Sedentary Behavior Interrupted: A Randomized Trial of 3-Month Effects on Biomarkers of Healthy Aging and Physical Functioning in the Real World (P2)

NCT03473145

March 29, 2022

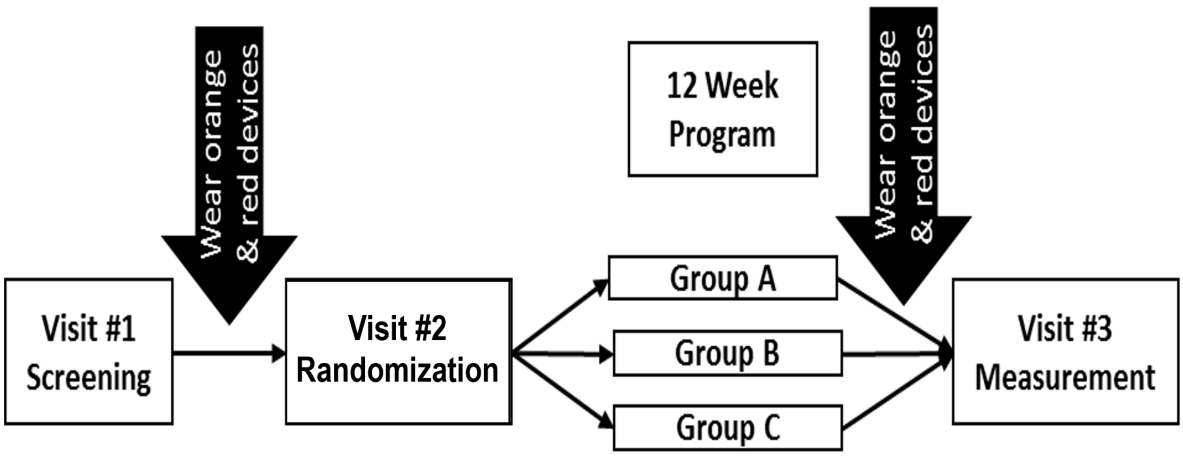
University of California, San Diego
Consent to Act as a Research Subject
Rise for Health - A randomized trial of 3-month effects on biomarkers of healthy aging and physical functioning in the real world

Sheri Hartman, PhD, and colleagues, have been funded by the National Institutes of Aging to conduct this research study to learn more about sitting in older women. Before you decide to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do. You are being asked to participate because you are a postmenopausal woman 55 years or older. There will be approximately 405 women who participate in this study.

Purpose of the Study: The purpose of this study is to test if different ways of breaking up sitting can improve health. Sitting for long periods of time can increase the risk for many diseases including heart disease and diabetes. We are testing the benefits of breaking up sitting time on different measures of health.

Study Duration: This study will take place over a period of about 13 weeks.

Description of the Study:



Study Visits

In order to determine if you are eligible to participate, you will complete some screening tests. These screening tests may take place at one of our study locations at UC San Diego or may take place at your home. All the screening tests need to be completed before you are eligible to enroll in the study.

Visit 1: The screening visit will take 60 - 90 minutes. At this visit, you will:

- Review and sign the informed consent document
- Have your height, weight, and blood pressure taken
- Test your ability to safely and comfortably stand up and walk
- Complete Thinking games
- Answer questions about your medical history and current medications

If you are eligible after the visit #1 is completed, you will be given two devices to wear for 7 days, have your blood drawn (either at Visit #2 or at your home in between Visit #1 and Visit #2), and complete some surveys at home.

Two devices:

- The orange device is worn on your thigh for 24 hours a day. This device can be worn while showering, bathing or swimming and measures time spent sitting and doing sit-to-stand transitions.
- The red device is worn on a belt around your waist. You may wear this under or over your clothes. You will also wear this device for 24 hours a day except when showering, bathing or when swimming.
- You will be asked to wear these devices for at least 7 days after your screening visit. You will be provided a log to fill out while wearing these devices.
- You will bring these devices to Visit #2 or mail them back to our study team.
- After 7 days of wearing the devices, data from your study devices will be reviewed to see if it meets the eligibility criteria.

Complete Surveys
In between Visit #1 and Visit #2, you will also be asked to complete surveys on a computer or on paper at your home. The questions may ask you about your sleep, daily activities, feelings, home and work environment, physical activity, sedentary behaviors. The surveys will take between 45 – 60 minutes to complete and do not need to be completed all at once.

Blood Draw
You will have a small amount of blood taken (~3 tablespoons) to measure blood sugars and other molecules in your blood that may influence healthy aging. You must be fasting for at least 10 hours before your blood draw. The blood draw may take place at Visit #2 or may take place in between Visit #1 and Visit #2, by a certified phlebotomist (a person who has specialized training to draw blood) at your home.

