Title of Research Study: TECHNOLOGY SUPPORTED PHYSICAL ACTIVITY INTERVENTION FOR METASTATIC BREAST CANCER PATIENTS: Fit2ThriveMB (IRB# STU00208930)

Investigator: Siobhan M. Phillips, PhD, MPH

Supported By: This research is supported by a grant from The National Cancer Institute

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of this study is to test the effectiveness of a remotely delivered, technology-supported intervention, Fit2ThriveMB, to promote physical activity, primarily by increasing steps, in metastatic breast cancer survivors. You will be asked to complete two study assessments that both include online questionnaires, wearing an accelerometer physical activity tracking device for 7 days, and a video conference appointment with two Fit2ThriveMB staff members via Zoom video conference software where you will be asked to perform a variety of functional tasks (i.e. balancing on one foot,6 minute walk, standing up from a chair). **This study requires no in-person study visits to participate.** We expect that you will be in this research study for 3 months. All participants in the study will have access to a Fitbit and smartphone app specifically designed for this study. Half of participants will obtain immediate access and half will obtain access to these materials at a later time.

The primary risk of participation is injury due to increasing physical activity. If you choose to participate, there may or may not be benefit to you. The main benefit is helping researchers better understand how participation in a technology-supported physical activity intervention may influence physical activity and well-being in metastatic breast cancer survivors.

If you agree to participate in this study, you will be asked to indicate this by selecting ‘Accept’ and typing your name at the end of this form. Informed consent is an agreement that you, or your authorized representative, sign indicating a willingness to participate in this research.

Why am I being asked to take part in this research study?

You are being asked to take part in a research study because you have been diagnosed with metastatic breast cancer and have been a patient at a facility associated with Northwestern University Feinberg School of Medicine. The purpose of the Fit2ThriveMB study is to test a remotely delivered, technology-supported intervention to promote physical activity in metastatic breast cancer survivors. This program is designed with progressions so that individuals of varying abilities will be able to exercise safely. We will be testing the effectiveness of Fit2ThriveMB in relation to physical activity, functional fitness and well-being and quality of life.

How many people will be in this study?

We expect 50 women will be included in the present study.

What should I know about participating in a research study?

This informative document will tell you about the reason for the study, what you will do if you choose to be in this research study, the way we (i.e. Northwestern University) would like to use information about you and your health and the potential risks and benefits of participating in this study. You should consent only after you have been given all the necessary information and have had enough time to decide whether you wish to participate. Indicating your willingness to participate by signing your name at the end of this form is voluntary. Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you. You can ask all the questions you want before you decide.

What happens if I say, "Yes, I want to be in this research"?

As a participant interested in Fit2ThriveMB, you will attend a 10-20 minute recruitment session with a study team member. During this session, study staff will explain the study in detail, and you will be given your rights as a subject before answering any questions or completing assessments. If interested, you will be asked to give your consent to participate in the study. If you are eligible and consent to participate, we will ask you to complete baseline assessments which will include: a) answering an on-line battery of questionnaires, b) wearing an accelerometer activity tracker for 7 consecutive days and c) undergoing remote functional performance testing during a video conference session via Zoom. Details regarding these assessments are listed below. **You will be required to get physician consent prior to participation in the functional performance testing.**

Group Placement

All participants in Fit2ThriveMB will be "randomized" into one of the study groups described below. The group you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what intervention you get. You will have an equal chance of being assigned to any given group. You will have a 1 in 2 chance of being placed into one of these groups. You will find out your group assignment after you have completed all baseline assessments.

Group 1: Fit2ThriveMB Intervention Group

- If you are placed in Group 1, you will receive the Fit2ThriveMB mobile smartphone application ("app"), a Fitbit, and weekly support calls focused on helping you become more physically active. You will be provided with a daily step goal to gradually and safely increase your physical activity.
    - As a participant in this group, you will be asked to:
        - Download the Fit2ThriveMB smartphone app
        - Download the Fitbit app and link the Fitbit to the Fit2ThriveMB app
        - Provide the study team with access to all data collected by the Fitbit. The Fit2ThriveMB app will not store any of your personal information. Your Fitbit data will only be linked to you by a unique study ID number. (We will not able to control the information collected from the Fitbit app including device information, phone numbers, and usage)
        - Wear the Fitbit daily for the duration of the 3 month intervention period
        - Track your physical activity using the Fitbit and Fit2ThriveMB app every day during the 3 month study period.
        - Answer the phone when the study team calls you for support calls, and talk with the study team member for approximately 10-20 minutes weekly
        - Join a participant messaging board where you can communicate with other participants for encouragement and support

