Optimizing efficiency and impact of digital health interventions for caregivers:
A mixed methods approach

ClinicalTrials.gov NCT04986904

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the NIH.

Key Information About This Research Study

Principal Investigator:	Kelly M. Shaffer, PhD PO Box 801075 Charlottesville, VA 22908 Ph: 434-982-1022 Email: kshaffer@virginia.edu Fax: 434-244-7516
Sponsor:	NIH

Many people who care for a loved one because of health conditions or disabilities experience sleep problems. Our research team developed and tested an online insomnia treatment called SHUTi (Sleep Healthy Using the Internet). It was tested and was successful in helping adults in the general population. It was not customized for caregivers.

The purpose of the study is to better understand the unique sleep problems that occur when caregiving. We also want to understand how well SHUTi treats these sleep problems for caregivers.

You are being asked to be in this study because you provide unpaid care (practical, medical, and/or emotional support) to a family member or "family-like" close person, and you have problems sleeping. You might like to take part in this study because your sleep may improve from using the SHUTi program. Your taking part in this study may benefit future caregivers.

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision. Taking part in this study is not expected to interfere with, nor should it replace, any usual care you are receiving.

Up to 130 people will be in this study.

What will happen if you are in the study?

STUDY PROCEDURES

This entire study from this moment to the final thing you do will last about three months. Everything in the study takes place by telephone or online with secure websites, so you never have to come to our office in person. We will help you through each phase of the study, answering any questions you have.

Study Schedule

Step	Weeks	Study Phase	What will I do?	Time required?
1	0	Screening	Complete Interest Form Review/Sign Consent Form Phone Interview	40 minutes
2	2	Pre-Assessment	Answer survey questions 10 sleep diaries in 14 days	30 minutes 3 minutes
3	3-12	Intervention	Use SHUTi	
If you complete any of the SHUTi program "Cores":				
4a	12	Post-Assessment	Answer survey questions Enter 10 sleep diaries in 14 days	30 minutes 3 minutes
If you do not complete any SHUTi program "Cores":				
4b	12	Post-Assessment	Answer survey questions	10 minutes

SCREENING (PHONE INTERVIEW)

- The Study Coordinator will call you at your appointment time.

- We will ask you to identify yourself. We will review the study's requirements, which include your duties as a caregiver. You can discuss any questions or concerns you may have about participating in the study.
- If you agree to take part, you will do the following:
    - We will email you to access the online consent form.
    - We will go through the consent form with you to make sure you have all the information about the study and have had all of your questions answered.
    - You will digitally sign your name to consent to be in the study.
    - You will be able to download a copy of the consent form. We will store the document in our database as well.
- Next, we will ask you more questions about being a caregiver, your sleep habits, your health, and health history. You will also be asked questions about your feelings (whether you feel irritable) and lifestyle habits (alcohol and substance use).
- If you are eligible for the study, you will be sent a Welcome email with instructions for setting your password for the SHUTi program.
- If you are not eligible for the study, you will be told at that time.

PRE-ASSESSMENT

- Using your email and password, you will sign in to the study website.
- Survey questions: You will answer questions online about your general health, mental health, sleep habits, caregiving responsibilities, and daily life activities.
    - If you have any concerns about the questions, please contact the Study Coordinator.
    - You will receive reminder emails to answer the questions.
    - Press the submit button at the end of the survey questions when finished to advance to the Sleep Diary phase.
- Sleep Diaries: You will record your sleep online by entering Sleep Diaries every day for two weeks.
    - You must enter at least 10 diaries in 14 days to complete this activity with success.
    - You will receive daily reminder emails from SHUTi to complete the Sleep Diaries.
- After you have completed both, the program advances you to the SHUTi intervention. You will have access to the program for the next nine (9) weeks. It is not a required part of the study to use the program, but it has helped other adults improve their sleep. We

would value your opinion about whether it is useful to you as a caregiver. If you decide you would like to use the program, you should start it immediately after completing your sleep diaries.

INTERVENTION (9 weeks):

You will receive access to the SHUTi intervention after you answer the survey questions and complete the sleep diaries.

SHUTi Internet Intervention:

You will have access to a website program designed help to improve your sleep. The program is made up of six "Cores," which are like chapters in a book. Cores are completed one at a time, in order. Each Core is expected to take 45 to 60 minutes to complete.

Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. You will receive automated emails encouraging you to complete tasks. You will be asked to complete weekly to dos and enter daily Sleep Diaries to track your sleep.

It may take you up to one week to complete a Core. After you complete a Core, you will have one week to review and practice what you learned. Seven days later the next Core will unlock so you can open it to start it. To review and follow the recommendations may take you another 30 to 45 minutes.

POST-ASSESSMENT:

If you complete one or more Cores in SHUTi, you will repeat the same process as you did in the Pre-Assessment.

- Survey Questions: At the end of the 9-week intervention period, you will answer the Post-Assessment Survey Questions. You will log on to the study website and answer questions about your sleep, activities, health, and well-being.
- Sleep Diaries: You will record your sleep by entering Sleep Diaries online every day for two weeks. You must enter at least 10 in 14 days to complete this activity with success.
- You will receive reminder emails about completing the Post-Assessment surveys. You will also receive reminders to complete the daily diaries.
- You can continue using SHUTi for the entire study period.

If you did not complete any Cores in SHUTi, you will be asked to provide feedback regarding why on a brief survey.

- Survey Questions: You will be asked to answer some brief questions about why you did not complete any activities in SHUTi and about your sleep.
- You will receive reminder emails about completing the Feedback Survey.

How long will this study take?

The total time to complete all phases of this study is not expected to exceed 4 hours. Your taking part in this study will require the completion of screening, answering survey questions, and doing the SHUTi intervention at your convenience. Time spent on the SHUTi intervention is not included in the time estimates, and the amount of time you spend during the study may vary depending on how much you use the program. All parts of this study will be completed remotely, by Internet or phone.

If you want to know about the results before the study is done:

During the screening phase, your study leader will let you know of any test results that may be important to your health. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to answering the survey questions and completing the intervention include:

<u>Breaches of privacy and/or confidentiality</u>

- The risk of a violation of privacy and confidentiality is rare. This means someone outside of the study team may see your private health information. The study team will take precautions to treat your information as highly sensitive.

<u>Emotional discomfort due to</u>:

- **Internet concerns**

  Some adults may not have concerns doing online activities (going to a website, giving information, etc.). Rarely, some others may feel less comfortable doing this or have concerns about the confidentiality of their digital data.

- **Answering questions of a personal nature**

  Questions of a sensitive and personal nature will be asked during the study during the initial phone call. These include questions about your health history and substance use. This may cause some likely emotional discomfort for some. In rare instances, if the study team is concerned about you, you may be referred to someone for counseling.

Risks from Completing Survey Questions:

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them in rare instances. If you do not wish to answer a question, you may skip it and go to the next question.

Increased tiredness due to restricted time in bed:

- You may contact us if you have significant concerns. We will provide recommendations based on your situation.
- You will be told to avoid operating a car or other heavy machinery when you feel tired.
- We will instruct you to contact your primary care provider or seek professional help at a sleep clinic if needed.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would be determined by your physician.

Will you be paid for being in this study?

You will be paid up to $80 in gift cards for finishing this study. You will be paid based on your completion of the following:

- $40 gift card after the Pre-Assessment
- $40 gift card after the Post-Assessment

All payments will be sent via email, within about a week after you complete the assessment. You will not be paid if you decide not to finish an assessment. However, if the study leader decides you should not continue, but you followed the steps in the timeline presented, you will be paid the full amount for the study.

Will being in this study cost you any money?

Being in this study will not cost you any money. The surveys and intervention are being done for research purposes, and will be provided at no cost to you or your health insurance. Standard text messaging and data usage rates apply should you use a mobile device to complete any part of this study, and you will not be compensated if you go over your plan's limit.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance

does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. You will be notified if this occurs.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, phone number, email address, and year of birth

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of

Virginia. They will not be sent with information that could identify you such as name, address or phone number.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you stopped being in the study.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVA to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483, Charlottesville, Virginia 22908, Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (HSR210255), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Communicating with the study team by email or text message

You must be willing to be emailed as part of this study, but you do not have to agree to communicate with the study team by text message to be in this study. By communicating with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.

If you agree to texting, the study team will collect your phone number from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE