

Previvors Recharge: A Resilience Program for Cancer Previvors (*PreCharge*)

NCT06378749

Informed Consent Form: R43CA275673

March 21, 2023

INFORMED CONSENT FORM

Title of Research

PreCharge Study

Principal Investigator

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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 a new digital program for individuals with hereditary cancer syndromes who have never been diagnosed with cancer.
- If you choose to take part, you will be asked to use a digital program and to complete online surveys. The program is designed to help the user increase and maintain their well-being.
- This will take between 1-2 hours over the next 30 days. 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 individuals with hereditary cancer syndromes.
- You will be paid up to \$120 in gift cards, over the next month, for taking part in this study.
- The program includes text messaging. Depending on your phone plan, you may be charged by your provider for those text messages.
- 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 at any time.
- The study team takes steps to confirm that all accounts are valid. Each person is only eligible to have one account. This means that each person can only complete the screening survey once. Information you provide will be reviewed carefully. Accounts will be deactivated if we have reason to believe that they are linked to other accounts or have been created by individuals who do not meet the study screening criteria. In that 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 precharge@prochange.com, or call (888) 399-2117.

- 1) **Purpose of Study:** The purpose of this research is to test a new digital program designed to support individuals with hereditary cancer syndromes who have never been diagnosed with cancer. To take part, you must be able and willing to get text messages. You must also have access to the Internet using a smartphone, iPad, tablet, or computer.
- 2) **What You Are Being Asked to Do:** Up to 160 people who have a confirmed hereditary cancer syndrome but have never been diagnosed with cancer will take part. You've already completed a survey that shows that you qualify for the study. You will be asked to complete two digital surveys during the next month. You'll be linked to the first one today and will be asked to complete the next one in approximately 1 month. These online surveys should take about 10 minutes each. You will also be asked to:
 - a. Use an online program over the course of 30 days. You can use the program as little or as much as you choose.
 - b. Read text messages and other information, during the next 30 days, that the program will send you daily.

You will be able to choose to receive an Amazon.com gift card (restrictions apply, see [amazon.com/gc-legal](https://www.amazon.com/gc-legal)) or a Walmart.com gift card for each assessment you complete: \$50 for the survey today, and \$70 at 1 month.

- 3) **Risks:** 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, but that may affect your incentive. If you want to talk to someone about those issues or have questions or concerns later, please contact one of the organizations listed at the end of this form, or talk to some other person you trust.
- 4) **Benefits:** The information gathered in this research will help us test a new program for individuals with hereditary cancer syndromes who have never been diagnosed with cancer. Some may find that taking part in this project is interesting and personally helpful.
- 5) **Costs/Payment:** There is no cost to you. This project is funded by the National Institutes of Health, National Cancer Institute. 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 \$120 in gift cards, over the course of 1 month, for participating in this study.
- 6) **Confidentiality:** Information from online sessions, text messages, and surveys will be kept private and used only for research purposes. There are a few exceptions to the promise of confidentiality:
 - a. 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 that information to the proper authorities.
 - b. 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.

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 those 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 takes steps to confirm that all accounts are valid. Each person is only eligible to have one account. This means that each person can only complete the screening survey once. Information you provide will be reviewed carefully. Accounts will be deactivated if we have reason to believe that an account is linked to other accounts or has been created by an individual who does not meet the study screening criteria. In that 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. While this may impact your ability to receive an incentive, your choice about taking part in this research will in no way impact your relationship with the organization that 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, Madison Gilmore at precharge@prochange.com or (888) 399-2117 (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.