UT Austin IRB Approved
Protocol Number: 2019-02-0064
Approved: 07-15-2019

Title of the Project: Assessing The Utility and Effectiveness of Monitoring Technology for Reducing Caregiver Burden for Alzheimer's Disease
Principal Investigator: Robin Hilsabeck, PhD, Associate Professor of Neurology
Study Sponsor: Texas Alzheimer's Research and Care Consortium (TARCC)

Consent to Participate in Research

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

What is the study about and why are we doing it?

The purpose of the study is to examine the usability of and satisfaction with a GPS-based watch provided by a company called Theora Care. It is hoped that use of this technology will reduce burden experienced by family members and help keep persons with cognitive impairment safe.

About 70 dyads of caregivers and care recipients with cognitive impairment will be enrolled in the study and followed for three months. The data collected in this research study will be kept confidential to the extent allowed by the law. Your participation is completely voluntary. You may decide not to begin or to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. You can ask all the questions you want before you decide.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to participate in an enrollment visit, two phone calls and a three-month post-survey. During the enrollment visit (approximately one hour in length), you and your care recipient will be screened for eligibility to participate in the study. If eligible, your care recipient will be given a Theora Care watch, and you will be given access to the Theora Care smartphone application and instructions on how to use the tool. The Theora Care system will allow you to monitor the location of your care recipient, set safe zones (to minimize the need for direct supervision), and initiate two-way voice communication between you and your care recipient. You must agree to the Theora Care terms and conditions to use the watch and the smartphone application. The system will collect the information about your use of the watch and app, safe zones, and two-way communications. At each contact, investigators will ask questions about you and your care recipient. The information to be studied includes your year of birth, gender, and medical history and your care recipient's age of onset of cognitive impairment and cognitive test results. There will be two intermittent telephone calls (10-15 minutes in length) at the first week and first month to provide you technical assistance and assess the usability, satisfaction, and recommendations for technology enhancements, as well as any changes in the status of care recipient. At the beginning of each phone call, the investigators from our coordinating site, Texas A&M will ask for your permission to record the phone call. However, the recording is not mandatory. Between the enrollment visit and three-month post-survey, you will receive 4 automated e-mails and your care recipient will be asked to

wear the Theora Care watch, and you will be asked to use the Theora Care app. The three-month post-survey will be approximately 30 minutes in length.

How long will you be in this study and how many people will be in the study?

Participation in this study will last approximately 3 months, total time completing study requirements is approximately 2 hours. Our site will recruit about 30 care recipients and their caregivers for a total of 60 participants.

What risks and discomforts might you experience from being in this study?

There are some risks your care recipient might experience from being in this study. Care recipients may experience discomfort or agitation from wearing the device. However, there is no more risk than wearing any other type of devices, such as a Smart Watch or Fit Bit. The watch is removable and the care recipient may take it off upon experiencing any discomfort or at any time they prefer.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

If effective, the Theora Care watch may reduce your caregiving burden and distress by keeping you informed about the location of your loved one and allowing you to communicate easily if he or she ventures out of a safe zone.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect data from you such as: name, address, date of birth, email, and phone number. This information will be kept on a password-protected and encrypted spreadsheet. We will also use online surveys to collect information from you such as: alcohol use, depression history, current medications, medical history, and mental health history. Note that our survey platform contains an “anonymize” feature to prevent the collection of your IP address.

We will also collect data from your care recipient’s smart watch such as: amount of time watch is worn, number of push messages received, number of preset safe zones, distance of safe zones, and the number of connections made between you and your care receiver. This information will be collected and analyzed by our coordinating site, Texas A&M University.

How will we protect your information?

We will protect your information by keeping all written study-related materials in a locked filing cabinet behind a secure door here at the Cognitive Disorders Center at UT Health Austin. Electronic data will be kept on a password-protected encrypted spreadsheet. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the sponsor **Texas Alzheimer’s Research and Care Consortium (TARCC)**
- Representatives of UT Austin and the UT Austin Institutional Review Board

- Other collaborating organizations **Texas A&M University, and the University of North Texas Health Science Center**

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers may include information that can directly identify you. Researchers will not contact you for additional permission to use this information.

Texas A&M University will have access to your data because they are the coordinating site for this research project. Their research team members will be available to you for support throughout the project. They also may reach out to you to ask you questions about your use of the watch.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

Under certain circumstances, we may break confidentiality. If during the study we learn about elder abuse, neglect, or exploitation we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research or analysis. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

How will we compensate you for being part of the study?

You will be mailed or e-mailed a $25 HEB gift card for your participation in the study. Payments will occur upon completion of the post-test questionnaire at the end of the three months. You will be responsible for any taxes assessed on the compensation.

In addition, your care recipient will be allowed to keep the smart watch and receive an additional 6 months of free service (valued at over $200) following completion of the study. If you decide to withdraw from the research before the end of the study, your care recipient will still be allowed to keep the smart watch and receive the additional 6 months of service. However, you will not receive the HEB gift card if you discontinue the study before completing the three-month follow-up assessment.

What other choices do you have if you do not take part in this study?

The alternative to participation is not to participate. The watch and app are commercially available.

Your Participation in this Study is Voluntary

It is your choice to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin or your healthcare provider. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your

mind and stop at any time. You do not have to answer any questions you do not want to answer.

