THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Mobile-Health Delivery of Lifestyle Interventions for Women with Breast Cancer Multicenter Pilot Trial
2020-1190

Study Chair: Lorenzo Cohen

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this research study is to develop a lifestyle program to improve clinical outcomes in women with breast cancer who do not have a healthy diet, regular exercise habits, or ways to manage their stress well. The program will include support and counseling in healthy eating, physical activity, stress management and mindfulness, learning sleep hygiene techniques, and behavioral counseling in addition to social support.

This is an investigational study.

Taking part in this study may help teach you about improving the quality of your life and healthy lifestyle choices. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses, compensation, and time commitment.

You can read a full list of potential risks below in the Possible Risks section of this consent.

Your active participation in this study will be over after you complete the follow-up visits.

There will be no cost for you participating in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Study Groups

If you agree to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one group is better, the same, or worse than the other.

- If you are in **Group 1,** you will take part in the comprehensive intervention program for 12 weeks and then you will have further weekly counseling for another 14 weeks. You will have a total of 26 weeks/6 months of lifestyle counseling.
- If you are in **Group 2,** you will not have any intervention program for about 9 months but will continue to have the study visits described below. After 9 months, you will have the opportunity to take part in the 12-week comprehensive portion of the intervention.

Up to 30 participants will be enrolled in this study. Participant recruitment and research activities will take part at MD Anderson and Wake Forest Baptist Health. Up to 18 will take part at MD Anderson.

Baseline Visit

You will have a baseline visit so researchers can measure how you have changed before and after taking part in the intervention program. You will come to the clinic for some of these tests/procedures and others will be completed from your home.

At the clinic:

- Blood (about 2 teaspoons) will be drawn for tests to measure hormones and your immune system responses. You will need to fast (have nothing to eat or drink except water) for 12 hours before this blood draw. You will be provided with healthy snacks after your blood draw.

At home:

- You will have strength tests of your upper and lower body, lasting no more than 60 seconds. During these tests, you will sit in a chair and then stand up and sit down again. You will sit and stand as many times as you can in 60 seconds. You will also be asked to perform as many bicep curls as you can in 30 seconds while holding a 5-pound weight. The test will be guided and supervised by the study coordinator using an approved video platform.
- You will complete a 2-minute step test using a small step that will be provided to you. During this test, you will be asked to step on and off the step as fast as possible using a wall to maintain balance. Researchers will measure how many steps you can take in 2 minutes.

- You will have your weight, body fat, and muscle mass measured using a portable scale that will be sent you. You will send the scale back to the study staff in a self-addressed, pre-paid box that you will be given. Your hip and waist circumference will also be measured. These measures may also be collected in the clinic visit.
- You will be given an accelerometer to wear for 5 days. The accelerometer is worn on the wrist and measures how many steps you take each day. At the end of 5 days, you will send the accelerometer back to the study staff in a self-addressed, pre-paid box that you will be given.
- You will complete questionnaires electronically about your emotional and physical health, including the general quality of your life, your sleeping habits, how you have been feeling, diet, and exercise as well as questions about how you view the world and any difficult experiences during your childhood. It should take between 30 and 45 minutes to complete.
- You will complete 3 dietary recalls electronically about your dietary habits. A dietary recall is when you are asked to remember what you have eaten in the past. These recalls will occur on 3 randomly selected days; 2 weekdays and 1 weekend day. It should take between 20 and 30 minutes to complete each recall.

Group 1 Participants Only

If you are in Group 1, you will take part in a comprehensive intervention program (called mobile integrative research intervention program - MyCAMP). As part of the MyCAMP program, you will have online sessions counseling you in the areas of diet, exercise, mind-body practice, and behavior change over the course of up to 12 weeks.

You will first have an online (virtually through a video call platform called Zoom) orientation session with the study coordinator. This session will be scheduled at your convenience.

Each week for 12 weeks you will have 1 physical activity session, 1 nutrition/diet session, and 1 mind-body practice session (yoga and meditation). Each session will last about 60 minutes and you will have a total of 12 sessions in each of the three areas. You will also have 1 behavioral counseling session each week for a total of 26 sessions.

After the 12-week portion of the intervention, you can have 1 booster session for each of the 3 areas of dietary, exercise, and mind-body counseling between 12 and 26 weeks. After the 26-week behavioral counseling sessions end, you can have 1 booster session of each of the 4 areas of dietary, exercise, mind-body, and behavioral counseling.

