

# **CONSENT FORM**

**Health Aging Resources to Thrive (HART)**

**NCT03739762**

**IRB Approval Date: Dec 15, 2020**



Kaiser Permanente Washington  
Health Research Institute

## Health Aging Resources to Thrive (HART) Study Consent Form

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### Researchers

#### Kaiser Permanente Washington Health Research Institute

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We are asking you to be in a research study. This form explains the details of the study.

Please take as much time as you need to read through this information and make your choice. Ask questions if anything isn't clear or if you would like more information.

You do not have to be in this study. If you say yes, you can quit the study at any time.

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### What is this study about?

Kaiser Permanente Washington is doing research to look at different strategies to improve the health of adults over age 60 who have added health challenges such as being overweight. We are testing two different approaches that include practical ways to increase healthy habits without having to exercise. Both programs fit within your daily life and are personalized to your situation. We developed the programs to work for people with different levels of ability, fitness, and health conditions

### What will happen if I take part in this study?

This study is open to men and women aged 60-89 who receive their primary care at a Kaiser Permanente clinic in the greater Seattle area.

If you join the study, we will ask you to:

- **Wear the activPAL for a week.** After you agreed to participate over the phone, we mailed you a small, lightweight activity monitoring device called an activPAL. The activPAL is worn with a waterproof tape dressing or mild adhesive gel on the front of your thigh. We asked you to wear it for one week and go about your normal routine. This allows us to see what your usual amount of activity is. After you wear it for one week, we ask that you mail it back to us.
- **Take part in an initial phone-based measurement visit.** Before the visit we will mail you a blood pressure monitor, scale, and measuring tape. During the phone measurement visit, study staff will walk you through collecting your blood pressure, height, weight and waist circumference. We will also have you complete a sit-stand exercise and fill out a questionnaire (either on your own online or on the phone). If your blood pressure results are out of range, we will contact the study physician on call and confirm that there are no irregularities of concern. You may be advised to contact your primary care provider after the visit if there is a concern. None of your measurements/results from this series of tests will disqualify you from the study. The questionnaire includes some sensitive questions, including questions about mood, alcohol use, health status, race and ethnicity. You do not have to answer any questions that you don't want to answer. Your first research study visit will last approximately 10 minutes. If you would like study staff to go through the survey with you on the phone, the visit will last about an hour.

At the end of the phone visit, we will mail you \$30 as a thank-you for your time.

- **Receive a randomized group assignment.** After the measurement part of your phone visit, you will be randomly assigned to program A or program B. You will have a 50/50 chance of being in either group. Once you have been assigned to a group, you will meet over the phone with your health coach to go over the study materials and to set goals.

**There are two health programs; you will be randomized to one of these two groups:**

<b>IF YOU ARE IN PROGRAM A:</b>	<b>IF YOU ARE IN PROGRAM B:</b>
<ul style="list-style-type: none"><li>• We will email or mail you (your choice) a study workbook with relevant topics and supportive tools.</li><li>• You will receive ten (10) 15-30 minute phone calls over six months from your health coach. These will be pre-</li></ul>	<ul style="list-style-type: none"><li>• We will email or mail you (your choice) a study workbook with goal-setting information, and detailed information about a variety of healthy aging topics.</li><li>• You will receive ten (10) 15-30 minute phone calls with a health coach,</li></ul>

scheduled with you by your health coach. Your coach will help you set goals to work on. You are free to skip any questions or to end the call. We may ask your permission to audio-record some of these phone calls for training purposes.

- **OPTIONAL:** At 6 weeks, you have the option to wear the activPAL monitor again and review your progress with your coach.
- We will mail you another activPAL activity monitor at the 3-month timepoint to wear for one week and mail back to us in a postage-paid envelope. You will also have a 3-month phone measurement visit where we will repeat the same steps that occurred at the baseline phone visit. These visits will last roughly 10 minutes as with your first measurement visit. However, if you would like study staff to go through the survey with you on the phone, the visit will last about an hour. You will receive \$30 as a thank you when you return the activPAL to us by mail.
- At 6 months, you will have another measurement visit by phone, and the same steps that occurred at the baseline visit will be repeated. These visits will last roughly 10 minutes as with your first measurement visit. However, if you would like study staff to go through the survey with you on the phone, the visit will last about an hour. Prior to the visit, we will mail you an activity monitor to wear for a week and mail back to us. You will receive another \$30 for this visit sent by mail.
- After the 6-month visit, you will be *re-randomized* (another 50/50 chance) to either continue to receive 5 extra

approximately every 2-3 weeks over the course of six months. These will be pre-scheduled with you by your health coach. Your coach will help you set goals to work on. You are free to skip any questions or to end the call. We may ask your permission to audio-record some of these phone calls for training purposes.

