoners
- The research is not FDA regulated human research.

Note: If the above items are not true or the research does not meet one or more of the 6 categories below then the submission needs to be submitted under Expedited Review.

Contact the OIRB for assistance at (210) 567-8250 or IRB@uthscsa.edu.

1.1 Does your research evaluate different instructional strategies or compare the effectiveness of instructional techniques, curricula, or classroom management methods in an established or commonly accepted educational setting?

45CFR46.104(d)(1)

☒	No – *Go to 1.2*
☐	Yes – answer the following question:

1.1.1 Will the study interfere with normal education practices?

☐	Yes – STOP - **Not Eligible** for Exemption.
☐	No – ✔ - Your study qualifies for Exemption

1.2 Does your research involve interactions involving educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observations of public behavior (including visual or auditory recording) influenced by the investigator?

45CFR46.104(d)(2)

☐	No – *Go to 1.3*
☒	Yes – answer the following question:

1.2.1 Does your study include **an intervention** with a **pre/posttest**?

☐	Yes - STOP - **Not Eligible** for Exemption. *You cannot use this form.*
☒	No – answer the following question:

1.2.2 Will you record identifiers (or assigned code) linked to the data/subject responses?

☐	No- ✔ Eligible for Exemption #2
☒	Yes – answer the following question:

1.2.3 Will you record any information which could pose a risk (civil, criminal, employability, insurability, reputation, etc.) to individuals if it were accidentally released?

☒	No - ✔ - Eligible for Exemption #2
☐	Yes - ✔ - Eligible for Exemption #2. (A Limited Review is required)

1.3 Does your research involve benign behavioral interventions in conjunction with the collection of information?

45CFR46.104(d)(3)

☐	No – *Go to 1.4*
☒	Yes - Select the appropriate statement below:

☐	The information obtained is not identifiable. ✔ - Eligible for Exemption
☒	Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability; or be damaging to the subjects' financial standing, employability, insurability or reputation. ✔ - Eligible for Exemption
☐	Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. ✔ - Eligible for Exemption (A Limited Review is required)

1.4 Does your research involve the collection of data and/or specimens that are originally collected for other purposes (i.e., educational records, medical records, specimens in pathology, etc.)?

45CFR46.104(d)(4)

☒	No – *Go to Item 1.5*
☐	Yes – Categorize the research activities by selecting the appropriate statement(s) below:

☐	The identifiable private information or identifiable biospecimens are publicly available. ✔ – Eligible for Exemption #4
☐	The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects. ✔ – Eligible for Exemption #4
	Confirm the following: ☐ Access to record will occur only **once**. ☐ **NO study codes** will be assigned to the subjects on the subject list *Note: No Institutional follow-up required. Refer to Institutional Review Policy.*
☐	The secondary research activity is regulated under HIPAA (HIPAA waiver is required). ✔ – Eligible for Exemption #4
	Access to record may occur **more than once** A **link may be created** *Note: Institutional follow-up is required if the study is still active in 3 years. Refer to Institutional Review Policy*
☐	The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected. ✔ – Eligible for Exemption #4
☐	None of the above, STOP - **Not Eligible** for Exemption. *You cannot use this form.*

1.5 Is this project a Research or Demonstration Projects Approved by Federal Department/Agency Head? *(This is not common)*

45CFR46.104(d)(5)

☒	No – *Go to Item 1.6*
☐	Yes – Check the box for each true statement below (all must be true to be eligible for exemption):

☐	1.5.1 The research is conducted by or subject to the approval of federal Department or Agency heads
☐	1.5.2 The research is designed to study, evaluate, or otherwise examine at least one of the following: (select as applicable): ☐ public benefit or service programs ☐ procedures for obtaining benefits or services under public benefit or service programs ☐ possible changes in or alternatives to public benefit or service programs ☐ possible changes in methods or levels of payment for benefits or services under public benefit or service programs
☐	1.5.3 The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

☐	1.5.4 The research is conducted pursuant to specific federal statutory requirement	
☐	1.5.5 There is no statutory requirement that an IRB review the research.	
☐	1.5.6 The research does not involve significant physical invasions or intrusions upon the privacy of participants.	

☐	All are **checked** (1.5.1 to 1.5.6) - ✔ - Eligible for Exemption
☐	Any are **unchecked** (1.5.1 to 1.5.6) - STOP - **Not Eligible** for Exemption. *You cannot use this form.*

1.6 Does your research involve taste and food quality evaluation or consumer acceptance studies? *(This is not common)*

45CFR46.101(b)(6)

☒	No – *Go to Item 1.7*	
☐	Yes - ✔ - Eligible for Exemption - Select the appropriate statement below:	
	☐	Wholesome foods without additives are consumed
	☐	If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following: (delete those not applicable) the Food and Drug Administration; the Environmental Protection Agency; the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1.7 Did you answer YES to at least one of items 1.1-1.6 above?

☐	No – STOP (if **No** to **all items** 1.1-1.6, your study is **not eligible** for Exemption, submit as Expedited or contact OIRB for assistance)
☒	Yes - ✔ - Eligible for Exemption – *Go to Section 2*

Section 2 – Will you obtain specimens or private information without needing to interact with individuals?

☒	No *continue to Section 3*	
☐	Yes	Approximately how many separate records or specimens do you plan to obtain?

Section 3 – Will you be interacting or intervening with living individuals?

☐	No	
☒	Yes	
	What is the age range?	18 +

Section 4 – Identification of Subjects/Records/Specimens

4.1 How will you identify subject or data/specimens for inclusion criteria?

☒	During regularly scheduled event: When participants sign up to participate in an educational program offered by the UTHSA Caring for the Caregiver Program, they will be informed of the opportunity to participate.
☐	Records Search: [describe event: i.e., medical records, academic records, employee records, etc.]
☐	Other:

4.2 Does the information reviewed contain both health information and identifiers?

☒	No- *Skip to Section 5*
☐	Yes - submit Form J – HIPAA Waiver – *Go to Section 5*

Section 5 – Initial contact

5.1 Provide a brief summary of how subjects will be asked to volunteer.

☐	Personal Contact
☐	PI clinic
☒	Other: When Caregivers register through Eventbrite to participate in the Learning Skills Together Program, they will be notified of the research study. Participants may also be referred by community partners and practitioners who may share a flyer about the program and research study. Caregivers may also learn about Learning Skills Together through newsletters and flyers shared by the Caring for the Caregiver Program.
☐	N/A. (i.e., Charts, EMR)

Section 6 Purpose and rationale *Insert purpose, objectives and research questions/hypotheses here.*	The purpose of this study is 1) to test the feasibility and acceptability of an online program to improve the self-efficacy when completing complex care tasks among family caregivers to individuals living with mid-stage Alzheimer's Disease (AD), and 2) to evaluate whether participation in this program is likely to affect mean levels of self-efficacy and mastery. **Research Questions:** 1) Can Learning Skills Together be feasibly delivered to family caregivers to individuals living with mid-stage Alzheimer's Disease (AD) online, and is online delivery of Learning Skills Together acceptable to caregivers? 2) Do caregivers to individuals living with mid-stage AD have increased self-efficacy and mastery following completion of the Learning Skills Together program? **Primary hypothesis:** Caregivers to individuals living with mid-stage AD will have higher self-efficacy and mastery scores, on average, after completing the Learning Skills Together program. **Study aims:** **Aim 1:** Develop a manual to train interventionists to deliver a standardized version of LST. An interdisciplinary team of healthcare faculty with experience delivering an earlier version of the classroom-based intervention will prepare the content of this manual and its accompanying caregiver workbook. **Aim 2:** Conduct a pilot study to test study protocols and examine outcome data to inform a sample size calculation for an efficacy study. We will implement LST in using videoconferencing over 2 weeks. Pre-post surveys examining self-efficacy and mastery will be administered to participants (N=40) to: 1) examine for trends for these outcomes, and 2) obtain effect size estimates to inform the sample size for a future study to test intervention efficacy. Analyses will be conducted using paired t-tests. **Aim 3:** Examine the feasibility of delivering LST, intervention fidelity, and caregiver satisfaction. We will collect data on fidelity through direct observation by the interprofessional team on the delivery of their profession specific content using a structured fieldnote guide and fidelity checklist. Barriers and facilitators to delivering and participating in the program will be evaluated in post-session telephone debriefings with interventionists, as well as one-on-one in-depth interviews with 10 participants. To evaluate caregiver satisfaction, we will collect survey feedback data from caregivers after the workshop and booster session. Given the circumstances surrounding COVID-19, while updating the Learning Skills Together program, we propose to test the feasibility of delivering LST online to adhere to social distancing recommendations.