Group 2: Healthy Lifestyle Waitlist Group

- If you are placed in Group 2, you will be asked to go about your usual activities during the initial 12 week period. You will receive the Cancer.Net mobile application and receive weekly support calls focused on healthy living. You will receive the Fitbit and access to the Fit2ThriveMB app after completion of week 12 assessments.
    - As a participant in this group, you will be asked to:
        - Download the Cancer.Net app and use it regularly.
        - Answer the phone when the study team calls you for support calls, and talk with the study team member for approximately 10-20 minutes weekly

Assessments

You will be asked to complete the following procedures at baseline, prior to randomization, and at the end of the 12 week intervention period. Each assessment will include completion of an online questionnaire, wearing the accelerometer for 7 consecutive days, and attending a remote video conference to complete functional performance testing. At baseline, you will attend two video conferences. The first will be an individual session with you and study staff and will include only functional performance testing and will last approximately 60-90 minutes. The second video conference will include an individual or group (depending on scheduling availability) orientation and will take approximately 30-60 minutes. At 3 months, there will be another video conference to complete functional performance testing and will take approximately 60-90 minutes. Participants in the intervention group will also engage in a post-study information and feedback session via phone call or video conference that will take about 30 minutes. Participants in the healthy lifestyle waitlist control group will have the option to sign up for an orientation to the Fit2ThriveMB physical activity program study materials at week 12. We will also have you complete a short questionnaire at 3 weeks. Details regarding these assessments are listed below. These assessments are being done solely for the purposes of this study. All participants, regardless of their group assignment, will be asked to participate in the testing procedures.

- ***Questionnaire Battery:*** You will be emailed a link an individualized, secure link to a series of online questionnaires. These questionnaires will assess your health history, health behaviors and symptoms and should take approximately 30-45 minutes to complete. This survey is being hosted by https://redcap.nubic.northwestern.edu and involves a secure connection. All questionnaires should be completed within 1 week of receipt.
- ***Activity monitor:*** The activity monitor will be mailed to your house via USPS. You will be asked to wear an activity monitor during all waking hours, except when bathing or swimming, for 7 consecutive days. This apparatus is similar to a pedometer. It is about the size of a pocket watch and is worn around your waist on the non-dominant hip. You will be asked to fill out an Activity Monitor Log to indicate when you put the monitor on/took it off each day as well as any times you did not wear the monitor. You will be asked to mail your activity monitor back to the study team after you complete functional performance testing using a pre-paid envelope.
- ***Individual VideoConference Functional Performance Testing:*** Functional performance testing will be conducted via video conference at the location of your choosing.You will be doing the testing by yourself with the option to have a family member or friend assist. You will be on a video conference with two Fit2ThriveMB staff members via Zoom video conference software.It will take approximately 60-90 minutes to complete. Functional performance testing measures include:
    - Measurement of weight and blood pressure.
    - The Short Physical Performance Battery (SPBB) which measures walking speed, ability to rise from a chair, and standing balance. Walking speed will be measured using the

better of two recorded times over a 4-meter course. Chair stand time will be measured as the time needed to rise five times from a seated position in a chair, with arms folded across the chest. For the balance test, participants will be asked to maintain their feet in side-by-side, semi-tandem and tandem positions for 10 seconds each.

- The Senior Fitness Test We will use several items from the Senior Fitness Test including a) the 8-Foot Up-and-Go, a test of physical agility and dynamic balance, which measures the speed at which an individual walks around a cone 8 feet away and back; b) the Arm Curl test, which assesses arm muscle strength endurance, specifically of the biceps, by measuring the number of arm curls that can be completed using a 5 lb. weight in 30 seconds; c) and the 2 minute step test, which assesses endurance by counting the amount of in-place steps taken in two minutes.You will also be asked to complete a one legged stand test on each leg that will last up to 30 seconds.
- 6-minute Walk Test You will complete a 6 minute walk test to assess submaximal level of functional capacity. The goal is for the participant to walk as far as she can during these 6 minutes. Distance is measured once the 6 minute walk is complete, and provides information regarding cardiopulmonary and musculoskeletal systems that are used during physical activity that points toward exercise tolerance. You will be asked to wear the activity monitor and a pedometer on your hip during this test.