Visit #2:
This visit will take about 1 hour if you had your blood drawn at home prior to Visit #2 or it will take about 1.5 hours if you need to have your blood drawn at Visit #2. If both your blood values and device data are eligible, you will enroll in the study. At this visit, you will meet with your Health Coach who will give you an overview to the group you have been assigned (see Intervention activities below).

Visit #3:
This visit will occur at the end of the study at 13 weeks. It will take about 1 hour if you had your blood drawn at home prior to this visit or it will take about 1.5 hours if you need to have your blood drawn at Visit #3.
At this visit, you will:

- Have your height, weight, and blood pressure taken
- Test your ability to safely and comfortably stand up and walk
- Complete Thinking games

You will also have a small amount of blood taken (~3 tablespoons) to measure blood sugars and other molecules in your blood that may influence healthy aging. You must be fasting for at least 10 hours before the blood draw. The blood draw may take place at one of our study locations or the blood draw may take place at your home by a certified phlebotomist.

Before the 13-week visit, you will be mailed the red and orange devices to wear just as you did at the start of the study and bring back to Visit #3. You will also be asked to complete some surveys either on paper or on the computer. The questions may ask you about your sleep, daily activities, feelings, home and work environment, physical activity, sedentary behaviors, and satisfaction with the study.

Blood samples

Biospecimens (such as blood) 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 use of your biospecimens and/or information obtained from them.

Intervention Activities

There are 3 groups in this study; two focused on breaking up the time you spend sitting and one focused on learning more about healthy living for older adults. **You will be randomly assigned to one of these groups.** This means that you will be assigned by chance to a study group. Your chance of being assigned to each group is 1 in 3. Neither you nor the researcher(s) can choose the group to which you will be assigned.

The three study arms include:

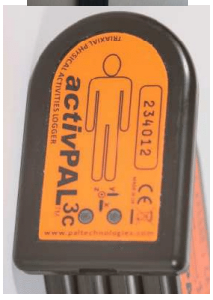
- Healthy Living – in this group you will learn about various strategies for being healthy including tips on improving sleep, reducing stress, and staying hydrated
- Reduce Sitting – in this group you will be encouraged to reduce your time spent sitting by about 2 hrs a day
- Sit-to-Stand – in this group you will be encouraged to increase your transitions from sitting to standing by about 30 a day

You will be assigned a Health Coach who will go over the details for the group that you were randomly assigned. You will have in-person and video or phone counseling sessions that will last about 20 – 60 minutes each.

The table shows the schedule of counseling sessions for each group:

Week	Healthy Living Group	Reduce Sitting Group and Sit-to-Stand Group
1	Health Coach Session #1 (In-Person)	Health Coach Session #1 (In-Person)
2	Health Coach Session #2 (Video/Phone)	Health Coach Session #2 (In-Person)
3	Health Coach Session #3 (Video/Phone)	Health Coach Session #3 (In-Person)
4	Health Coach Session #4 (Video/Phone)	Health Coach Session #4 (In-Person)
6	Health Coach Session #5 (Video/Phone)	Health Coach Session #5 (Video/Phone)
8	Health Coach Session #6 (Video/Phone)	Health Coach Session #6 (In-Person)
11	Health Coach Session #7 (Video/Phone)	Health Coach Session #7 (Video/Phone)

The Health Coach sessions will be audio or video recorded. You will provide consent to have the sessions audio or video recorded in the Rise for Health audio or video consent form.



If you are assigned to one of the groups aimed at breaking up sitting time (Reduce Sitting Group or Sit-to-Stand Group), you will be given a wrist worn device such as a WatchMinder to support you in meeting your goals. You will also be asked to wear the orange device for a week during week 1, week 2, week 3, week 7, and week 8. You will receive personalized feedback about your sitting goals from the device at each in-person study visit. You will also have the option to use various tools that may help you reach your goals. These tools include objects like a stop watch, egg timers, or recommendations for mobile apps. If you are assigned to the Reduce Sitting Group you may also receive a standing desk or standing table. All tools and devices are to be used during the duration of the study and will be returned to the study team by the end of the study.

The in-person Health Coach Sessions may take place at one of our study locations at UC San Diego, may take place at your home, or may happen by video chat or phone. Directions and parking will be provided for each in-person Health Coach session.

Risks or Discomforts

The risks involved in this study are minimal.