Section 7

Background

Describe past experimental and/or clinical findings leading to the formulation of your study.

The Caring for the Caregiver Program (CCP) was established in 2017 at the UT Health San Antonio School of Nursing by a team of interdisciplinary health professionals. Family caregiver input has been an essential part of the CCP program development, through involvement of Caregiver Specialist, Sheran Rivette, and other caregivers to guide programming and research. An initial version of LST was developed by the CCP in response a community-identified need for caregiver training at a community forum [1]. This program was delivered to over 250 caregivers, half of whom are Latino. An ongoing need for training on complex care tasks was affirmed by a stakeholder group of caregivers and people living with dementia participating in the Patient Centered Outcomes Research Institute (PCORI) grant led by PI Dr. Carole White. **LST is designed to improve self-efficacy to complete complex care tasks among caregivers to individuals living with mid-stage AD.**

Improving caregiver self-efficacy improves caregiver mental health. We define self-efficacy as an individual's belief that they are capable of accomplishing a task, such as managing behavioral symptoms [2]. Self-efficacy is an essential component of chronic disease self-management; lessons from this field can be readily applied to AD caregiving, as caregivers take on previously self-managed tasks related to recipients' chronic disease symptoms [3-5]. Mastery of skills, such as how to provide complex care tasks and problem solve, can improve caregiver self-efficacy [6, 7]. Self-efficacy when providing care is positively associated with lower levels of caregiver depression, and partially mediates the relationship between caregiving stressors and mental health outcomes [8-10]. Improvements in self-efficacy through skill-building interventions is associated with improved caregiver mental health [11, 12]. Group-based education may confer an additional mental health benefit through access to social support, as complex care responsibilities put caregivers at risk of social isolation [13, 14]. Further, caregivers value group interventions where they can learn from other caregivers [15, 16].

Caregivers to individuals living with mid-stage Alzheimer's Disease experience low self-efficacy and poorer mental health. Individuals living with mid-stage cognitive impairment are most likely to exhibit behavioral symptoms relative to those in early- and late-stages of the disease [17, 18]. Higher severity of behavioral symptoms among care recipients is associated with lower self-efficacy and mental health for their caregivers [19]. In a survey of caregivers referred to a community organization in Los Angeles, just 32% indicated they felt confident about handling problems like the patient's memory loss and behavioral symptoms [19]. At the same time, only 39% received advice about how to do so. These findings suggest low levels of self-efficacy are common among caregivers and that few receive skills training that could boost self-efficacy.

Caregivers need training on personal and complex care that could improve self-efficacy. People caring for someone living with dementia who needs assistance with two or more self-care needs are more likely than caregivers to persons with no self-care needs to manage medical tasks (20.5% v. 9.2%) and manage medications (65.4% v. 36.8) [20]. Behavioral symptoms of dementia such as resistance to care exacerbate the difficulty of providing complex care tasks [21-24]**.** A new online platform to identify translated evidence-based dementia caregiver interventions (www.caregiver.org) features numerous interventions shown to improve caregivers' management of behavioral symptoms and self-care [25, 26]. Using the program's search filters, we identified 13 interventions that address medical care topics and improve caregiver mastery, skills, and/or efficacy. *Of these, none were focused on addressing caregivers' ability to conduct complex care tasks.* This preliminary search is supported by findings from a recent integrative review on complex care tasks provided by caregivers, which identified an unmet need for interventions to train caregivers to conduct complex care tasks [24].

Learning Skills Together addresses the need for concise and accessible intervention programs. The feasibility of attending multiple-session in-person interventions can be challenging for caregivers due to care demands and geography, particularly for caregivers living in rural areas, such as our South Texas service region [27]. Further, month's-long interventions cost hundreds of dollars per caregiver and, with few reimbursement options, many community-based programs cannot afford to deliver intensive interventions [28-30]. **The Learning Skills Together program is designed to be completed in four, 1.5 hours online sessions over 2 weeks, plus one booster session, to increase its accessibility, caregiver adherence to the program, and affordability.**

In the earlier version of LST, the skills workshop, an interdisciplinary team of healthcare faculty members including nurses, occupational therapists, speech language pathologists, nutritionists, and dental hygienists delivered lecture-based presentations to caregivers. During this period, the workshop has been adapted to meet the diverse needs of caregivers, such as providing more culturally familiar nutritional content to Latino attendees. We also collected post-intervention satisfaction data. Most caregivers said they "strongly agree" (87%) or "agree" (13%) with the statement that participating in this earlier intervention provided them with useful information. Participants also enjoyed the chance to engage with and learn from other caregivers. However, multiple attendees commented they were interested in more interactive training and further group discussion. Based on this experience and feedback, we recognized the need for a theory-based intervention, Learning Skills Together, to provide caregivers with confidence and self-efficacy around complex care tasks.