- ***Week 3 Questionnaire:*** You will be asked to complete a series of online questionnaires. These questionnaires will assess your health behaviors and motivation and should take approximately 10 minutes to complete. All questionnaires should be completed within 1 week of receipt.

Continued App Use

At the conclusion of the study, if you are assigned to the Fit2ThriveMB Intervention Group, you will be permitted to keep the Fitbit and have the option to keep the Fit2ThriveMB app on your phone for continued use for 12 months. If you are assigned to the Healthy Lifestyle Waitlist Group, you will have the opportunity download the app to your phone to use for 12 months. If you choose to keep and/or use the Fit2ThriveMB app, it will continue to collect the following data from your phone: your login frequency, app usage, any data you enter into the app including symptom burden, goal selection and physical activity and data transmitted from your Fitbit, including physical activity and steps taken. This data will be collected for 12 months for the purpose of analyzing your use of the app and your physical activity after you have completed the study. You may choose to delete the app at any time during these 12 months and this will stop the data collection.

Audio Recordings

At the end of this consent form, you will be given the option of allowing us to make audio recordings of you. If you agree, the individual telephone support calls will be audiotape recorded for research and training purposes. Only study staff will have access to the audiotapes, and they will be kept on secure server. At the end of the study, all audiotape recordings will be destroyed.

Photographs or Video Recordings

In addition, at the end of this consent form, you will be given the option of allowing us to take photographs or videos of you during the functional performance testing video conference, audio record phone calls, audio and video record other study sessions completed via video conferencing including the study orientation sessions, post-program information session for those assigned to the intervention group and the optional end-of-study Fit2ThriveMB study materials orientation for the control group. These recordings will be used for quality control and training purposes.

You will also be given the option to agree to allow us to share photos or videos of you from functional performance testing or that you have posted on the study applications message board. If you agree,

photographs or videos may be shared on our research website, in scholarly presentations or publications when they serve to help others understand the research. Your video recording or photographs will not be shared, if you do not agree to this.

Will being in this study help me in any way?

This study may or may not have direct benefits for you. We cannot promise any benefits to you or others from your taking part in this research. However, your participation may help researchers better understand how participation in a technology-supported physical activity intervention may influence physical activity and well-being in metastatic breast cancer survivors.

Is there any way being in this study could be bad for me?

It is necessary to inform you that when individuals who have been sedentary increase their physical activity levels, there is a chance of incurring minor injury and some discomfort due to the intensified use of major muscle groups that have not been used on a regular basis. Although the content of the program has been designed to offer safe, progressive activities, it is conceivable that you could be injured or experience discomfort as a result of engaging in the exercise program. However, we do not anticipate any major injuries to occur. Should you become injured due to exercising, we encourage you to notify study staff immediately and to consult your physician, if necessary. There is also a very slim chance that sudden death or cardiac irregularities can occur while exercising. As noted, this is very rare and the benefits of exercise are known to outweigh the risks. We strongly suggest you pay close to attention to all the safety instructions included with study materials.

The risks of physical activity participation also exist during the remote functional performance testing sessions. Again, serious physical injury is considered unlikely. In order to reduce and/or prevent injuries during testing, two study staff members will be present on the video conference to provide remote assistance. Study staff will be thoroughly trained on assessment procedures and be required to follow specific scripts to ensure safety. Further, all staff who participate in testing will be required to be First-Aid/CPR/AED certified and will be available to provide verbal instructions to you if needed in the unlikely event of an emergency situation. Staff will be required to use a computer for the functional performance video conference, and keep their cell phone available in the event of an emergency. Study staff will take measures to ensure participants will be able to receive timely medical assistance in the unlikely event of an emergency.

