**Informed Consent Form**

**Protocol Title:** Efficacy of a Virtual Intervention for Informal Caregivers of Adults with Frontotemporal Dementia

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# UNIVERSITY OF PENNSYLVANIA
# RESEARCH SUBJECT
# INFORMED CONSENT FORM

**Protocol Title:** **Efficacy of a Virtual Intervention for Informal Caregivers of Adults with Frontotemporal Dementia**

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## Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to evaluate the efficacy of a virtual support intervention to reduce stress and poor self-care for caregivers of persons with behavioral variant Frontotemporal Degeneration (bvFTD) compared to receiving health information alone.

If you agree to join the study, you will be asked to complete questionnaire assessments of self-care, perceived stress, coping, and health status at the baseline visit and by phone at the 3- and 6-month follow-ups. At baseline and 3 and 6 months you will also be asked to complete

assessments of self-care, stress, coping, health status, depression, and burden. A brief cognitive exam will be administered at the baseline visit.

You will be randomly assigned to one of two study groups. One of the study groups will receive access to an internet site providing health information. The other group will receive 10-sessions of virtual health coaching in addition to the internet sites providing health information. These sessions will be completed using a computer tablet that will be provided to you by the research staff.

Your participation will last for 6 months.

The most common risks of participation are fatigue and stress.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

## Why am I being asked to volunteer?

You are being invited to participate in this study because you are the primary caregiver to someone diagnosed with bvFTD or you are a patient diagnosed with bvFTD.

If you decide to participate, you will be asked to sign this form. The study is being conducted through the Penn School of Nursing and the Penn School of Medicine.

Your provider may be an investigator in this research study. You do not have to participate in any research study offered by your provider. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your provider is interested both in your clinical welfare and in the conduct of this study.

## What is the purpose of the study and why was I asked to participate?

Caregivers of adults with dementia report stress and poor self-care. Virtual Caregiver Coach for You (ViCCY [“Vicky”]), a support intervention, may relieve stress and promote self-care in dementia caregivers. Even less is known about the effect of caregiver support interventions on dementia patient outcomes. We don’t know if this intervention will relieve stress and promote self-care in dementia caregivers. This study will help develop and inform our understanding of how to help those caregivers.

You are being asked to join this study because you have been diagnosed or are the primary caregiver of someone who has behavioral variant Frontotemporal Degeneration (bvFTD). Your participation is voluntary, which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this

consent form to read. You may also decide to discuss it with your family, friends, or family doctor.

## How long will I be in the study?

The study will take place over a period of 6 months. This means for the next 6 months we will ask you to spend at least 4-5 days a month participating in this study. Each session will last approximately 1-2 hours.

## Where will the study take place?

The initial session may be done virtually or in person. This may be at the Hospital of the University of Pennsylvania. If you cannot come to the hospital but would still like to participate, a member of the study team can conduct the session virtually. The remainder of the study will be done remotely. Data will be collected virtually by a member of the research team. If you are assigned to a group that receives coaching, coaching sessions will be done virtually, at your convenience, not in person.

## What will I be asked to do?

You will be asked to provide data to the study team during 4 study sessions (baseline, and 1-, 3- and 6-month follow-up sessions) in the form of questionnaires. You may receive coaching from a trained member of the research team over the 6 months in the study.

Baseline:
This session may be done virtually or in person. You will both meet with a member of the research team to learn about the study and determine whether you are eligible to participate. If you are eligible you will be randomly assigned to one of two study groups. The caregivers in one study group will receive access to an internet site that provides health information content. The other group of caregivers will receive the same access to health information plus 10-virtual health coaching sessions by trained health coaches for the 6 months you are in the study. These sessions will be completed using a computer tablet that will be provided to you by the research staff.

Additionally, caregivers will be asked to complete questionnaires to measure social determinants of health, self-care, stress, coping, health status, relationship mutuality, depression, and burden.

Patients will complete two brief cognitive measures, an assessment of functionality and behavioral symptoms.

