Study Consent Form for University of Washington School of Medicine,

Department of Rehabilitation Medicine study:

Efficacy and mechanism of a community wellness promotion program for middle-aged adults living with long-term physical disability

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NCT 03653390

UW IRB STUDY00007984

Initial IRB Approval: April 11, 2018

Document Last Updated: May 28, 2021

Document Update IRB Approval: June 18, 2021

UNIVERSITY OF WASHINGTON

CONSENT FORM

A community wellness study for adults with long-term physical disability

Researchers:

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RESEARCHERS' STATEMENT

We are asking you to participate in a research study. The purpose of this statement is to give you the information you will need to help you decide whether you want to participate in this study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all your questions, you can decide if you want to enroll in the study. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

You are being asked to participate in this study because you are an adult between the ages of 45-64 years who has a long-term physical disability.

The purpose of this study is to see if a health and wellness program called EnhanceWellness is helpful for adults with a long-term physical disability (such as Muscular Dystrophy, Multiple Sclerosis, Post-Polio Syndrome, or Spinal Cord Injury). The EnhanceWellness program helps people take on health or behavior-related goals and maintain control of their lives. We recently adapted the program to help people with physical disabilities. Now, we would like to study if EnhanceWellness is helpful for adults with a long-term physical disability. To study this, we need to compare survey answers from people with physical disabilities who are not enrolled in the EnhanceWellness program with people who are in the program. This research study is looking for about 600 adults with long-term physical disability to participate.

STUDY PROCEDURES

If you decide to participate in this study, you have an equal chance (33%) to be assigned to 1 of 3 groups at random or on a 1:1:1 ratio. Each group is slightly different in what you will be asked to do. You will be randomly assigned to the group using a math program, and the researchers will not pick for you. You cannot change which group you are assigned to, but you can always choose to not participate.

Group 1: EnhanceWellness

If you decide to participate in this study, you might be assigned to an intervention group called EnhanceWellness.

This is a 6-month program where you will work with a wellness coach over the telephone or via Zoom (HIPAA compliant video call). You will work towards health or behavior-related goals of your choice. To find out if EnhanceWellness works or not, you will fill out a survey at different times during this study.

EnhanceWellness: You will receive 8 to 10 sessions with a wellness coach who will help you work toward the goal of your choice. The number of sessions you have with the coach depends on the goal you choose and your preferences. These sessions will be over the telephone or via Zoom HIPAA compliant video call. We will audio-record all sessions; however, only some will be selected for review by a designated research staff member for quality control purposes. Depending on your goal, you may incur financial charges related to meeting your goal (e.g. purchasing a gym membership, yoga mat, etc.). Please note that we cannot reimburse you for any expenses that you incur while enrolled in this program.

- **Session 1 (about 1 hour).** The wellness coach will give you an overview of the program. During this session, you will also review and consider the EnhanceWellness consent form to answer any questions that you may have. In this session, you will complete an EnhanceWellness survey with your coach. This is different from the other research survey you will be asked to complete. Your answers to the survey will help to inform your goals for the program. For example, if you indicate that you are experiencing a lot of stress, the wellness coach might recommend relaxation techniques.

- **Session 2 (about 1 hour).** You and your wellness coach will talk about and decide on a health or behavior-related goal that you would like to work on. For example, this could be managing symptoms related to your disability (such as pain or fatigue), becoming more physically active, or preventing falls. You and your wellness coach will develop an action plan based on the goal that you choose and will schedule follow-up sessions. As part of the program, the wellness coach may ask for your consent to share your action plan with your primary care physician to encourage collaboration. This is optional and you may choose not to share your action plan.

- **Health Screen Phone Calls.** All participants who choose a physical activity goal will be asked to complete a short health screen phone call two times throughout the study: before starting the goal and three months later. Both calls will take

place with a UW Rehabilitation Medicine Physician. On this call, the UW Physician will ask you various questions about your current health such as “Do you have any current infections” or “Do you have any balance issues”. You will be asked these questions to make sure the goal you are choosing is safe for you. If the Physician has any concerns about your health and the goal, they will ask you to check with your regular doctor before beginning. They may also encourage you and your health coach to pick a different goal to work on. These calls are only to make sure the goal is safe for you. The UW Physician will NOT give any medical advice or care on the calls, and the calls are NOT the same as talking to your regular doctor.

