PROTOCOL COVER PAGE

OFFICIAL TITLE OF THE STUDY: The Senior Companion Program Plus (SCP Plus): A Psychoeducational Intervention for African American Dementia Caregivers

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Informed Consent/Assent Document

[Researcher to read aloud the following form.] My name is [researcher's name].

PRINCIPAL INVESTIGATOR
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TITLE OF PROJECT
The Senior Companion Program Plus (SCP Plus)

INTRODUCTION

You are being asked to participate in a research study that addresses the needs of African American dementia caregivers who may experience caregiver burden and/or stress. Cultural issues in caregiving may also be important to consider in caring for a person with dementia. Your participation is voluntary. If you choose not to participate, or decide to withdraw your participation at any time, you will not be penalized or lose the benefits you would otherwise be given. Please ask questions if there is anything that you do not understand.

PURPOSE

The specific purpose of this research study is to deliver and evaluate a new program designed for African American dementia caregivers. The program is called the Senior Companion Program Plus (SCP Plus).

DURATION

Participation in this study will last approximately 6 months. Study participants will be randomly put in either the new program group (SCP Plus) or the comparison group (services as usual from the Senior Companion). If you are randomly put in the SCP Plus group, you will be asked to participate in a 9-week program over a 3-month period (1 session per week). There will be a follow up visit with you 6 months after you complete the study.

If you are randomly put in the comparison group, you will receive services as usual as part of the Senior Companion Program for the entire 6 month study period.

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NUMBER OF PARTICIPANTS

The number of anticipated participants in this research study is 300.

PROCEDURES

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Study participants will be randomly put in either the SCP Plus group or the comparison group (services as usual). You will be put in only one group.

If you are randomly put in the SCP Plus, the procedures which will involve you as a research participant include:

1) Completing a pre-test survey prior to the start of the 9-module program. Items on the survey will ask you a vareity of questions related to your experience as a caregiver including items about caregiver stress/burden, coping skills, social support, and cultural issues related to caregiving. For example, you will be asked about the challenges that you may (or may not) face as a dementia family caregiver. A member of the research team will call you and ask you these questions over the phone at a time that is convenient for you.

2) Participating in a 9-week program (1 session per week). Every week for 9 weeks, your Senior Companion will meet with you for one hour to share and discuss topics related to dementia and family caregiving. The Senior Companion will also be providing their usual services to your loved one during the 9-weeks. The only difference is that as part of the SCP Plus group you will receive one hour per week of one-on-one time with your Senior Companion to learn and share about dementia caregiving. You will also have a SCP Plus book that will guide you through each module.

The SCP Plus modules will contain information about:

- Facts about Alzheimer's Disease and dementia
- Home care and home safety for a person with dementia and their caregivers
- Managing problematic behaviors related to dementia
- Communication skills

- Information about community-based services and supports
- Coping skills
- Cultural beliefs and traditions related to caregiving
- Strengthening and enhancing the meaning of caregiving

3) Half of the SCP Plus sessions will be audio-recorded in order to ensure quality and consistency of the SCP Plus.

4) At the close of each module, the Senior Companion will ask you to reflect on the content of the module, which will be written down in the form of brief notes by the Senior Companion. For example, the Senior Companion will ask you what you learned most in the module, what you liked best about the module, etc.

5) Completing a post-test survey after the completion of the the 9-module program. Items on the survey will be the same as those on the pre-test. A member of the research team will call you and ask you these questions over the phone at a time that is convenient for you.

6) Completing a 6-month follow up survey that will include the same items as those on the pre and posttest surveys and will include additional open-ended questions (audio recorded) to explore your experiences with the SCP Plus. For example, the open-ended questions will ask you about what you learned from the SCP Plus and about the skills that you may (or may not) have used from the SCP Plus to cope with the challenges of dementia family caregiving.

<u>If you are randomly put in the comparison group</u>, the procedures which will involve you as a research participant include:

1. You will not be part of the SCP Plus program but you will continue to receive services as usual from your Senior Companion during the 6-month duration of the study.

