Improving Cognition After Cancer (ICAN)

NCT04049695

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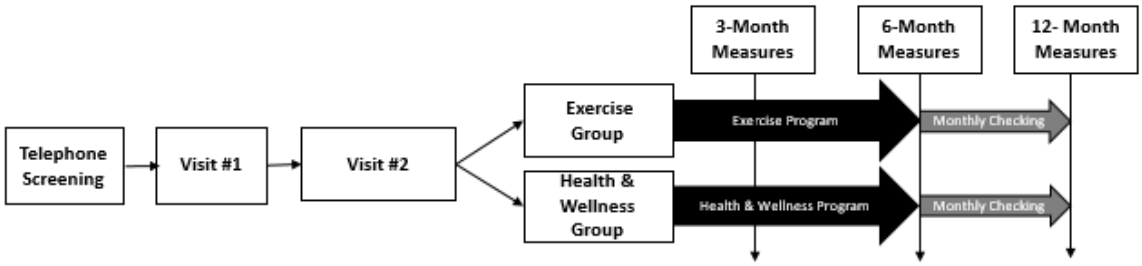
University of California, San Diego
Consent to Act as a Research Subject

Improving Cognition After Cancer

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Sheri Hartman, PhD, Assistant Professor at UC San Diego and colleagues are conducting a research study to find out how health behaviors can improve brain health. You have been asked to participate in this study because you have had breast cancer and told us on the phone that you have had problems with your memory and attention. Your participation in this study is completely voluntary. There will be about 250 breast cancer survivors enrolled in this study.

Why is this study being done?
The purpose of this study is to see if the two study groups improve brain health.

What will happen to you in this study, and which procedures are experimental?



If you agree to be in this study, the following will happen to you:

Attend 5 study visits
You will attend 5 study visits at the UCSD Moores Cancer Center. Your parking will be paid by the study.

- Visit #1. Once you have agreed to be in the study, we will measure your height & weight. We will also collect a 26 ml blood sample (less than 2 tablespoons). You will be asked to do some tests of your memory and attention on the computer/tablet. You will answer questions about your medical history, feelings, alcohol use, mental health, fatigue, sleep, and daily activities. These questions will be on a computer/tablet. We will also review your breast cancer related medical records for details about your breast cancer pathology, surgery, and treatment. At the end of this visit you will be given a red device to wear for the next 7 days. This red device is a small square you wear on your waist to measure your movement throughout the day. When you are wearing the red device, you will receive a short call from the study staff to see if you have any questions. You will be asked to bring the red device to your next visit. This baseline visit will take 2 - 2.5 hours.

Red device & device belt

- Visit #2. This visit will be about 7 days after your first visit. At this visit, we will check that the red device was worn for enough time. If you did not wear it for at least 12 hours each day for 7 days, you may be asked to wear it again and this visit will be rescheduled. You will be asked to do some tests to measure your physical activity such as a step and sit-to-stand test. Once all the measures are finished you will be assigned by chance to a study group. You have an equal chance of being assigned to either group. Neither you nor the researcher(s) can choose your group. We will give you materials for your group, go over your group in detail, and show you how to use the study materials. This visit #2 will take about 1.5 - 2 hours.

- 3-Month, 6-Month, 12-Month Visits. You will have visits at 3-months, 6-months and 12-months. About 10 days before each of these visits, we will mail you the red device that you wore after visit #1. You will be asked to wear it for at least 12 hours a day for 7 days. You will be asked to bring this device with you to each of these visits. At these visits, we will do the same measures as the first visit including a 26 ml blood draw (less than 2 tablespoons). These visits should take 1.5 - 2 hours.

If there are COVID-19 concerns or restrictions, some of these visits may be able to take place at your home. Two staff members would come to your home to do the visits.

Study Groups

If you participate in the study, you will be assigned by chance to one of two study groups.

- **Exercise Group.** If assigned to this group, you will be helped to increase your exercise to meet your personalized goal. You will get a wrist worn monitor that tracks your activity to wear every day for the entire 12 months. You will be asked to charge it and sync it at least once a week. Your Health Coach will be able to see your activity from the monitor and use it to reach out to you and make sure that your exercise goals are right for you.
- **Health & Wellness Group.** If assigned to this group, you will get tips and tools to improve a variety of health and wellness behaviors. Topics include stress management, sleep, and nutrition.

Activities for both Groups

You will meet your Health Coach who will go over the details for the group that you were assigned. The table below outlines the schedule of activities. The content of the health coaching calls and emails differs based on your group.

Week	Activities for both groups
1	1 hour Visit: Group orientation
1 - 23	1-2 emails per week with reminders, information, and resources. Your Health Coach may email, text, or call you with additional information and support as needed.
3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23	20-minute Health Coaching Phone Sessions with Health Coach to discuss topic of week, review questions from previous week
24 - 52	Once a month Phone Sessions with your Health Coach & every other week emails with reminders, information and resources

Audio Recording of Health Coach Sessions
We would like to audio record the Health Coach sessions. You do not have to agree to have your Health Coach sessions recorded. You can stop any recording at any time without impacting your participation.

Do you agree to have your Health Coach Sessions recorded?

___Yes, you agree to have your Health Coach Sessions recorded.

___No, you do not agree to have your Health Coach Sessions recorded.

The two study groups are *experimental*, but both have been used in other studies of breast cancer survivors and older women.

