Informed Consent

Study Title: Mobile Technology and Data Analytics to Identify Real-time Predictors of Caregiver Well-Being

NCT #: NCT04556591

Date of IRB Approval of Attached Informed Consent: February 4, 2021

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Mobile Technology and Data Analytics to Identify Real-Time Predictors of Caregiver Well-Being

Company or agency sponsoring the study:
Michigan Institute for Clinical & Health Research (MICHR) and Institute for Healthcare Policy & Innovation (IHPI), University of Michigan

Principal Investigators:
Noelle Carlozzi, Ph.D., Associate Professor, Physical Medicine & Rehabilitation, University of Michigan
Sung Choi, M.D., Associate Professor, Pediatrics & Communicable Diseases, University of Michigan
Srijan Sen, M.D., Ph.D., Associate Professor, Psychiatry, University of Michigan
Zhenke Wu, Ph.D., Assistant Professor, Biostatistics, University of Michigan

1.1 Key Study Information

Invitation to Enroll
You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to provide consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information.

Research studies do not always offer the possibility of treatment. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, like the time it might take to participate. In your decision to participate in this study, consider all of these matters carefully.

Summary of Study
This research study is evaluating a new mobile app we've developed to help improve the well-being of caregivers. You will enter daily ratings of your mood and stress, and you will wear a Fitbit® to collect information about sleep and activity. The app may use this information to deliver personalized tips and suggestions for self-care. You will also take some longer surveys throughout the study that ask about your mood, stress, sleep and functioning. Your entire time in the study is about 3 ½ months.

Randomization

This study involves a process called randomization. This means that chance (like the flip of a coin), not you or the researchers, will determine if you are in the group that receives the personalized tips and suggestions for self-care from the mobile app. This will allow the researchers to see if the personalized tips and suggestions for self-care work to improve mood and stress. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

Risks

There can be risks associated with joining any research study. For this study, these risks are minimal. They include fatigue, frustration, stress and/or anxiety from completing study activities, skin irritation from wearing the Fitbit®, or loss of confidentiality.

Benefits

By being in this study you might find that you feel better overall, or that your sleep and mood are improved. On the other hand, there is a chance that you won't experience any direct benefit as a result of your participation. What the researchers learn in this study may benefit others in the future.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Care partners (caregivers) of individuals with health problems often experience high levels of stress. This stress can affect their physical and mental health, as well as that of the person they care for. While programs to reduce stress may be helpful, care partners often have limited time and energy to prioritize their self-care. The purpose of this study is to test whether personalized messages from an easy-to-use mobile app improves mood and stress among care partners and to see if care partners like using the app.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

This study is for adults (at least 18 years old) who provide some form of care (e.g., help with activities of daily living, shopping, finances) to an adult with a spinal cord injury, Huntington disease or a hematopoietic (bone marrow or stem cell) transplant recipient. Participants must provide their own internet-connected mobile device (smartphone, tablet) and be willing to install the study apps on their personal device. Participants must also be willing to wear a Fitbit® and complete all study assessments.

You cannot be in this study if you are a professional, paid caregiver.

3.2 How many people are expected to take part in this study?

60-90 care partners will complete this study at University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Participation in this study involves completing a baseline survey session, a 10-day start-up period, and a 3-month home monitoring period.

Baseline survey session: This session will be completed though a videoconference (like Zoom). This session will take about 1 hour to complete. You will complete surveys that ask about you and the person you care for, including questions about your mood, stress, sleep and functioning. You will download the study mobile app and the Fitbit® app, and learn about the study home monitoring period. The study coordinator will get your address at this appointment and will mail you the Fitbit® you'll use in the study. Once you receive the Fitbit® you will complete the registration. During this session you will be randomized into the group that receives personalized messages or the group that does not; your chance of being in the group that receives the messages is like the flip of a coin (50%). If the person you care for does not receive medical care at Michigan Medicine, you may be required to provide documentation of their medical condition in order to be eligible for the study.

10-day start-up period: There will be a 10-day period between the baseline survey session and the 3-month home monitoring period. During this time, you will begin using the study app and wearing the Fitbit®. You will wear the Fitbit® 24 hours a day except when charging. You will also upload the Fitbit® data (syncing) at the end of each day. Participants who are randomized to receive the personalized messages on the mobile app will receive short messages on about half of the days. You'll spend about 5

minutes per day answering the study questions, syncing the Fitbit® and reading the personalized messages (if you are randomized to receive them).