- **Follow-up Sessions (up to 1 hour each).** Follow-up sessions will be scheduled with the wellness coach depending on your previous sessions and your goal. These typically last up to 1 hour each.

- **6-Month Session (about 1 hour).** The final session will take place about 6 months after your first session. In this session, you will complete an EnhanceWellness survey with your coach. Your answers to this 6-month survey will help to track your progress toward reaching your goals.

Research Survey: You will complete a survey at 4 different times during this study. The wellness program is 6 months long, which is part of a 12 month long research study. The 4 survey time points are:

- Before you start the 6-month program
- 3 months into the program
- 7 months (about 1 month after the end of the 6-month program)
- 12 months (at the end of the research study)

The 12 month survey at the very end will help us find out if EnhanceWellness works or not. The survey will ask you questions about your disability, quality of life, and symptoms related to your disability, such as depression, pain, and fatigue. The most sensitive question we will ask is, “In the past seven days, how often did you feel worthless?”

You can take the survey online, by paper-pencil, or over-the-phone. You are free to not answer any questions that you choose. If you decide to take the survey online, we will send you a link to the survey and instructions on how to log in. If you are using a paper version of the survey and choose to skip a question, please write “skip” next to the question. This way, we will know that you meant to skip that question and will not contact you to ask why the question was left unanswered.

Group 2: Education Program

If you decide to participate in this study, you might be assigned to an education control group that will receive information on pre-selected health and wellness topics.

This is a 6-month program where you will meet with a wellness coach over the telephone or via Zoom HIPAA compliant video call to review information on 8 health and

wellness topics. You will fill out a survey at 4 different times during this study (described below).

Wellness Education: You will receive 8 sessions with a wellness coach who will provide education on 8 topics that we have already selected. They are: (1) blood pressure management, (2) maintaining social contact, (3) cancer screening, (4) regulation of blood glucose, (5) decreasing LDL cholesterol, (6) physical activity, (7) bone, joint and muscle health, and (8) immunizations. Each session will last about 45 minutes. These sessions will be over the telephone or via Zoom HIPAA compliant video call. We will audio-record all sessions; however, only some will be selected for review by a designated research staff member for quality control purposes.

Research Survey: You will complete a survey at 4 different times during this study. The education program is 6 months long, which is part of a 12 month long research study. The survey time points are:

- Before you start the 6-month program
- 3 months into the program
- 7 months (about 1 month after the end of the 6-month program)
- 12 months (at the end of the research study)

The survey will ask you questions about your disability, quality of life, and symptoms related to your disability, such as depression, pain, and fatigue. The most sensitive question we will ask is, “In the past seven days, how often did you feel worthless?”

You can take the survey online, by paper-pencil, or over-the-phone. You are free to not answer any questions that you choose. If you decide to take the survey online, we will send you a link to the survey and instructions on how to log in. If you are using a paper version of the survey and choose to skip a question, please write “skip” next to the question. This way, we will know that you meant to skip that question and will not contact you to ask why the question was left unanswered.

Group 3: Usual Care

If you decide to participate in this study, you might be assigned a control group that will not be enrolled in the EnhanceWellness program or the Education program.

We will ask you to go about your day to day activities as usual. You will fill out a survey at different times during this study.

Research Survey: You will complete a survey at 4 different times during this study. The survey time points are:

- Before you are randomly assigned to a group
- 3 months into the research study
- 7 months into the research study
- 12 months (at the end of the research study)

The survey will ask you questions about your disability, quality of life, and symptoms related to your disability, such as depression, pain, and fatigue. The most sensitive question we will ask is, “In the past seven days, how often did you feel worthless?”

