Compass4Care: A Theory-driven Mobile Solution to Promote Self-care and Well-being Among Caregivers of Individuals With Alzheimer's and Related Dementias

Informed Consent Form

NCT06249139

February 5, 2024

INFORMED CONSENT FORM

Title of Research: ***Compass for Care*** **Study**

Principal Investigator: **Kerry Evers, Ph.D.**
ProChange Behavior Solutions
91 Point Judith Road STE 26, Unit #333
Narragansett, RI 02882
(888) 275-7485

DESCRIPTION OF THE RESEARCH AND THE RIGHTS OF PARTICIPANTS

Key Information:

- You are being invited to take part in a research study.
- The purpose of the study is to test new online programs for people who spend at least 8 hours/week caring for a family member or friend with Alzheimer's disease or a related dementia.
- If you choose to take part, you will be asked to use one of two online programs and complete online surveys. Half of those who agree to participate in the study will be randomly selected by the survey technology to have access to one program, and half of those who agree to participate will be randomly selected to have access to another. Both programs are designed to assist caregivers. One focuses on well-being and the other on safety.
- This will take between 1-3 hours over the next 9 months. You may also be able to choose to spend more time interacting with optional program activities, but that is not required.
- Risks from this research include possible discomfort answering some questions.
- The study will have no direct benefits to you. The results of this study may help us develop programs that can help caregivers.
- You will be paid up to $150 in gift cards, over the next 9 months, for taking part in this study.
- You will be able to view and print a copy of this consent form from the program.
- Taking part in this research project is up to you. You don't have to participate, and you can stop any time.
- The study team created an account for you so that you could access the survey. Each person is only eligible to have one account. This means that each person can only complete the screening survey once. Accounts will be deactivated if at any point we have reason to believe that an account is linked to other accounts or is being used by someone who does not meet the study screening criteria. In this case, no gift cards will be earned.

More details are provided below. If you have any questions about this study, please contact the research team at care@compassforcare.com, or call (888) 275-7485.

1) **<u>Purpose of Study</u>**: The purpose of this research is to test two new online programs designed to support caregivers. To take part, **you must be able and willing to get email or text messages**. You must also **have access to the Internet** using a smart phone, iPad, tablet, or computer.

2) **<u>What You Are Being Asked to Do</u>**: Up to 300 people who spend at least 8 hours/week caring for a family member or friend with Alzheimer's disease or a related dementia will take part. You've just completed a survey that shows that you qualify for the study. You will be asked to complete four online surveys during the next 9 months. You'll be linked to the first one today, and the next ones will come in 3, 6, and 9 months from now. Those online surveys should take about 10 minutes each. You will also be asked to:

   a. <u>Use an online program</u>, over the course of 3 months. You can use the program as little or as much as you choose.
   b. <u>Read text or email messages</u> and other information the program will send you daily during the next 3 months. This information could be related to caregiving, but could also be related to health and safety behaviors.

   You will be able to choose to receive an Amazon.com gift card (restrictions apply, see amazon.com/gc-legal) or a Walmart.com gift card for each assessment you complete: $30 for the survey today, $35 at 3 months, $40 at 6 months, and $45 at9 months.

3) **<u>Risks</u>**: You may find that some of the questions in the program make you uneasy and that you don't want to answer them. That's OK. You are free to stop answering questions at any time. If you want to talk to someone about these issues or have questions or concerns later, please contact one of the programs listed at the end of this session, or talk to some other person you trust.

4) **<u>Benefits</u>**: The information gathered in this research will help us test new programs for caregivers. One program focuses on well-being and the other focuses on safety. Some people find that taking part in this project is interesting and personally helpful. Also, at the conclusion of this research study, you may be offered access to the program that you did not use during the study.

5) **<u>Costs/Payment</u>**: There is no cost to you. This project is funded by the *National Institutes of Health, National Institute on Aging*. Costs of all services and materials will be covered by a grant awarded to ProChange Behavior Solutions. You will have the chance to receive up to $150 in gift cards for participating in this study over the course of 9 months.

6) **Confidentiality**: Information from online sessions and surveys will be kept private and used only for research purposes. There are a few exceptions to the promise of confidentiality:

   - If we see or are told that someone is being abused or neglected or that someone is planning to harm themselves or someone else, we will disclose this information to the proper authorities.
   - If it is required by law, such as in response to a court order, we will disclose personal information.

   Your data from the surveys will be sent to researchers outside of ProChange for data analysis. Any personal information that could identify you will be removed before the data are shared for data analysis.

   Your data from using the program may also be shared with Headversity (headversity.com), ProChange's development partner and the company hosting part of the Compass for Care program. We may also contract with other companies to perform functions for us, such as additional website hosting, authentication, and sending text and email messages. In addition, the organization funding this study, the National Institutes of Health (NIH), may review and copy records pertaining to this research. We require these partners and organizations to protect and limit access to your personal information.

   When you give us a phone number or other contact information, we may contact you using that information and we may query a service to confirm the owner of the number, type of service and provider name to aid in troubleshooting and in fraud detection. For example, if needed, we look to see if a number is associated with a cellular provider to confirm that text messages can be received.

   The study team created an account for you so that you could access the survey. Each person is only eligible to have one account. This means that each person can only complete the screening survey once. Accounts will be deactivated if at any point we have reason to believe that an account is linked to other accounts or is being used by someone who does not meet the study screening criteria. In this case, no gift cards will be earned.

7) **Right to Refuse to Participate**: **Taking part in this research project is voluntary and up to you.** You have the right to refuse to take part in this research and to stop taking part at any time. Your choice about taking part in this research will in no way impact your relationship with the organization which invited you to participate in this study or ProChange.

Questions/Concerns: This research study is being conducted by ProChange Behavior Solutions. If you have any questions or concerns about this research, please contact the study's Principal Investigator, Dr. Kerry Evers, or the Project Manager, Deborah Van Marter at care@compassforcare.com or (888) 275-7485 (toll free).

If you have questions or concerns about your rights as a research participant, if this study causes you any harm, or if you feel you are receiving pressure to continue in this research against your wishes, please contact the ProChange Institutional Review Board at (401) 489-8332.

Digital consent:

Do you consent to participating in this research study?

☐ **Yes.** I have read the consent form and have no further questions about taking part in this research study at this time. I understand that I may ask any other questions later, that taking part is voluntary, and that I may withdraw from this research study at any time. I understand the information given to me and agree to take part in this research study.

☐ **No.** I do not consent to be a part of this research study.