Learning Skills Together is informed by Social Learning Theory (SLT) as it is used in the chronic disease self-management literature [3, 4]. Self-efficacy encourages behavior modification by supporting intrinsic motivation to engage in an appropriate health-promotion response to an illness-related challenge [2]. Faced with novel and evolving caregiving demands and limited training, caregiver self-efficacy is undermined [19, 24]. Self-efficacy is enhanced by mastery of complex care skills though hands-on training, modeling others' behaviors, reframing unhelpful perspectives to better address complex care tasks, and social persuasion from peers engaged in skill-building [3, 4]. Management of complex care tasks requires caregivers to adapt as needs change, and thus problem-solving skills are an essential component on which to intervene in addition to discrete tasks [3, 7]. Tailored goal setting enhances intervention effects by facilitating a sense of meaningful accomplishment among learners [3]. LST also draws on Transformative Learning Theory (TLT). According to TLT, learning occurs when individuals encounter a disruptive event that leads them to question their current assumptions, followed by critical self-reflection that involves modification of those assumptions. We intend to disrupt unhelpful ideas about the caregiving role during a simulation scenario and debriefing (e.g., the care recipient is engaging in disruptive behaviors on purpose). Although infrequently used in caregiver education programs, there is a strong evidence-base for simulation learning among healthcare trainees [31, 32].

The proposed intervention addresses a significant need to prepare family caregivers with training to provide complex care tasks. The majority of caregivers take on this care with no training, learning by trial and error [33]. In response to calls to make interventions more accessible and translatable, we propose a 4-session, online videoconference workshop with a 2-hour booster [30, 34]. This theory-based intervention translates best practice in chronic disease self-management and education for healthcare professionals to train family caregivers of people with mid-stage AD on how to provide complex care tasks. The expertise of the

	interprofessional team will contribute to the training manual that will be used to deliver the program with fidelity and will contribute to future dissemination.

Section 8 – Subject Population

e.g., a population can be individuals with type 2 diabetes controlled with diet and/or a population of healthy controls. Or a population can be individuals attending an education program, etc.

8.1 Study Population(s) Being Recruited

In your recruitment plan, how many different **populations** (groups, cohorts, etc.) of subjects do you plan to target?

Provide number of populations here:	1

8.2 Inclusion & Exclusion Criteria List each different population on a separate row and provide a short descriptive **label** for each: *(e.g., normal-healthy, diabetics, parents, children, etc.)* *To add rows use copy & paste*	Identify the criteria for **inclusion** below:	Identify the criteria for **exclusion** below:
Family caregivers to individuals living with mid-stage Alzheimer's Disease	• Family member (including families of choice) to an individual living with AD who has received a diagnosis from a physician • Ages 18 and older • Provides assistance with at least two instrumental activities of daily living or one activity of daily living • Care recipient is described as being within mid-stage Alzheimer's Disease • There are no plans to place the care recipient in a skilled nursing facility within the next 3 months	• The caregiver is paid to provide care • The caregiver does not have reliable access to a computer and internet • The caregiver is unable to read and speak English • Care recipient is described as being within mild or end-stage Alzheimer's Disease • There are plans to place the care recipient in a skilled nursing facility within the next 3 months.

Section 9 – Research Plan / Description of the Research Methods

9.1 Step-by-Step Methods *Provide a **comprehensive narrative** describing the **research methods**.*

Aim 1: The interdisciplinary team of healthcare faculty who have delivered the Caregiving Skills intervention over the previous 3 years will build on their existing materials and experiences to develop a standardized LST training manual during the first two months of the pilot study year. In addition to updating existing presentations and learning objectives, faculty and topics experts will integrate interactive activities and handouts for family caregivers. Team members will provide guidance for a general audience, so that the program can be administered by interventionists with a variety of qualifications in different settings. After drafting sections, the investigator team and Caregiver Specialist, a former caregiver, will review and suggest revisions. The draft training manual and workbook will then be shared with the whole team for a second review round. Adherence to manual procedures will be examined as a part of intervention fidelity in Aim 3. We currently use a checklist to examine fidelity in the skills workshop, and this will be revised for LST.