You can take the survey online, by paper-pencil, or over-the-phone. You are free to not answer any questions that you choose. If you decide to take the survey online, we will send you a link to the survey and instructions on how to log in. If you are using a paper version of the survey and choose to skip a question, please write "skip" next to the question. This way, we will know that you meant to skip that question and will not contact you to ask why the question was left unanswered.

Groups 1, 2, and 3:

GPS Tracking and Travel Diary: You may be invited to wear a small GPS tracking device to measure your activity for 1 week at 2 different times in this study (once at the beginning of the study and another time at the end, 12 months later). You would also be asked to keep a diary of all the places that you go to over the 1-week period and to go about your daily routine as you normally would. Half of all participants (50%) will participate in this GPS sub-study. The selection of participants for this sub-study is random and uses a math program to decide. The researchers will not pick participants. You do not have to participate in the GPS sub-study in order to participate in the research program.

RISKS, STRESS, OR DISCOMFORT

Loss of Privacy and Confidentiality
Because this study involves collecting identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality, which may be upsetting to you. To minimize this risk, we will assign you a study number. All of the information we collect will be stored in a secure manner.

If you are randomized to the EnhanceWellness Group or Education Program, audio recordings will be collected and may be used for quality control purposes. There is a risk of loss of confidentiality from using these recordings. The audio recordings are not used directly for research purposes and are strictly for quality control. Only the Principal Investigator (or designated, qualified staff) and the EnhanceWellness Master Trainer will have access to the recordings. Each recording will be kept as securely as possible, to minimize the risk of information security.

You may find the GPS device and travel diary intrusive. You may decline to participate in the GPS sub-study without affecting your participation in the Community Health program. You may also ask for your GPS recordings to be destroyed at any time.

Mandated Reporters
By law, the study team must release certain information (first and last name, birth date, address) to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others. There is a chance you may not be notified if a report has been filed. In the event that research staff learn of any of the above, you will be offered a call with a Research Clinician.

Psychological Distress or Discomfort
Some of the questions in the surveys include sensitive questions about depression, pain and quality of life. You may find these questions personal or sensitive. You are free to

skip any questions that you prefer not to answer, and you are free to stop the surveys at any time. You are still able to participate if you chose to not answer any of the questions.

Physical Risks

EnhanceWellness Physical Risks

Participants assigned to the EnhanceWellness Group may have increased physical risk such as injury, illness, or fatigue, depending on the health goal you choose. For example, if your goal involves physical activity, there are some risks associated with exercise such as muscle soreness, fatigue, falling, and strain.

To minimize the risk of injury from physical activity, all participants in the EnhanceWellness Program who choose a goal related to physical activity will be asked to complete a short phone call with a UW Rehabilitation Medicine Physician at the beginning of the program, and 3 months in. On each call, participants will be asked basic health questions like “Do you have any active infections?” and “Do you have any balance problems?” If the UW Rehabilitation Physician has any concerns about the risk of injury due to physical activity, you will be asked to talk with your regular doctor before beginning your goal. The UW Physician may also work with your health coach and recommend choosing a different goal with less risks. It is important to note that while the call is with a UW Physician, they are NOT providing medical advice or care recommendations, and the calls are NOT the same as talking to your regular doctor.

You might also choose a goal such as participating in the community more, which might increase risk of injury from travel or increase the risk of exposure to covid-19. These risks are very small. The programs that are part of EnhanceWellness have been developed for persons who are aging with varying levels of mobility and physical function. The wellness coach will help you identify safe and reasonable goals, the possible risks associated with each goal, and help you find ways to reduce risks associated with the goal(s) you chose. This is to make sure that each goal is safe and sensible for each participant. You will also be reminded that you can change your goal at any time, and can always choose not to participate.

GPS Physical Risks

You may find the GPS device uncomfortable to wear. The study team will work with you to find the easiest and most comfortable way to wear or carry the GPS device to minimize any possible discomfort.