- You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.
- You may experience mild muscle soreness, stiffness, and/or fatigue initially as you increase the time you spend standing each day or doing sit-to-stand transitions. These should diminish over time as your body becomes used to standing and moving more.
- You may experience local skin irritation from the orange device's mild adhesive or from wearing the red device belt or the wrist device if randomized to the Reduce Sitting Group or Sit-to-Stand Group.
- You might feel dizzy or at risk for a fall from standing more often or doing more sit-to-stand transitions. Although we think it is unlikely that you will experience any physical harm from this study, it's important to seek immediate health care attention if you experience chest pain, lightheadedness, an injury, or symptoms that concern you. If you feel any discomfort during one of the Study Visits please notify a staff member immediately so precautionary measures may be taken.
- Risks associated with blood draws can include pain or discomfort at the needle site, bruising, bleeding and rarely, infection and fainting.
- There is also a potential, but unlikely risk of loss of confidentiality. To reduce this risk, all subject data will stripped of individual identifiers following data collection. We will assign each person a study ID and all data records will be coded with the study ID rather than personal identifiers. The code that links the study ID and the name will be stored in a separate place than the data file until all of the measurements are complete. Your contact information will be kept so that research staff may reach you during or after the study. Your data will be stored appropriately in locked cabinets and on a secure computer server that is password protected in order to minimize the risk of loss of confidentiality.
- 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.

Confidentiality

Research records will be kept confidential to the extent provided by law. All responses and data collected will be kept confidential within the research team and your data will be stored appropriately in locked cabinets and on secure computer servers. Results of this study may be reported in scientific journals, meetings, and news media. None of these reports will use your name or use data that can point to any person who took part in the study. Strict security measures will be taken to insure that none of these procedures results in release of any information you provide us. Research records may be reviewed by the UCSD Institutional Review Board.

Data Use

You give your permission for your data and blood samples to be:

1. Used for analyses that have not yet been specifically planned at this time by researchers at UCSD and other universities. Dr. Hartman will be responsible for deciding how your data will be used. There will be no direct benefit to you from future studies since you will not be provided with any results or information regarding research done with your data. Dr. Hartman, her associates, or her successors in these studies will keep your data and the information derived from it for an indefinite period.
2. De-identified data will be uploaded to ClinicalTrials.gov, a web-based resource that provides the public with easy access to information on publicly and privately supported clinical studies.
3. Shared on a public website and/or data repository. Only de-identified data (i.e. data with no personal identifiers) will be shared on a public website or data repository.

You consent to such uses.

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 the Web site at any time.

Benefits

You may or may not benefit from participating in this research study. We do hope the results of this study will help ongoing and future work in reducing sitting time and healthy aging.

Payment for Participation
You will receive a parking code to cover the cost of parking for all in-person visits. You will not receive any compensation for completing the Screening Visit (Visit #1) other than a parking code. If you complete Study Visit #2 at one of our study offices, you will receive $10 to cover the cost of travel to Study Visit #2 and if you complete Study Visit #3 in one of our study offices, you will receive $10 to cover the cost of travel to Study Visit #3. You will receive $25 for completing Study Visit #2 and $100 for completing Study Visit #3. If you enroll in the study and complete Study Visit #2 and Study Visit #3 you may receive up to a total of $145 ($20 for travel if you come to one of our study offices and $125 for completing the Study Visits). There will be no cost to you other than your time. You will not be financially liable for the cost of the replacement of the measurement device should it be lost or damaged.

Voluntary Nature of Participation
Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time. Your decision of whether or not to participate will not jeopardize your future relations with the University of California San Diego or benefits to which you are otherwise entitled. You may be withdrawn from the study if the Principal Investigator believes that it is in your best interest.

Alternatives to Participation
The alternative to participating in this research project is to choose not to participate.

Care If Harmed
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.

Procedures for Termination
If you decide to withdraw from this study, you need to notify a member of the research team and return any devices you have.

Questions about the Study: Dr. Hartman or her staff has explained this study to you and answered your questions. If you have questions later about the research, you may contact the Rise for Health study office at 858-534-9333.

Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and withdraw your consent to participate at any time. A copy of this consent form will be given to you.

_____
Name of Participant (please print)

_____ _____
Signature Date

_____ _____
Witness Date

Future Contact:
We may want to contact you again at some point in the future to get your feedback on what you liked or didn't like about this study or to let you know about future studies that you may like to participate in. You do not have to agree to being contacted again.

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

Optional DNA Storage
DNA and RNA will be collected from your blood. DNA is material in our bodies that contains genes. RNA is another material that plays a role in the way genes work. This study examines your DNA and RNA to learn whether genes and gene products can help us understand the risk of diseases in adults like cancer and heart disease. The investigators on this study will not examine your DNA to diagnose diseases nor to do clinical genetic testing or counseling. Therefore, the results of this research will not be reported to you or to others who may request this information for clinical use.

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.

There is information contained in your DNA and these specimens and their derivatives may have significant therapeutic value. Your DNA, or the information from it, may be used by Dr. Hartman or other scientists for additional research in the future.

Are you willing to have your DNA stored and studied for research?
___Yes, you agree to have my DNA stored.
___No, you do not agree to have my DNA stored