

**Evaluation of a Carepartner-Integrated Telehealth Rehabilitation Program for Persons
with Stroke**

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Research Design and Methods

The objective of this proposal is to identify the potential benefits of a home-based, intervention designed to facilitate carepartners' roles in stroke survivor rehabilitation. Family members are a key component in stroke recovery, but they frequently experience high levels of burden, including increased anxiety, depression and social isolation when they assume the role of carepartner. To date, *research has placed little emphasis on how to integrate the family into the rehabilitation process without increasing negative carepartner outcomes.* Our recent pilot work explored a novel intervention (CARE-CITE) designed to facilitate carepartner involvement in the application of constraint-induced movement therapy (CIMT) for the upper extremity. Encouraging preliminary results indicated improvements in stroke survivors' task performance in addition to reductions in depressive symptoms and family conflict for carepartners. This study will expand upon that work by assessing the impact of a home-based CARE-CITE application that uses an innovative and user-friendly telehealth delivery system. The central hypothesis underpinning this research is that a theory-based, carepartner-centered intervention *focused* on skill building and problem-solving will improve stroke survivor physical function while reducing carepartner negative outcomes and increasing accessibility of participation. To test this hypothesis, first we will translate the intervention to a telehealth platform and assess usability. We will estimate the effects of the intervention on carepartner mental health, family conflict surrounding stroke recovery, and stroke survivor upper extremity function using a two-group experimental design with 32 intervention dyads and 16 control dyads (who will receive CIMT without structured carepartner involvement) to provide foundation for larger, future clinical studies.] The overall significance of this research plan is to increase the understanding and further development of interventions that may serve as models in rehabilitation fostering family involvement in the rehabilitation process and promoting more integrative therapy strategies throughout physical therapy practice.

Aim 1: To evaluate usability and acceptability of the CARE-CITE intervention for stroke survivors and carepartners using a novel technology platform for home-based delivery.

To facilitate delivery within the home environment, the existing content of the workbook will be converted to electronic tablet format. Emory University's Digital Scholarship Commons (DiSC), offers faculty members space, expertise and project management assistance to develop multidisciplinary projects. Planning meetings have been initiated with DiSC program digital strategists and options for a web-based versus dedicated software applications currently are being evaluated. Electronic tablets with 3G capability allow for use of a secure, password-accessible website that improves ease of content modification, decreased cost and possibility of consumer use (compliance with carepartner intervention) monitoring. Video links to demonstration of CIMT, mitt wearing, and task modifications will be developed. Emory University's Office of Information Technology will provide support in further refinements of technical project management and in collaboration with Emory Internal Review Board (IRB), will review unique human subjects and information security protection concerns relative to telehealth applications to ensure all guidelines and regulations are appropriately anticipated and addressed. Regular meetings with colleagues at Georgia Tech Design and Technology for Healthy Aging (DATHA) group will allow multi-disciplinary input into user interface and system design, web development, and feasibility testing. Using criteria identified below (Aim 2), three carepartners will be selected to evaluate the usability and acceptability of the intervention, based upon recommendations by Nielsen and Landauer (1993) of the minimum number of subjects needed to detect a majority of interface design usability problems. After a two week period of reviewing the CARE-CITE material, carepartners will complete the Post-Study System Usability Questionnaire - PSSUQ (Lewis, 2002) to assess challenges of technology use,

readability of content, and ease of user-interface design. The Modified Computer Self Efficacy Scale - MCSES (Laver et al, 2012), developed to assess technology self-efficacy in the clinical rehabilitation population, will be used as a process variable to identify characteristics of older patients who may be more open to using new technologies. Expected Results: Success in achieving adequate usability will be indicated by PSSUQ scores that are better than established normative scores. *Potential limitations:* If a web-based platform is not feasible or the user-interface proves to be too difficult for the targeted population, we will evaluate transferring the education workbook directly on the tablet device in an application software bundling approach. Feedback from this testing will guide refinement of the design and Aim 2 will be initiated. We will carry forward monitoring usability with the PSSUQ through Aim 2.

Aim 2: To determine feasibility of the CARE-CITE intervention for stroke survivors and carepartners. This study will use a repeated measures design (pretest, post test and one month follow-up) with 48 dyads (stroke survivor/caregiver pair).

