Study Protocol 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

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INSTRUCTIONS

- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example (**1.1**) must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: A community wellness program for adults living with long-term physical disability

1.1 Home institution. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[X] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

Data collected under UW IRB #47035 (PI: Ivan Molton; Title: Project Enhance for Adults Aging with Long-Term Physical Disability) will serve as a pilot for this current study. Over the course of the previous study (data collected 2013-2017), individuals with either spinal cord injury, post-polio syndrome, multiple sclerosis, or muscular dystrophy completed a 6-month trial of "EnhanceWellness", an empirically supported motivational interviewing intervention designed to promote health and wellness in older adults in community settings. Participants completed outcome surveys of health, mood and quality of life before and following the program. IRB#47035 enrolled participants into three groups: individuals with disabilities who received the EnhanceWellness intervention (group 1), an age and gender matched control group of able bodied older adults (group 2), and people with disabilities who did not participate in the program (group 3). The current proposed study will build upon IRB #47035 by enrolling a larger and more diverse sample into a randomized controlled trial: (1) The EnhanceWellness for Disability intervention

(EW-D), (2) an attention control condition (8 sessions of wellness education, based on the CDC's "10 Keys to Healthy Aging" course), or (3) treatment as usual (TAU).

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

☐ **No**

☒ **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

NIH has asked for JIT information (including the IRB approval letter) by 3/21/2018. While we realize that review and approval will take considerably longer than 1 week, we would appreciate an expedited review of this application.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

We propose a 3-arm randomized clinical trial of 600 individuals with physical disabilities. Study participants will be randomly assigned to one of three conditions, each lasting 6 months: (1) The intervention (EW-D), (2) an attention control condition (8 sessions of wellness education, based on the CDC's "10 Keys to Healthy Aging" course), or (3) treatment as usual (TAU). Assessments will be conducted at baseline, 3 months, 7 months, and 12 months. We seek to evaluate the EW-D intervention to serve disabled individuals in middle-age. Our primary treatment target is satisfaction with community participation. We will also look at mediators of these effects, including disease management self-efficacy and resilience. Our intervention will be compared to the two control conditions – one based on educational materials and a second based in treatment-as-usual. Both self-report and GPS based data will be used to test the study hypotheses.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This is a randomized, controlled trial of an adapted wellness promotion intervention to be carried out in a large sample of middle-aged adults with long-term physical disabilities.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☐	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device
☐	11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

We lack evidence-based health and wellness interventions to serve middle-aged individuals with acquired, long-term physical disabilities (LTPD). People aging with LTPD are an underserved, but significant part of the population - between 27-39% of adults with disabilities experienced onset prior to age 44, and represent 12 million adults in the US. Middle-age is an especially vulnerable period in the life course for these individuals, since during this time they often experience rapid declines in health and function, with associated losses in quality of life and community participation. There is an urgent need for evidence-based interventions designed to improve long-term health trajectories for this population. Unfortunately, there are very few evidence-based wellness interventions that are available to individuals with LTPD in community settings. Middle-aged individuals with LTPD fall into a gap in the evidence base for health and wellness promotion.

To close this gap in the evidence base, we argue that the most efficient approach is adaptation. By selecting an already existing, evidence-based wellness promotion program designed for older adults, and adapting it to meet the needs of middle-aged adults with LTPD, we can maximize impact by creating a program that (1) is also evidence-based for older adults, (2) will be evidence-based, with only minor modifications, for middle-aged adults with LTPD, (3) has a proven track record of demonstrated sustainability and funding stability in community settings, and (4) can be disseminated through existing community agencies already serving older populations.