The intervention programs will be provided by a licensed professional (such as a personal trainer, dietitian, or yoga instructor). Each session will be video and audio-recorded.

You will be given the contact information for the personal trainer, dietitian, behavioral counselor, and/or yoga instructor in order to answer any questions or concerns you may have during the study.

You will also be given a Fitbit watch to use during the study. This device will track how physically active you are during the day and your sleep quality at night. The study staff will explain how to use the Fitbit. If a Fitbit is lost or stolen, the research team will not replace the device. You can still continue tracking on the Fitbit app by manually entering the exercises, mind-body practices, and food intake. If the Fitbit becomes faulty by no fault of your own, the research team will replace the faulty Fitbit with another working device. At the end of the study, you will be able to keep the Fitbit at no cost to you.

You will be emailed a link to complete electronic questionnaires, about your sleeping habits, how you have been feeling, diet, exercise, and the general quality of your life. You will be asked to use a hand-held device (such as a tablet), a smartphone, a computer, or a laptop to complete the electronic questionnaires. It should take between 20 and 30 minutes to complete. Digital copies of the educational information you will receive throughout the program will be provided.

Physical Activity
During each online session, a personal trainer will advise you on types of exercises you should be performing during the week. A personal trainer will work with your individual fitness level to create an exercise program for you. You may be asked to exercise with the trainer during these sessions. The trainer can help you modify the exercises, if needed. You should exercise 3-5 times each week for about 30-60 minutes each time with varying degrees of intensity. The personal trainer will tell you how often to exercise and how intensely you should be exercising.

If any medical issues occur that may affect your safety while performing physical activity during the study, you will need to be evaluated by your doctor and get a medical release.

You will use your profile on the Fitbit app to track your exercise.

Diet/Nutrition
During the diet/nutrition sessions, you will be taught to shop and how to cook a mostly vegetarian diet. The dietitian will tell you about healthy foods, cooking techniques, and which restaurants and places to shop are considered healthy.

You will be asked to use your profile on the Fitbit app to track your eating habits.

Mind-Body Practice
During these sessions, you will be taught meditation techniques and yoga-based practice. You should practice these techniques for about 1 hour every day.

You will be asked to use your profile on the Fitbit app to track your mind-body practice.

Behavioral Counseling and Social Support
As part of behavioral counseling and social support, you will be given workbooks on paper and/or online to work on goal-setting and to address barriers you face in your day-to-day life. You will meet with a counselor 1 time each week online or by phone for 26 weeks.

Follow-up Visits
If you are in **Group 1**, you will have follow-up visits after you have completed 12 weeks of the intervention program and then again about 3 and 6 months later.

If you are in **Group 2**, you will have a follow-up visit at about 3, 6 and 9 months after you were assigned to Group 2. If you decide to take part in the intervention program, you will complete an additional online questionnaire following the 12-week portion of the intervention, but you will not have a blood sample drawn or fitness measures collected. If you choose to not take part in the intervention program your participation in the study will end after the 9-month assessment.

During these follow-up visits, you will complete the same tests/procedures performed at the baseline visit. Blood samples will only be taken at the 3- and 9-month visits. In addition, you will complete questionnaires online on a desktop, laptop, tablet, or smartphone about what you have eaten recently.

All participants will also have an exit interview after they have completed participation in the intervention program. The interview will be audio and video recorded and will ask about your participation in the study, the parts you liked and did not like, and parts that you would change for future participants.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the study procedures, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study procedures.

If the **actigraph or scale** are lost, broken, or stolen, please tell the study team right away. If the devices are stolen, please file a police report and provide a copy, if available, to the study team.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen. All study data (including video and audio recordings) will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

You may receive wrong information from **general internet usage**. The use of the internet for purposes outside of this study may put you at risk for problems such as identify theft. You should be careful in providing personal information on other websites.

Mild to moderate **physical activity** may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

If you are feeling distressed and the study staff or doctor thinks it is needed, you will be referred to another doctor or therapist for additional help.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Fasting may cause your blood sugar to drop. You may feel tired, hungry, and/or nauseous. If you have diabetes, it is important to talk to your doctor about managing your blood sugar while fasting.

This research is covered by a **Certificate of Confidentiality** (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information 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 protected by this CoC 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).

The CoC 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. You should understand that a CoC 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 CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you may join a series of webinars (seminars that are held online using the Zoom platform) throughout the course of the study that is hosted by a member of the study staff. The number of webinars will depend on the interest and availability of patients in this study. Each webinar will last about 60 minutes and cover a special topic related to counseling and social support and will involve interactive discussions.

