UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

STUDY TITLE:

Memory training versus yogic meditation training in women with subjective memory complaints

INTRODUCTION:

Helen Lavretsky, M.D., and associates from the Department of Psychiatry at the University of California, Los Angeles are conducting a research study. You have been asked to participate because you are at least 50 years old with identified cardiovascular risk factors and have reported that you are suffering from mild memory problems. Approximately 100 subjects will participate in this study. This study will require 18 visits over a 12-month period that will include 6 assessment visits and 12 classes.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare Memory Enhancement training to Kundalini yoga and Kirtan Kriya meditation with women reporting mild memory problems. You will be randomized to receive either Kundalini yoga or Memory Enhancement training compared to yoga training on cognitive performance and mood. Another purpose of the study is to use functional magnetic resonance imaging (fMRI) to better understand brain aging as it relates to memory.

This study has several parts:

1) In the first part of the study, you will be asked to complete surveys about your mental and physical health. You will also receive a physical exam and ECG. Questionnaires will be administered at baseline and each assessment visit.
2) In the second segment of the study, you will complete an fMRI scan which will take a picture of your brain. The pictures from the scan will help the investigators better understand the relationship between the structure and function of the brain and how it works. This will be done twice: at baseline and after 12 weeks of treatment.
3) You will participate in cognitive testing in order to investigate the effect of memory training or yoga on cognitive performance.
4) You will participate in some tests of respiratory function to investigate the effects of the interventions on the autonomic nervous system.
5) You will complete a blood draw for genetic analysis. The purpose of this is to

determine the role of genes that are involved in the mechanisms of stress and cognition. We will also explore changes in gene expression, immune system, and telomerase levels with treatment using special tests. This will be done at baseline, after 12 weeks of treatment, and at 6 months.

6) You will have 12 weekly 60-minute sessions of either memory training or yoga meditation. You will be assigned home practice and asked to log your home practice.
7) We will follow up at 6 and 12 months by repeating cognitive and behavioral questionnaires.

The following definitions may help you understand how this research study is designed:

- Electrocardiogram (ECG) – measures the electrical activity of your heart.
- Randomized / randomization – assigned to a group by chance, like flipping a coin.
- Functional Magnetic Resonance Imaging (fMRI) Scan – a medical imaging technique used in radiology to visualize internal images of the body in detail.

This study is being funded by the Alzheimer's Research and Prevention Foundation.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

One hundred (100) women will take part in this study at UCLA.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:

Initial Screening Visit:
Before you begin the study, you will need to read and sign this consent form. A member of our research team will ask you about your general medical and psychiatric history (20 minutes). Your vital signs (blood pressure, pulse) will be assessed (5 minutes). We will also ask you to complete a questionnaire asking about your mood, daily functioning, and patterns of thinking and memory (1 hour). The questionnaires and screening procedures are performed to determine your eligibility for participating in the study and are for research purposes.

In total, the initial visit will last approximately 2 hours.

During the study:

Baseline Visit: Part 1

Neuropsychiatric Evaluation. If you are eligible and decide to take part in this study, during the second visit a member of our research team will conduct a neuropsychiatric evaluation using questionnaires and cognitive assessments (1.5 hours). If the researchers discover a diagnosis of dementia, we will refer you to the appropriate clinics for dementia care in the UCLA Geriatric Psychiatry clinic and the Alzheimer's Disease Center at UCLA, and you will not be eligible to participate in the study. We will offer to discuss the diagnosis with you and your family, as well as with your primary care physician.

Blood Samples. Blood will be drawn by needlestick from your arm for routine laboratory testing and genetic analysis (15 minutes). The blood samples will be processed at the UCLA Clinical and Translational Research Center (CTRC). Approximately 8 tablespoons of blood will be drawn. Venipuncture is a routine procedure used for obtaining blood samples by inserting a needle into a vein in the arm and withdrawing a small blood sample. Although one attempt at venipuncture is usually sufficient, additional attempts may be necessary if the first attempt proves unsuccessful. These tests will also be done to ensure that you meet the medical requirements for participating in the study. A phlebotomist will perform blood drawing and measure your vital signs. Blood samples will be processed by the Core Laboratories of UCLA Department of Human Genetics.

Electrocardiogram. An electrocardiogram (ECG), a measure of the electrical activity of your heart, will be performed (25 minutes).

In total, this visit will take up to 2.5 hours.