2.1 Sample criteria/size: Using similar criteria as our preliminary work, stroke survivors will be 1 month to 5 years post ischemic or hemorrhagic event and must have minimal to moderate upper extremity deficits (ability to initiate wrist and finger extension), no severe cognitive deficits (Mini-mental test >24), and the presence of carepartner. Carepartners must be greater than 18 years of age, able to read and write English and have no significant cognitive deficits (Mini-mental test >24). Stroke survivors with carepartners will be recruited from a variety of settings, using existing recruitment screening techniques established by this investigator within the Emory Healthcare system and regional Atlanta hospitals. Having screened over 5,000 patients for multiple clinical trials as project coordinator, this valuable and extensive recruitment experience will help to ensure efficient and reliable identification of participants the current study. Potential dyads must meet all specified inclusion/exclusion criteria and read/sign Emory IRB approved consent/HIPAA forms. We will obtain a medical screen from the stroke survivors' physician prior to initiating participation. Given the time required to adapt the intervention and the timeline of the proposal, a sample size of 48 dyads is proposed to evaluate feasibility.

2.2 Intervention: During an initial 1-hour orientation session, each carepartner will be instructed in the use of the electronic tablet, and will practice accessing the online educational content modules and completing the self-reflective worksheets. The carepartner online education modules are designed to occur in parallel to the stroke survivor CIMT interventions, occurring over 10 sessions. The content begins with an introduction to the principles of CIMT, including how CIMT is thought to work, methods to adapt tasks at home, the importance of progressing challenging tasks and safety when wearing the mitt. Strategies to address potential stroke survivor frustration and improving adherence are reviewed. Underpinning the content will be discussion of the concept of autonomy support, with examples of fostering empathy (carepartner wearing mitt on dominant hand during activities), problem solving (guidance for adaptation of functional activities at home consistent with CIMT principals), instruction in the use of non-controlling language with role playing situations and the importance of creating choice in activities. For each module, the carepartner will go online to a secure, password accessible website to review each module, and observe CIMT video link demonstrations. Remotely, the therapist will be available throughout the treatment period to answer questions via email. Access to an expert has been a component of other web-facilitated work (Page and Levine, 2007). The stroke survivor will be instructed in standard CIMT protocol which includes wearing a soft mitt on the less affected limb for 90% of waking hours and a behavior contract will be used to identify activities to be performed while wearing mitt as well as any safety concerns. The intensive functional task practice and adapted task practice (shaping) will be administered in the home by a trained therapist in 10 three-hour sessions across a period of 2-3 weeks. During this early feasibility phase of the home-based, CARE-CITE intervention, the same dosage, duration and intensity will be used from the earlier preliminary work to maintain consistency of the

intervention and enable the research focus to remain on the technological adaptation of the carepartner content to the home environment. Building on this foundation, future work will evaluate administration of CIMT via tablet technology, with camera usage for the therapist to remotely observe the stroke survivor and network meeting software to provide real-time communication and task practice with the carepartner.

2.3 Data Collection: Project staff, identified in our preliminary work, are standardized evaluators for several clinical trials and will administer the outcome assessments within the home environment at time points pre/post and 1 month follow-up (a portable template and table will be used for WMFT).

2.4 Instruments: Outcome measures used in the pilot study will be carried forward to this phase and have evidence of established reliability and validity (see references section). The Family Care Climate Questionnaire, an autonomy support questionnaire for carepartners (FCCQ-F) developed by Dr. Clark and Dr. Dunbar, will be used as a process variable of the intervention. Stroke survivors will maintain an activity log to assess adherence levels to CIMT practice. Because this is a feasibility study, the sample size is not adequately powered to test for statistically significant differences; therefore, estimation of effect sizes will be determined as a basis for estimating the sample sized needed for a future larger study testing the intervention.

Expected Results: We predict that carepartners will have reduced scores on the CES-D (depression) and lower scores on FCCS (family conflict) consistent with moderate to large effect sizes. We expect stroke survivors will have higher scores on the MAL and CAHM (improved use and self-efficacy of arm function) with reduced scores on the WMFT (faster speed of movement) consistent with moderate to large effect sizes. Both members of the dyad will have increased autonomy support (FCCQ-F). **Potential limitations:** Carepartner gender and relationship of carepartner to stroke survivor (e.g. spouse, adult child) may confound data interpretation with the small sample size. Demographic data regarding participants gender, relationship in dyad, race, education, income, co-morbidities, medication will be collected and potential relationships explored.

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