Type of Research Application: T1 (Early Translation)

Title: A Preliminary Test of a Carepartner-Integrated Telehealth Rehabilitation Program for Persons with Stroke

Investigators:

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A Preliminary Test of a Carepartner-IntegratedTelehealth Rehabilitation Program for Persons with Stroke

Abstract

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. Next we will test the feasibility of CARE-CITE in the home setting, using a quasi-experimental, repeated measures design to quantify the effects on carepartner mental health, family conflict surrounding stroke recovery, and stroke survivor upper extremity function. Comparison of stroke survivor results to an historical comparison group of CIMT (without carepartner involvement) will provide estimation of effect sizes for further studies. Data acquired will be used towards: (1) an AHRQ R03 grant (Small Research Grant to Improve Health Care Quality through Health Information Technology-IT) submission to further develop the telehealth administration of CIMT and (2) a NICHD Mentored Patient-Oriented Research Career Development Award (K23) for the PI (S Blanton). 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.

Specific Aims

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. Exit interview results from our clinic based CARE-CITE intervention indicated carepartners struggled to meet the time and travel demands of attending the sessions. A digital format of CARE-CITE accessed via electronic portable tablet devices within the home environment will provide an ecologically valid delivery option that reduces time and transportation barriers to participation.

Hypothesis: *Translation of CARE-CITE to a telehealth platform will be a usable and acceptable home based mode of delivery as indicated by scores on a standardized system usability assessment.* Data will be collected from carepartner questionnaires regarding challenges of technology use, readability of content, and ease of user-interface design. Feedback from this testing will guide refinement of the design before Aim 2 will be initiated.

Aim 2: To determine feasibility of the CARE-CITE intervention for stroke survivors and carepartners. Carepartner interventions that use active strategies to facilitate problem solving (Grant et al., 2002 and Smith et al., 2012) and skill building (Bakas et al., 2009) improve quality of life and reduce carepartner burden. Despite increasing evidence that family involvement can foster physical recovery after stroke, few studies have assessed how to integrate the family into the rehabilitation process without increasing negative carepartner outcomes.

Hypotheses: (Data to support these hypotheses is presented in Section D.)

2.1*. Carepartners receiving the CARE-CITE intervention will have reduced depression and family conflict related to stroke recovery at one month post intervention as compared to baseline.*

2.2. *Stroke survivors receiving the CARE-CITE intervention will have improved upper extremity function at one month post intervention as compared to baseline.*

Aim 3: To investigate the impact of the CARE-CITE intervention on stroke survivor outcomes as compared to administration of CIMT without carepartner involvement. Carepartner involvement in an

exercise program is a stronger determinant of improved upper limb function than severity of motor impairment and exercise intensity (Harris et al., 2010). We believe integrating the family in the application of CIMT will enhance the impact of this intervention in the stroke survivor.
Hypothesis: *Stroke survivors receiving the CARE-CITE intervention will have greater improvements in upper extremity function as compared to an historical comparison group.*

Research Strategy

A. Background and Significance

Stroke affects individuals (on average) every 40 seconds in the United States (Roger et al., 2012) and is a leading cause of serious, long-term disability. Carepartner management can improve stroke survivor recovery; but can also increased the carepartner's fatigue, depression, frustration, and resentment (Clark et al., 2004, Haley et al., 2009). Factors, such as stroke recovery-related family conflict or stroke survivor deficits (behavior and memory problems, low motor function), can increase burden and be detrimental to carepartner mental health (McCullagh et al., 2005, Perrin et al., 2009, 2010). Unmet carepartner needs negatively affect the rehabilitation of the stroke survivor and increase carepartner risk of mortality (Bakas et al., 2009, Perkins et al., 2012).

With carepartner well-being affecting health outcomes in both individuals (carepartner and stroke survivor) and an increasing proportion of rehabilitation occurring in the home, addressing the caregiving burden is essential. Early pilot work revealed that a home-based, family-supervised CIMT intervention with 7 chronic stroke survivors was as effective as traditional, therapist-supervised CIMT (Barzel et al., 2009). However, this study did not evaluate the potential negative impact of the increased demands upon the carepartner or attempt to mitigate them with an educational intervention. Yet, improving carepartner skills (stroke knowledge, caring for stroke survivor, managing moods and emotion, and addressing carepartner needs) clearly benefits the carepartner, with decreased depression and burden and improved quality of life (Bakas et al., 2009). Additionally, interventions that promote an autonomy supportive environment (characterized by empathy, problem solving, choice and reducing use of controlling language; part of a self-determination motivation theory) foster individual autonomy and confidence and result in better adherence to health behaviors such as diabetes control (Williams et al., 2009) and low sodium diets (Dunbar, Clark et al., 2008). A family-centered approach would involve therapeutic interventions designed to collaboratively engage the stroke survivor and carepartner in a mutually supportive environment, with broader and progressive family education content to meet carepartner needs. CARE-CITE improves carepartner skills and promotes an autonomy-supportive home environment to facilitate positive health outcomes for both the carepartner and the stroke survivor. This family-centered intervention is a key advancement, moving the rehabilitation field toward stroke care that effectively addresses both survivor and carepartner needs in tandem.

B. Innovation

Currently, most caregiver interventions occur within the clinic or by telephone and are subject to the restrictions inherent to those platforms. An environment of rapidly changing technological advancements dictates a creative response from rehabilitation clinicians to effectively use alternative methods of intervention delivery. Emerging technology can enhance these interventions by: (1) providing a more dynamic learning platform, (2) increasing potential impact by reaching a greater number of individuals, and (3) improving real-time access to rehabilitation experts. A recent review of telerehabilitation in stroke care found these types of interventions showed promising results for both stroke survivor and carepartner health, including improved quality of life, health status and reduced depression (Johansson et al., 2011). Evidence is evolving for internet-based (Marziali et al., 2006 and Pierce et al., 2009) and telephone-based (Bakas et al., 2009) carepartner psychosocial/educational interventions. Preliminary work by Page and Levine (2007) suggests that a home-based delivery of modified CIMT may be feasible using simple personal computer based cameras and network meeting software. Despite these promising results in carepartner and stroke survivor outcomes, the literature does not address creative telerehabilitation approaches in interventions that collaboratively engage the carepartner and stroke survivor in a mutually supportive environment. Accordingly, the *specific objective of this proposal* is to identify the potential benefit of a unique, stroke survivor – carepartner integrated, upper extremity intervention that uses contemporary technology for remote service delivery within the home

environment. We expect that our proposed study potentially will provide a template for future models of family supported, home-based care.

C. Approach

Preliminary Data

Encouraging results from pilot data provide the framework for this proposal and demonstrate that the CARE-CITE intervention can improve outcomes in both stroke survivors and their carepartners (Blanton et al., 2012). The preliminary study was a one-group, quasi-experimental design using pre-, post and 1-month follow-up evaluations with 7 stroke survivors and carepartner dyads. Stroke survivors, median age 60 (range 24-72), 57% males, with mild to moderate UE deficits, underwent CIMT in an outpatient clinic for 3 hours per day for 10 therapy sessions across 2-3 weeks. The carepartner, median age 45 (range 29-60), 86% female (4 adult children, 2 spouses and 1 parent) received an intervention that included an interactive workbook and attendance at portions of the CIMT sessions. Outcome measures for the carepartner included: Stroke symptom/risk factor knowledge (Stroke Knowledge Test), depression (Center for Epidemiological Studies Scale, CES-D), fatigue (Piper Fatigue Scale), and family caregiver conflict surrounding stroke recovery (FCCS). Feasibility of intervention was assessed through carepartner exit interview and program adherence. Stroke survivor outcome measures included: upper extremity function (Wolf Motor Function Test-WMFT; Motor Activity Log-MAL), self-efficacy (Confidence in Arm and Hand Scale-CAHM) and quality of life (Stroke Impact Scale-SIS). **Results:** The CARE-CITE intervention appeared feasible based upon high dyad adherence rates (100% adherence) and carepartner reported value of the intervention. All 7 dyads completed the intervention; however, 3 carepartners were unable to attend every clinic CIMT session with their family member and review of workbook was completed via telephone. Exit interviews indicated carepartners were willing to participate in the study again, evaluated their participation as worthwhile and *believed that their involvement contributed to their stroke survivors' success.* Although potentially overestimated due to a small sample size, calculated effect sizes ranged from moderate to large improvements (Cohen's d 0.562 – 0.882) for carepartner variables of depression, fatigue and family conflict surrounding stroke recovery (See Table). Stroke survivors were able to do more tasks in the home environment as measured by the MAL, with moderate to large effect sizes (Cohen's d 0.638-0.739) on upper extremity functional outcomes noted in the MAL and CAHM and trends toward faster speeds on the WMFT. Results from this study indicate that involving carepartners in CIMT through a structured educational content addressing skill building and autonomy support may be effective in reducing negative outcomes for the carepartner while improving stroke survivor UE function. Application of CARE-CITE within the home environment has yet to be studied and is the intent of this investigation.

Table: Effects of CARE-CITE intervention on caregivers (preliminary results). Self-reported outcome measures at baseline, post-test, and 1 month post-treatment indicate that the intervention is feasible and effective in reducing caregiver depression and fatigue, in addition to family conflict. The reduced frequency of memory and behavior problems in the stroke survivors suggests that the intervention may have improved the caregivers' ability to address such issues. N=7. **Large effect size *Moderate effect size

Measure Range	Baseline M±SD	Post CARE-CITE M±SD (Cohen's d)	1 Month Post CARE-CITE M±SD (Cohen's d)
Depression (CES-D; 0-60)	16.42 ±12.75	5.86 ±2.97 (1.14)**	10.14 ±11.05 (0.526)*
Fatigue (PFS; 0-10)	3.62 ±2.70	1.25 ±1.16 (1.14)**	1.63 ±1.65 (0.885)**
Family Conflict (FCCS; 15-105)	41.43 ±19.92	---	30.00 ±17.42 (0.612)*
Memory/Behavior problems (MBPC; Frequency 0-76)	25.71 ±14.78	5.11 ±9.39 (0.727)*	17.14 ±8.36 (0.666)*

Research Design and Methods

All specific aims will be completed during the one year grant period (See Figure: Timeline June 2013-June 2014 for Specific Aims 1-3 completion dates).

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 quasi-experimental design with repeated measures (pretest, post test and one month follow-up).

2.1 Sample criteria/size: Using similar criteria as our preliminary work, stroke survivors will be 3 months to 2 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 8 dyads is proposed to evaluate feasibility (2 dyads/month from January-May, 2014).

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 surivor (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.

Aim 3: To investigate the impact of the CARE-CITE intervention on stroke survivor outcomes as compared to administration of CIMT without carepartner involvement. Outcome data (WMFT and MAL) for the CARE-CITE stroke survivor will be compared to an historical comparison group. This analysis (total n=16) will be conducted using a randomly selected, matched (age, gender, stroke characteristics) data-base sample of EXCITE (Extremity Constraint Induced Therapy Evaluation RCT) participants receiving CIMT without carepartner involvement to develop an estimate of effect sizes for future studies. Expected results: We expect CARE-CITE stroke survivors to have greater improvements in speed (WMFT) and increased use (MAL) than individuals without carepartner involvement, consistent with moderate to large effect sizes. *Potential limitations*: Although we will match historical controls on some variables there may be other differences between the groups that we are unable to control. However, use of the historical control adds strength to the design by providing a comparison group that used the same physical function measures for stroke survivors and will allow us to estimate the effect of the CARE-CITE intervention as a basis to determine the sample size for future studies.

Other Analysis Points: An exit interview questionnaire developed in the pilot CARE-CITE study will be used at the end of the study to assess participant, perceived benefit, usefulness and ease of use, and satisfaction with the intervention. Carepartner time logged into the specific modules will be tracked. Participant suggestions for improvement will be obtained. Preliminary information on the costs of CARE-CITE administered in the early clinic-based environment as compared to a home-based delivery model will be evaluated to provide a framework for potential future assessments of CARE-CITE cost effectiveness and impact of this alternative service delivery model.

D. Budget Justification

Personnel: No salaries for faculty are included, and all effort of the part of the investigators is contributed. All salaries and fringe benefits for Emory staff are based on existing Emory University salary rates and fringe benefits. Estimated costs for supplies and subject and personnel travel and expenses, are based on the time line presented at the end of the budget justification.