3-month home monitoring period: The 3-month home monitoring period is an extension of the start-up period, and will continue in the same way: wearing and syncing the Fitbit, and spending about 5 minutes per day using the study app to answer questions about your mood and stress, and reviewing the personalized messages (if you are randomized to receive them).

At the end of each month, you will complete longer surveys about your mood, stress, sleep and functioning through the mobile app. Each monthly survey takes about 15 minutes to complete.

4.2 When will my participation in the study be over?
Your participation in the study will be over after you complete the last survey. Your expected duration of study participation is about 3 ½ months.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the Sponsor listed above but would not include information that could be used to identify you.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies, but would not include information that could be used to identify you.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are rare and not usually serious.

- You could feel inconvenienced or frustrated when completing the study surveys, when receiving the personalized messages from the mobile app or from wearing the Fitbit®;
- The Fitbit® may irritate your skin;
- You may feel fatigue, stress and/or anxiety related to completing the study activities;
- There may be a risk of loss of confidentiality or privacy.

The researchers will try to minimize these risks by limiting the survey questions and personalized messages to only those needed for the research.

- You may skip any questions that make you feel uncomfortable;
- If you receive an alert from the mobile app when it is inconvenient, you can wait to open the app and look at it when it is more convenient for you;
- If you experience any irritation with the Fitbit®, please remove it and contact the study team;
- The study team does many things to protect your confidentiality including using participant IDs instead of your name and using secure electronic systems to collect and store your data; see Section 9 for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Yes, but please let a member of our study team know if you are involved in other studies.

5.4 How could I benefit if I take part in this study? How could others benefit?
It is possible that participating in this study will improve your well-being and/or make you more aware of your activity level and sleep. However, you may find that you do not receive any personal benefits from being in this study. This study may benefit others in the future by helping researchers further develop a personalized intervention to help caregivers.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
You can choose not to enroll in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You can change your mind about being in the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, we may keep that information as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No. If you leave the study before it is finished, we may ask you to share your opinions about your study participation.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.

- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

You will need to provide your own smartphone or tablet, and pay for any associated data or WiFi charges associated with completing the study activities, like syncing the Fitbit® and interacting with the study app. The study will provide you with the Fitbit® and the study app. You may choose to use your personally-owned Fitbit® instead (if it is a comparable model).

You will not receive a bill from the study, nor will your insurance company be billed for any study procedures.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You may receive up to $140 for participating in this study, as detailed below:

- You will receive $20 for completing the baseline survey session
- You will receive $10 for each monthly survey you complete (3 surveys, $30 possible)
- You will receive $1 per day for each day you have daily data (answer daily questions, wear Fitbit®) during the 3-month home monitoring period (90 days, $90 possible)

You may also keep the Fitbit® after you complete the study.

8.3 Who could profit or financially benefit from the study results?

No one involved with this study is expected to profit or financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF RESEARCH RECORDS

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

You will be assigned a participant ID by the study team and this will be used instead of your name or other identifying information where possible. The electronic systems used to store the data collected in this study are secure systems with password protection and restricted access. Any paper documents related to your participation in this study will be stored in a locked cabinet or office. No names or other identifying information will be used in any report or publication of this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Consenting to this study gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Noelle Carlozzi, Ph.D.
Mailing Address: 2800 Plymouth Rd., Building NCRC B14, Ann Arbor, MI 48109-2800
Telephone: 734-764-0644

Study Coordinator: Christopher Graves
Mailing Address: 2800 Plymouth Rd., Building NCRC B14, Ann Arbor, MI 48109-2800
Telephone: 734-764-0644
Email: PMR-CODAlab@med.umich.edu

Study Coordinator: Kristen Gilley
Mailing Address: 1500 E. Medical Center Drive, D4206 MPB, Ann Arbor, MI 48109-5718
Telephone: 734-936-2263
Email: gilleykr@med.umich.edu

Study Coordinator: Christine Cislo
Mailing Address: 1500 E. Medical Center Drive, D4206 MPB, Ann Arbor, MI 48109-5718
Telephone: 734-936-2263
Email: ccislo@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (on this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your typed name in the next section means that you have received a copy of the following document:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file)*

12. SIGNATURE

By typing your name into the box below, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will receive a copy of this document for your records and 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 in section 10 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.

Type your name to indicate your consent to enroll in this study: _____