Caregiver Self-Management Needs Through Skill-Building

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Informed Consent Form

UNIVERSITY OF Cincinnati

Adult Consent Form for Research
University of Cincinnati
Department: College of Nursing
Principal Investigator: Tamilyn Bakas

Title of Study: Caregiver Self-Management Needs through Skill-Building

Introduction:
You are being asked to take part in a research study. Please read this paper carefully and ask questions about anything that you do not understand. This research is sponsored by the University of Cincinnati (UC) and the College of Nursing. This research is also sponsored by the National Institute of Nursing Research (NINR).

Who is doing this research study?
The person in charge of this research study is Dr. Tamilyn Bakas of the UC College of Nursing. There may be other people on the research team helping at different times during the study.

What is the purpose of this research study?
The purpose of this study is to test a program for family caregivers of stroke survivors. The program is called the Telephone Assessment and Skill-Building Kit (TASK III). The TASK III program will be compared with an Information Support and Referral (ISR) program.

Who will be in this research study?
About 74 family caregivers of stroke survivors will take part in this study. Family caregivers are family members or close friends caring for a person with stroke. Whether or not you take part in this study will not affect the care that you or your family member will receive from your healthcare providers.

What will you be asked to do in this research study, and how long will it take?
If you are eligible, you will be asked to take part in a baseline data collection interview. The baseline interview will take place by online videoconferencing or by telephone. The baseline interview will last about 60 minutes. You will be asked about:

- your age, gender, race, and your background
- the care that you provide for the stroke survivor
- your health and well-being

Once the baseline interview is completed, you will be randomized to either the TASK III group or to the ISR group. Randomization is like "flipping a coin."

The TASK III group will receive a TASK III Resource Guide that we developed and 8 weekly calls from a nurse. The nurse will call again a month later. The TASK III nurse will help you assess your needs and concerns, build your skills as a caregiver, and refer you to community resources.
The ISR group will receive an American Heart Association brochure and 8 weekly calls from a nurse. The nurse will call again a month later. The ISR nurse will provide information, support,

and referral to community resources.
The TASK III and ISR calls are expected to last about 15 to 60 minutes each. The TASK III and ISR calls will take place by online videoconferencing or by telephone based on your preference. The TASK III Resource Guide and ISR materials (American Heart Association brochure) will be mailed as hard copies. You may also receive these materials in other formats (e.g., USB drive, website, iBook, eBook). In addition, you will receive a pedometer to track your daily steps.

You will be asked to take part in two follow up data collection interviews. One will occur after the 8 weekly calls with the nurse (8 weeks), and the other after the booster call with the nurse (12 weeks). These two data collection interviews (8 weeks, 12 weeks) are similar to the baseline interview, and are expected to last about 60 minutes each.

Overall, there will be 3 data collection interviews (baseline, 8 weeks, 12 weeks) lasting about 60 minutes each and up to 9 TASK III or ISR calls with a nurse lasting about 15 to 60 minutes each. All interviews and calls will be made using online videoconferencing or telephone based on your preference.

Are there any risks to being in this research study?
Some questions may make you feel uncomfortable. You can refuse to answer any questions that you don't want to answer. The risk is not expected to be more than you would have in daily life.

Are there any benefits from being in this research study?
You will probably not get any benefit from taking part in this study. But, being in this study may help caregivers better understand their needs.

What will you get because of being in this research study?
You will not be paid to take part in this study. You will be able to keep the pedometer and the TASK III or ISR materials given to you during the study.

Do you have choices about taking part in this research study?
If you do not want to take part in this research study you may simply not participate. Your participation in this study is completely voluntary. You may withdraw at any time.

How will your research information be kept confidential?
Calls with you will be made from a private location. Information sent by the internet, email, texting, online videoconferencing, or other electronic methods (e.g., website, Facebook, iBook), may not be private. The data collection interviews and TASK III and ISR calls with the nurse will be audiotaped. Audiotapes will be erased as soon as they are transcribed or checked for how well the data collectors and nurses interact with you. Your name will not be used on any typed transcripts or data collection forms. A study ID number will be used instead of your name. Your name and contact information will be stored separately from the transcripts and research forms. All data will be kept on a password-protected computer, password-protected secure REDCap, Box, OneDrive, or research drive at the University of Cincinnati, or in locked file cabinets. Within 3 years after the study is over, all research data will be de-identified. Your information

will be kept confidential, unless authorities have to be notified about abuse or immediate harm that may come to you or others. If you or the stroke survivor have a health issue, you will be encouraged to contact a healthcare provider. In an emergency, a healthcare provider or the emergency medical system may be contacted on your behalf. Agents of the University of Cincinnati may inspect study records for audit or quality assurance purposes. A description of this clinical trial will be available on 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.

What are your legal rights in this research study?
Nothing in this consent form waives any legal rights you may have. This consent form also does not release the investigator, the University of Cincinnati, the institution, or its agents from liability for negligence.

What if you have questions about this research study?
If you have any questions or concerns about this research study, you should contact Dr. Tamilyn Bakas at 513-558-2254, tamilyn.bakas@uc.edu. If you would like further information mailed to you after the study is over, please contact Dr. Bakas. The UC Institutional Review Board reviews all research projects that involve human participants to be sure the rights and welfare of participants are protected. If you have questions about your rights as a participant, complaints and/or suggestions about the study, you may contact the UC IRB at (513) 558-5259. Or, you may call the UC Research Compliance Hotline at (800) 889-1547, or write to the IRB, 300 University Hall, ML 0567, 51 Goodman Drive, Cincinnati, OH 45221-0567, or email the IRB office at irb@ucmail.uc.edu.

Do you HAVE to take part in this research study?
No one has to be in this research study. Refusing to take part will NOT cause any penalty or loss of benefits that you would otherwise have. You may start and then change your mind and stop at any time. To stop being in the study, you should tell Dr. Tamilyn Bakas 513-558-2254, tamilyn.bakas@uc.edu. BY TAKING PART IN THIS RESEARCH YOU INDICATE YOUR CONSENT FOR YOUR ANSWERS TO BE USED IN THIS RESEARCH STUDY.

Agreement:
I have read this information and have received answers to any questions I asked. I give my consent to participate in this research study. I have received a copy of this signed and dated consent form to keep.

Participant Name (Please Print): _____

Participant Signature: _____ Date: _____

PLEASE RETURN THE ORIGINAL AND KEEP THE COPY OF THIS INFORMED CONSENT FORM FOR YOUR REFERENCE.
>>>>> ***SEE NEXT PAGE FOR ADDITIONAL QUESTION*** >>>>>

Are you willing to be contacted about opportunities to participate in future studies?

_____ No

_____ Yes:

Name: _____

Phone number(s): _____

Best time to reach you? _____

Email address(s): _____

Thank you.