Aim 2: Using a pre-post design, caregivers will complete self-administered surveys up to 2 weeks prior to participating in the LST program, 4 weeks later, and 4 weeks after the booster session that will occur 6 weeks after the final core LST group session. Data will be used to examine trends and to obtain effect size estimates to calculate the sample size for a future efficacy study.

Study Setting and Recruitment. We will recruit a convenience sample of 40 caregivers. Caregivers learn about LST through word-of-mouth, community referrals, and local advertising (e.g., Eventbrite). We will cap classes at 12 caregivers per month, and deliver one course per month. As such, we anticipate recruiting ~6 caregivers/month for 8 months to meet our recruitment goal. (We will add sessions, if needed, to meet this recruitment goal.) When caregivers register for LST online or by phone, we will share information about the study with them (purpose, activities involved, risk and benefits) and screen for eligibility if they express interest in participating. Study information may also be shared through word-of-mouth referrals, community presentations, and flyers distributed by community partners and at events. We will aim to recruit 20 non-Latino and 20 Latino caregivers, such that participants represent the San Antonio community and the current clientele of the Caring for the Caregiver Program. **Regardless of whether a caregiver is interested in the research study and/or eligible to participate in the research study, they will still be allowed to participate in the Learning Skills Together program as it is being provided as a regular resource to the community.**

Inclusion and Exclusion Criteria. Inclusion criteria will follow those used by the National Institute on Aging-funded Resources for Enhancing Alzheimer's Caregiver Health (REACH) trials [35] such that: 1) the caregiver is a family member to an individual living with AD who has received a diagnosis from a physician, 2) they are aged 18 years or older, 3) they provide assistance with at least two instrumental activities of daily living or one activity of daily living, and 4) they are not paid to provide care. Further, participating caregivers must care for a person with living with moderate dementia, as measured by a score of 5 or 6 of the Global Dementia Scale.[36] We will also ask that participants be able to attend both the main workshop and the booster session. Exclusion criteria are: inability to read and speak English, and having plans to place the care recipient in a skilled nursing facility within the next 3 months.

Intervention. Learning Skills Together is a 4-session online intervention delivered using the Zoom videoconferencing platform. Caregivers will be emailed call information, including a password, prior to the scheduled sessions, and will be asked to login at the scheduled time. Prior to joining the videoconference sessions, caregivers participating in LST will first meet with an interventionist during a one-on-one scheduled telephone call to 1) make sure the caregiver is prepared to participate (e.g., caregiver is comfortable with technology used to deliver LST), 2) build trust with the interventionist, and 3) set up individual goals. The 4 group-based Zoom-delivered sessions lasting ~1.5 hours each will cover topics including managing behavioral symptoms of dementia, communication, oral hygiene and other common complex care issues caregivers frequently encounter when assisting someone with mid-stage AD. Presentations will integrate discussion and interactive activities delivered using multiple web-based tools (e.g., videos, downloadable PDFs, chat box, polls). Presentations will be based on materials developed by an inter-disciplinary team of healthcare professionals and compiled into a caregiver workbook that will include standardized materials (e.g., Powerpoint slide decks, handouts). Zoom "breakout" groups will be used to facilitate small group discussion and activities. Additional resource and post-session assignments will be sent to participants by email. One month after completing the 4-week program, caregivers will participate in a booster session in which they will reflect on their goals and raise further questions they may have encountered since program completion.

Data Collection. Data will be collected using an online, self-administered questionnaire using REDCap. Surveys will be linked with a unique identifier. Outcomes will be measured at baseline (up to 2 weeks prior to workshop) (T_0), 1 month later (T_1), and 1 month after the booster session (T_2).