- Wear activPAL for one-week at 3 months. We will mail you the activPAL activity monitor at the 3-month timepoint to wear for one week and mail back to us in a postage-paid envelope. You will also have a 3-month phone measurement visit where we will repeat the same steps that occurred at the baseline phone visit. You will receive \$30 as a thank you when you return the activPAL to us by mail.
- At 6 months, you will have another measurement visit by phone and the same steps that occurred at the baseline visit will be repeated. These visits will last roughly 10 minutes as with your first measurement visit. However, if you would like study staff to go through the survey with you on the phone, the visit will last about an hour. Prior to the visit, we will mail you an activity monitor to wear for a week and mail back to us. After the visit, we will mail you \$30 as a thank-you for your time.

<p>sessions with your health coach or no further contacts.</p> <ul style="list-style-type: none"> <li>• If you are in the group that gets extra contacts with your health coach, you will have 5 additional brief phone calls. We will also offer you the <b>option</b> to wear the activPAL again at the 9-month timepoint. We will mail it to you along with a postage -paid return envelope.</li> <li>• We will mail* you <b>optional</b> tools to support your goal setting in this intervention group.</li> </ul> <p><i>*For these mailings, we will need to give your name and address to an external/third party vendor such as Amazon or Target or other web-based vendor to have the item mailed directly to you. You may decline both of these items.</i></p>	
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**BOTH GROUPS:**

- **OPTIONAL:** At 6 months, participate in an interview about your experience in the study during the first 6 months of the one year period. You will have completed your 6-month measurement phone visit and completed 10 coaching calls by this point. You do not have to participate in the 6-month exit interview if you do not want to. We would like to audio-record the discussion and have a professional transcriptionist type the discussion word-for-word for research purposes only. Recordings will be stored on a secure server where only study team members have access. Recordings will be uploaded to the transcription company's website without identifying information. You can still participate in the 6-month interview even if you do not agree to have the conversation recorded.
- At 12 months, you will have a final measurement phone visit and the same steps that occurred at the first three phone visits will be repeated. These visits will last roughly 10 minutes as with your first measurement visit. However, if you would like study staff to go through the survey with you on the phone, the visit will last about an hour. You will receive another \$30 by mail for this visit. After the 12-month phone visit, which is your last visit, we will also provide you with a copy of the other group's workbook if you request one. If you completed all of the activities assigned to your group, we will mail you an extra \$30 as a thank you.
- **OPTIONAL:** Participate in a study exit interview. After you complete the study, we may ask to talk with you by phone about your experience with the program and any feedback you have. This will help us improve the program. You do not have to participate in the exit interview if you don't want to. We would like to audio-record the discussion and have a professional transcriptionist type the discussion word-for-word for research purposes only. Recordings will

be stored on a secure server where only study team members have access. Recordings will be uploaded to the transcription company's website without identifying information. You can still participate in the exit interview even if you do not agree to have the conversation recorded

- **OPTIONAL:** What does audio-recording involve? We may ask you for your permission to record some of the study phone calls for training purposes. We will also request your permission to record the exit interview call so that it can be typed up and used for research purposes. We will erase all recordings as soon as possible, and no later than June 1, 2028. You can still participate in the study phone calls and exit interview even if you do not agree to have the conversation recorded.
- **OPTIONAL: Allow us to collect some information about your health from your electronic medical record.** We may want to see if our study benefits longer term health. For this reason, we request your permission to access your electronic health records via computerized search, starting one year prior to your consent to the study and up to 5 years after the study ends, no later than June 1, 2028. The type of information we will collect may include: if you have various chronic conditions (e.g. diabetes, cardiovascular conditions); lab values for HbA1c, cholesterol and fasting glucose; blood pressure; blood pressure medications; height and weight; medical events (e.g. falls, hospitalizations, heart attack, stroke, blood clots); and, healthcare costs. You may choose not to give us this permission and still participate in the study.

As described above, we will mail you cash as a thank you for your participation in measurement activities. ALL participants are eligible for the following:

\$30 for baseline phone visit

\$30 for 3 month phone visit

\$30for 6 month phone visit

\$30 for final/12 month phone visit

\$30 for completing all phone visits as a bonus

\$150 total possible if you complete ALL measurement activities

### **Will there be any costs to me?**

There will not be any costs to you.

### **Will being in this study help me?**

You may find general health improvements from your participation. But, we can't guarantee that you will benefit from being in this study. We hope the results will help ongoing and future work to learn more about improving the health of older adults.

### **Can anything bad happen to me from being in this study?**

You might feel uncomfortable answering some study questions. You may skip any questions you don't want to answer.

It's possible that someone other than the researchers could find out you were in the study or see your private study information. The steps we take to keep this from happening are described below.

You may experience local skin irritation from the activPAL's waterproof tape dressing.

If you are injured because of study activities, KPWHRI will pay for your care according to your Kaiser Permanente plan coverage. There are no plans to pay for care not covered by your health plan. KPWHRI will not pay for care related to this study if you are no longer enrolled at Kaiser Permanente. This does not take away any of your legal rights. You are responsible for co-pays, co-insurance and deductibles.

You may experience mild muscle soreness, stiffness, and/or fatigue initially if you increase the time you spend standing and moving each day. These should diminish over time as your body becomes used to standing and moving more. You also might fall from standing more often. If you have low blood pressure and increase your time standing and moving, you may experience dizziness, lightheadedness, nausea, or fainting. If you choose to increase your physical activity level, there is a chance you could injure yourself. 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.