Collaborators from Emory, Georgia State and Georgia Institute of Technology

Primary

Sarah Blanton, PT, DPT, NCS, Assistant Professor, Division of Physical Therapy, Department of Rehabilitation Medicine, Emory University is the Project Director/Principal Investigator. She will provide overall leadership and management of the project and will be responsible for: (1) creating intervention and project materials, (2) hiring, training and evaluating project staff, (3) overseeing all protocols and procedures, (4) developing quality control criteria and quality monitoring, and (5) data analysis. She will implement protocols to ensure data confidentiality and will work with the IRB to ensure human subject protection certifications are maintained for all personnel. She will communicate with funding contacts regarding approvals, annual reports and consultations as needed. Finally, in collaboration with her co-investigators, she will oversee the dissemination of the results through appropriate abstract reports, submission of manuscripts and final reports. Dr. Blanton has successfully coordinated over 10 stroke rehabilitation research studies at Emory University, including the NIH funded, multi-site, Extremity Constraint Induced Therapy Evaluation (EXCITE) randomized clinical trial (RCT), the largest study evaluating CIMT to date. Recognized internationally as an expert in CIMT, she developed and managed the first CIMT clinic in the region and has provided over 80 workshops, lectures and inservices on the clinical application of the intervention. She collaborated with Dr. Patricia Clark to develop the CARE-CITE intervention and was the principal investigator on the successfully implemented pilot CARE-CITE study, funded by the Emory Comprehensive Neuroscience Center. She will contribute 25% effort (in kind).

Sandra B. Dunbar, RN, DSN, FAAN, FAHA, the Associate Dean for Academic Advancement and Charles Howard Candler Professor of Cardiovascular Nursing, Nell Hodgson Woodruff School of Nursing, Emory University will serve as co-principal investigator and will assist in overall project management, data analysis, outcome interpretation and evidence dissemination. Dr. Dunbar has a distinguished career in nursing research, with over 30 years of research and teaching experience, over 110 publications and over 40 internal and external grants including funding from NIH, the American Heart Association, and industry. She has unique and extensive experience in the areas of psychoeducational interventions for cardiovascular patients and their families, family functioning, stroke recovery and evaluating the effects of family-focused interventions on self-management behaviors. Currently, she is the principal investigator of a new NIH/NINR T32 entitled “Training in intervention research for improving outcomes in chronic illness” and an NIH/NINR R01 examining the effect of an integrated self-management program delivered for patients with heart failure and diabetes on outcomes of self-care, quality of life and costs. Dr. Dunbar is the principal investigator of an ACTSI *Health Care Innovation Seed Program* funded study conducting preliminary testing of the “iHealthHome for Improving Outcomes in Heart Failure Patients with Diabetes”. With her extensive experience in caregiving research and current work in telehealth interventions, Dr. Dunbar provides invaluable support and guidance for this project.

Patricia Clark, PhD, RN, FAHA, FAAN, Professor, Byrdine F. Lewis School of Nursing and Health Professions, and recent Associate Dean for Research, Georgia State University will be a co-investigator on this project. Recognized as a national expert in research specifically targeting carepartners of stroke survivors, she has developed the carepartner assessment instrument in this proposal (Family Caregiver Conflict Surrounding Stroke Recovery-FCCS). Dr. Clark was instrumental in the development of the theoretical basis underlying the CARE-CITE approach and was co-PI with Dr. Blanton on the pilot CARE-CITE study. She will contribute to the overall project aims, as well as refinements to the educational material development, data interpretation and insight into behavioral mechanisms underlying outcomes.

Brian Jones, MSEE, Senior Research Engineer, Georgia Tech Interactive Media and Technology Center, is also the Director of the Aware Home Research Initiative and co-founder of Data and Technology for Healthy Aging (DATHA) Initiative. He conducts research evaluating home-based technological interventions and is co-principal investigator with Dr. Dunbar of the ACTSI *Health Care Innovation Seed Program* funded study conducting preliminary testing of the “iHealthHome for Improving Outcomes in Heart Failure Patients with Diabetes”. Mr. Jones will serve as a co-investigator on this project and will supervise the translation of the

CARE-CITE intervention to a telehealth platform (Specific Aim 1, Research Design and Methods Section). He will provide technical and engineering expertise for adapting the electronic tablet based system to the needs of the project by: (1) developing the interface between the system and patient home, (2) coordinating the work of the graphic design and web consultant and (3) participating in project implementation and dissemination.
Robert Lyles, PhD, Director of the Emory Biostatistics, Epidemiology and Research Design (BERD) program and Associate Professor, Department of Biostatistics and Bioinformatics, Rollins School of Public Health, Emory University, will provide oversight for the project biostatistics. As collaborator, he will supervise the data analysis, as well as study design and power calculations relating to pilot work and future proposal development. For data analysis, Dr. Lyles will oversee a staff biostatistician, Jessica Vakili, MSPH, in the Department of Biostatistics and Bioinformatics for data analysis, who will provide .10 effort **($7,028)**.
Steven L. Wolf, PhD, PT, FAPTA, Professor in the Departments of Rehabilitation Medicine and Medicine at Emory University, with additional appointments in Cell Biology and the Nell Hodgson Woodruff School of Nursing, will be a collaborator on this project to offer guidance in CIMT and outcome data interpretation. Dr. Wolf has extensive research and publication experience, serving as principal investigator or co-investigator in 50 grants with over 200 published articles and was the principal investigator of the Extremity Constraint Induced Therapy Evaluation (EXCITE) randomized clinical trial (RCT). He has invaluable experience in NIH-funded grant applications, with funding totaling over $31 million in direct costs and will assist in developing grant applications for subsequent external sponsorship of future work building on this data.
Catherine Maloney, PT, MHA, FACHE, is Director, Emory Center for Rehabilitation Medicine (CRM) and Associate Administrator, Emory University Hospital. She has played an integral role in the implementation of previous, NIH-funded, clinical stroke trials at Emory CRM by supporting active screening and recruitment of participants and engagement of clinicians to identify potential stroke survivors who may benefit from this intervention. She will support this investigation in recruitment and by sharing her expertise in resource utilization, efficiency and value. She will provide valuable insight into the interplay of quality and cost considerations for future studies evaluating CARE-CITE.
Project Staff: Dr. Blanton will train and supervise four **Doctor of Physical Therapy (DPT) students** in the implementation of CIMT with the stroke survivors. The only costs associated with DPT student participation are noted under travel expenses. **Kimberly Lang,** a current doctoral student in our lab with experience in stroke rehabilitation studies, will assist in project administration, communication with participants, and data collection. She will provide .25 effort for the entire project duration and is supported by the Department of Neuroscience**.**
Consultants: The **clinician evaluator** for this project will be a physical therapist who has expertise in stroke rehabilitation, research training and who is standardized in the administration of the outcome measures that will be used in the CARE-CITE study. **Aimee Reiss, PT, DPT**, an expert clinician and an evaluator in our lab for the past 6 years, will serve in this consultant role. Hiring of Dr. Reiss will occur for the last 9 months of the project, at which time each of the 8 dyads will have three evaluations. A total of 24 evaluations will occur during this period (January-May, 2014) each lasting approximately 3 hours **($4,320). Graphic Web Interface Designer/Computer Scientist,** TBA, will be identified at Emory and supervised by Brian Jones for the purpose of adapting the CARE-CITE intervention to the electronic tablet format **($7000).**

Equipment: No additional evaluation equipment required. We will continue to use existing evaluation materials for the Wolf Motor Function Test available in Dr. Wolf's lab.

Travel: Funds are requested to cover travel reimbursement to study participant's homes for evaluations and training. Average round trip, 30 miles @ 0.555/cents per mile (NIH reimbursement rate) = $16.65/visit.
Evaluator (Dr. Reiss) will complete 24 evaluations (3 evaluations per each of 8 dyads).
During usability/acceptability portion of study (Specific Aim 1), the study PI (Dr. Blanton) will have 9 visits (3 visits/carepartner).
During feasibility portion of study (Specific Aims 2-3), 88 intervention visits will be completed by Dr. Blanton and DPT students (11 treatment visits/dyad).

Total Travel: **$2,015**

Participant Support Costs: Each of the 8 dyads will receive $100 for participating in the study.

Total Participant Stipend: **$800**

Other Direct Costs: Equipment required to address 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). The CARE-CITE intervention will be delivered via electronic tablet uniquely configured for the proposed study.

Materials and Supplies

- Videography system to create CIMT videos viewed on tablet for CARE-CITE intervention
  - Camcorder and tripod @ $453
- IPads (with attached keyboards/covers) with 1 year service over 3G wireless network
  - 3 units @ $637 = $1911
- CIMT mitts
  - 8 mitts @ $40 = $320

Total Materials and Supplies: **$2684**

- Rental/User Fees
  - 12 months 3G internet service @$30/month

Total Rental/User Fees: **$720**

Figure: Timeline June 2013-June 2014

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	June July Aug	IRB approval Work with graphic design consultant, convert CARE-CITE to telehealth platform Instruct DPT students in theoretical framework for intervention
	Sept Oct	Finalization of the technical aspects of the system Prototype pilot test Recruitment and screening of potential participants Instruct DPT graduate students in CIMT intervention
	Nov Dec	Usability testing with 3 carepartners
Aim 2 To determine feasibility of the CARE-CITE intervention for stroke survivors and carepartners	Jan Feb March April May	Pilot testing and data collection for 8 dyads (2 dyads/month)
Aim 3 To investigate the impact of the CARE-CITE intervention on stroke survivor outcomes as compared to administration of CIMT without carepartner involvement.	June	Data analysis (Aims 2 & 3)

E. Human Subjects Research

Risks to Subjects

E1. Human subject involvement and characteristics: We plan to enroll 3 carepartners to address Specific Aim 1 and 8 stroke survivor/carepartner dyads to address Specific Aim 2. Participants will be men and women, at least 21 years of age or older, of any ethnicity/race, who can read, write and speak in English and have no severe cognitive deficits. Carepartners will be those individuals who self-identify as a family caregiver of stroke survivors. The stroke survivors will have a documented (by medical imaging) ischemic or hemorrhagic event within 3 months to 2 years and must have minimal to moderate upper extremity deficits (ability to initiate wrist and finger extension). Exclusion criteria: Ethnicity will not be used as exclusion criteria and all efforts will be made to include minority populations and women. Participants in the CARE-CITE pilot study were 86% non-white and carepartners were 86% female (which we have found typical of our recruitment experience). Vulnerable populations (i.e. prisoners, institutionalized individuals) and children will not be included. To encourage participation for the entire study, an incentive of $100 will be paid to each dyad and will be pro-rated for early study withdrawal.

E2. Sources of data: Material obtained from carepartners will include self-report information about physical health status, depression, and family variables at baseline, post-intervention and one-month follow-up. Material from stroke survivors will include physical assessments of upper extremity functional use, and self-report questionnaires regarding upper extremity use, self-efficacy and quality of life. Demographic data will be collected on all participants, including age, gender, ethnicity, education, medications, and co-morbidities. All data will be coded by participant identification numbers and kept in a locked file and all demographic data and personal health information (PHI) will be kept in a separate locked file. Only the PI will have access to each participant's identities.

E3. Potential risks: The risks to participants are minimal and include the inconvenience of completing assessments at each evaluation. A conservative time estimate required for completion of assessments is 3 hours for the dyad. For the carepartner, additional time is required to review each CARE-CITE module across the treatment period. During the early pilot work with CARE-CITE, no carepartners reported any adverse events. Although no significant risks have been associated with the administration of CIMT, stroke survivors wear a mitt on the less involved upper extremity to encourage use of the hemiparetic limb. The primary risks involve fatigue or frustration when attempting challenging tasks or balance with the mitt donned. A behavior contract is reviewed with the patient to identify any tasks in which safety is a concern or that should be avoided when wearing the mitt. These guidelines are individually tailored to the participant and the carepartner is involved in the process.

Because we will be administering a questionnaire that is an indicator of depression, we will notify carepartners who score above the established cut-off of 16 on the CES-D that their response indicates that they may need an evaluation for depression. We will recommend that they contact their primary health care provider for a referral. If they do not know of someone, we will provide resources for their consideration. The consent form will contain a statement explaining this process. The applicant and her mentors, Dr. Clark and Dr. Dunbar, have experience addressing mood changes with participants in previous studies and the protocol outlined has worked well in those instances.

Adequacy of protection against risks

E4. Recruitment and informed consent: The informed consent documents, including the HIPAA Authorization documents, and any subsequent modifications will be reviewed and approved by the Emory IRB. Participants who cannot sign for themselves are excluded from the study. The consent form will describe the purposes of the study, the procedures to be followed and the risks and benefits of participation. Dr. Blanton will explain the consent to the potential participant, including the nature of the study, study procedures, importance of compliance, potential risks and benefits, and duration of the study. The process will allow ample time for the prospective participant to read the informed consent form. A copy of the consent form will be given to the participant and this transfer will be documented in the patient's record.

E5. Protection against risk: The prospective participant will be informed that he/she is not obligated to participate in the study. The informed consent process will clearly state that there is no penalty for *not* participating in a clinical trial and that treatment will not be compromised if individuals do not participate or if they cease participation at any time. Participants will be assured of confidentiality in maintenance and reporting of research results. All data will be coded by the participants' identification numbers and kept in a locked file in Dr. Blanton's office. There is a risk of loss of confidentiality related to the transfer of electronic data. Dr. Blanton will work with her collaborators to provide adequate security of information transferred electronically. Drs. Dunbar, Wolf, Clark and Mr. Jones all have experience in studies with various aspects of telerehabilitation and electronic data submission and will provide valuable guidance to assure appropriate steps are taken to maintain patient confidentiality. Additional resources through Emory University's Digital Scholarship Commons and Georgia Tech's DATHA group will provide support to regularly review issues of information security protection throughout the study period. A medical authorization will be obtained by each participant's primary care physician prior to enrollment. All adverse events will be monitored and reported to Emory IRB. In the event of a serious adverse event, the participant's physician will be notified and medical approval will be re-obtained prior to resuming study activities.