Unknown Risks

Because this is a research study, there may be other risks or negative effects that are not yet known. If we learn about any new risks during the study, the study team will let you know and see if you would like to continue participating. Additionally, if you experience any harm or discomfort throughout the study let the study team know using the contact information listed above, and they will work with you to minimize any risks or discomforts that are a direct result of participating in the research.

ALTERNATIVES TO TAKING PART IN THIS STUDY

No matter what group you are randomized or assigned to, you are still able to receive your normal health care. By not participating in this study, there will be no change in what services are available to you and you can continue receiving the same care you receive now. If you choose not to participate in this study, you may speak to your health care provider about the different options for aging with physical disability that may be available to you. Your choice to be in this study is entirely up to you. Participation is voluntary, and you can decide not to participate at any point throughout the study with no negative effects. Your medical care will not be affected in any way whatsoever by your choice to participate or not. Standard care that is available would include working with a rehabilitation psychologist, licensed counselor, or therapist to work towards health-related goals. Health insurance may or may not cover this depending on your plan.

You may still be able to receive services from EnhanceWellness if you decide not to take part in this research study. Please note that if you participate in EnhanceWellness outside of this study, any suggested donations or costs to the program would be your responsibility.

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You are free to skip any survey questions you do not wish to answer. If you want to withdraw from this study, please contact us at 1-866-928-2114 or **communityhealthstudy@uw.edu**.

BENEFITS OF THE STUDY

EnhanceWellness

In the same way that the risks of this study depend on your goal, so do the benefits. You may not experience individual benefit by participating in this study. Other participants in EnhanceWellness have improved their overall health and wellness. We do not know if these benefits will be the same for adults with a long-term physical disability. The benefits of this study may vary based on the goal that you decide to work on.

Education Program

You may not experience individual benefit by participating in this study. The benefits of this study may vary based on what you do with the information you are presented.

Usual Care

There are no direct benefits that you will experience from participating in this study. However, we hope the information that you provide will help us learn if EnhanceWellness is also an effective program for individuals with a long-term physical disability.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institute of Nursing Research (NINR).

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information that you provide will be confidential (linked to identifiers). However, if we learn that you intend to harm yourself or others, we must report that to authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

De-identified EnhanceWellness survey data may be entered and stored on the Sound Generations network—Sound Generations developed the EnhanceWellness program and this will allow them to collect data about their intervention. Your de-identified study data may also be shared with other researchers at University of Washington or from other institutions.

COSTS AND COMPENSATION

As a thank you for your time and effort, you will be mailed a check for $25 after you complete and submit each survey. Therefore, you may receive a total of $100 for completing all four surveys. If you participate in the GPS sub-study, you will receive $10 for each day you complete or up to $70 for the week. You may also receive up to $70 for completing the GPS sub-study again 12 months later.

RESEARCH-RELATED INJURY

If you think you have been harmed by participating in this study, contact the study staff **866-928-2114** right away. They will refer you for treatment, if appropriate.

STATEMENT OF INFORMED CONSENT

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Participant Signature:

Printed name Signature Date

Study Staff Printed Name Signature Date

PERMISSION FOR AUDIO RECORDINGS

If you are assigned to the EnhanceWellness program or to the Educational Program, all telephone/Zoom HIPAA compliant video call sessions will be audio/video recorded to check for therapist compliance with the study procedures. Because Zoom automatically records both audio and video, only the audio recordings will be kept from Zoom calls and the video recordings will be immediately deleted after the call. The audio recordings will only be reviewed by the Principal Investigator, designated study staff, and/or the EnhanceWellness Master Trainer. These recording will only be reviewed to make sure everyone is getting consistent treatment, and only a number of randomly selected audio recordings will be reviewed. The audio recordings will not be used in any research analysis or further studies, just to check for compliance. You do not have to agree to be recorded to participate in the research. If your session is chosen to be recorded for compliance, we will notify you. At any time during the study or in an audio-recorded session, you can ask to review the recordings yourself, and we will provide you with a copy in the format you prefer (such as an audio tape or email). Some calls may not be recorded due to technical difficulties.

