Stepping Into Survivorship: Harnessing Behavioral Economics to Improve Quality of Life in Ovarian Cancer

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Research Consent Form
for Social and Behavioral Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH /DFCI/MGH/Partners Network Affiliates

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Protocol Title: Stepping into Survivorship

DF/HCC Principal Research Investigator / Institution: Alexi A. Wright, MD, MPH / Dana-Farber Cancer Institute

Descriptor: Consent Form for Stepping into Survivorship

A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." This research study is evaluating wearable accelerometers and a behavioral health platform called Way to Health. The intervention was designed to help improve ovarian cancer survivors' physical activity, energy levels, and quality of life.

It is expected that about 168 participants will take part in this research study at Dana-Farber Cancer Institute.

An institution that is supporting a research study, either by giving money or supplying something that is important for the research, is called the "sponsor." The sponsors of this protocol are the National Cancer Institute and the Dana-Farber Cancer Institute. The sponsors have provided funding for the research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

We encourage you to take some time to think this over and to discuss it with other people and to ask questions now and at any time in the future.

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B. WHY IS THIS RESEARCH STUDY BEING DONE?

The transition from active treatment to survivorship is one of the most challenging periods for ovarian cancer survivors. After completing intensive surgery and chemotherapy, survivors often transition to a surveillance period without further treatment and limited contact with their oncology team. Many survivors struggle to reintegrate into their "normal" lives. Exercise has been shown to improve quality of life, fatigue and mood in several cancers, and ovarian cancer survivors report an interest in participating in home-based, walking programs to increase physical activity.

Stepping into Survivorship is testing a behavioral health platform called Way to Health, with a wearable accelerometer (also called a fitness tracker), in ovarian cancer patients in the survivorship phase. The study is designed to collect information about study participants' health and behaviors and to encourage participants to exercise.

This research is being done to improve participants' quality of life. We hope that the Way to Health platform and fitness tracker will help increase their activity and help patients feel better. It is also being done to understand participants' experiences while using the Way to Health platform and the fitness trackers in order to see if we can improve the study.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following options:

- Decide not to participate in this research study

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you enroll in the research study, you will be randomly assigned to one of two study arms. In both study arms, you will be asked to use the Way to Health platform and fitness trackers. In one of the study arms, you will be given two fitness trackers and asked to "pair" your accelerometer with a loved one (i.e. a friend or family member).

Baseline Study Visit: After signing consent, you will meet with a study team member at your regularly scheduled clinic visit.

This visit will involve the following:

- **Interview:** You will be asked questions about your background, family and household, health, quality of life, and treatment preferences and goals. You will also be asked about how you are feeling, what physical symptoms you may be experiencing, and how comfortable you are with computers and certain tasks. The interview should take about 20 minutes.
- **Instructional Session:** The study team member will teach you how to use the Way to Health platform and the wearable accelerometers.

Post-Baseline Study Visits: You will meet with a study team member at one of your regularly scheduled clinic visits about 14 weeks and 26 weeks after your Baseline Visit.

This visit will involve the following:

- **Interview:** You will be asked many of the same questions that you answered in the first interview. You will also be asked questions about your experience participating in the study and what you would do differently in future studies. The interview should take about 15-20 minutes.
- **Debriefing Interview:** During the final study visit, some participants will be asked to provide feedback on their experiences in the study in a short debriefing interview. This debriefing interview will be audiotaped.

During the study: You will be asked to use the Way to Health platform and wearable accelerometers.

Your use of the Way to Health platform and accelerometers will involve:

- **Wearing the accelerometers:** You will be asked to wear the fitness tracker every day.
- **Way to Health:** You will be asked to share data with the study team using the Way to Health platform.
- **Contact:** We may contact you if we are concerned that the fitness tracker is not working or that you are experiencing symptoms that may interfere with your ability to walk.

You have the right to decline any interview or survey question you choose.
Data Collection: The study team, smartphone app, and fitness tracker will collect information from you while you are enrolled in the study.

The data that will be collected from you includes:

- **Medical chart abstractions:** The study team will review your electronic health record for information about your diagnosis and cancer treatment. The team will also review it for information about the care you receive and phone calls you make to your doctor's office while you a participant.
- **Accelerometer data:** The accelerometer will collect information about your activity and movement.
- **Survey data:** The study team will collect data from your answers to the questionnaires and any answers you report on the Way to Health platform

If you stop using the Way to Health platform or accelerometer for an extended period of time, the study team will send you brief reminders to continue using them or contact you to see if they are not working properly.

Compensation: You will receive the fitness tracker when you enroll, $25 when you complete the 14-week assessment, and $50 when you complete the 26-week assessment.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for about 26 weeks (6 months). You may be a participant a little bit longer depending on the date of your Post-Baseline Visit.

The research Investigator may decide to take you off the research study for reasons such as:

- It is considered to be in your best interest
- The study procedures are found to be unsafe or ineffective
- There is any problem with following study procedures
- There are any problems with research funding
- Or for any other reason

If you are removed from the research study, the research Investigator will explain to you why you were removed.

In addition, you can stop participating in the research study at any time.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. The risks associated with this study are small.

First, there is small risk of physical injury. Participants could experience discomfort while wearing the accelerometer on their wrist.

Second, there is some chance participants could experience emotional distress or discomfort while answering some questions. Please know that your responses are voluntary. You have the right to not answer questions that make you uncomfortable. If you find that they upset you and would like to talk to someone, you can contact the study Principal Investigator, Dr. Alexi Wright, 24 hours a day and 7 days a week at ([redacted]

Third, there is a small risk for loss of privacy or confidentiality. Your interviews and health information are de-identified and recorded using a unique study ID. Careful data security measures are put in place to protect all of the information collected on both the Way to Health platform and the questionnaires. The research assistant will be able to explain these security measures in detail.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about whether or not the Way to Health platform and accelerometer can improve patients' quality of life by helping them increase their activity levels.

There are potential benefits to you as an individual. We hope that participating in this study will help you become more physically active, reduce fatigue, and improve your quality of life. You may also benefit from talking to an interviewer and it may make you more aware of how you are feeling.

There are also potential benefits to society. You may benefit from knowing that if the Way to Health platform and accelerometer are shown to be beneficial in this study, they could be used to improve the care that future cancer patients receive.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or Investigator.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

I. WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

If you have questions about your insurance coverage, please call financial services for information. The contact information for financial services

- Dana-Farber Cancer Institute: [redacted]

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

http://www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

J. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments will be billed to your

insurance company. You will be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We will not use this information for any other purpose.

K. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

All information obtained in this study will be kept strictly confidential. As soon as you agree to participate in the study, you will be issued a study ID that will be used on all of your study data. The only document linking you to your study ID will be kept in an encrypted, password protected Excel file on a restricted computer hard drive at Dana-Farber.

The Way to Health will never record or store any information that could identify you personally. All Way to Health data is de-identified and stored in information technology systems with appropriate information and environmental security.

Medical information created by this research study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS.

The results of this research study may be published. You will not be identified in publications without your permission.

This trial will be registered on https://www.clinicaltrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

L. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

Dana-Farber Cancer Institute

- Alexi A. Wright, MD, MPH: 617-632-2334

24-hour contact: DFCI: Alexi A. Wright, MD, MPH at [redacted] or page at [redacted]

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

M. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;

- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug for the purpose of this or other research relating the study drug and its use in cancer; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies

- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant
or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

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Adult Participants

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

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