Follow-up:
At 1, 3 and 6 months, caregivers will be asked to provide follow-up data on self-care, stress, coping, health status, depression, burden, relationship mutuality, and work status.

Intervention Groups:
Caregivers in the *Health Information* group are asked to spend at least 30 minutes weekly using the computer tablet provided to you by the study team to access recommended websites.

Caregivers in the *Health Information + Health Coaching* group will also receive ViCCY, with 10 virtual coaching sessions during the 6-months in the study. Session will be weekly at first with decreasing frequency over time. All sessions are scheduled at your convenience. The focus of these sessions is helping you take care of yourself.

The audio of these sessions are recorded to ensure the quality of the intervention. These audiotapes will be transcribed for analysis and then destroyed. After the 6-month follow-up, a member of the research team will collect the computer tablet.

## What are the risks?

You may experience fatigue during enrollment at baseline or during one of the follow-up sessions. To minimize the most likely risk of fatigue during data collection, we selected surveys that are as short as possible. Completion of the self-report survey packet requires less than one hour. Testing will be scheduled at a time that is convenient for you. If you are too fatigued to complete all measures, we can separate the surveys administered into different visits, but all data must be provided *before* randomization and within a 2-week period.

You may become stressed during data collection because of the questions asked, the burden of data collection, or for other personal reasons. If you become stressed, data collection will be terminated, delayed, or abbreviated to only essential items. Significant stress will be reported to the Project Manager who will contact you to discuss the issue if indicated.

Since this data storage system is behind multiple firewalls, is monitored regularly, and is accessible only to key personnel who receive private network/firewall, server/password, and data directory access rights, the risk of unlawful penetration is not a significant data safeguard concern.

## How will I benefit from the study?

There is no direct benefit to you. However, your participation could help us understand the efficacy of ViCCY, which can benefit you indirectly. In the future, this may help other caregivers to reduce stress and burden.

## Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for participants. Research results will not be returned to you. Research results will not impact the clinical care of you or the person to whom you are caregiver.

## What other choices do I have?

Your alternative to being in the study is to not be in the study.

## What happens if I do not choose to join the research study?

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. Your therapist, social worker, nurse, doctor will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

## When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health - you will be informed of the reasons why.
- You have not followed the study instructions.
- The PI, the sponsor or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime.

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact **Dr. Barbara Riegel** at **215-898-9927** or briegel@nursing.upenn.edu or your primary point of contact for the study to notify them of your decision to withdraw. There is no risk or penalty to you for withdrawing from the study.

## Can I change my mind about giving permission for use of my information?

You may withdraw from the study for any reason simply by explaining this to the Principal investigator or a member of the study team. If you decide not to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

You may also withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

## How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

To protect your personal information, all data forms will be coded with unique identifiers. The unique identification number will be kept separate from the files with protected health information (PHI) to protect your confidentiality. Every effort will be made to prevent anyone who is not on the research team from knowing what information was collected from you.

An exception to confidentiality is if you report child or elder abuse or neglect, or if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

***Future Use of Data***

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

**What is an Electronic Medical Record and/or a Clinical Trial Management System?**

We will collect information on the patient from the Electronic Medical Record (EMR), an electronic version of the record of care within the health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

## What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

## Will I have to pay for anything?

You will not have to pay anything to participate in this study.

## Will I be paid for being in this study?

Yes, caregivers will receive $25 at enrollment, $25 at 3 months, and $75 after the 6-month data are provided and your tablet is returned. That is, you will receive $125 for full participation.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is

required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

**Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with **Dr. Barbara Riegel** at **215-898-9927** or briegel@nursing.upenn.edu. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (215) 898 2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

| Printed Name of Caregiver | Signature of Caregiver | Date |
|---|---|---|

| Printed Name of Patient | Signature of Patient | Date |
|---|---|---|

| Printed Name of person obtaining consent | Signature of person obtaining consent | Date |
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