SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:*** **04/04/2016 06:37 PM**

Revised Date:

Application Number: **1 I01 HX001860-01A2**

Principal Investigator

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Applicant Organization: VETERANS HEALTH ADMINISTRATION

Review Group: **HSR6**
HSR-6 Post-acute and Long-term Care

Meeting Date: **03/03/2016** ***RFA/PA:*** **HX16-005**
Council: **MAY 2016**
Requested Start: **07/01/2016**

Project Title: **Spanish Online & Telephone Intervention for Caregivers of Veterans with Stroke**

SRG Action: **Impact Score:148 Percentile:2**

Human Subjects: **20-Human subjects involved - No exemption designated**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**

Project Year	Direct Costs Requested
1	276,739
2	262,688
3	269,355
4	291,218
TOTAL	1,100,000

KEY SUMMARY POINTS:

1. The application proposes a randomized clinical trial (RCT) of a telephone-based and online problem-solving intervention using an existing Spanish version of the VA RESCUE stroke caregiver website, compared to a usual care control. The intervention targets issues of depression, burden, problem-solving, and quality of life among Hispanic caregivers of Veterans who have suffered a stroke. This would be the first RCT of an intervention specifically for Spanish-speaking caregivers.
2. The investigators have responded well to concerns noted in the prior review. This is a well-designed study.
3. A minor concern is that the investigators will not have an objective means of tracking website access in the control group.
4. A minor concern was noted related to handling of data quality.

DESCRIPTION (provided by applicant):

Stroke is major cause of disability and a leading cause of outpatient medical utilization within the Veterans Health Administration (VHA). Non-paid caregivers, particularly family members, are the major sources of support for stroke survivors. Unlike other chronic diseases, strokes occur suddenly and family members have little time to prepare and adjust to their new, caregiving roles. Previous research has found that family members, particularly Hispanics, have high rates of depression and burden when their stroke survivors return home. Providing caregivers with culturally-appropriate information, support, and skills has the potential to reduce negative caregiver outcomes and increase the likelihood that stroke survivors remain in the community. Unfortunately, no studies have focused on support interventions specifically for Hispanic caregivers. The main objective is to test the efficacy of a brief, telephone and online problem-solving intervention, using the Spanish version of the VA RESCUE stroke caregiver website. The objectives are: 1) reduce caregiver burden and depression, 2) improve caregivers' problem-solving abilities, self-efficacy, and quality of life, 3) improve Veterans' functional abilities and determine the intervention's impact on Veterans' healthcare utilization, 4) determine budgetary impact, and 5) determine caregivers' perceptions of the intervention. The long-term goal is to partner with leaders to implement a culturally relevant, accessible, and cost-effective intervention for caregivers of Veterans post-stroke throughout the VHA. The project is guided by the relational/problem solving model of stress. A two-arm (8-session intervention vs. standard care), randomized controlled clinical trial with three assessment points will be conducted. A sample of 290 stroke caregivers will be randomly assigned to either an intervention or a standard care group. Study participants will be recruited from the VA Caribbean Healthcare System in San Juan, Puerto Rico (PR). The intervention consists of a problem-solving intervention and information/tools on the previously developed, evidenced-based Spanish-version of the RESCUE stroke caregiver website to improve stroke caregiver outcomes. The intervention will be conducted via telephone by a trained rehabilitation counselor. The intervention consists of four components: 1. Introduction to the RESCUE website and the problem-solving method; 2. Illustrative example on how to use the problem-solving approach and the RESCUE website to address caregiving problems; 3. Individualized practice exercise to develop a personalized problem-solving plan; and 4. Summary of the problem-solving method. Baseline measurements will be conducted with the caregivers prior to the intervention. Post-test assessments will be collected at 1 and 12 weeks post-intervention. In addition, we will obtain pre- and post-test measures of Veteran-related variables via CPRS electronic health records. Qualitative interviews will be conducted to assess caregivers' perceptions of the intervention. The Advisory Consortium will collaborate in all aspects of the project. A general linear mixed model for repeated measures will be used to examine the relationship between treatment assignment and each outcome over time. We will measure the budgetary impact of providing intervention by comparing the costs of the intervention group to the costs of the control group.

CRITIQUE 1

1. Significance.

The study addresses multiple areas of high priority in VHA care, including healthcare access and healthcare disparities, caregiving, and mental and behavioral health. The investigators also purport that that it is the first randomized clinical trial of a caregiver intervention designed for the Hispanic/Spanish-speaking population of caregivers of Veterans, with caregiving for stroke being the current condition being addressed. Hispanic service members comprise one of the mostly rapidly growing segments of the military, and health disparities among Hispanic Veterans were described as currently inadequately addressed.