POSSIBLE BENEFITS
By participating in this study, you will be providing important information to help evaluate the SCP Plus for African American dementia family caregivers. Your participation in this study will also contribute to enhancing the Senior Companion Program.

POSSIBLE RISKS/DISCOMFORTS

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There are no perceived risks or discomforts for participating in this research study. Should you experience any discomfort please inform the researcher, you have the right to quit any study procedures at any time at no consequence.

COMPENSATION

If you are randomly put in the SCP Plus group, you will be offered a $10 Wal-Mart gift card for each completed module as well as a $10 Wal-Mart gift card for each completed study survey (e.g. pre, post, follow up). The total opportunity for compensation for the caregivers is $120.00 in the form of Wal-Mart gift cards. Gift cards will be distributed at the agency (where your Senior Companion is a volunteer) halfway and at the end of the 9-week SCP Plus.

If you are randomly put in the comparison group, you will be offered a $10 Wal-Mart gift card for each pre/post/follow up test during 6-month study period. The total amount of incentive for participants in the comparison group is $30 in the form of Wal-Mart gift cards. Gift cards will be distributed at the agency (where your Senior Companion is a volunteer) halfway and at the end of the 9-week SCP Plus.

If you decide to withdraw from the study at any time, partial payments will be provided to you. Partial payment will be calculated using the hourly rate for the family caregivers in this study ($10/hour).

All participants are responsible for reporting research payments to the IRS.

ALTERNATIVE PROCEDURES

There are no alternative procedures offered for this study. However, you can elect not to participate in the study or quit at any time at no consequence.

If your Senior Companion in the study decides to withdraw from the study, this means that you will automatically withdraw as there is no way to reassign you to a new Senior Companion. Senior Companions and family caregivers are matched by the agency as part of the Senior Companion Program, not by the research team invovled with the SCP Plus.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You have the right to decline participation in any or all study procedures or quit at any time at no consequence. Should you choose not to complete all study procedures, you will still receive the gift card for the module/s that you have completed. Your participation in this research study will not impact any

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services that you are currently receiving or may receive in the future from the Senior Companion Program.

CONFIDENTIALITY

Every attempt will be made to see that your study results are kept confidential. A copy of this verbal assent form and all data collected including digital files from this study will be stored in the locked offices of Dr. Noelle Fields in the UT Arlington School of Social Work for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a participant. Additional research studies could evolve from the information you have provided, but your information will not be linked to you in anyway; it will be anonymous. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the UTA Institutional Review Board (IRB), and personnel particular to this research will have access to the study records. Your records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as noted above. The IRB at UTA has reviewed and approved this study and the information within this consent form. If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, the University of Texas at Arlington will protect the confidentiality of those records to the extent permitted by law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report elder abuse or neglect). The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of elder abuse or neglect.

CONTACT FOR QUESTIONS

Questions about this research study may be directed to Dr. Noelle Fields at (614) 947-9783. Any questions you may have about your rights as a research participant or a research-related injury may be directed to the Office of Research Administration; Regulatory Services at 817-272-3723 or regulatoryservices@uta.edu.

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As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

_____

Signature and printed name of principal investigator or person obtaining consent **Date**

_____

Printed name of participant (to be completed by study representative) **Date**

ASSENT FOR PARTICIPANT

By saying yes to participate, you are saying that you had this entire paper read to you and you confirm that you are 18 years of age or older. You have been informed about this study's purpose, procedures, and possible benefits and risks. You have been given the opportunity to ask questions before you say "yes," and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By say "yes" to this form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

If you verbally agree, please say so.

Do you agree to audio recording as part of the SCP Plus sessions? If you verbally agree, please say so.

AUDIO RECORDING OF SESSIONS (Check one) ☐ Yes ☐ No

Do you agree to audio recording as part of the 6-month follow up interview? If you verbally agree, please say so.

AUDIO RECORDING OF 6-MONTH FOLLOW UP (Check one) ☐ Yes ☐ No

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