Data Safety and Monitoring Plan (DSMP)

A DSMP will be developed and implemented according to the guidelines of the Institutional Review Board of Emory University and the ACTSI CIN. This plan will include anticipation of adverse risks, monitoring study

progress and safety of participants assuring compliance with requirements for confidentiality, and plans for performing data reviews. All procedures for identifying adverse advents and reporting requirements will be clearly delineated in the plan. The PI in collaboration with the biostatistician will assume responsibility for defining and implementing the DSMP. This study is considered a minimal risk to participants. They will meet periodically to review the screening and enrollment data and to identify any human subjects issues that arise. All individuals involved in the study will be trained in the protection of human subjects according to university and NIH regulations and will be required to be certified in human subjects research training (CITI) in accordance with the Emory University IRB procedures. We will conduct random and periodic audits of research records to ascertain that informed consents are signed, witnessed and complete for each subject, and that confidentiality procedures are being maintained. Data reviews will be periodically conducted to ascertain the quality of the data and degree of missing data, reasons, and steps to correct. A tracking database will be developed to assure study activities are performed for each participant and will be monitored monthly for compliance with the study protocol.

Potential benefit of proposed research the subject and others

Multiple studies have documented the benefits of CIMT for stroke survivors. Psychoeducational interventions for carepartners have been beneficial to improve not only carepartner quality of life but also impact stroke survivor recovery. However, at the stage of stroke recovery that participants will enroll in this proposal (3 months to 2 years), little to no rehabilitation therapy is occurring and resources for carepartners are scarce. Consequently, benefits of participation likely outweigh the limited risks involved.

Importance of knowledge to be gained

While studies have evaluated the impact of carepartners on stroke recovery, little work has evaluated potential avenues to facilitate the role of the family in stroke rehabilitation in a manner that addresses carepartner needs during the integration process. This work will serve as a model for family education during stroke recovery, improving clinical practice and access to care. Preliminary information on the costs of the intervention will be evaluated to provide a framework for future assessments CARE-CITE cost effectiveness and impact of this home-based service delivery model.

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BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: *Salary and fringe benefits. Applicant organization only*.	11,348				
CONSULTANT COSTS	7,000				
EQUIPMENT					
SUPPLIES	2,684				
TRAVEL	2,015				
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	1,520				
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*	24,567				
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	24,567				

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD	**$** 24,567

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Personnel: No salaries for faculty are included, and all effort of the part of the investigators is contributed. All salaries and fringe benefits for Emory staff are based on existing Emory University salary rates and fringe benefits. Estimated costs for supplies and subject and personnel travel and expenses, are based on the time line presented at the end of the budget justification.

Collaborators from Emory, Georgia State and Georgia Institute of Technology

Primary

Sarah Blanton, PT, DPT, NCS, Assistant Professor, Division of Physical Therapy, Department of Rehabilitation Medicine, Emory University is the Project Director/Principal Investigator. She will provide overall leadership and management of the project and will be responsible for: (1) creating intervention and project materials, (2) hiring, training and evaluating project staff, (3) overseeing all protocols and procedures, (4) developing quality control criteria and quality monitoring, and (5) data analysis. She will implement protocols to ensure data confidentiality and will work with the IRB to ensure human subject protection certifications are maintained for all personnel. She will communicate with funding contacts regarding approvals, annual reports and consultations as needed. Finally, in collaboration with her co-investigators, she will oversee the

Budget Justification

dissemination of the results through appropriate abstract reports, submission of manuscripts and final reports. Dr. Blanton has successfully coordinated over 10 stroke rehabilitation research studies at Emory University, including the NIH funded, multi-site, Extremity Constraint Induced Therapy Evaluation (EXCITE) randomized clinical trial (RCT), the largest study evaluating CIMT to date. Recognized internationally as an expert in CIMT, she developed and managed the first CIMT clinic in the region and has provided over 80 workshops, lectures and inservices on the clinical application of the intervention. She collaborated with Dr. Patricia Clark to develop the CARE-CITE intervention and was the principal investigator on the successfully implemented pilot CARE-CITE study, funded by the Emory Comprehensive Neuroscience Center. She will contribute 25% effort (in kind).

Sandra B. Dunbar, RN, DSN, FAAN, FAHA, the Associate Dean for Academic Advancement and Charles Howard Candler Professor of Cardiovascular Nursing, Nell Hodgson Woodruff School of Nursing, Emory University will serve as co-principal investigator and will assist in overall project management, data analysis, outcome interpretation and evidence dissemination. Dr. Dunbar has a distinguished career in nursing research, with over 30 years of research and teaching experience, over 110 publications and over 40 internal and external grants including funding from NIH, the American Heart Association, and industry. She has unique and extensive experience in the areas of psychoeducational interventions for cardiovascular patients and their families, family functioning, stroke recovery and evaluating the effects of family-focused interventions on self-management behaviors. Currently, she is the principal investigator of a new NIH/NINR T32 entitled "Training in intervention research for improving outcomes in chronic illness" and an NIH/NINR R01 examining the effect of an integrated self-management program delivered for patients with heart failure and diabetes on outcomes of self-care, quality of life and costs. Dr. Dunbar is the principal investigator of an ACTSI *Health Care Innovation Seed Program* funded study conducting preliminary testing of the "iHealthHome for Improving Outcomes in Heart Failure Patients with Diabetes". With her extensive experience in caregiving research and current work in telehealth interventions, Dr. Dunbar provides invaluable support and guidance for this project.

Patricia Clark, PhD, RN, FAHA, FAAN, Professor, Byrdine F. Lewis School of Nursing and Health Professions, and recent Associate Dean for Research, Georgia State University will be a co-investigator on this project. Recognized as a national expert in research specifically targeting carepartners of stroke survivors, she has developed the carepartner assessment instrument in this proposal (Family Caregiver Conflict Surrounding Stroke Recovery-FCCS). Dr. Clark was instrumental in the development of the theoretical basis underlying the CARE-CITE approach and was co-PI with Dr. Blanton on the pilot CARE-CITE study. She will contribute to the overall project aims, as well as refinements to the educational material development, data interpretation and insight into behavioral mechanisms underlying outcomes.

Brian Jones, MSEE, Senior Research Engineer, Georgia Tech Interactive Media and Technology Center, is also the Director of the Aware Home Research Initiative and co-founder of Data and Technology for Healthy Aging (DATHA) Initiative. He conducts research evaluating home-based technological interventions and is co-principal investigator with Dr. Dunbar of the ACTSI *Health Care Innovation Seed Program* funded study conducting preliminary testing of the "iHealthHome for Improving Outcomes in Heart Failure Patients with Diabetes". Mr. Jones will serve as a co-investigator on this project and will supervise the translation of the CARE-CITE intervention to a telehealth platform (Specific Aim 1, Research Design and Methods Section). He will provide technical and engineering expertise for adapting the electronic tablet based system to the needs of the project by: (1) developing the interface between the system and patient home, (2) coordinating the work of the graphic design and web consultant and (3) participating in project implementation and dissemination.

Robert Lyles, PhD, Director of the Emory Biostatistics, Epidemiology and Research Design (BERD) program and Associate Professor, Department of Biostatistics and Bioinformatics, Rollins School of Public Health, Emory University, will provide oversight for the project biostatistics. As collaborator, he will supervise the data analysis, as well as study design and power calculations relating to pilot work and future proposal development. For data analysis, Dr. Lyles will oversee a staff biostatistician, Jessica Vakili, MSPH, in the Department of Biostatistics and Bioinformatics for data analysis, who will provide .10 effort **($7,028)**.

Steven L. Wolf, PhD, PT, FAPTA, Professor in the Departments of Rehabilitation Medicine and Medicine at Emory University, with additional appointments in Cell Biology and the Nell Hodgson Woodruff School of Nursing, will be a collaborator on this project to offer guidance in CIMT and outcome data interpretation. Dr. Wolf has extensive research and publication experience, serving as principal investigator or co-investigator in

50 grants with over 200 published articles and was the principal investigator of the Extremity Constraint Induced Therapy Evaluation (EXCITE) randomized clinical trial (RCT). He has invaluable experience in NIH-funded grant applications, with funding totaling over $31 million in direct costs and will assist in developing grant applications for subsequent external sponsorship of future work building on this data.
Catherine Maloney, PT, MHA, FACHE, is Director, Emory Center for Rehabilitation Medicine (CRM) and Associate Administrator, Emory University Hospital. She has played an integral role in the implementation of previous, NIH-funded, clinical stroke trials at Emory CRM by supporting active screening and recruitment of participants and engagement of clinicians to identify potential stroke survivors who may benefit from this intervention. She will support this investigation in recruitment and by sharing her expertise in resource utilization, efficiency and value. She will provide valuable insight into the interplay of quality and cost considerations for future studies evaluating CARE-CITE.
Project Staff: Dr. Blanton will train and supervise four **Doctor of Physical Therapy (DPT) students** in the implementation of CIMT with the stroke survivors. The only costs associated with DPT student participation are noted under travel expenses. **Kimberly Lang,** a current doctoral student in our lab with experience in stroke rehabilitation studies, will assist in project administration, communication with participants, and data collection. She will provide .25 effort for the entire project duration and is supported by the Department of Neuroscience**.**
Consultants: The **clinician evaluator** for this project will be a physical therapist who has expertise in stroke rehabilitation, research training and who is standardized in the administration of the outcome measures that will be used in the CARE-CITE study. **Aimee Reiss, PT, DPT**, an expert clinician and an evaluator in our lab for the past 6 years, will serve in this consultant role. Hiring of Dr. Reiss will occur for the last 9 months of the project, at which time each of the 8 dyads will have three evaluations. A total of 24 evaluations will occur during this period (January-May, 2014) each lasting approximately 3 hours **($4,320). Graphic Web Interface Designer/Computer Scientist,** TBA, will be identified at Emory and supervised by Brian Jones for the purpose of adapting the CARE-CITE intervention to the electronic tablet format **($7000).**

Equipment: No additional evaluation equipment required. We will continue to use existing evaluation materials for the Wolf Motor Function Test available in Dr. Wolf's lab.

Travel: Funds are requested to cover travel reimbursement to study participant's homes for evaluations and training. Average round trip, 30 miles @ 0.555/cents per mile (NIH reimbursement rate) = $16.65/visit.
Evaluator (Dr. Reiss) will complete 24 evaluations (3 evaluations per each of 8 dyads).
During usability/acceptability portion of study (Specific Aim 1), the study PI (Dr. Blanton) will have 9 visits (3 visits/carepartner).
During feasibility portion of study (Specific Aims 2-3), 88 intervention visits will be completed by Dr. Blanton and DPT students (11 treatment visits/dyad).

Total Travel: **$2,015**

Participant Support Costs: Each of the 8 dyads will receive $100 for participating in the study.

Total Participant Stipend: **$800**

Other Direct Costs: Equipment required to address 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). The CARE-CITE intervention will be delivered via electronic tablet uniquely configured for the proposed study.

Materials and Supplies

- Videography system to create CIMT videos viewed on tablet for CARE-CITE intervention
  - Camcorder and tripod @ $453
- IPads (with attached keyboards/covers) with 1 year service over 3G wireless network
  - 3 units @ $637 = $1911
- CIMT mitts
  - 8 mitts @ $40 = $320

Total Materials and Supplies: **$2684**

- Rental/User Fees
    - 12 months 3G internet service @$30/month

Total Rental/User Fees: **$720**

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Blanton, Sarah R.	Assistant Professor, Department of Rehabilitation Medicine
eRA COMMONS USER NAME SARAHBLANTON	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Virginia	BA	1987	Biology
Emory University, Atlanta, Georgia	MPT	1992	Physical Therapy
Emory University, Atlanta, Georgia	DPT	2003	Physical Therapy

A. Personal Statement

The goal of the proposed research is to examine the feasibility of using a telehealth platform for the delivery of a theory-based, family-centered upper extremity intervention program for stroke survivors in the home setting. The aim of the intervention is to reduce carepartner burden and depressive symptoms while improving stroke survivor upper extremity function. As a PI on an internally funded grant, I created the foundation for the proposed research by developing, with Dr. Patricia Clark, a novel carepartner focused adaptation of an upper extremity intervention, constraint-induced movement therapy (CARE-CITE). The current preliminary study grant proposal submitted to the Emory/Georgia Tech Healthcare Innovation Program (HIP) and the Atlanta Clinical and Translational Science Institute (ACTSI) will provide an opportunity to build upon this prior work and gather additional data to seek extramural funding to enhance my training through a NINDS Mentored Patient-Oriented Research Career Development Award (K23) and AHRQ R03 grant (Small Research Grant to Improve Health Care Quality through Health Information Technology-IT). I have chosen Dr. Dunbar as a co-principal investigator, to provide expertise in psychoeducational interventions for patients and families and additional training in dyad research. With guidance from my study co-investigator, Brian Jones and Georgia Tech colleagues I plan to convert the existing intervention to a digital format accessed through electronic portable tablet devices providing an ecologically valid delivery option of CARE-CITE within the home environment. Ultimately, the skills and experience I will acquire carrying out the research in this proposal will serve as preparation to apply for an R01 for future testing of the intervention. I am an expert clinician (neurological specialty certification for ten years and internationally recognized expertise in constraint-induced movement therapy) with a strong research background, including over twelve years of experience in the implementation of two major randomized clinical trials in stroke rehabilitation. My specific research skills include: (1) clinical site project management; (2) standardization procedure development and application; (3) intervention development, training and administration; (4) subject recruitment; and (5) evidence dissemination (manuscripts, platform and poster presentations and clinician focused, continuing education courses). In summary, my extensive knowledge in stroke rehabilitation and my strong foundation of clinical trial management experience have prepared me to lead the proposed project.