Table 2: Summary of pre- and post-test survey measures	
Construct	**Measure**
Targeted proximal outcomes	
Self-efficacy (overall)	Pearlin and colleagues (1991) Competence Scale (*alpha*=0.74)[37]

Self-efficacy (responding to disruptive behaviors)	Revised Scale for Caregiver Self-Efficacy (test-retest reliability= r=0.70)[9]
Self-efficacy conducting complex care tasks (investigator-generated through expert discussion)	How confident caregivers feel conducting each task and skill area taught during the LST intervention (0=Not confident at all; 5=Very confident) [3]
Caregiver Mastery	Pearlin and Schooler (1978) Mastery Scale (*alpha*-0.78) [38]
Participant characteristics	e.g., age, gender, race, ethnicity, relationship to care recipient, years in role
Caregiving intensity	Functional ability of the care recipient [39, 40], presence of behavioral symptoms of dementia [41], subjective stress [42, 43]

Sample size and justification. We will recruit 40 caregivers to account for attrition, such that we will have a final sample of 34 caregivers. We estimated this sample size using a power analysis conducted in G*Power where we assume a large effect size (*d*=0.50) with a 2-tailed test at 0.80 power with an alpha of 0.05. The effect size, which may be arguably sizeable, is traditional for a pilot study; these data will inform subsequent power calculations in a future large-scale trial. [44].

[redacted]

Aim 3: We propose multiple methods to examine the delivery feasibility, fidelity, and caregiver satisfaction.

Examining interventionists' fidelity to the training manual through direct observation. *Data Collection*. Each member of the interdisciplinary team responsible for developing the training manual will observe at least one workshop to examine how the section(s) they developed is(are) being implemented. Feedback will be recorded in a structured field-note worksheet as well as a checklist of essential components for delivery [46]. Checklists will be developed collaboratively while developing the training manual. A second observer will also observe each session to monitor fidelity. *Analysis:* Checklist scores from each observer will be summed at each session; we will calculate a kappa score to examine inter-rater reliability. Qualitative notes will be reviewed, and a content analysis will be applied to identify additional measures of fidelity and to refine existing items.

Post-workshop telephone debriefings to examine barriers and facilitators to intervention delivery per interventionists. *Data collection:* After completion of each LST monthly program, we will conduct a telephone debriefing session with interventionists and students to discuss strengths and weaknesses in program delivery and ways to improve its administration. **One-on-one interviews to examine barriers and facilitators to delivery per caregivers, as well as application of training.** *Data collection:* In-depth semi-structured one-on-one half-hour interviews will be conducted with 10 participants. Caregivers will be asked about their experiences, including what they learned, barriers to participation, and changes they recommend, including how to improve LST's cultural relevance and tailoring to individual needs. *Recruitment*. We will circulate flyers at the workshop to recruit caregivers. Participant will be compensated $20 for their time. **Reflective journals to evaluate caregiver learning and application of skills.** We will also collect caregivers' reflective journal entries to assess caregiver learning from all participants. Entries will be from worksheets completed for the booster session. *Analysis:* Discussion notes, transcribed interviews, and reflection worksheets will be analyzed with thematic content analysis, a method we selected for its flexibility [47]. Data will be iteratively coded by two members of the research team with input among the investigative team.

Self-administered surveys to assess caregiver satisfaction with LST. *Data.* All caregivers who participate in the LST intervention will receive a satisfaction survey immediately following the workshop and after the reflective booster sessions. Surveys will be completed online or by phone. Surveys will ask about satisfaction with each program component and the program's structure. *Analysis:* Descriptive statistics will be used to examine satisfaction survey data, including means, frequencies, and measures of dispersion.

9.2 Data Analysis Plan *Provide the **plan for data analysis** (include as applicable the **sample size calculation**).*

Aim 1:

Not applicable

Aim 2:

We will compare scores on self-efficacy and mastery at T_0, T_1, and T_2. We will first examine bar graphs for caregivers in-aggregate and for each caregiver; the x-axis will be the assessment number (i.e., T_0, T_1, T_2) and the y-axis will be the targeted outcome scores. Next, we will compare the means and dispersion at each assessment point for each score. Finally, we will conduct t-test analyses to detect statistically significant differences in mean scores over time. *Exploratory analyses.* We will also complete exploratory analyses on stratified samples to assess differences in scores according to caregiver ethnicity and caregiving intensity. Although the sample size will likely be too small to observe differences, we may observe informative trends. Finally, we will compare the characteristics of participants who completed the intervention and those who dropped out to inform retention efforts in future studies.

Aim 3:

Discussion notes, transcribed interviews, and reflection worksheets will be analyzed with thematic content analysis, a method we selected for its flexibility [47]. Data will be iteratively coded by two members of the research team with input among the investigative team.

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