### **How will you protect my confidentiality?**

All KP Washington researchers sign a confidentiality pledge that requires them to keep your information private.

The researchers listed on the first page and their staff will use your study information for research only. We won't use your name in study reports or write it on your survey or any other documents. Instead, we will label everything with a code number only. We won't tell your doctor whether or not you join this study or add information to your medical record. We won't tell your doctor whether or not you join this study unless your blood pressure results are outside of our expected range and the MD on call believes it requires s/he write a letter to your provider out of concern. We won't add information to your medical record, although your doctor might decide to if your results are outside of the expected range. Similarly, if we contact the KP consulting nurse service during the course of one of your phone visits out of concern for your health due to elevated or out-of-range measurements of blood pressure, the nurse will make a note in your medical record of the call.

We plan to keep your study information as described in this form until June 1, 2028. At that time, we will destroy any study records that include your name or other information that points to you.

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.

**If you are selected for Program A, you have the OPTION to receive tools used in this group which will be sent to you from Amazon.com. In order to do this, we will give your name and address to the vendor for purposes of mailing these optional items to you. You may choose not to agree to this activity at the end of this consent form.**

**We do not plan to contact you by e-mail unless you give us your email address and ask us to do so.** Information shared by e-mail is not considered secure. We cannot guarantee the privacy of e-mail, and we will be careful to limit the amount of personal information included in messages we send you. For instance, a reminder email would include: date and time. Your coach may use email, if you permit, to email you workbook materials (which do not contain any personal health information). If you are in group A, the coach may also use *encrypted email*, if you permit, to send you copies of data from your activPAL. Instructions on how to decrypt the email will also be provided. If you do not wish to use email for these purposes, we will mail materials/reminders to you at the address we have on file..

#### **Can my participation in this study end early?**

We hope that you will be able to participate for the duration of the 12-month study; however, you are free to choose to stop participating in the study at any time. While we think it is unlikely, if the research team ever develops concerns about the safety of your participation in the study because of changes in your health status or other unexpected complications, we may end your participation in specific study activities of the study as a whole without your direct consent.

#### **How does HIPAA apply to this study?**

Your health information is protected by a federal privacy law called HIPAA. KP Washington must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By signing this form, you are giving KP Washington permission to allow the researchers to collect, use, and share the following information about you for this study:

1. Information from your medical record as described on page 5 unless you opt out
2. Your survey answers.
3. Data collected at the four phone visits (such as weight and blood pressure)
4. Data from wearing the activPAL device (measuring sedentary time)
5. Your name and address will be released to Amazon.com in order to mail you support tools for this study as described on page 7, unless you opt out.



It is possible that staff from KP Washington and the funding agency (National Institutes of Health) may look at our study records for oversight. We will not share the information we collect for this study with anyone else except as allowed by law.

The HIPAA privacy law does not always apply to those who are given protected health information. Once KP Washington has given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

You will be offered a yes/no option at the end of this form to allow us to review your medical record. If you choose “yes” and grant us this access your permission for this access expires 5 years after the study ends on June 1, 2028.

### **Do I have to be in this study?**

No, being in this study is up to you. You are free to say no now or to leave the study at any time later. Either way, there will be no penalty. Your decision won't affect the health care you receive or benefits that you are entitled to.

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

You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:

Dori Rosenberg, PhD, MPH  
Kaiser Permanente Washington Health Research Institute  
1730 Minor Ave, Suite 1600  
Seattle, WA 98101

If you take back your consent, it will not affect your health care or benefits at KP Washington. We may still use the study information we collected before we received the letter taking back your consent. But we will destroy any record of your name or other information that could identify you.

### **Who do I call if I have questions?**

- If you have questions or concerns about the study, please call the project manager, Julie Cooper, at 206-287-2802.
- If you have questions about your rights as a research participant, please call the KP Washington Human Subjects Review Office at 206-287-2919.
- If you have any bad effects from this study, call your doctor and let the study staff know. If you have KP Washington insurance, you can get advice from a nurse by calling 1-800-297-6877.

## Subject's Statement

This study has been explained to me. I volunteer to take part in this research. If I change my mind later, I may leave the study at any time. I've had a chance to ask questions, and they've been answered to my satisfaction. If I have more questions later, I may call the researchers listed in this form or their staff. I will get a copy of this form to keep.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Please **PRINT** your name

Do you give permission for us to collect study-relevant information from your medical record as described on page 5 of this form? *Please check the appropriate box to confirm your selection.*

☐ Yes

☐ No

Do you give permission for us to give your name and address to Amazon.com as described on page 7 of this form? *Please check the appropriate box to confirm your selection.*

☐ Yes

☐ No

\_\_\_\_\_  
Signature of study staff obtaining consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of study staff obtaining consent

\*Please mail this form back to us using the enclosed pre-paid envelope. When we receive it, the study staff member who obtained consent from you will also sign the form, then make a copy and mail one back to you. We will keep the master signed version on file.