B. Positions and Honors

Positions and Employment

1992-2000 Staff Physical Therapist, Emory Center for Rehabilitation Medicine
2000-2007 Project Coordinator, Extremity Constraint Induced Therapy Evaluation (EXCITE) Clinical Trial, Emory University

2002-2005	Assistant Project Coordinator, Motor Map Plasticity in Constraint Therapy for Stroke - Functional Imaging and Constraint-Induced Therapy Evaluation (FICIT) clinical trial, Emory University
2004-2007	Assistant Project Coordinator, Mental Imagery and Constraint-Induced Therapy (MICIT) study, Emory University
2004-2006	Associate Director, Research Projects, Emory University School of Medicine, Center for Rehabilitation
2006-present	Assistant Professor of Rehabilitation Medicine, Emory University School of Medicine
2008-present	Clinical Site Coordinator, Interdisciplinary Comprehensive Arm Rehabilitation Evaluation Stroke Initiative (I-CARE) RCT, Emory University
2007-2010	Principal Investigator, Family centered care of stroke survivors and caregivers to facilitate health related quality of life assessment and treatment study, Emory University

Other Experience and Professional Memberships

1990-present	American Physical Therapy Association (APTA)
1990-present	Georgia Chapter American Physical Therapy Association
1992-present	American Physical Therapy Association Neurological Section
1997-1999	Abstract Editor, *Neurology Report*, Neurology Section, APTA
2005-present	Manuscript Reviewer: *Stroke, Physical Therapy, Archives of Physical Medicine and Rehabilitation, Journal of Rehabilitation Medicine, Journal of Neurologic Physical Therapy, American Journal of Physical Medicine and Rehabilitation, Tohoku Journal of Experimental Medicine, Neurorehabilitation and Neural Repair*
2010/2012	International Think Tank on Stroke Rehabilitation Committee, Canada
2011-present	Gerontological Society of America
2011-present	American Physical Therapy Association Research Section
2011	National Stroke Association Caregiving Steering Committee
2011	Rehabilitation Node Expert Reference Group of the Joanna Briggs Institute, Australia
2012	World Confederation of Physical Therapy-Data Base of Experts
2012	*Rehabilitation Research and Practice*, Editorial Board
2013	*Open Access Rehabilitation Medicine*, Editorial Board
2013	American Congress Rehabilitation Medicine Stroke Task Force Committee - Living Life after Young Stroke

Honors

2002	Specialty certification in Neurology through American Board of Physical Therapy Specialties (ABPTS); re-certification 2012
2003-2006	Appointment to the Specialization Academy of Content Experts to assist in the role of exam preparation or the American Board of Physical Therapy Specialties (ABPTS)
2007	Honorary Research Fellow, Faculty of Health and Social Care Sciences St. George's, University of London
2009	Keynote Lecturer, Association of Chartered Physiotherapists Interested in Neurology (ACPIN) National Conference, Northhampton, England
2012	Invited participant, 10th Annual Enhancing Rehabilitation Research in the South (ERRIS) Intensive workshop on grant writing, preparation, and submission in rehabilitation research. University of Virginia, NIH-NCMRR-NICHD Grant#1T15HD050255-05A1

C. Selected peer-reviewed publications (Selected from 21 peer-reviewed publications)

Most relevant to the current application

1. Nichols-Larsen DS, Clark PC, Zeringue A, Greenspan A, **Blanton S**. Factors influencing stroke survivors' quality of life during sub-acute recovery. *Stroke.* 2005; 36:1480-1484. PMID: 15947263

2. Klinedinst J**,** Clark PC**, Blanton S,** Wolf SL**:** Congruence of depressive symptom appraisal between persons with stroke and their caregivers. *Rehabil Psychol*. 2007; 52:215-225.
3. **Blanton S**, Morris DM, Prettyman MG, McCulloch K, Redmond S, Light KE, Wolf SL. Lessons learned in participant recruitment and retention: The EXCITE Trial. *Phys Ther.* 2006; 86:1520-1533. PMID: 17079752
4. **Blanton S**, Wilsey H, Wolf SL. Constraint-induced movement therapy in stroke rehabilitation – Perspectives on future clinical applications. *NeuroRehabilitation.* 2008; 23:15-28 PMID: 18356586
5. **Blanton S**, Clark PC, Cussen D, Holmes A, Regan B, Schwartz C, Aycock DM. **"**Family-Centered Care during Constraint Induced Movement Therapy." Combined Sections Meeting of APTA, Chicago, IL, February, 2012 [abstract].

Additional recent publications of importance to the field (in chronological order)

1. Winstein CJ, Miller PM, **Blanton S**, Taub E, Uswatte G, Morris D, Nichols D, Wolf SL. Methods for a multi-site randomized trial to investigate the effect of constraint-induced movement therapy in improving upper extremity function among adults recovering from a cerebrovascular stroke. *Neurorehabil Neural Repair* 2003; 17:137-152*.* PMID: 145034351
2. Underwood, J, Clark, PC, **Blanton, S.**, Aycock, DM, & Wolf, SL. Pain, fatigue, and intensity of practice in persons with stroke receiving constraint-induced (CI) movement therapy. *Phys Ther.* 2006; 86:1241-1250. PMID: 16959672
3. Wolf SL, Winstein CJ, Miller JP, Thompson PA, Taub E, Uswatte G, Morris G, **Blanton S**, Nichols-Larson D, Clark PC. Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: the EXCITE randomized trial. *Lancet Neurol*. 2008; 7:33-40. PMID: 18077218
4. Park SW, Wolf SL, Winstein CJ, **Blanton S**, Nichols-Larsen D. The EXCITE Trial: Predicting a clinically meaningful motor activity log outcome. *Neurorehabil and Neural Repair*. 2008; 22:486-93. PMID: 18780883
5. Sawaki L, Butler A, Leng X, Mohammad Y, **Blanton S**, Sathian K, Nichols-Larson D, Wolf S, Good D, Wittenberg G. Constraint-induced movement therapy results in increased motor map area in subjects 3-9 months after stroke. *Neurorehabil Neural Repair.* 2008; 22:505-13. PMID: 18780885
6. Clark PC, Dunbar SB, Aycock DM, **Blanton S**, Wolf SL. Pros and woes of interdisciplinary collaboration with a national clinical trial. *J Prof Nurs.* 2009; 25: 93-100. PMID: 19306832
7. Wolf SL, Thompson PA, Winstein CJ, Miller JP, **Blanton** SR, Nichols-Larsen DS, Morris DM, Uswatte G, Taub E, Light KE, Sawaki L. The EXCITE stroke trial: comparing early and delayed constraint-induced movement therapy *Stroke.* 2010; 41:2309-15. PMID: 20814005
8. Woodbury M, Velozo CA, Thompson PA, Light K, Uswatte G, Taub E, Winstein CJ, Morris D, Blanton S, Nichols-Larsen DS, Wolf SL. Measurement structure of the Wolf Motor Function Test: *Neurorehabil Neural Repair*. 2010; 24:791-801. PMID: 20616302
9. **Blanton S,** Clark P, Aycock D, Bodian S, Caldwell A, Obrien A, and Pratt D. "Cope to Hope: Depression and Fatigue in Higher Functioning Chronic Stroke Survivors." Combined Sections Meeting of APTA, New Orleans, LA, February 2011 [abstract].
10. Winstein CJ, Wolf SL, Dromerick AW, Lane CJ, Nelsen MA, Lewthwaite R, **Blanton S**, Scott C, Reiss A, Cen SY, Holley R, Azen SP; ICARE Investigative Team. Interdisciplinary Comprehensive Arm Rehabilitation Evaluation (ICARE): A randomized controlled trial protocol. *BMC Neurol*. 2013;13:5 PMID: 23311856

D. Research Support

Ongoing Research Support

1 R01 NS056256 Winstein, Wolf, Dromerick (co-PIs) 04/01/08 – 03/31/13
Interdisciplinary Comprehensive Arm Rehab Evaluation (I-CARE) for Stroke Initiative
This multisite trial determines whether a specific upper extremity procedure, accelerated skill acquisition program (ASAP) can improve function and quality of life among patients who are 1-3 months post stroke.
Role: Emory site coordinator and trainer

1 RC3 NS070646-01 Alberts, Wolf, Koeneman (co-PIs) 06/01/10-06/06/12
Home Arm Assistance Progression Initiative (HAAPI)
This multisite trial evaluates the use of a robotic and intense practice within the home environment to improved paretic hand function in patients with stroke as compared to a traditional upper extremity home exercise program.
Role: Emory site co-project coordinator

Completed Research Support

CARE-CITE Blanton/Clark (PIs) 6/07-5/10
Emory Comprehensive Neuroscience Center
This pilot study, Family-centered Care of Stroke Survivors and Caregivers to Facilitate Health Related Quality of Life Assessment and Treatment, gathered feasibility data evaluating the effect of a caregiver and constraint-induced movement therapy (CARE-CITE) intervention on health related quality of life and upper extremity function in patients with chronic stroke and their carepartners.
Role: Principal Investigator

Active Hand Study Wolf/Milton (PIs) 8/07 – 6/11
Allergan
This double blind study examined the extent to which Botox improves paretic hand function over a 4 month interval in patients with minimal wrist and finger extension compared to a saline placebo.
Role: Emory site co-project coordinator

R01 HD 37606 Wolf (PI) 4/00 – 3/07
NCMRR(NICHD)-NINDS
Extremity Constraint-Induced Training Evaluation (EXCITE) national randomized clinical trial
This study examined the extent to which two weeks of constraint of the uninvolved upper extremity in patients with sub-acute and chronic stroke resulted in meaningful functional improvement.
Role: Project and Clinical Site Coordinator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Dunbar, Sandra B.	Charles Howard Candler Professor
eRA COMMONS USER NAME (credential, e.g., agency login) SBDUNBA	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Florida State University, Tallahassee, FL	B.S.N.	03/72	Nursing
University of Florida, Gainesville, FL	M.N.	06/73	Nursing
University of Alabama, Birmingham, AL	D.S.N.	06/82	Nursing

A. Personal Statement

The goal of the proposed research is to examine the potential benefit of a home based, family focused intervention designed to facilitate carepartners' roles in stroke survivor rehabilitation. Based on the PI's preliminary work which demonstrated improved stroke survivors task performance and reduced carepartner depressive symptoms and family conflict, the study will develop and test the impact of a home-based CARE-CITE approach using an innovative and user-friendly telehealth delivery system that increases accessibility and improves ease of treatment delivery. The central hypothesis underpinning this research is that a theory-based carepartner-centered intervention based upon skill building and problem-solving will foster integration of the family into the rehabilitation process, improving stroke survivor physical function while reducing caregiver negative outcomes and increasing accessibility of participation. Based on my research experience studying clinical and quality of life outcomes in persons with heart failure as well as conducting formative work to develop biobehavioral interventions for HF patients and their family caregivers, I have the expertise and willingness to contribute to the science of the study. I have specifically carried out NIH funded studies to identify the needs and pilot test of self management interventions with patients and families living with heart failure. I have led interdisciplinary teams in each of these projects, and we have studied outcomes of chronic conditions including quality of life, symptoms, psychological states, functional status, and health resource use both pre and post intervention and self management behaviors. I am currently testing self management interventions for persons with diabetes and heart failure with QOL and biomarker (BNP, HGA1c) outcomes. We also have a current P01 to improve outcomes (lipids, inflammatory cytokines) in family caregivers of persons with heart failure. I am qualified to consult on this project regarding recruitment strategies, design, measurement of variables, and to participate in dissemination as appropriate. I have mentored medical and nursing predoctoral trainees, postdoctoral fellows, and junior faculty (K awards) with successful outcomes and am committed to this proposal.