You can ask to have any part of or all of your audio recordings deleted. All audio recordings used in the study will be kept electronically on a secure server and de-identified. If you decide after the study ends that you no longer want your audio recordings stored, they will be destroyed at your request.

Subject's statement

The audio recording portion of this study has been explained to me, and I have read and understand the above information. If I am randomized to the EnhanceWellness program or to the Education Program, I voluntarily agree to have my telephone or video sessions audio recorded. I understand that I may withdraw this consent at any point, and I can request for the recordings to be destroyed.

Please check one box below and sign underneath:

☐ **YES, I agree to be video/audio recorded**.

☐ **NO, I do not agree to be video/audio recorded**.

Printed name	**Signature**	**Date**

PERMISSION AND CONSENT FOR GPS SUB-STUDY

If you are assigned to the GPS sub-study, you will be asked to carry or wear a GPS location tracking device for a total of 14 days during the study (7 days in the beginning, and 7 days a year later, at the very end of the study). You will also be asked to complete a travel diary, documenting the types of locations you visited (e.g., grocery store, friend's house, a doctor's office). You will be given the option to complete the travel diary electronically or via paper. We will notify you if you are randomized to this sub-study. You do not have to participate in the GPS sub-study in order to participate in the research program. The data collected from this sub-study will be de-identified, and only a number will be associated with it to minimize the risk of loss of confidentiality. Only designated study team staff will have access to this data. The GPS location data will be stored electronically on a secure server. The travel diary we will ask you to fill out will be stored in our research office in a locked file cabinet. If you chose to complete the travel diary electronically, you will be emailed an electronic version of the travel diary. Once completed, you will then be sent a unique link for you to upload the completed travel diary onto our secure REDCap website. Your travel diary will be de-identified and only a participant ID will be used on it.

You can ask to have any part or all of your GPS recordings deleted. All GPS recordings used in the study will be kept electronically on a secure server and de-identified with no personal identifying information tied to it. If you decide after the study ends that you no longer want your GPS recordings stored, they will be destroyed at your request.

Subject's statement

The GPS portion of this study has been explained to me, and I have read and understand the above information. I voluntarily agree to participate in the GPS device tracking and to complete the travel diary, if I am assigned to this group. I understand that I may withdraw this consent at any point, and that I am able to still participate in the study, even if I do not want to use the GPS.

Please check one box below and sign underneath:

☐ **YES, I agree to participate in the GPS sub-study**

☐ **NO, I do not wish to participate in the GPS sub-study**

Printed name	**Signature**	**Date**

Study Procedures for All Participants

Procedure	Session #	Group	Time from Baseline Survey	Time Required	Compensation
Screening	N/A	1, 2, 3	N/A	10 mins	None
Enrollment & Survey1	0	1, 2, 3	Day 0	45-60 mins	**$25**
GPS Sub-Study 1	0	1, 2, 3	Days 0-7	7 days	**$10/day up to $70**
Telephone Call 1 (TC1)	1	1, 2	Day 0-7	5-15 mins	None
TC2	2	1, 2	2 weeks	45-60 mins	None
TC3	3	1, 2	1 month	45-60 mins	None
TC4	4	1, 2	1.5 months	45-60 mins	None
TC5	5	1, 2	2 months	45-60 mins	None
TC6	6	1, 2	3 months	45-60 mins	None
Survey 2	3	1, 2, 3	3 months	45-60 mins	**$25**
TC7	7	1, 2	4 months	45-60 mins	None
TC8	8	1, 2	5 months	45-60 mins	None
TC9	9	1	6 months	45-60 mins	None
Survey 3	9	1, 2, 3	7 months	45-60 mins	**$25**
TC10	10	1	As needed	45-60 mins	None
TC11	11	1	As needed	45-60 mins	None
GPS Sub-Study 2	12	1, 2, 3	12 months	7 days	**$10/day up to $70**
Final Survey	12	1, 2, 3	12 months	45-60 mins	**$25**