2. Approach.

The proposed study is a randomized clinical trial of a two-site telephone-based caregiver intervention that uses a website built for caregivers for content delivery. The two sites include Gainesville, Florida and San Juan, Puerto Rico (PR) and focus on recruiting Spanish-speaking caregivers of Veterans at the PR site who have had strokes. The design is a two-arm RCT of 290 Spanish-speaking caregivers (N = 145 in each arm), with the control condition being usual clinical care. Outcomes proposed include depression, caregiver burden, positive aspects of caregiving, problem-solving orientation and style, and health-related quality of life. Veteran records accessed will include functional abilities, healthcare utilization, and VA cost data.

The intervention is an 8-session telephone intervention that guides the use of the caregiver resource website, which has a range of information and tools, including problem-solving guidelines. The intervention is heavily focused on problem-solving, reduction of stress and depressive symptoms, with additional themes of developing ways to get personal respite from caregiving and accessing resources. The intervention was previously piloted, receiving positive results assessed by within-subjects change. The Spanish-speaking VA-based web-site is currently active and openly accessible outside VA. Although there is no electronic means of obtaining use statistics of the website, self-reported use is a planned assessment for the intervention group, and both groups appear to be queried regarding accessing the resource (as well as other caregiver resources).

3. Impact and Innovation.

The innovation in this study is incremental, in that the problem-solving intervention and web-based resource information developed and tested in the English-speaking caregiver population has been adapted to a Spanish-speaking population of caregivers of Veterans. These Veterans likely speak English but may not be able to participate as fully in their own care. If successful, the intervention being tested could have a moderately high impact for this group. No similar intervention for the Spanish-speaking intervention has been developed and tested in VA in an RCT, although a previous single group, clinical intervention test that included some Spanish-speaking caregivers was previously conducted in preliminary work. The investigators note that 99% of the caregivers (as estimated from the PR population as a whole) prefer communicating in Spanish, even though the Veterans they are caring for are likely to speak English.

4. Investigator Qualifications; Facilities and Resources.

The PI and other investigators are highly qualified to conduct this study. As noted after the first round of reviews, the PR staff has been enhanced and additional changes in the involvement of the PI in the PR-based activities has been enhanced as described below.

5. Multiple PI Leadership Plan.

Not Applicable.

6. Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study.

The previous review noted that the frequency of involvement of the PI in conference calls was not detailed and appeared to be only once a month. This has been addressed by describing that all of the team members at both sites will meet twice a month in conference calls (presumably including the PI). Given that the primary responsibility and expertise necessary to conduct the study rests in the PI, this is an important change. The frequency of the research team meetings is addressed.

The investigators clarified that both groups will be queried regarding their use of various non-study resources.

Travel is now provided for in the budget request of this proposal, rather than depended on from other sources.

The concerns responding to issues of data quality were adequately addressed.

It is unclear that the budget pages list the fringe benefits correctly (i.e., they are not listed separately in their own column), but given the applicants' assurance that fringe benefits are included in the salary totals, this is primarily an administrative rather than a substantive issue.

7. Protection of Human Subjects from Research Risk.

No issues; this is a low-risk study and all potential issues of risk have been addressed.

8. Inclusion of Women and Minorities in Research.

No issues; caregivers are frequently women and highly likely to be in high proportion. The sample will be exclusively representative of Hispanic caregivers.

9. Budget.

The budget now includes travel for the study, rather than depending on HSR&D Center-provided travel funds.

10. Overall Impression.

The investigators have appropriately and thoroughly responded to the previous critiques and described them adequately, with very minor exceptions.

11. Key Strengths.

1. Highly qualified team.

2. Well-developed line of preliminary and supporting intervention work.

3. The study addresses an important area of need (disparities in caregiver burden and depression in a growing Spanish-speaking population of caregivers of Veterans.)

4. The use of combined technologies to deliver efficient, potentially effective, intervention.

12. Key Weaknesses

1. A minor weakness is the lack of electronic means of assessing the website utilization by study participants in addition to the self-report measure.

CRITIQUE 2

1. Significance.

This resubmitted IIR proposal aims to test effects of an eight-session telephone and online problem-solving intervention among caregivers of people with stroke. Investigators will also examine self-efficacy, health-related quality of life, acceptability of the intervention, costs, and Veterans' outcomes such as functional abilities and healthcare utilization. This is important work because stroke is common, and caregivers have a high burden and need education and tools to solve problems. Depression is common in this group. The Spanish-speaking population is not well studied in this regard and continues to have a high burden. The methods are significant because they provide an appropriate approach that will yield usable knowledge filling a current gap.

2. Approach.

The approach is well detailed and uses an innovative array of techniques targeting the Web site. A well designed technique has been developed and tested for providing an orientation, examples, practice exercise, and summary of the problem-solving method. The array of assessment instruments appears comprehensive and includes attention to streamlining the time requirements.

3. Impact and Innovation.

This is innovative work because the Spanish-speaking population has not been studied and targeted adequately with regard to stroke and follow-up care of stroke. Although informative Web sites are common worldwide, the methods are innovative in their systematic and detailed approach to the teaching. This could have important impact in significantly improving outcomes.

4. Investigator Qualifications; Facilities and Resources.

Investigators seem well qualified, and the Caribbean team appears well positioned and resourced to accomplish the proposed work.