B. Positions and Honors

Positions and Employment

1972	Staff Nurse, St. Vincent's Medical Center, Jacksonville, FL
1974-1975	Staff Nurse, Tallahassee Memorial Regional Medical Center
1975-1979	Assistant Professor of Nursing, Florida State University, Tallahassee, FL
1981-1988	Assistant /Associate Professor of Nursing, University of Miami, Miami, FL
1986-1988	Co-Director, Institute for the Study of Culture and Nursing, University of Miami, Miami, FL
1988-1995	Associate Professor, Adult Health, Nell Hodgson Woodruff School of Nursing, Emory University, and Clinical Director of Critical Care Nursing, Emory Univ. Hospital, Atlanta, GA
1995-1997	Department Chairperson, Adult and Elder Health, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA
1996-Present	Professor, Adult and Elder Health, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA
2000-Present	Charles Howard Candler Professor of Nursing, Emory University, Atlanta, GA

2001-Present Professor, Division of Cardiology, Department of Medicine, School of Medicine, Emory University, Atlanta, GA

Other Experience and Professional Memberships

1996-1997 AREA NURS, CSR, NIH, Reviewer
1996-1998 American Heart Association, Georgia Affiliate Grant in Aid Research Reviewer
1998-2001 NURS, CSR, NIH, Temporary Reviewer, R01
1999-2000 Veteran's Administration Research & Development Grants, Atlanta VA
2001-2004 NURS, CSR, NIH Reviewer;
2008 NURS, CSR, NIH Reviewer; Panel for P01 Reviews

Honors (representative sample)

1990 Fellow of the American Academy of Nursing
1992 Outstanding Alumni Award, Florida State University
1994 Fellow of Council of Cardiovascular Nursing, American Heart Association
1997 Great Teacher Lecture Series – Emory University
1999 Katherine Lembright Award for Cardiovascular Nursing Research, American Heart Association
2002 Heart Failure Society of America Nursing Research Award
2003 GNA Nurse Researcher of the Year
2005 AACN Distinguished Researcher
2006 AHA Best Abstract Award, Council of CVN
2009 One in One Hundred Mentors Award, Emory University postdoctoral fellows program
2010 Distinguished Researcher Award, Southern Nurses Research Society
2010 Council for Advancement of Nursing Science (CANS) Distinguished Researcher Award
2010 UAB 60 Visionary Leader Award (in honor of their 60th anniversary)

C. Selected Peer-reviewed Publications (Selected from peer-reviewed publications)

Most relevant to the current application

1. Dunbar, S.B., Clark, P.C., Deaton, C.D., Smith, A., De, A., & O'Brien, M.C. (2005). Education and Family Support interventions in Heart Failure: A Pilot Study. Nursing Research, 54(3), 158-166. PMID: 15897791.
2. Lennie, TA, Song EK, Wu JR, Chung, ML **Dunbar, SB**, Pressler SJ, Moser DK (2011) Three Gram Sodium Intake is Associated with Longer Event-Free Survival Only in Patients with Advanced Heart Failure, Journal of Cardiac Failure 17(4): 325-30. PMID: 21440871
3. Dunbar, S.B., Clark, P.C., Quinn, C., Gary, R., & Kaslow, N. (2008). Family Influences on Self Care in Heart Failure. JCVN, 23(3), 258-265. PMID: 18437068.
4. Dunbar, SB, Langberg, JL, Reilly, CM, Viswanathan, B, McCarty, F, Culler, SD, O'Brien, MC, Weintraub, WS. (2009). Effect of a Psychoeducational Intervention on Depression, Anxiety and Health Resource Use in ICD Patients, Pacing and Clinical Electrophysiology, 32: 1259-1271. PMID: 19796343
5. McMillan, S, **Dunbar, SB**, Zhang, W (May/June 2007) The prevalence of symptoms in Hospice Patients with End State Heart Disease, J Hospice and Palliative Nursing, 9 (3): 124-131

Additional recent publications of importance to the field (in chronological order)

1. Dunbar, S.B., Jacobson, L., & Deaton, C. (1998). Heart Failure: Patient Education Strategies to Enhance Self Management. AACN Clinical Issues, 9, 244-256. PMID: 9633275
2. **Dunbar SB**, (2005) Psychosocial Issues for Implantable Cardioverter Defibrillator Patients, American Journal of Critical Care, 14(4):294-303.
3. Weintraub, W.S., Barnett, P., Chen, S., Hartigan, P., Casperson, P., O'Rourke, R., Boden, W.E., Lewis, C., Veledar, E., Becker, E., Culler, S., Kolm, P., Mahoney, E.M., Dunbar, S.B., Deaton, C., O'Brien, B., Goeree, R., Blackhouse, G., Nease, R., Spertus, J., Kaufman, S., & Teo, K. (2006). Economics methods in the Clinical Outcomes Utilizing percutaneous coronary Revascularization and Aggressive Guideline-driven drug Evaluation (COURAGE) trial. Am Heart J., Jun 151(6), 1180-5. PMID: 16781215.
4. Gary, RA **Dunbar, SB**, Higgins, MK, Musselman, DL, Smith AL (2010) Combined exercise and cognitive behavioral therapy improves outcomes in patients with heart failure, Journal of Psychosomatic Research 69(2) 119-31. PMID:20624510

5. Reilly, C.M., Higgins, M., Smith, A., Gary, R.A., Robinson, J., Clark, P.C., McCarty, F., & Dunbar, S.B. (2009). Development, psychometric testing, and revision of the Atlanta Heart Failure Knowledge Test. Journal of Cardiovascular Nursing, 24(6), 500-509. PMID: 19858959.
6. Kalogeropoulos, A.P., Georgiopoulou, V., Giamouzis, G., Smith, A.L., Agha, S.A., Waheed, S., Laskar, S., Puskas, J., Dunbar, S.B., Vega, D., Levy, W.C., & Butler, J. (2009). Utility of the Seattle Heart Failure Model in Patients with Advanced Heart Failure. J Am Coll Cardiol, 53(4), 334-42. PMID: 19161882.
7. Grossniklaus, D., Dunbar, S.B., Clark, P.C., & O'Brien, C. (2008). Nutrient Intake in Heart Failure. Journal of Cardiovascular Nursing, 23(4), 357-363. PMID: 18596500.
8. Riegel, B., Moser, D.K., Anker, S.D., Appel, L.F., Dunbar, S.B., Grady, K., Gurvitz, M.Z., Havranek, H.P., Lee, C.S., Lindenfeld, J., Peterson, P.N., Pressler, S.J., Schocken, D.D., & Whellan, D.J. (2009). State of the Science: Promoting Self-Care in Persons with Heart Failure: A Scientific Statement from the American Heart Association. Circulation, 120(12), 1141-1163. PMID: 19720935.
9. Kirkendoll, K., Clark, P.C., Grossniklaus, D., Igho-Pemu, P., Mullis, R., Dunbar, S.B. (2010). Metabolic syndrome in African Americans: views on making lifestyle changes J Transcult Nurs. Apr;21(2):104-13. PMID: 20220030
10. Quinn, C., Dunbar, S.B., Higgins, M. (2010). Heart failure symptom assessment and management: can caregivers serve as proxy? Journal of Cardiovascular Nursing. 25(2):142-8, Mar-Apr. PMID: 20168194

D. Research Support

Ongoing Research Support

1R01NR011888-01 Dunbar (PI) 07/01/09-6/30/13 (NCE)
NINR/NIH
Cost Effectiveness and Quality of Life in Heart Failure Patients with Diabetes
This project will examine the effect of an integrated self-management program delivered in the outpatient setting for patients with heart failure and diabetes on outcomes of self-care, quality of life and costs.
Role: PI

1P01NR011587-01 Bauer-Wu and Miller (Co-PIs) 09/30/09-07/31/14
NINR/NIH
Caregiver Stress: Interventions to Promote Health and Wellbeing
A comprehensive health promotion intervention for caregivers of persons with Alzheimer's Disease and Heart Failure will be tested for its effects on caregiver outcomes, stress biomarkers, and health risks.
Role: PI-Project 2

1R010000010829 (Druss - PI) 6/15/2011-3/31/2016
NIH
A Peer-Led, Medical Disease Self-Management Program for Mental Health Consumers
This study will test a fully peer-led strategy for improving physical self-management in persons with mental illness that can be used in consumer networks.
Role: co-investigator

1-T32-NR012715-01A1 (Dunbar) 07/01/2012-06/30/2017
NIH/NINR
Training in Interventions to Improve Outcomes in Chronic Conditions
This training grant will provide research training centered on design and testing of self management interventions aimed at prevention and improved health outcomes for those at risk or with chronic conditions.
Role: PI

1U10HL110302-01; (Butler PI) 1/1/12-11/30/16
NIH; NHLBI
Heart Failure Clinical Trials Network
This project provides funding for the the Division of Cardiology at Emory University to serve as a Regional Clinical Center (RCC) within NHLBI's Heart Failure (HF) Clinical Research Network, a network of centers with active HF programs conducting clinical trials and generating and promoting evidence-based HF practice.
Role: Co-investigator

Completed Research Support

R01NR08800 Dunbar (PI) 06/01/04-11/30/09
NIH/NINR
A Family Partnership Intervention in Heart Failure
A randomized trial of a family intervention in heart failure to test the effects on diet and medication adherence.
Role: PI

U01HL079156-01 Quyyumi (PI) 10/01/04-09/30/09
NIH/NHLBI
Emory-Morehouse Partnership to reduce Cardiovascular Disparities
A multi-aim research project to examine associated variables and effects of interventions on cardiovascular outcomes in African Americans with Metabolic Syndrome.
Role: Co-Investigator, PI Aim II

P20NR07798 Hepburn (PI) 07/01/05-06/30/09
NIH/NINR
Exploratory Center for Research: Symptoms, Symptoms Interaction and Health Outcomes
This Center is to develop resources and programs of research to support collaborative, interdisciplinary studies related to symptoms, symptom interactions and health outcomes.
Role: Former Director, 09/01/06-01/01/09

R01NR009280-01A1 Lennie (PI) 09/01/05-05/31/09
NIH/NINR
BMI, Nutrition, Inflammation and Heart Failure Outcomes
This project will examine survival and health resource use over 1 year in HF patients at varying levels of BMI in relation to nutrition status and inflammatory markers.
Role: Co-Investigator (Site PI)

1R21NR011204-01 Dunbar (PI) 09/01/09-08/31/11
NINR/NIH
Improving Self Management and Outcomes in Heart Failure Patients with Diabetes
This project will develop and test an inpatient intervention to improve self-management approaches in patients with the combined chronic conditions of heart failure and diabetes.
Role: PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Clark, Patricia C.	Professor
eRA COMMONS USER NAME PAT_CLARK	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of South Alabama, Mobile, AL	BSN	1980	Nursing
University of Kentucky, Lexington, KY	MSN	1983	Nursing
University of Rochester, Rochester, NY	Ph.D.	1998	Nursing
Emory University, Atlanta, GA	Postdoc	2000-2001	Nursing

A. Personal Statement

The goal for the proposed study is to pilot an intervention for carepartners of stroke survivors designed to optimize family involvement in stroke rehabilitation strategies. This is the first step of a long term goal of testing innovative family focused models in rehabilitation care that improve stroke survivor outcomes while reducing the negative effects of caregiving. I played a key role in the development and refinement of the theoretical framework for this approach and was co-PI of the initial pilot research. I have a wealth of experience in research related to family caregivers of those with chronic illness, primarily stroke and heart failure. I co-developed a family partnership intervention for patients and families with heart failure that was subsequently tested in a study funded by NINR. This intervention also has been piloted in caregivers of stroke survivors. I have been involved in large interdisciplinary studies which have all resulted in multiple peer-reviewed publications and abstracts from these projects, several which have been recognized with awards. My cumulative research experience is the foundation of my expertise in research design and methods for intervention studies. Through all of these experiences I have served as a mentor to numerous students and other faculty with a strong record of successful outcomes. In my role as co-investigator for this study, I will contribute to the overall project aims, as well as refinements to the educational material development, data interpretation and insight into behavioral mechanisms underlying outcomes.

B. Positions and Honors

Positions and Employment

06/75-02/82	Various staff/charge nurse positions
06/83-06/87	Instructor, College of Nursing, University of Rhode Island, Kingston, RI
06/87-06/88	Clinical Assistant Professor, College of Nursing, University of Rhode Island, Kingston, RI
1990, Summer	Instructor, School of Nursing, University of Rochester, Rochester, NY
08/95-12/97	Assistant Professor, School of Nursing, Lenoir-Rhyne College, Hickory, NC
01/98-10/04	Assistant Professor, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA
03/01-6/08	Adjunct Assistant Professor, School of Medicine, Emory University, Atlanta, GA
6/09-present	Adjunct Professor, School of Medicine, Division of Geriatrics, Emory University, Atlanta, GA
10/04-07/05	Associate Professor with tenure, School of Nursing, Emory Univ., Atlanta
08/05-7/08	Associate Professor, B. F. Lewis Sch. of Nursing, Georgia State University(GSU), Atlanta, GA
6/11-present	Adjunct Professor, Dept. of Rehabilitation Medicine, School of Medicine, Emory University
7/11-7/12	Associate Dean for Research, B. F. Lewis Sch. Of Nsg and Health Professions, GSU
8/08/-present	Professor with tenure, B. F. Lewis Sch. of Nsg, GSU, Affiliate faculty in Gerontology Institute

Other Selected Experience and Professional Memberships

1998-1999	Institutional Review Board, Emory University
1998-Present	Georgia State Nurses Association and American Nurse Association
1998-Present	American Heart Association, Council on Cardiovascular Nursing
2001-2004	University Research Committee, Grant Reviewer

2001	Invited participant, Informal Caregiving State of the Science Workgroup Meeting, NINR, NIH
2002	Invited participant, Health Disparities in Stroke, NINDS, NIH
2003-2008	Grant Reviewer, Center for Scientific Review, NIH, Special Emphasis Panels
2005-2009	Association of Rehabilitation Nurses, Member Editorial Board, Rehabilitation Nursing
2010 & 2012	Grant reviewer, Rosalynn Carter Caregiving Institute
Present	Manuscript reviewer, *Nursing Research, Stroke*, *Journal of Cardiovascular Nursing*

Selected Honors

1999	Teaching Scholar Award, Nell Hodgson Woodruff School of Nursing
2001	Mentor Award, Region Seven, Sigma Theta Tau International
2001	Scholar, Hartford Institute Geriatric Nursing Research Scholars & Fellows Program
2002	Nurse Researcher of the Year Award, Georgia Nurses Association
2003	Eva Tupman Nurse Researcher Award, Georgia League for Nursing
2004	Fellow, Council on Cardiovascular Nursing, American Heart Association
2004	Clinical Article of the Year Award, Council on Cardiovascular Nursing, AHA
2005	Southern Nursing Research Society Hartford Geriatric Nurse Researcher Award
2005	Fellow in the American Academy of Nursing (FAAN)
2006	Stroke Article of the Year Award, Council on Cardiovascular Nursing, AHA
2006	Appointed to the Rosalynn Carter Institute for Caregiving Board of Directors
2009	Competence in Aging Award for distinguished research in aging from CVN, AHA
2010	Selected as one of 50 Distinguished Alumni, College of Nursing, Univ. of Kentucky, 50th Anniversary Celebration

C. Selected Peer-reviewed Publications (Selected from 40 peer-reviewed publications)

Most relevant to the current application

1. Miller, E.L., Murray, L., Richards, L., Zorowitz, R.D., Bakas, T., Clark, P., Billinger, S.A., and on behalf of the American Heart Association Council on Cardiovascular Nursing and the Stroke Council (2010). Comprehensive overview of nursing and interdisciplinary rehabilitation care of the stroke patient: A scientific statement from the American Heart Association. *Stroke*, 41, 000-000. Full text accessed on 9/3/10 at http://stroke.ahajournals.org/cgi/reprint/STR.0b013e3181e7512bv1.pdf (Refereed)
2. Klinedinst, NJ, Gebhardt, MC, Aycock, DM, Nichols-Larsen, DS, Uswatte, G, Wolf, SL & Clark, PC (2009). Caregiver characteristics predict stroke survivor quality of life at 4 months and 1 year. *Research in Nursing & Health, 32,* 592-605 Awarded the 2010 Stroke Article of the Year by the Council on Cardiovascular Nursing, American Heart Association
3. Nichols-Larsen DS, Clark, PC, Zerinque A, Greenspan A & Blanton S. Factors influencing stroke survivors' quality of life during sub-acute recovery. *Stroke* 2005; 36, 1480-1484. PMID: 15947263
4. Dunbar SB, Clark PC, Quinn C & Kaslow N. (2008) Family influences on heart failure self-care outcomes. *Journal of Cardiovascular Nursing,23(3), 258-265*. PMID: 18437068
5. Clark PC, Dunbar SB, Shields CG, Viswanathan B, Aycock D, & Wolf SL. Influence of stroke survivor characteristics and family conflict surrounding recovery on caregivers' mental and physical health. *Nursing Research*, 2004; 53(6):406-13. PMID:15586137

Additional recent publications of importance to the field (in chronological order)

1. Clark PC, Shields CG, Aycock D & Wolf SL. Preliminary reliability and validity of a family caregiver conflict scale for stroke. *Progress in Cardiovascular Nursing* 2003;18(2):77-82.
2. Clark PC & Dunbar SB. Family partnership intervention: A guide for a family approach to care of heart failure patients. *AACN Clinical Issues*; 2003;14:467-476. PMID: 14595206 (Clinical Article of the Year Award) by CVN, AHA
3. Clark PC & Dunbar SB. Preliminary reliability and validity of a family care climate questionnaire for heart failure. *Families,Systems & Health*; 2003; 21:281-291. PMID: 12732800
4. Dunbar SB, Clark PC, Deaton C, Smith AL, De AK & O'Brien MC. Family education and support interventions in heart failure: A pilot study. *Nursing Research,* 2005; 54(3), 158-166. PMID: 15897791

5. Clark PC, Dunbar SB, Aycock DM, Courtney E & Wolf SL. Caregiver perspectives of memory and behavior changes in stroke survivors. *Rehabilitation Nursing* 2006; 31, 26-32. (Stroke Article of the Year Award) by CVN, AHA and Editor Choice Manuscript Award, Rehabilitation Nursing PMID: 1622042
6. Clark PC, Ashford S, Burt R, Aycock DM & Kimble LP. A factor analysis of the Revised Piper Fatigue Scale in a caregiver sample. *Journal of Nursing Measurement,* 2006;14(2), 71-79.
7. Klinedinst JN, Clark PC, Blanton S & Wold SL. Congruence of depressive symptom appraisal between persons with stroke and their caregivers. *Rehabilitation Psychology*, 2007;52, 215-225
8. Wolf SL, Winstein CJ, Miller P, Thompson P, Taub E, Uswatte G, Morris D, Blanton S, Nichols-Larsen D & Clark PC. Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: EXCITE randomized trial. *Lancet Neurology*, 2008;7 , 33-40, PMID: 18077218
9. Clark PC, Dunbar SB, Aycock DM, Blanton S & Wolf SL. (2009) Pros and woes of interdisciplinary collaboration with a national clinical trial. *Journal of Professional Nursing,25,93-100*
10. Quinn, C, Dunbar, SB, **Clark, PC**, Strickland, O. (2010) Challenges and strategies in dyad research: Cardiovascular examples. *Applied Nursing Research, 23, e15-20.* (Refereed)

C. Research Support

Ongoing Research Support

1-UB4HP19215-01-00 T. Johnson (PD) 7/1/10-6/30/15
HRSA (contract)
Atlanta Regional Geriatric Education Center – Collaboration Allows for Enhanced Senior Care (COALESCE)
This funding supports the development of a geriatric education consortium for the Atlanta area
Role: GSU project team

Completed Research Support

Allergan Pharmaceuticals P. Clark (PI) 6/1/07-5/31/10
Exploring Rehabilitation Treatment Effects: Stroke Survivor Quality of Life and Family Caregiver Outcomes
A pilot study to explore family caregiver outcome in stroke survivors receiving intensive physical therapy.
Role: Principal Investigator

R01NR08800-01A1S. Dunbar (PI) 6/1/04-5/30/08 (no cost extension 11/30/09)
National Institute of Nursing Research, NIH
A Family Partnership Intervention for Heart Failure
A randomized trial of a family intervention in heart failure to test the effects on diet and medication adherence. This study includes a biomarker of the disease process.
Role: Co-Investigator

1 V01 HL079156-02 A. Quyyumi (PI)
National Heart, Lung, and Blood Institute 10/01/04-09/30/09
National Institutes of Health
The Emory-Morehouse Partnership to Reduce Cardiovascular Health Disparities
A multi-aim research project to examine effects of interventions on cardiovascular outcomes in African Americans with Metabolic Syndrome. Multiple biomarkers are being collected as part of this study.
Role: Co-Investigator

AG025688, Levey (PI) 06/01/05 - 05/31/10
National Institute of Aging
Alzheimer's Disease Research Centers
A multi-aim project to facilitate interdisciplinary Alzheimer's Disease research.
Role: Co-PI (Education Core) – Came off project 04/06 to pursue other projects.

1 P20 NR 07798 Parker (PI) 07/01/01-06/30/04
NIH/NINR (No cost extension through 08/31/05) Renewal funded beginning 10/05-9/08

Exploratory Center for Research: Symptoms, Symptoms Interaction and Health Outcomes
This Center is to develop resources and programs of research to support collaborative, interdisciplinary projects related to symptoms, symptom interactions and health outcomes.
Role: Co-Investigator Came off project with change in academic institution.

R01 HD37606 Wolf (PI) 03/01/00-03/31/05
NCMRR
The EXCITE (Extremity Constraint-Induced Movement Therapy Evaluation) national clinical trial
The purpose of this study is to test constraint-induced therapy for improving upper extremity function after stroke.
Role: Co-Investigator

1 R01 NR 07612-01 Clark (PI) 09/01/00-08/31/03
NIH/NINR (No cost extension through 08/31/05)
Family Function, Stroke Recovery, and Caregiver Outcomes
This study is complementary to a national, experimental, multi-site clinical trial to examine relationships of stroke survivor (3-9 months post stroke) characteristics and family function with caregiver outcomes and stroke recovery over time.
Role: PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Wolf, Steven L.	Professor, Department of Rehabilitation Medicine
eRA COMMONS USER NAME SLWOLF	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Clark University, Worcester, MA	BA	1965	Biology
Columbia University, New York, NY	Certificate	1966	Physical Therapy
Boston University, Boston, MA	MS	1968	Physical Therapy
Emory University, Atlanta, GA	MS	1972	Anatomy
Emory University, Atlanta, GA	Ph.D.	1973	Neurophysiology

A. Personal Statement.

I explore novel interventions to improve upper extremity use in patients with stroke as well as mechanisms of cortical reorganization and inter-joint coordination associated with such changes. Within the past 23 years I have led several NIH funded clinical trials governing this concept. More recently, our lab has been emphasizing measures of neural plasticity for interventions designed to improve posture in older adults or stroke survivors as well as to improve limb function in the latter group. These new studies involve use of robotics and mixed reality, both of which have telerehabilitation capabilities and are directed toward home-based treatment post-stroke that is quite compatible with the current application. Our present NINDS ICARE RCT explores a novel intervention for upper extremity recovery in acute stroke survivors. I have extensive experience evaluating the upper extremity intervention, constraint-induced movement therapy (CIMT), which provides the foundation for the approach in this study and I was the principal investigator of the Extremity Constraint Induced Therapy Evaluation (EXCITE) randomized clinical trial (RCT). I have a long history of mentoring investigators in the development of NIH-funded grant applications, with my own research funding totaling over $31 million in direct costs. As collaborator on this study, I will provide guidance in the application of CIMT, assist in outcome data interpretation and will assist in developing grant applications for subsequent external sponsorship of future work building on this data.

B. Positions and Honors.

Positions and Employment

1985- Professor, Dept. of Rehabilitation Medicine, Emory University School of Medicine, Atlanta, GA
1996- Professor of Geriatrics, Dept Medicine, Emory University School of Medicine, Atlanta, GA
2002- Professor, Department of Adult and Elder Care, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA
2009- Professor, Dept Cell Biology, Emory University School of Medicine, Atlanta, GA

Other Experience and Professional Memberships

Canadian Stroke Network Review Panel, 2003-
NINDS, Study Section A (Ad hoc reviewer), 2001-NIH NCMRR Musculoskeletal and Rehab Sci Study Section, 2004-07
NIH NCMRR Advisory Council, 2006-2010 and representative to NICHHD, 2008-2010
Series Editor, Contemporary Perspectives in Rehabilitation, F.A. Davis Company, Philadelphia, PA, 1985-
Associate Editor, Topics in Stroke Rehabilitation, 1988-, J Electromyography and Kinesiology, 1992-, Canadian J. Rehabilitation, 1994-, Neurorehab and Neural Repair, 2002 –, J Neuroengineering and Rehabilitation, 2004-
Editorial Board, Physical Therapy Reviews, 1996-

Advisory Board Member, Internat Physiotherapy Research Journal, 1995-
Assoc Editor, Physiotherapy Research International, 1995-2000
Manuscript reviewer: JAGS, J Geront, NEJM, JAMA, Brit Med J, Arch PM&R, Exp Neurol, Exp Brain Res, J Neurophys

Recent Honors
Stroke Council, American Heart Association, 1999-. Mary McMillan Lecturer, APTA 2002.
Keynote Speaker (Phys Ther): University of Delaware (2001), Pittsburgh (2002), Emory (2003), Arcadia (2004), Cleveland Clinic (2004), Temple University (2005), Columbia Univ. (2006), 17th Annual Japan Neurorehabilitation Society Mtg, 2005, Kaleckas Lecturer 2010 (Northwestern University), U Mass (2011), University of Otago 2013. 2009 APTA "Living Legend;" Evelyn Smith Visiting Professorship, Department of Arts, Media and Engineering, Arizona State University, 2010-2013.