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back this permission, the researchers may still use or disclose health information they have already collected about you for this study. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study. If you take back this permission you may no longer be allowed to participate in the research study. To take back this permission, you must write to the Principal Investigator. If there has been no activity on the watch for 1 week, you will receive up to three phone calls from researchers at our coordinating site, Texas A & M University. If there has been no activity for 2 weeks, you will be automatically withdrawn from the research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Robin Hilsabeck, PhD
Phone: 512-495-5553
Email: robin.hilsabeck@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference study number 2019-02-0064

Your Consent

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records. If you have any questions about the study later, you can contact the study team using the information provided above.

_____

Signature of Person Obtaining Consent Date

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Printed Subject Name

Signature Date

TEXAS
The University of Texas at Austin

UT Austin IRB Approved
Protocol Number:2019-02-0064
Approved: 07-15-19

Title of the Project: Assessing The Utility and Effectiveness of Monitoring Technology for Reducing Caregiver Burden for Alzheimer's Disease
Principal Investigator: Robin Hilsabeck, PhD, Associate Professor of Neurology
Study Sponsor: Texas Alzheimer's Research and Care Consortium (TARCC)

Consent to Participate in Research

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

What is the study about and why are we doing it?

The purpose of the study is to examine the usability of and satisfaction with a GPS-based watch provided by a company called Theora Care. We want to understand if this technology will help family members of people with memory or thinking problems. It is hoped that use of this technology will reduce burden experienced by family members and help keep persons with memory and thinking difficulties safe.

About 70 dyads of caregivers and care recipients with memory and thinking difficulties will be enrolled in the study and followed for three months. The data collected in this research study will be kept confidential to the extent allowed by the law. Your participation is completely voluntary. You may decide not to begin or to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. You can ask all the questions you want before you decide.

What will happen if you take part in this study?

If you agree to take part in this study, you and your caregiver will be asked to participate in an enrollment visit (approximately 1 hour) and your caregiver will be asked to participate in two phone visits (10-15 minutes each) and a three-month post-survey (30 minutes). The enrollment visit is expected to take about an hour. During the visit, you will be asked questions to see if you are eligible to participate in the study. If eligible, you will be given a TheoraCare watch. Your caregiver will be given access to the Theora Care smartphone application and instructions on how to use the tool. The smartphone application will collect information about your use of the watch. You must agree to the Theora Care terms and conditions to use the watch and smartphone application. At each visit, your caregiver will be asked how you are doing and if you are using the watch, as well as about caregiving experiences with the Theora Care tool. Between the enrollment and three-month post-survey, you will be asked to wear the Theora Care watch, and your caregiver will be asked to use the Theora Care app.

How long will you be in this study and how many people will be in the study?

Participation in this study will last approximately 3 months, total time completing study requirements is approximately 2 hours. Our site will recruit about 30 care recipients and their caregivers for a total of 60 participants.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. One such risk is that you may find wearing the watch uncomfortable. However, there is no more risk than wearing any other type of device, such as a Smart Watch or Fit Bit. The watch is removable and you may take it off upon experiencing any discomfort or at any time you prefer. You may decide not to begin or to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

If it works, the watch can help your caregiver know your location and that you are safe. At the end of the study, you can keep the watch, and the Theora Care service will be free for six months after you complete the study.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect data from you such as: name, address, date of birth, email, and phone number. This information will be kept on a password-protected and encrypted spreadsheet.

We will also collect data from your smart watch such as: amount of time watch is worn, number of push messages received, number of preset safe zones, distance of safe zones, and the number of connections made between you and your caregiver. This information will be collected and analyzed by our coordinating site Texas A&M University.

Texas A&M University will have access to your data because they are the coordinating site for this research project. Their research team members will be available to you for support throughout the project. They also may reach out to you to ask you questions about your use of the watch.

How will we protect your information?

We will protect your information by keeping all written study-related materials in a locked filing cabinet behind a secure door in the Cognitive Disorders Center at UT Health Austin. Electronic data will be kept on a password-protected encrypted spreadsheet. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the sponsor **Texas Alzheimer's Research and Care Consortium (TARCC)**
- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations **Texas A&M University, and the University of North Texas Health Science Center**

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers may include information that can directly identify you. Researchers will not contact you for additional permission to use this information.

Under certain circumstances, we may break confidentiality. If during the study we learn about elder abuse, neglect, or exploitation we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research or analysis. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

How will we compensate you for being part of the study?

As compensation for your participation in this study, you will be allowed to keep the smart watch and receive an additional 6 months of free service (valued at over $200) following completion of the study. If you decide to withdraw from the research before the end of the study, you will still be allowed to keep the smart watch and receive the additional 6 months of service.
You will be responsible for any taxes assessed on the compensation.

What other choices do you have if you do not take part in this study?

The alternative to participation is not to participate. The watch and app are commercially available.

Your Participation in this Study is Voluntary

It is your choice to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin or your healthcare provider. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back this permission, the researchers may still use or disclose health information they have already collected about you for this study. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study. If you take back this permission you may no longer be allowed to participate in the research study. To take back this permission, you must write to the Principal Investigator. If there has been no activity on the watch for 1 week, your caregiver will receive up to three phone calls from researchers at our coordinating site, Texas A & M University. If there has been no activity for 2 weeks, you will be automatically withdrawn from the research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Robin Hilsabeck, PhD
Phone: 512-495-5553
Email: robin.hilsabeck@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference study number: 2019-02-0064

Your Consent

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records. If you have any questions about the study later, you can contact the study team using the information provided above.

_____
Signature of Person Obtaining Consent Date

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

_____
_____
Printed Name of Legally Authorized Representative Date

_____
Signature of Legally Authorized Representative Date