Optional Procedure #2: If you agree, you may take part in a Facebook group for program members and staff only, designed to increase sharing of information, recipes, experiences, and so on. If you choose to belong to this virtual group, you can communicate with others in the program in addition to staff members. You are encouraged to only share information that you are comfortable sharing with all other program members and the study staff. The group will be monitored by MD Anderson staff and will be closed after the study is complete.

Optional Procedure #3: Throughout the study, if you agree, quotes/testimonies from you will be used, published, and shared as needed. These quotes/testimonies may be drawn from the Facebook group (if you take part), or the video- and audio-recordings during the intervention sessions above. These quotes/testimonies will be de-identified (meaning your name or any other identifying information will not be connected to them).

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks:
Your quotes/testimonies will be de-identified, so there are currently no known risks in taking part in this optional procedure. However, if you share personal information as part of your quote/testimony or participation in the Facebook group and webinars, it is possible that someone could learn you have taken part in this study and have (had) cancer. This may be upsetting.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to take part in the webinars?

YES NO

Optional Procedure #2: Do you agree to take part in the Facebook group?

YES NO

Optional Procedure #3: If you agree to take part in the Facebook group, do you agree to allow your quotes/testimonies to be used, published, and shared as needed?

YES NO

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Wake Forest NCORP Cancer Center Research Base for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study- related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

All participants will be given the following items at no cost for their participation in the study: a blender, tote bag, cookbooks, a yoga mat, resistance training bands, a 5 lb. weight, a Fitbit watch, instructional video and audio recordings, and access to the Fitbit app. If you are in Group 1, you will receive these items when you start the study. If you are in Group 2, you will receive these items after you switch to Group 1 (after the 9-month follow-up).

Your parking costs will be paid if they are not covered by the hospital. You will need to provide receipts for the cost of parking. You will also be given $25 for completing the assessments (patient-reported outcomes, weight, body fat, fitness assessments, and anthropometrics) and $25 for providing blood samples. This means you may be

able to receive a total of $50 at each visit where blood samples, questionnaires, and fitness measures are collected (3 visits) and $25 for the visit where no blood sample is collected (1 visit) (up to $175 total during the course of 9 months). If you are in Group 2, you will be given an additional $15 for completing the online questionnaire after the 12-week intervention (up to $190 total during the course of your participation).

If you are part of Group 1, you will receive up to $7 per week for reporting your behaviors (in all three programs: exercise, mind-body, and diet) every day in the Fitbit app ($1 for 1 day of reporting, $2 for 2 days of reporting, $3 for 3 days of reporting, and so on).. This is “Level 1” of compensation. At the end of each week, you may receive additional compensation (Level 2 compensation) based on whether you meet your pre-set goals for exercise, diet, and mind-body practice. You will receive $0 additional compensation for each goal you do not meet. You will receive an additional $2 for each goal you meet. You will receive an additional $3 for each goal you exceed. You can achieve only 1 of these categories for each goal. Thus, at the end of each week or “game round” you can earn up to $9 per week by exceeding all 3 pre-set goals at Level 2, for a maximum of $16 compensation when combined with your Level 1 compensation. You can participate in “the game” for 12 weeks (earning a maximum of $192 during the first 12 weeks). After 12 weeks, you can continue to earn $7 per week by reporting and tracking behaviors in the Fitbit app every day for the rest of the 26-week program.

If you are in Group 1, you may receive up to $290 total over the course of 26 weeks for reporting behaviors. You will be given a reloadable debit card that will be electronically loaded with money. If this card is lost or stolen while you are on study, please notify the research staff immediately. The stolen card will be cancelled and a new card will be issued to you if any funds are remaining in the stolen card.

The maximum study compensation for Group 1 could be up to $490 for completion of study assessments and intervention tracking and $382 for Group 2 participants who make the decision to crossover to Group 1. For those Group 2 participants who elect *not to* crossover to Group 1, the maximum compensation for study assessments will be $175. The money you receive may be taxable. If you receive more than $600 in a calendar year for being in research studies, you will be given an IRS Form 1099-MISC for tax reporting purposes.

Additional Information

4. You may ask the study chair (Dr. Lorenzo Cohen, at 713-745-2668) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from

participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by Wake Forest NCORP Cancer Center Research Base (WF NCORP RB) through a grant from the National Cancer Institute.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Wake Forest University Baptist Medical Center
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2020-1190.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION