

Information and Consent Form to Participate in a Research Study

BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Center for Applied Health Research
Dallas and Temple, Texas

CONSENT FORM AND PRIVACY AUTHORIZATION (AIM 2)

Project Title: GamePlan4Care: Online Support for Family Caregivers
National Clinical Trial #
Principal Investigator (“PI”): Alan B. Stevens, PhD
Telephone Number: 254-771-4880

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

Why Have I Been Asked to Take Part In This Study?

You are being asked to take part in this research study because you are caring for a person diagnosed with Alzheimer’s disease or related dementia.

Why is This Study Being Done, And How Long Will It Last?

The purpose of this study is to compare different ways of using the internet to help deliver education and supportive services to persons caring for someone living with Alzheimer’s disease or dementia.

We think that you will be in the study for six months if agree to take part.

What Will I Be Asked To Do In This Study?

If you decide to take part in this study, you will be assigned to one of two online systems designed for family caregivers.

Group 1: GamePlan4Care (GP4C). In the online system called GamePlan4Care, participants will receive educational resources, skills training and support services tailored to the unique needs of the caregiver.

Group 2: Resources4Care (R4C). In the online system called Resources4Care (R4C), participants will receive access to educational resources that will allow them to view online articles and videos about Alzheimer’s disease and dementia.



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IRB EXPIRATION DATE: 03/23/2021

As a participant, you will be asked to use the online system over the next 6 months. You can use the system as much or as little as you want, but we encourage you to use the system at least once a week. During the course of the study, you will also be contacted by a Dementia Care Specialist where you may talk to her about your caregiving situation and how you are using the information from the system in your day-to-day situation.

Why Might I Want To Take Part In This Study?

If you agree to take part in this study, there will not be direct medical benefit to you. However, you would gain more knowledge about dementia caregiving and that could lead to decreased stress, burden, or depression associated with your caregiving situation. We hope that the information learned from this study will benefit other caregivers in the future.

Why Might I Not Want To Take Part In This Study?

You may decide that you do not want to take part because you may feel some emotional discomfort when discussing your caregiving situation. Also, the study would require you to use the online system and that would require some time.

What Other Options Are There?

You may choose not to take part in this study. Alternatively, you may continue to receive support services available at your local community-based agencies such as Alzheimer's association or area agency on aging. Being in this study is completely voluntary and you do not have to take part.

How Will Taking Part In The Study Affect Me Financially?

There is no additional cost to you if you take part in this study. You will be paid \$30 gift card after completion of the baseline questionnaire and an additional \$30 gift care after completion of the follow up questionnaire at the six months follow-up.

What is the Status of the Drugs (Devices or Procedures) Involved in This Study?

There is no drug or medical procedure involved in this study. Instead, we are studying the effectiveness of delivering an evidence-based caregiver intervention online. This intervention has been shown to improve caregiver quality of life when administered at the community level by personnel in local Area Agencies on Aging.



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How Many People Will Take Part In The Study?

About 240 people will take part in this study in Central Texas.

What Will I Be Asked To Do?

If you agree to participate in the research study, you will participate in one of two online systems designed for family caregivers.

Group 1: GP4C

In the online system called GamePlan4Care, participants will receive educational resources, skills training and support services tailored to their unique needs. Examples of services can include answering questions about your caregiving situation, receiving automated feedback about your caregiving situation, interacting with online articles and videos about caregiving skills, and receiving regular phone call or email check-in's with a professional who is trained to support family caregivers (a Dementia Care Specialist).

As a participant, you will be asked to use the online system over the next 6 months. You can use the system as much or as little as you want, but we encourage you to use the system at least once a week. During phone calls or emails with the Dementia Care Specialist, you will be asked to talk about your caregiving situation and how you are using the information from the system in your day-to-day situation. During your study participation, you may receive up to 9 automated emails and 4 outreach calls from your Dementia Care Specialist. Each call with a Dementia Care Specialist could take 15-45 minutes.

Group 2: R4C

In the online system called Resources4Care, participants will receive access to educational resources that will allow them to view online articles and videos about Alzheimer's disease and dementia. Resources will cover a wide range of topics including home safety, caregiver stress management, and best practices for providing dementia care.