Blood Tests
Tests will be done on your blood to look at aging and wellness in breast cancer survivors. DNA and RNA will be collected from your blood. DNA is what genes are made of. RNA is another material that plays a role in the way genes work. This study may look at your DNA and RNA to learn whether genes and gene products can help us understand the risk of diseases like problems with brain health. The researchers will not look at your DNA to diagnose diseases. They will not do clinical genetic testing or counseling. You will not get your results of any blood tests. As part of this study, you are giving permission for your data and blood samples to be used for future breast cancer and brain health related studies by researchers involved with this study.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?
Participation in this study will last about 12 months. There are 5 in-person visits that take a total of about 8 - 9 hours:

- Visit #1 takes about 2-2.5 hours.
- Visit #2 takes about 1.5-2 hours.
- Visits #3-5 (3-Month, 6-Month, 12-Month Visits) take about 1.5-2 hours each.

There are 11 phone calls in the first 6 months and 6 phone calls in the second 6 months. These calls will last about 20 minutes each. Based on your need and interest your health coach may contact you between these scheduled phone calls. You may get 0 up to 11 extra contacts. Reading weekly emails will take about 2-10 minutes. Time spent working on goals with your health coach will vary based on the personal goals you set.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include:

1. You may become upset or tired while doing the questionnaires. Some of the questions may be sensitive or personal. If you are bothered by any of the questions, you can take a break, skip questions, or stop. Please let study staff know, so that we can provide breaks.

2. You may have discomfort or soreness because you may exercise more. There is a small chance that you could become injured while exercising. If you have an injury, you should let your Health Coach or research staff know as soon as possible.

3. You may have minor discomfort, bruising, bleeding at the site of the blood draw.

4. There is an unlikely risk of loss of confidentiality. To reduce this risk, all data are saved in a secure database or kept in locked study cabinets in our secure study offices. The databases are password protected. Only study staff can use our databases.

There is also a potential risk of loss of confidentiality of data collected by the wearable activity device. Data from the wearable device is stored on the device company's server. The company owns this data and may use the data in ways that we will not know about. We are using activity data from the devices including steps, active minute, and heart rate. The devices being used for this study do not have a GPS and do not track your location. If you would prefer to not use your personal email for your device account, we can provide a study email for you to use. Once we download your device data, we will link it with your unique study ID.
Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
Study participation is voluntary. The alternative to participating in this study is to not participate.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you for being in the study. The researchers may learn more about how healthy behaviors improve brain health.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. By participating in this study, you are not giving up any rights. You may stop being in the study at any time without penalty or loss of benefits. If you decide that you no longer wish to be in this study, please let the research team know verbally or in writing. If you still have the red device you will need to return it. We will send you a postage-paid envelope to mail it back to us. You will be told if any important new information is found that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study if you do not follow the study directions. You may also be withdrawn if the researchers think it is in your best interest not to continue.

Will you be compensated for participating in this study?
You will get a code that will pay for your parking for each in person visit at UCSD. You will get $20 for finishing all the measures at the start of the study. You will get $50 for finishing the measures at each of the follow-up visits (3-month, 6-month, and 12-month). You will receive an additional $50 if you do the measures for all the in-person visits. If you finish all the study measures, you will get a total of $220. All incentives will be provided via a Visa gift card.

Are there any costs associated with participating in this study?
There will be no cost to you for being in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All identifiable information will be kept in locked cabinets in locked offices at UC San Diego Moores Cancer Center or in a HIPAA-compliant database. Only study staff can use our study databases. All participants are given a unique ID. Data will be coded only with this ID. Only the study staff will see any identifiable information. Research records may be reviewed by the UCSD Institutional Review Board and the National Cancer Institute.

You will also be asked to read and sign a HIPAA Authorization in Research form. This form allows us to collect information about your breast cancer pathology, date and type of surgery, and types of treatment. This information will become part of your research record. Only members of the research team will see any identifiable information. Research records may be reviewed by the UCSD Institutional Review Board and the National Cancer Institute.

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. You can search this website at any time.

Data Sharing
To learn more about breast cancer survivors, Dr. Hartman and the study team may want to share data or blood samples in this study with others that are not part of the study team, but who also conduct research on aging and wellness in breast cancer survivors. You will have the option to share or not share your data and blood samples with others outside this research team.

This may include the DNA and RNA that is collected from your blood. DNA is what genes are made of. RNA is another material that plays a role in the way genes work. This study may look at your DNA and RNA to learn whether genes and gene products can help us understand the risk of diseases like problems with brain health. The researchers will not look at your DNA to diagnose diseases. They will not do clinical genetic testing or counseling. You will not get your results of any blood tests.

Biospecimens (blood samples) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. It is your choice if you want to share your data and blood samples with others outside of the research team.

There may be some risks with sharing data collected from the red device, questionnaires, measures completed at your study visits, and your blood samples.

1. There is an unlikely risk of loss of confidentiality. To reduce this risk, all data that are shared will not have any information that would link the data back to you. You should be aware that any data, and especially genetic information, may become identifiable in the future despite what the researchers do to remove information about you. You will have the option to share or not share your data and blood samples with others outside the research team.

Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: a) Health insurance companies and group health plans may not request your genetic information that we get from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that these laws do not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

It is your choice whether or not to share any of your data with others. Are you willing to have your data including blood samples stored and studied for future breast cancer related research with others outside this research team?

___Yes, I agree to have my data and blood sample, including genetic information, stored and used in future breast cancer research with others outside this research team.
___No, I do not agree to have my data and blood sample, including genetic information, stored and used in future breast cancer research with others outside this research team.

Future Contact:
We may want to contact you in the future to get your feedback on this study. We may also want to let you know about future studies. You do not have to agree to being contacted again.

Do you agree to be contacted in the future by study staff?

___Yes, I agree to be contacted in the future by study staff.
___No, I do not agree to be contacted in the future by study staff.

Who can you call if you have questions?
Dr. Sheri Hartman and/or_____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Sheri Hartman at 858-534-9235 or sjhartman@ucsd.edu.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____

Name of Participant (please print)

_____ _____

Signature Date & Time

_____ _____

Witness Date