Wolf SL, Barnhart HX, Kutner NG, et al: Exercise training and subsequent falls among older persons: Comparison of Tai Chi and computerized balance training. JAGS 44:489-497, 1996. (reprinted 2003 as "Best paper of the 1990's" (JAGS).

Greenfield B, Goldberg, A, Wolf SL**,** Curtis C: Ethical, legal and social issues of genomics: Implications for physical therapy education. J Phys Ther Education, 2008;22:4-14. Winner of the 2009 Stanford Award for Outstanding 2008 in Physical Therapy Education Journal**.**

B. Selected peer-reviewed publications (10 papers in chronological order from over 200).

Wolf SL, Winstein C, Miller JP, Taub E, Uswatte G, Morris D, Giuliani C, Light K, Nichols-Larsen D: Improving Upper Extremity Function among Patients 3-9 Months Post-stroke: The EXCITE National Randomized Clinical Trial . JAMA, 2006;296-2095-2104.

Wolf SL**,** Winstein C, Miller JP, Thompson P, Taub E, Uswatte G, Morris D, Blanton S, Clark PC Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: the EXCITE randomised trial. Lancet Neurology, 2008, 7:33-40

Schweighofer N, Han C, Wolf SL, Arbib M, Winstein C: Understanding the functional threshold: Predictions from a computational model and supporting data from the Extremity Constraint-Induced Therapy Evaluation (EXCITE) Trial. Phys Ther, 2009;89:1327-1336.

Wolf SL, Thompson PA, Winstein CJ, Miller JP, Blanton SR, Nichols-Larsen DS, Morris DM, Uswatee, G, Taub E, Light KE, Sawaki L: The EXCITE Trial: Outcomes after crossover of usual and customary care to constraint-induced movement therapy. Stroke, 2010;41(10):2309-2315.

Lehrer N, Attygalle S, Wolf SL, Rikakis T: Exploring the bases for a mixed reality stroke rehabilitation system, Part I: A unified approach for representing action, quantitative evaluation, and interactive feedback, Journal of NeuroEngineering and Rehabilitation 2011, **8**:51 doi:10.1186/1743-0003-8-51

Lehrer N, Chen Y, Duff M, Wolf SL, Rikakis T: Exploring the bases for a mixed reality stroke rehabilitation system, Part II: Design of Interactive Feedback for upper limb rehabilitation. , J Neuroengineering and Rehabilitation, 2011, Sept 8;8:54. PMID:21899779

Duff M, Chen Y, Cheng L, Liu S-M, Blake P**,** Wolf SL, Rikakis T: Adaptive mixed reality rehabilitation improves quality of reaching movements more than traditional reaching therapy following stroke, Neurorehabilitation and Neural Repair 2012, PMID:23213076

Hidaka Y, Han CE, Wolf SL, Winstein CJ, Schweighofer N: Use it or lose it? Causal interactions between arm function and use in humans post-stroke. PLoS Computational Biology, Feb. 2012, e1002343

Winstein CJ, Wolf SL, Dromerick A, Blanton S, Nelsen MA, Land C, Cen S, Scott C, Lewthwaite R, Holley R, Reiss A: Protocol for the Interdisciplinary Comprehensive Arm Rehabilitation Evaluation (ICARE) trial: A randomized controlled trial. J BMC Neurology, 2013 Jan 11;13(1):5

C. Research Support

Ongoing Research Support

1 R01 NS056256 Winstein, Wolf, Dromerick (co-PIs) 08/01/08 – 07/31/14 3.6

Interdisciplinary Comprehensive Arm Rehab Evaluation (I-CARE) for Stroke Initiative
This multisite trial determines whether a specific upper extremity procedure, accelerated skill acquisition program (ASAP) can improve function and quality of life among patients who are 1-3 months post stroke.
Role: Emory site PI

RC3 NS070646-01 Koeneman, PI (Wolf, Emory PI; Alberts, Cleveland Clinic PI) 4/1/10 - 9/30/13 3.6
An Innovative Home Stroke and Rehabilitation System
This study determines the efficacy of a home based Hand Mentor robotic device compared to a home exercise program in improving hand function within 6 months post-stroke and transmitting data to a centralized location (tele-rehabilitation)
Role: Emory site PI

Nichols TR (Principal Investigator), SL Wolf (Co-Principal Investigator), Training Movement Scientists: Focus on Prosthetics and Orthotics, 1 T32 HD055180-06, ($1,963,724), 3/13 – 2/18. Gratis
This training grant is designed to provided doctoral training for students interested in motor control, prosthetics or orthotics

Mueller M, Delitto A, Binder-Macleod SA, (SL Wolf, Investigator), COORT: Comprehensive Opportunities in Rehabilitation Research Training (Multicenter Career Development Program for Physical and Occupational Therapists). K12 HD055931, 1/12 -12/17 Gratis
This training grant provides physical and occupational therapists post-doctoral training in the development of their research careers.

Nudo R: Kansas University Training Program in Neurological and Rehabilitation Sciences (T32HD057850), Steven L. Wolf (Scientific Advisory Board), 3/09 – 2/14 Gratis
This training grant provides rehabilitation scientists pre-doctoral training to develop their research careers.

van Vliet, P: Pilot study for a randomised controlled trial of task-specific reach-to-grasp training at home. University of Nottingham; British Stroke Association. (SL Wolf, consultant), £159, 448, 12/09 – 11/13. Gratis
This study examines the effect of a specific upper extremity home-based training program on functional recovery in acute stroke survivors

Completed Research Support

AMES EMG BF Study R44NS060192-02 Cordo (PI), Wolf (Site PI) 1/1/10 – 1/31/12 .6
This study is intended to determine the nature of optimal feedback incorporated within the AMES (assisted movement with enhanced stimulation) device for upper extremity wrist rehabilitation; specifically the extent to which muscle feedback options are better than torque feedback.

Active Hand Study Allergan Wolf/Milton (PIs) 3/1/07 – 12/31/12 3.6

This double blind study examines the extent to which Botox improves paretic hand function over a 4 month interval in patients with minimal wrist and finger extension compared to a saline placebo.
Role: PI

Cognitive/Motor Therapy Application Using Console-Based Videogame Platform. 6/10 – 9/12 .6
J. Koeneman (PI), Department of Defense, Contract No. W81XW-09-C-0130,
The purpose of this proposal is to meld clinical strategies used in treating TBI patients with intrinsically motivating video games.

Pending

R01 HD057020-01A Alberts (PI) 09/01/12 – 08/30/13 2.4
The Stroke Assistive Repetitive Motion Trial
This multi-site trial determines the extent to which use of a robotic device as part of an upper extremity stroke rehabilitation training procedure is superior to a dose equivalent standardized upper extremity treatment program in post-acute patients.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Jones, Brian Drury	Senior Research Engineer
eRA COMMONS USER NAME (credential, e.g., agency login) BDJONES1	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Georgia Institute of Technology	BEE	1989-1993	Electrical Engineering
Georgia Institute of Technology	MS	1994-1996	Electrical Engineering

A. Personal Statement

As a Senior Research Engineer at Georgia Institute of Technology (Georgia Tech), my research is focused on interactive media with particular interest in health and wellbeing interventions in the home. I am also Director of the Aware Home Research Initiative (AHRI) at Georgia Tech, where I work with faculty and students from various disciplines around Georgia Tech as well as our partner institutions, communities and industry, to build interdisciplinary interest in projects related to the home. The Aware Home Research Initiative has a heavy focus on research involving technology to benefit older adults at home. I have served as PI/Co-PI and participated as co-investigator in several research projects to develop social communication technologies and other technological solutions in the home and on the go that address the needs of older adults. My interest in this space is moving toward HealthIT that may have more clinical relevance. I am also co-founder/coordinator of the Design and Technology for Healthy Aging (DATHA) Initiative, where we have brought together researchers, service providers, practitioners, community organizers, and industry to learn from each other and build new collaborative relationships. With experience both in the interactive media domain and with experience working with telehealth systems, I am in a unique position to provide guidance and insight to guide Dr. Blanton in her proposed research “A Preliminary Test of a Carepartner-Integrated Telehealth Rehabilitation Program for Persons with Stroke”.

B. Positions and Honors

Positions and Employment

1993-1994	Student Research Assistant
1994-1998	Research Engineer I
1999-2008	Research Engineer II
2008-present	Senior Research Engineer

Other Experience and Professional Memberships

1994	Engineering In Training (EIT) Certification
2005-2008	Manager, Broadband Institute Residential Laboratory (Aware Home), Georgia Institutute of Technology
2007-2008	Associate Director, Aware Home Research Initiative, Georgia Institutute of Technology
2007 -present	Faculty, GVU Center, Georgia Institutute of Technology
2008-present	Director, Aware Home Research Initiative, Georgia Institutute of Technology

2008 -present	Co-founder, Design and Technology for Healthy Aging Initiative (DATHA), Georgia Institutute of Technology
2010 – present	Member, GVU Center Faculty Advisory Committee, Georgia Institutute of Technology
2011 - present	Member, Institute for People and Technology Health Systems Strategy Task Force Committee, Georgia Institute of Technology
2011 - present	Member, Science Advisory Board, SimpleC, Inc
2012 – present	Member, Advisory Board, Sensiotec, Inc

Honors

1995	Atlanta Journal and Constitution: Top 5 Museum Exhibits
2001	Silver Axiem Award, National Security for the 21st Century CD-ROM, International Finalist

C. Selected peer-reviewed publications (in chronological order).

1. **Jones, B. D.** (1997). *Texture Maps From Orthographic Video*. The Art and Interdisciplinary Programs of SIGGRAPH '97 Visual Proceedings, 161.
2. **Jones, B. D.,** Cole, C., & Quay, A. (2001). *i-irasshai: An Immersive Cultural Learning Experience.* Proceedings of the 2001International Cultural Heritage and Informatics Meeting, 1, 93-105.
3. Peifer, J., **Jones, B.,** Lippincott, B., & Wilson, J. (2005). *Sharing Accessibility Information among a Mobile Wireless Community*. RESNA Conference Proceedings
4. **Jones, B.,** Forbes, J., & Oquinn, T. (2007). *The Gates of Paradise Interactive Kiosk*. In Proceedings of the International Cultural Heritage and Informatics Meeting (ICHIM)
5. Kientz, J.A. S.N. Patel, **B. Jones**, E. Price, E.D. Mynatt, G.D. Abowd. (2007) *IT Systems to Support Aging in Place: Aware Home Research Initiative at the Georgia Institute of Technology.* In the Proceedings of the International Future Design Conference on Global Innovations in Marco- and Micro-Environments for the Future, Seoul, Korea. pp. 276-286.
6. Patel, S.N., J.A. Kientz, **B. Jones**, E. Price, E.D. Mynatt, G.D. Abowd. (2007) *An Overview of the Aware Home Research Initiative at the Georgia Institute of Technology.* In the Proceedings of the International Future Design Conference on Global Innovations in Marco- and Micro-Environments for the Future, Seoul, Korea. pp. 169-181.
7. Kientz, J. A., Patel, S. N., **Jones, B.,** Price, E., Mynatt, E. D., and Abowd, G. D. (2008). *The Georgia Tech Aware Home.* In CHI '08 Extended Abstracts on Human Factors in Computing Systems (Florence, Italy, April 05 - 10, 2008). CHI '08. ACM, New York, NY, 3675-3680.
8. Winegarden, C., **Jones, B.** *Sympathetic Devices: Communication Technologies for Inclusion Across Housing Options*, (2009) In Proceedings of Universal Access in HCI, Part II, HCII 2009, LNCS 5615-0127.
9. Gandy, M., **Jones, B.,** Robertson, S., O'Quinn, T., Johnson, A., *Rapidly Prototyping Marker Based Tangible User Interfaces*, **(**2009) In Proceedings of Universal Access in HCI, Part II, HCII 2009, LNCS 5615-0127.
10. Robertson, S., **Jones, B.,** O'Quinn, T., Presti, P., Wilson, J., Gandy, M. *Multiuser Collaborative Exploration of Immersive Photorealistic Virtual Environments in Public Spaces*, (2009) In Proceedings of Universal Access in HCI, Part II, HCII 2009, LNCS 5615-0127.
11. Choi, M., **Jones, B**., Shim, J., Hong, K., Shah, D., *Enabling Clinical Decision-Making Through Home Monitoring and Health Information Technology*, INFORMS Data Mining and Health Informatics Workshop, 2010.
12. Winegarden, C., **Jones, B.** *Sympathetic Devices: Communication Technologies for Inclusion*, Physical & Occupational Therapy in Geriatrics, March 2011, Vol. 29, No. 1 : Pages 44-58 (doi: 10.3109/02703181.2011.555060)
13. Yi-Luen Do, E., **Jones, B.**, "Happy Healthy Home", Handbook of Ambient Assisted Living - Technology for Healthcare, Rehabilitation and Well-being, Ambient Intelligence and Smart Environments, Volume 11, 2012, pages 195 – 210. DOI: 10.3233/978-1-60750-837-3-195

14. Lowe, S., Rodríguez-Molinero, A., Glynn, L., Breen, P., Baker, P., Sanford, Jon, **Jones, B.**, ÓLaighin, G., "The Evolution of Functional Assessment of Older Adults", Journal of Clinical Epidemiology, In Press, Corrected Proof, 2012. Ms. Ref. No.: JCE-11-423R2. Jones was an advisor on the inclusion of content and provided review of the paper.

D. Research Support.

Ongoing Research Support

P01 AG17211 Wendy A. Rogers & Arthur D. Fisk, Co-Principal Investigators for "Aging and the design of technology" (8/15/04 - 7/31/14)
Center for Research and Education on Aging and Technology Enhancement (CREATE III)
Research goals are to enhance the usefulness and usability of technology, establish knowledge base on technology: needs, preferences, patterns of use, problems with existing systems, design solutions, expand research on aging and technology.
Role: Co-Investigator: Outreach and dissemination

Georgia Tech Research Institute Strategic Initiative (HomeLab) Fain, B (PI) (07/2011 - ongoing)
The goal of this project is to build a large pool of participants age 50+, maintain and updated database of information on these individuals, study various aging related research questions through longitudinal research studies and to offer services to industry that will help improve product design and function for an older adult population. Products to be evaluated will include home health technology devices.
Role: Co-investigator

A Preliminary Test of iHealthHome for Improving outcomes in Persons with Heart Failure and Diabetes.
ACTSI/HIP seed grant program, NIH Dunbar, S (Emory University), Jones, B (7/2012 – 4/2013)
This small pilot study will adapt and test the iHealthHome system to support self management for persons who have heart failure and concomitant diabetes. The iHealthHome system is a comprehensive in-home monitoring communication and collaboration system developed for remote monitoring of elders living alone.
Role: Co-PI

SBIR: "System for Tracking and Managing Pain (STAMP)" (1R43TR000474-01A1APTIMA, INC.)
Knott, Camilla Aptima, Inc (PI), NIH (11/2012 – 5/2013)
This project will develop a system to help older adults track pain easily to better understand the patterns associated with their pain and support self-management. The system will employ automated information capture from sensors available, e.g. activity sensors, in order to simplify the daily reporting tasks.
Role: Co-investigator: Technology advisor

Rehabilitation Engineering Research Center for Wireless Technologies-WirelessRERC (12/2003 – 10/2016)
NIDRR H133E060061 Mitchell (PI)
The Rehabilitation Engineering Research Center on Mobile Wireless Technologies for Persons with Disabilities promotes universal access to mobile wireless technologies and explores innovative applications in addressing the needs of people with disabilities.
Role: Project Director, Building Research Capacity in Wireless Accessibility and Usability, webmaster, and web accessibility

Completed Research Support (only last 3 years)

Personal Wellness Mashups, Humana Price, Ed (PI) (7/2011-11/2012)
This project involves development and study of a system for correlating personal data that may reveal unknown patterns in one's activities. The system consists of data from fitbit, withings scale, and an app on android phone capturing (location, weather, calendar free/busy, and self report food, mood, and pain). The app and supporting

devices are being evaluated for 3 months by 60 individuals to determine next steps.
Role: Project Manager – responsible for management of the study and oversight of system development

Georgia Tech Research Institute Internal R&D Higgins (PI) (03/2009 - 06/2011)
The goal of this project is to assess the feasibility of a large testbed of homes outfitted with health IT for longitudinal research studies and testing of industry home health devices with older adults.
Role: Co-investigator

Health Innovation Household through Healthcare Information Distribution System Framework
Health Systems Institute Seed Grant Choi and Jones (PIs) (09/2009 - 06/2010)
Health Innovation Household through Healthcare Information Distribution System Framework.
Goal of this project is to establish framework to collect and monitor inside house activities and individual health status through home sensors and to distribute the information among healthcare systems such as Electronic Health Record (EHR), data store, or health service providers such as clinics, hospitals, or physicians' devices. The framework is expected to support studies into the importance of everyday activity understanding in individual, clinical and caregiver decision-making.
Role: Co-PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Robert H. Lyles	Associate Professor
eRA COMMONS USER NAME rlyles	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Vanderbilt University (*summa cum laude*)	B.S.	05/88	Mathematics
University of North Carolina at Chapel Hill	M.S.	05/91	Biostatistics
University of North Carolina at Chapel Hill	Ph.D.	05/96	Biostatistics

A. Personal Statement.

My role in this research study is to provide supervision relevant to the necessary study design and data analytic aspects. I will work with the PI and a designated staff statistician from the Emory Department of Biostatistics and Bioinformatics to address the biostatistical needs of the project.

B. Positions and Honors.

Experience

1996-97 Research Associate, Department of Epidemiology, Johns Hopkins University, School of Public Health, Baltimore, MD.

1997-98 Assistant Scientist, Department of Epidemiology, Johns Hopkins University, School of Public Health, Baltimore, MD.

1999-2003 Assistant Professor, Department of Biostatistics, Rollins School of Public Health of Emory University, Atlanta, GA.

2003-Present Associate Professor, Department of Biostatistics and Bioinformatics, Rollins School of Public Health of Emory University, Atlanta, GA

2009-Present Director, Biostatistics Epidemiology Research Development (BERD) Program, within the Atlanta Clinical and Translational Sciences Institute (ACTSI)

Honors

Phi Beta Kappa; Delta Omega

Bernard G. Greenberg Award for Excellence in Doctoral Research, School of Public Health, The University of North Carolina, Chapel Hill, Spring 1996.

Young Investigator Award, Statistics in Epidemiology Section, The American Statistical Association, 1996

American College of Epidemiology/American Chemistry Council Early Career Award in Epidemiologic Methods, 2001

James E. Grizzle Distinguished Alumnus Award, Department of Biostatistics, UNC Chapel Hill, 2002

C. Selected relevant peer-reviewed publications (of 97 co-authored).

Lyles, R.H. and Kupper, L.L. “A Detailed Evaluation of Adjustment Methods for Multiplicative Measurement Error in Multiple Linear Regression, with Applications in Occupational Epidemiology”, *Biometrics*, 53:1008-1025, 1997. PMID: 9290228

Lyles, R.H. and McFarlane, G. “Effects of Covariate Measurement Error in the Initial Level and Rate of Change of an Exposure Variable”, *Biometrics* 56:634-639, 2000. PMID: 10877328

Lyles, R.H., Lyles, C.M., and Taylor, D.J. “Random Regression Models for HIV RNA Data Subject to Left Censoring and Informative Drop-outs”, *Applied Statistics* 49:485-497, 2000.

Lyles, R.H., Williams, J.K., and Chuachoowong, R. "Correlating Two Viral Load Assays with Known Detection Limits", *Biometrics*, 57, 1238-1244, 2001.

Lyles, R.H. and Allen, A.S. "Estimating Crude or Common Odds Ratios in Case-Control Studies with Informatively Missing Exposure Data", *American Journal of Epidemiology* 155:274-281, 2002. PMID: 11821253

Lyles, R.H. "A Note on Estimating Crude Odds Ratios in Case-control Studies with Differentially Misclassified Exposure", *Biometrics* 58:1034-1037, 2002. PMID: 12495160

Lyles, R.H., Lin, H-M., and Williamson, J.M. "Design and Analytic Considerations for Single-Armed Studies with Misclassification of a Repeated Binary Outcome", *Journal of Biopharmaceutical Statistics* 14, 229-247 (2004).

Lyles, R.H., Williamson, J.M., Lin, H.-M., and Heilig, C.M. "Extending McNemar's Test: Estimation and Inference When Paired Binary Outcome Data are Misclassified", *Biometrics* 61:287-294, 2005. PMID: 15737105

Lyles, R.H., Lin, H.-M., and Williamson, J.M. "A Practical Approach to Computing Power for Generalized Linear Models with Nominal, Count, or Ordinal Outcomes", *Statistics in Medicine* 26:1632-1648, 2007. PMID: 16817148

Lyles, R.H., Zhang, F., and Drews-Botsch, C. "Combining Internal and External Validation Data to Correct for Exposure Misclassification: A Case Study", *Epidemiology* 18:321-328, 2007. PMID: 17435440

Lyles, R.H., Poindexter, C., Evans, A., Brown, M., and Cooper, C.R. "Nonlinear Model-Based Estimates of IC_{50} for Studies Involving Continuous Therapeutic Dose-Response Data", *Contemporary Clinical Trials* 29, 878-886, 2008. PMCID:PMC2586183

Lyles, R.H. and Lin, J. "Sensitivity Analysis for Misclassification in Logistic Regression via Likelihood Methods and Predictive Value Weighting", *Statistics in Medicine* 29; 2297-2309, 2010. PMCID:PMC3109653

Lyles, R.H., Tang, L., Superak, H.M., King, C.C., Celentano, D., Lo, Y., and Sobel, J. "An Illustration of Validation Data-Based Adjustments for Outcome Misclassification in Logistic Regression", *Epidemiology* 22; 589-597, 2011. PMCID:PMC3454464

Lyles, R.H., Tang, L., Lin, J., Zhang, Z., and Mukherjee, B. "Likelihood-based methods for regression analysis with binary exposure status assessed by pooling", *Statistics in Medicine* 31, 2485-2497, 2012. PMCID:PMC3528351

Lyles, R.H., Guo, Y., and Greenland, S. "Reducing Bias and Mean Squared Error Associated with Regression-Based Odds Ratio Estimators", *Journal of Statistical Planning and Inference* 142, 3235-3241, 2012. PMCID:PMC3433076

D. Research Support.

Ongoing External Research Support:

1 RC4 NR012527-01 Lyles (PI) 09//24/10-08/30/13
NIH
Accessible Handling of Misclassified or Missing Binary Variables in CER Studies
The goal of this project is to develop sound statistical methodology for dealing with missing and/or misclassified binary data, with a focus on making the methods intuitively and computationally accessible to epidemiologists and applied public health researchers conducting comparative effectiveness research.

5 R01 ES012458-07 Lyles/Manatunga (PI's) 08/01/03-06/30/13
NIH
Analytical Methods: Environmental/Reproductive Epidemiology
The major goals of this project are to develop methodological research in measurement error adjustment, prediction of random effects, and modeling of repeated reproductive health marker and outcome data including repeated menstrual cycle length data and time-to-pregnancy information
Role: Joint PI

2 UL1RR025008-06 Stephens (PI) 09/17/07-05/31/17
NIH
Atlanta Clinical and Translational Science Institute (ACTSI)

The primary goal of the Biostatistics, Epidemiology and Research Design (BERD) Program is to strengthen the statistical science and rigor of Atlanta Clinical and Translational Science Institute (Atlanta-CTSI) related research. The Program will ensure professional quality collaboration.
Role: Core Director/Co-Investigator

5 T15 HL098122-03 Waller (PI) 08/20/09-07/31/13
NIH
Atlanta Summer Institute for Training in Biostatistics
This project provides training for up to 20 undergraduate students interested in careers in biostatistics.
Role: Co-Investigator

RSG-10-140-01-CSM D. Wu (PI) 07/01/10-06/30/14
American Cancer Society
Developing Novel Targeted Therapy for Prostate Cancer Bone Metastasis
The goals of this project are to explore new and innovative treatment strategies for metastatic prostate cancer.
Role: Biostatistical Support

1 R01 CA165306-01 Shim (PI) 03/09/12-02/28/17
NIH
Development of Anti-CXCR4 Compounds To Block Breast Cancer Metastasis
The intended outcome of this proposal is the development of orally available, safe, small molecules that will attenuate tumor metastasis in vivo by blocking a specific function of CXCR4.
Role: Co-Investigator

Completed Research Projects (past 3 years)

5 R21 CA141836-02 Shim (PI) 04/01/10-03/31/12
NIH/NCI
Using Proton MRS to Predict Response to SAHA Treatment in Glioblastoma
The major goals of this project are to develop and evaluate novel techniques to evaluate patient response to innovative treatment strategies.
Role: Biostatistical Support

5 R01 CA109366-05 Shim (PI) 07/15/06-05/31/12
Emtech Biotechnology, Inc.
Development of Small Molecule Drug Against CXCR4 for the Inhibition of Cancer Metastasis
The major goals of this project are to identify small molecules that attenuate tumor metastasis in vivo by blocking CXCR4 function.
Role: Biostatistical Support

1 R18 HS019259-01 Mayberry (PI; Lyles) 09/01/10-08/31/13
Morehouse School of Medicine/NIH
Adaptation, Education and Motivation: Improving Evidence-Based Medication Adherence among Adults with Type 2 Diabetes (iADAPT Project)
The primary goal of the project is to prevent or delay microvascular complications of diabetes, an increasing prevalent disease burden.
Role: Subcontract PI; Co-Investigator