5. Multiple PI Leadership Plan.

N/A

6. Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study.

The previous critique raised concerns about the PI's infrequent contact with the target site, contamination among the control group, and choice of 12 weeks as a primary measurement point. Investigators have responded well, indicating that they have increased the frequency of contact to biweekly, in addition to quarterly teleconferences and annual site visits. Contamination was addressed by targeting both study groups in assessment of informational resources used by participants. The new primary outcome time of one week following intervention has been added. Helpful details have been added to the background to support the assertions that the problem being addressed is prevalent, under-studied, and important.

A previous concern was lack of attention to handling problems with data quality. This remains an area of limited detail, as investigators indicate only that "a correction process will be implemented" if problems are discovered. They did refer to NIH quality assurance guidelines but without much detail.

7. Protection of Human Subjects from Research Risk.

Adequate.

8. Inclusion of Women and Minorities in Research.

Adequate.

9. Budget.

Adequate. Allocations of effort appear reasonable. Travel costs are included.

10. Overall Impression.

This is an innovative and useful randomized study examining the impact of a telephone-based and online intervention for caregivers of people with stroke. The problem of the caregiver's burden is common and important. The intervention has potential to improve outcomes significantly. Veterans' outcomes are included. This work could be disseminated if found to be useful. The methods are well detailed, and the team is qualified to conduct the work. Key criticisms have been addressed, especially the follow-up time and the frequency of team interaction. Some details are lacking regarding handling of data quality.

11. Key Strengths.

1. Important and common problem.

2. Intervention is well described and could improve outcomes significantly.

3. Qualified and experienced team.

4. Supportive setting.

12. Key Weaknesses.

1. Limited details about handling data quality.

CRITIQUE 3

1. Significance.

This resubmitted application proposes to conduct a randomized trial of a Spanish online and telephone intervention for caregivers of veterans with stroke. The study is significant because of stroke as a leading cause of long-term disability, greater incidence of stroke among Hispanics, the rate of caregiver depression, and growth of Hispanics as a group among veterans. Caregivers of veterans may also have to contend with co-occurring issues such as combat-related injuries/disability, PTSD, other mental health issues and lower income, which contribute to the relevance to veterans. The study addresses several VA HSR&D priority areas.

Puerto Rican veterans are a further subgroup of the subpopulation of Hispanic veterans, and obviously this limits the generalizability of findings. However, this reviewer believes the competing concern of inclusiveness also deserves merit even at the price of decreased generalizability. Otherwise, certain subgroups of veterans would be systematically excluded from reaping the benefits of research.

2. Approach.

All major components of approach, including study design, interventions, outcomes, randomization, statistical analysis and sample size justification, are described in adequate detail for review, and are reasonable and appropriate. The remaining concerns identified below are to be considered very minor.

The linear contrast to be tested B3 is misstated as B3+B4. This is likely a remnant from the previous cycle when primary outcome had been defined at 12-weeks post intervention.

A few additional exploratory analyses may offer greater insights. For example, stratifying the analyses by important veteran and caregiver characteristics may offer insights as to which type of dyad is most likely to benefit from the intervention.

3. Impact and Innovation.

The proposed study will be the first known study to test the effectiveness of an online and telephone intervention in Spanish-speaking caregivers of veteran stroke survivors. With recent increases in internet penetration to over 64%, the timing is ripe for the proposed intervention.

4. Investigator Qualifications; Facilities and Resources.

Excellent team of investigators with substantial experience. They have conducted 12 prior studies that have contributed to the design of the proposal, including a one-arm pilot trial of the proposed intervention.

5. Multiple PI Leadership Plan.

Not applicable.

6. Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study

Investigators have adequately responded to the prior critiques. They have proposed the immediate post-intervention time at one week after intervention as the primary endpoint to maximize the likelihood of success. They have also proposed the Stroke Impact Scale as a measure of function, which alleviates the known ceiling effects of the Barthel Index.

7. Protection of Human Subjects from Research Risk.

Acceptable. Investigators will use the HSR&D DSMB as a trial monitoring mechanism.

8. Inclusion of Women and Minorities in Research.

Acceptable. The focus of the project is a minority population.

9. Budget.

Acceptable.

10. Overall Impression.

This proposal has high significance and innovation as outlined above. The methodological concerns have been adequately addressed in the current resubmission. The focus on a narrow subgroup of veterans and the generalizability concern should be overlooked in favor of a more equitable distribution of the benefits of research to all veterans. This reviewer has a high level of enthusiasm for the proposed project.

11. Key Strengths.

1. High rates of depression in Hispanic caregivers, growing numbers of Hispanics in the veteran population, and greater challenges faced by caregivers of veterans due to unique concomitant conditions constitute a compelling rationale and contribute to the significance.

2. No known similar prior trials adds to the innovation.

3. Excellent team of investigators with prior experience have completed several studies that set the stage for the proposed trial, including a pilot study of the same intervention.

4. Methodological concerns raised in prior submissions have been addressed adequately.

12. Key Weaknesses.

None

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.