Baseline Visit: Part 2

Magnetic Resonance Imaging (MRI) Scan. You will be asked to have your first of two MRI scans of your brain at the beginning of the study. The procedure involves making brain images with magnetic fields and does not involve radiation, blood samples or injections. MRI scans use a large magnet to form a structural image of your brain. The scan will occur at the UCLA Brain Mapping Center. You will be asked to remove all metal from your person before the scan and lie still for about 75 minutes while the scan is taking place. During this scan you will be asked to do cognitive tasks, watch a video, and rest. You will also complete a breath counting task in which you will count the number of inhales within a 1 minute time frame. During the scan, you will wear a flexible band around your rib cage that assess your breathing rate, a finger probe that measures your heart rate, a probe on your hand that measures your sweat, and a small nasal cannula (a rubber tube) that will measure your breathing.

Physiological tests. Physiological testing will involve sitting in a chair with a device attached to your finger to measure blood oxygen levels (no needles required), electrodes attached to your chest to record your heart activity (electrocardiogram, ECG), and a band placed around your rib cage to record breathing. In addition, you will wear a nasal cannula (small rubber tube) under your nose to measure your breathing. You will also have a small blood pressure cuff placed around your finger to measure blood pressure, and sensors placed on your skin to measure sweat. You will perform several tasks to test your heart and breathing responses. Each exercise will last up to 10 minutes, and take up to 2 minutes to set up. This session will take about one hour. Ideally, you should not have any caffeine (coffee, soda, etc.) prior to testing as this can affect the results of the study. You will perform some or all of the following:

1) Sit resting
2) Breathe at a certain pace
3) Breathe hard into a tube
4) Hold your breath
5) Squeeze a bulb with your hand
6) Breathe in through a small tube

In total, this visit will take roughly 3 hours.

Weekly Yoga and Memory Training:
You will be randomly assigned to either yoga meditation or memory training classes once per week for 12 weeks. Sessions will last approximately 60 minutes and home practice will be assigned at each class. If you decide after completing one treatment that you would like to try the other treatment, we will offer that to you at no cost after you complete the study.

Follow-up Visits:
At week 6, we will ask you to complete a brief questionnaire (10 minutes). At each subsequent follow-up visit (i.e., at week 12, 6 months, and 12 months), your vital signs will be measured and questionnaires will be administered.

The week 12 follow-up visit will include a blood draw and physiological testing. This will also be the time point that you get your second brain MRI scan. The week 12 follow-up visit will last approximately 3.5 hours.

The 6-month follow-up visit will include cognitive and physiological testing and a blood draw and will last approximately 4 hours. The 12-month follow-up visit will include a cognitive testing and will last approximately 2.5 hours. (Please see the Assessment Schedule at the end of this document). *All screening and follow-up procedures are done for research purposes.*

HOW LONG WILL I BE IN THIS STUDY?

This study will last one year.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
Blood drawing may produce pain, infection, bruising, swelling at the site and rarely fainting. Physiological testing and cognitive testing may be uncomfortable or frustrating. If for any reason you are too uncomfortable during the study, you are free to discontinue the study at any time.

Unknown risks and discomforts:
This research study may involve risks that are currently unforeseeable. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

If you notice a negative change in your condition, notify the study doctor at (310) 794-4619. It is important that you discuss with the study doctor or the research study staff any unusual symptoms that you may experience. Any positive effects that are experienced should be discussed as well.

Risks Associated with Loss of Privacy in Genomic Research:
Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance and employment discrimination based on genetic information obtained about you.

Potential Risks and Discomforts of MRI:
The MRI scanning procedure requires that you be confined in a small partially enclosed space. Some individuals find this uncomfortable and may exhibit symptoms of claustrophobia including nervousness, sweating or other minor discomfort. The sound of the MRI scanner can be quite loud; you will be given special ear plugs to minimize the noise. In addition, the magnetism of the machine attracts certain metals; therefore, people with these metals within their bodies (such as certain pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from participating in this portion of the study. The "metal" in dental fillings is less responsive to magnetism and is therefore allowed. The research team will ask you if you have any metals within your body before scheduling your MRI. You will be expected to notify the research team of any metal in your body, other than dental fillings. There are no other known side effects resulting from exposure to the MRI scan.

Although there is no evidence that participation in this study by a pregnant woman would be harmful to her fetus, current guidelines for the use of MRI in clinical settings recommend that MRI studies be delayed until after the pregnancy when possible. Consequently, we request that women who are pregnant or think that they might be pregnant not participate in this research study. Because this is a research procedure, there may be risks that are currently unforeseeable. If a likely brain abnormality is discovered during your scan, a member of our study staff will discuss it with you. We will also be willing to discuss it with your primary care doctor if you so choose.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
You may not experience any benefit from participating in this study. The possible benefits you may experience from being in this study include an evaluation of symptoms, general health discussions with the study doctor and help in referrals for additional treatment if needed.

Possible benefits to others or society:
This study will help the researchers learn more about memory training, yoga, and meditation that may improve knowledge of effective treatments for memory problems. We hope that this information will help future patients with memory problems like yours. Research participants often express satisfaction from knowing they have been able to make a personal contribution to the advancement of human understanding and to the search for solutions to health problems.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, there may be alternative procedures or courses of treatment are available. Other alternative therapies are available to treat your condition. The alternative options

include psychotherapy, cognitive behavioral therapy, and other methods like physical exercise. You may choose to be treated with one or more of these rather than participate in the study. You may choose to receive these therapies at any point during the study, and if you do, your participation in the study will be discontinued. If you have questions about alternative therapies, ask the study doctor for additional information.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researcher will ask you to withdraw from participating in this research if circumstances arise which warrant doing so. The researchers or the study sponsor might also decide to stop the study at any time.

If you experience any of the following side effects like chest pain, aggravated hypertension with blood pressure above 160/90 mm Hg on two consecutive appointments, exhibit changes or have an abnormal reading on your ECG, develop any severe side-effects, or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Helen Lavretsky, M.D., M.S., will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out for any reason, the data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The only people who will know that you are a research subject are members of the research team. No information about you, or provided by you during the research, will be disclosed to others without your written permission except:

- if necessary to protect your rights or welfare (example, if you are injured and need emergency care); or
- if required by law

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

The researchers will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. However, participating in research involves a risk to privacy and confidentiality. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. All study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. The research team will carefully follow the coding, storage, and data sharing plan explained below.

Use of personal information that can identify you:
The research coordinator will assign a number code to track the questionnaires and

interview materials. We will remove identifying information from all data during the data analysis phase of the project and from all data presented publicly in lectures, seminars, or publications.

How information about you will be stored:
All paper files will be kept in locked cabinets to maintain the anonymity of participants and to bar any unauthorized access. The computerized database will be protected through the use of entry codes available only to authorized personnel.

People and agencies that will have access to your information:
Under California law, the privilege of confidentiality does not extend to information about sexual or physical abuse of vulnerable individuals (i.e., a child, elderly person, or dependent adult). Although all private information will be kept confidential and will not be discussed outside of the research group, investigators are obligated by law to report suspected or known sexual or physical abuse of a vulnerable individual.

In the event that you tell research staff or indicate on a questionnaire that you are thinking about killing yourself or someone else, the research staff will ask you more questions about those thoughts. Depending on the intensity of these thoughts, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or therapist; or work with you on a plan that may include getting you to a hospital for safety.

The research team and authorized UCLA personnel, the study sponsor, Alzheimer's Research and Prevention Foundation, and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How information about you may be used for future research:

It is possible that investigators conducting other research might request that de-identified data collected for this study be shared for further research. For example, investigators associated with the government agency supporting this study might make this request. Your de-identified data may be shared with other investigators, your name or other personal identifying information would not be revealed. Your information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study will pay for the cost of supplying and administering the study drug/device, and all required study items and services as described in this consent form.

WILL I BE PAID FOR MY PARTICIPATION?

After completing the 6-month follow-up, will receive a payment of $100 honorarium for your participation in the trial. For completing the 12-month follow-up, you will receive another $50. Those participating in fMRI scans will be paid $50 per scan (up to a total of $100). Those who complete all portions of the study (including both fMRI scans) will receive a total of $250 for their participation.

In addition, you will be reimbursed for out-of-pocket expenses for parking or bus transportation. We will offer reimbursement of $13.00 per visit for up to $234.00 for 18 visits, including classes.

If you must drop out because the investigator asks you to (rather than because you have decided on your own to withdraw), you will be paid $10.00 per visit for each visit you have attended so far, up to $100.

You will be asked for your Social Security number for the purposes of payment. UCLA employees other than the study team may know that you are participating in a research study, but this will only be for specific reasons such as processing your payments and they will not know specific details of the study. Information such as the study title, the nature of the research or the names of procedures undergone will not be indicated in the check request. This information will be protected and stored in a locked cabinet and shredded as soon as payment has been received. If you received more than $600 from UCLA in the course of a year, UCLA must report such income to the Internal Revenue Service.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

Principal Investigator: Helen Lavretsky, M. D.
760 Westwood Plaza, UCLA NPI, Room 37-372
Los Angeles, CA 90095
(310) 794-4619

You may contact Helen Lavretsky, M.D. at (310) 794-4619 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Helen Lavretsky, M.D. 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. 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.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away.
- The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

Assessment Schedule

	Screening	Baseline Part 1	Baseline Part 2	Week 12	6 Months	12 Months
Time	2 hrs	2.5 hrs	3 hrs	3.5 hrs	4 hrs	2.5 hrs
Questionnaire	X			X	X	X
Vital Signs	X			X	X	X
Cognitive Testing		X			X	X
Blood draw		X		X	X	
fMRI			X	X		
Physiological tests			X	X	X	