The university researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

There may also be a security risk in using Zoom video conference software to communicate during remote functional performance testing and orientation sessions. In order to minimize the risk of using Zoom video conference software and enhance security, you will be sent individual links to attend the video conference to their email with a password that will be required to enter the meeting. Study staff will also enable the 'waiting room' feature on Zoom so that only members permitted by the meeting host (study staff member) will present in the video conference.

In addition to the potential minimal risk associated with physical activity participation and remote functional performance testing, there are some potential minimal psychological risks associated with answering some of the questionnaires required for participation in this study. However, you will be given the option to skip any questions that make you feel uncomfortable. Should any individuals report scores

on the PROMIS Cancer Depression Scale, that are in the 75th percentile (i.e. ≥ 4.3) or confer a high level of distress in interactions with research study staff, they will be referred to the Supportive Oncology program at Northwestern: https://www.cancer.northwestern.edu/cancer-care/patient-support/index.html.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate or not to participate. You can leave the research at any time and it will not be held against you. Please notify the study team immediately if you would like to withdraw. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used. The study team will ask if you are willing to participate in any remaining assessments. If not, no more information will be collected from you.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you. You can indicate you do not want to answer any questions and you can withdraw at any time without penalty. Please notify the study team immediately if you would like to withdraw. When you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used. The study team will ask if you are willing to participate in any remaining assessments. If not, no more information will be collected from you. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. If you are a medical student, fellow, faculty, or staff at the Northwestern University, Northwestern Medical Faculty Foundation or Northwestern Memorial Hospital, your status will not be affected in any way.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and representative of the National Cancer Institute (NCI). Results of this study may also be used for teaching, research, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a code number rather than your name or other identifying information. All data collected from this study will be retained for 7 years as required by Northwestern Policy.

A description of this clinical trial (NCT04129346) will be available at http://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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Cancer Institute, which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The questionnaire assessments at baseline, 3 weeks and 12 weeks are being hosted by Redcap and involves a secure connection. Terms of service, addressing confidentiality, may be viewed at https://confluence.nubic.northwestern.edu/display/RUCP/REDCap+Security. Upon receiving results of your survey, any possible identifiers will be deleted. You will be identified only by a unique subject number. Your email address will be stored separately from your survey data, and is only being collected for payment purposes. All information will be kept on a password protected computer only accessible by the research team. The results of the research study may be published, but your name will not be used.

If you are assigned to the Fit2ThriveMB intervention group, you will be required to download the Fitbit app and Fit2ThriveMB app. If you are in the Healthy Living Waitlist Group you will have the opportunity to download the Fit2ThriveMB app at the end of the study. You will not be required to do so and may delete the app at any time. We will collect data from you in the Fit2ThriveMB app including your login frequency, responses to any survey prompts, usage data, and physical activity. If you choose to use the Fit2thriveMB app after the study is over, we will continue to collect data from it for 12 months to preserve its functionality and to study your use of the app and physical activity levels after you have completed the intervention.

In setting up the Fitbit app, we recommend that you enter your birthday, height, and weight for more personalized recommendations. The Fitbit app will also collect information including your number of steps, calories burned, movement, sleep length, and physical activity classification which the study team will access for research purposes. We will obtain these data from Fitbit via your usage of the Fitbit app. This information will be stored on a secure study server. Information on Fitbit data to be stored are provided by the Fitbit API and may include physical intensity classification, number of steps walked, calories burned, sleep length, movement and quality, body weight, percentage of body fat and food logged. Data is stored and indexed on a SQL server database housed in the Department of Preventive Medicine in day total, hour, and minute-by-minute intervals. Our database servers are IP firewalled and whitelisted such that they refuse any connection from IP addressed not pre-programmed by the research team. No GPS or other location information is collected. We use Secure Sockets Layer (SSL) for all authentication encrypting data transmitted between browser and webserver. All Fitbit data will be uploaded from the Fitbit server. The link between your Fitbit data and your personal information (i.e. name and email address will be removed). Fitbit data will then only be linked to the participant's identification number.

The Fitbit app also collects various information for their own use which we will be unable to control, including but not limited to device information, battery level, IP address, and your location. You may choose to link the app with your social media accounts or phone contact list. You may also choose to connect personal payment information to the app to make purchases within the app. More information on Fitbit's Privacy Policies can be found here: https://www.fitbit.com/eu/legal/privacy-policy. If you choose to do this, Fitbit may also collect information on friends connected within the app, purchases made from the Fitbit online store, and if connecting to social media, and basic information from your social media account. We will obtain Fitbit data via the Fitbit server via your usage of the Fitbit app.

HIPAA Authorization:
In order to participate in this study, we need to obtain your health information from your past, present, and future medical providers. Your signature on this consent with HIPAA Authorization is the means for getting access to that information. We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:
Information in a medical record including:

- Body weight and height
- Treatment characteristics: date of treatment, treatment type and dose of Treatment complications including hospitalizations and adverse events
- Surgery characteristics: date of surgery and type of surgery
- Cancer characteristics pre- and post- treatment collected via medical tests, blood and tissue samples (disease stage, estrogen receptor status, progesterone receptor status biomarkers of proliferation) and cancer recurrence
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a your cancer as well diaries and questionnaires

Under the HIPAA Authorization, the following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy except that such information may be viewed by the Study sponsor and its partners.

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Other health care providers who are not part of the study but may be involved in your care.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Unless you revoke your consent, it will expire 5 years after the end of study participation.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Siobhan Phillips
Northwestern University Feinberg School of Medicine
Department of Preventive Medicine
680 N. Lake Shore Drive
Suite 1400
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Data Sharing: De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you need medical care because of taking part in this research study, please seek medical treatment through the investigator or a treatment center of your choice. If you seek treatment from someone other than the investigator, contact the investigator to inform [her/him] about any related injury or illness. Generally, this care will be billed to you, your insurance or other third party. Northwestern University has no program to pay for medical care for research-related injury.

If at any point during the study period, study staff are trying to reach you and do not reach you or hear back from you after 3 phone or email attempts and a final e-mail attempt, we will attempt to contact the individual you identified as your emergency contact/locator person as a precaution to make sure you are safe.

Compensation: Participation in this study will involve no cost to you. If you agree to take part in this study, you will receive $41.50 ($40.00 for completing the assessment in its' entirety and an additional $1.50 for electronic bank transfer fee) for each completed assessment (at baseline and 12 weeks) for a total of $83.00. If a participant completes only a portion of the assessment at either time point, or withdraws before completing any portion of the assessment at either time point, payment will be pro-rated as follows: $10 for completing the questionnaires, $15 for wearing the accelerometer and $15 for completing functional performance testing.

All participants will also receive a Fitbit. Those in the Fit2ThriveMB Intervention will receive the Fitbit when the intervention starts. Those in the Healthy Lifestyle waitlist group will receive a Fitbit after 12 week data collection in complete.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has affected you in some way, please feel free to contact us. If you have any illness or injury during your time on this study, you should call us promptly.

Professor Siobhan Phillips in the Department of Preventive Medicine at Northwestern University is the principal investigator on this study. You can reach her by phone at (312) 503-2719 or by email at fit2thrive@northwestern.edu . If you want a copy of this consent for your records, you can print it from this screen or request a copy via e-mail at any time. If you would like documentation linking you to this research study, please email your request to the Principal Investigator at fit2thrive@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
		The researcher may contact me in the future to see whether I am interested in participating in other research studies.
		I agree to allow the researcher to contact me in the future to see whether I am interested in participating in follow-ups related to this current study
		The researchers may audio record me during calls for research and training purposes. The researcher will not share these recordings with anyone outside of the immediate study team.
		The researchers may take pictures of me and video record me during video conferencing session for research and training purposes. The researcher will not share these photos or videos with anyone outside of the immediate study team unless explicitly agree to below.
		The researcher may use video, and/or photographs of me in scholarly presentations or publications when showing my face might serve to help others understand the research. I may be identifiable as part of this activity.
		I would like to receive a plain language summary of study findings at the end of the study.

By clicking 'Accept' and typing your full name and today's date, you are documenting your permission to take part in this research.

If you do not wish to participate in this study, please select 'Decline', and your session will end.

Full Name: _____ Today's Date: _____

Sincerely,

Siobhan M. Phillips, PhD, MPH
Associate Professor, Department of Preventive Medicine
Northwestern University
680 N. Lakeshore Drive, Suite 1400
Phone: (312) 503-2719
E-mail: fit2thrive@northwestern.edu