As a participant, you will be asked to use the system over the next 6 months. You can use the system as much or as little as you want, but we encourage you to use the system at least once a week. You will also be contacted by a Dementia Care Specialist. During phone calls or emails with your Dementia Care Specialist, you may talk about your caregiving situation and how you are using the information from the system in your day-to-day situation. During your study participation, you will receive 2 emails and 2 outreach phone calls from a Dementia Care Specialist. Each call with a Dementia Care Specialist could take about 10-15 minutes.

Although the study is being conducted by Baylor Scott & White, you do not have to be a patient of Baylor Scott & White to participate, and study personnel will not be accessing your medical record or the medical record of the person for whom you care.



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We will use simple randomization scheme to assign participants to either GP4C or R4C groups, based on the random sampling using computer software. Each participant will have an equal chance to being assigned to either group.

Your Responsibilities as a Research Subject

Commitment: While you always have the right to change your mind and leave this study, you should enter this study only if you think you will want to be in it until it ends.

Visits: You agree to allow research staff review key computer/internet characteristics over the telephone such as use of internet browsers, possible system and software updates and conduct an internet speed test. You also agree to accept phone calls that are part of the study, receive emails that are part of the study, and to follow instructions of the research staff even if you stop using the intervention.

Problems: You will let research staff know immediately if any problems occur while you are involved in this study. You will let the research staff know if you have to go to an emergency room or hospital.

Other studies: You will not take part in any other study at the same time you are in this study (unless you are given permission by the PI)

How Long Will I Be In The Study?

You will be in this study for 6 months. You will be contacted by phone within 3 business days of referral for the initial screening interview. During this call, GP4C research staff will review key computer/internet characteristics over the telephone such as use of internet browsers, possible system and software updates and conduct an internet speed test. This call may last 45-90 minutes. You will also be asked to complete a questionnaire and create your account for either GamePlan4Care or Resources4Care. During the 6 months, you will receive either 2 or 4 phone calls from research staff. Each phone call will last about 16 to 30 minutes. At the end of six months, a study personnel will call and ask you to complete another series of questionnaires on phone. This call may last for 30-60 minutes.

The researcher may decide to take you off this study if any of the following occur:

- He/She feels that it is in your best interest.
- You are not able to follow the rules of this study.
- This study is stopped before it is finished.
- New information becomes available that indicates it would be best for you to stop being in this study.

You can stop taking part in this study at any time. However, if you decide to stop taking part in this study, we encourage you to talk to the researcher or his/her staff know so that they can make sure you are safely taken out of this study.

What Are The Risks Of This Study?

Although we do not expect any risks related to participation in the study, there could be a minor risk of emotional discomfort caused by answering questions and discussing your caregiving situation. In cases where there is significant distress, study personnel will make referrals to appropriate mental

health providers, but the study will not pay for any additional services. There are no physical risks associated with this project.

Conflict Of Interest

None

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 2001 Bryan St, Suite 2200, Dallas, TX 75201. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. While not required, you should also talk to your PI and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your research information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

A description of this clinical trial will be available on 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.

Additional Financial Information

There are no costs to you for being in this study. You will be paid \$30 after completion of the baseline questionnaire and an additional \$30 after completion of the follow up questionnaire at the six months follow-up. Your payment will be made from Baylor Scott & White Research Institute and is considered taxable income. You must be eligible to be paid in the United States and willing to complete all the necessary tax/legal paperwork to receive this payment.

What If I Become Injured Or Become Ill While Taking Part In This Study?



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The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, there are some things that you need to know:

- You should tell the researcher or his/her staff and they will help you to get necessary medical care. You or your insurance company may need to pay for the medical care.
- Baylor Scott and White Health and Baylor Scott and White Research Institute have not set funds aside to pay you money if you are hurt.
- You have not given up any of your legal rights by signing this form.

What Are My Rights As A Subject?

Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I Have Questions Or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact the Alan B. Stevens, PhD at 254-771-4880.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the Central IRB Office at 254-771-4854.



Statement Of Person Obtaining Consent

I have explained to _____ (printed name of subject and parent/legal representative if applicable) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

Signature Of Person Obtaining Consent Date Time

Statement Of Project Manager

As Project Manager of this study, I, Thomas Birchfield, confirm that to the best of my knowledge this subject has voluntarily agreed to take part in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above. I will review all the participant consent forms for completion within 2 weeks of their collection.

Thomas Birchfield, Project Manager Date

Confirmation Of Consent By Research Subject

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

Signature Of Subject Date Time