Therefore, we propose a randomized, controlled trial of an adapted wellness promotion intervention, in a large sample of middle-aged adults with LTPD. This intervention, called EnhanceWellness (EW), is an evidence-based, individualized wellness promotion program designed to improve the health and functional status of community-based older adults living with chronic conditions. As part of a recent ACL funded grant (IRB#47035; Molton, PI), we have used a Community-Based Participatory Research approach to adapt this intervention for younger adults with LTPD, using a formal adaptation process, and have completed pilot testing (see "preliminary work" below). We call our adapted version EnhanceWellness for Disability (EW-D). This intervention is now ready for larger scale effectiveness testing in community settings.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

EW-D was delivered to a pilot sample of 118 individuals over age 45, living with LTPD due to either: spinal cord injury, multiple sclerosis, muscular dystrophy or post polio syndrome. Data were collected at baseline, and again 6 months later. In 2016, we also recruited an age, disability and sex matched control group of individuals with the same medical conditions who did not receive the EW-D intervention (n=122). Three findings from this analysis are most relevant to this current study. First, as compared to the matched control group, the intervention led to statistically greater pre-post improvements in a number of participation-limiting secondary conditions, including daily fatigue and pain interference. Second, the intervention led to greater increases in disease management self-efficacy, ability to perform independent activities of daily living, and time spent in leisure time exercise. Third, and most important to this study, the intervention led to greater improvements in satisfaction with social roles, an important proxy of community participation, as well as overall quality of life (all p-values < .01). Participants were also highly satisfied with the program. In program satisfaction measures administered post-treatment, participants reported a mean score of 8.2 (on a 0-10 scale) and 86% indicated that the benefits of participation in the program either equaled or outweighed the costs.

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing

☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☒	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing
☐	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Participants will be adults with long-term physical disabilities age 45-64 years. We plan to recruit participants representing different genders and racial backgrounds. Our goal is to complete data collection with 600 participants; however, we will request approval for 750 participants in case of incomplete initial sessions/surveys, no shows, or withdrawals. Before initiating the intervention study, up to 10 pilot participants will provide feedback some of this study's procedures and materials.

Since this specific trial is looking at evaluating the effectiveness of the EW-D intervention in middle-aged adults with disabilities, the inclusion criteria includes only adults 45 to 64 years of age.

Neither the EW-D intervention nor the CDC educational materials are available in languages other than English. This study seeks to test the effectiveness of the EW-D intervention as it is currently developed in English; future studies should look at the effectiveness of the intervention translated into other languages.

2.2 Inclusion and exclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

The inclusion exclusion criteria for all participants (except for pilot participants where noted) are as follows:

Inclusion Criteria:

- 45 to 64 years of age at screening (turning 65 years after screening is ok);
- Able to read, write and understand English;
- Has a self-reported physical diagnosis of a medical condition affecting the muscular and/or neurologic systems (eg, muscular dystrophy, multiple sclerosis, post-polio syndrome, spinal cord injury, limb loss, prosthetic users, etc.), and the condition:
  - creates functional disability (impairment in ADL OR IADL)
  - symptom onset before age 40 years (main study only, not required for pilot participants)
- Able to participate via telephone or Zoom;
- Has a goal in mind if randomized to the EW-D intervention (main study only, not required for pilot participants);
- Has not participated in the original EnhanceWellness intervention group (main study only, not required for pilot participants).

Exclusion Criteria:

- Unable to read, write or understand English;
- Under 45 years of age or 65 or older at screening;
- Does not have a neurological or muscular condition affecting physical function (eg, persons with low back pain and shoulder pain would be excluded);
- Does not have functional disability;
- Disability symptom onset after age 40 years (main study only, not required for pilot participants);
- Significant cognitive impairment as defined by the Six-Item Screener, with participants reviewed on a case-by-case basis by the P.I.
- Psychiatric condition or symptoms that would interfere with participation, specifically:
  - Current, active suicidal ideation with current intent to harm oneself, or
  - Current schizophrenia, psychosis, or mania
- Unable to participate via telephone;
- Does not have a goal if randomized to the EW-D intervention (main study only, not required for pilot participants);
- Has participated in the original EnhanceWellness intervention group (main study only, not required for pilot participants).

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

[X] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

[ ] **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed or submitted.

Population	Worksheet
☐ Children	WORKSHEET: Children
☐ Children who are wards	WORKSHEET: Children
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates
☐ Pregnant women	WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

n/a

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[X] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[ ] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

[ ]

[X] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research ***For clinical trials: provide numbers for your site and for the study-wide total number***
Group 1: EnhanceWellness-Disability (EW-D)	250
Group 2: CDC health education	250
Group 3: Treatment as usual	250
Pilot participants	10

3 RESEARCH SETTING

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

Study staff will communicate with participants via mail, phone, Zoom HIPAA compliant video call, text, and/or email. Research intervention procedures will be conducted over-the-phone or Zoom HIPAA compliant video call (participants can choose) with the University of Washington (Groups 1 or 2) . Participants will complete the surveys and intervention or wellness education in a place convenient to them.

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

n/a

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

n/a

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

n/a

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Recruitment sources: We plan to recruit participants in a variety of ways:

- Department of Rehabilitation Medicine Participant Pool – Researchers in the Department of Rehabilitation Medicine maintain a registry of individuals interested in research involvement (IRB #28497, PI: Mark Jensen). This Participant Pool includes many people with physical disabilities who volunteered to be informed of future research studies. Individuals in the Pool had previously indicated their contact preference (mail, phone, and/or email). A list of individuals will be sent to study research staff who will then contact them (via invite letter-**Appendix 1** and flyer-see **Appendix 2** for description of recruitment materials, all appendices bolded the first time they appear in text) for this study. For all recruitment sources, study staff will use the recruitment script-**Appendix 3** and eligibility screening checklist-**Appendix 4** to screen individuals for interest and eligibility once people contact us.

- Registries at other institutions – We will request colleagues at other institutions with access to potential participants with LTPD (eg, The University of Rochester has a National Registry for adults with muscular dystrophy) to invite some of their registry participants to participate in this study. The institution staff would mail out invitations with our approved study flyer to their registry participants. If interested, individuals will be instructed to contact our research study staff. We will not have access to contact information of participants in other Registries. As soon as the registry participant contacts us, we will follow the currently approved recruitment procedures, as with all other interested participant inquiries.

- Advertising in clinics, hospitals, and on listservs and websites – study flyer will be posted in areas that may be frequented by people with disabilities (such as, clinics, local community centers, local support organizations for adults with disabilities). Study flyer or information from the flyer will be posted online

(such as UWCORR, UW Medicine, UW Rehab Medicine, UW MS Center at Northwest Hospital, Northwest Chapter of the National MS Society, Amputee Coalition of America, local Muscular Dystrophy Association, Northwest Regional SCI Model Systems, Social media such as Facebook, Twitter, Craigslist, etc.). Information will direct individuals to contact research staff to obtain information.

- Clinician referral – Clinicians will mention the study to patients whom they think may be interested. Clinicians will be provided with study flyer so they can pass the information onto patients. If patients are interested, they can choose whether they would like to contact research staff on their own, or if they would prefer the clinician forward their contact phone number and/or email to study staff. Individuals identified via this recruitment strategy will be contacted using the recruitment script.

- Potential subjects with a diagnosis of a physical disability will be identified from hospital/clinic admission records at clinical sites (such as Harborview and the University of Washington Medical Centers). We propose to search the clinic database for ICD-9 or -10 codes representative of adults age 45-64 years who may have a physical disability. Online UW data analytical tools such as Leaf or the ITHS bioinformatics team will be used to generate these lists of adult UW patients. Individuals identified via this recruitment strategy may be sent an invitation letter (**Appendix 5)** and flyer in the mail, be emailed (email template also in Appendix 5), or be contacted via phone. All individuals recruited using this method will receive and review all information in the recruitment description (**Appendix3**) as part of the screening process. A copy of the UW Confidentiality Agreement is included with this application; the original is being mailed separately.

- Recruit through word-of-mouth, by seeing if our enrolled participants know of anyone they think would be interested in the study and suggest they send them our study flyer or hand out in a support group they are attending. Information will direct individuals to contact research staff to obtain information.

- Centers for Independent Living - The Information and Advocacy arms of a network of three community embedded Centers for Independent Living (CIL's) in Washington State and Idaho will assist with informing individuals about this study. These three community organizations (called the Disability Action Center, the Center for Independence, and the Alliance of People with Dis-Abilities) are federally funded to provide information and referral services to individuals with disabilities. Staff at these organizations will mention the study to people whom may meet study criteria. If people are interested, they can choose whether they would like to contact research staff on their own, or if they would prefer the organization staff forward their contact phone number and/or email to study staff. Individuals identified via this recruitment strategy will be sent an invitation letter-**Appendix 6** or contacted using the recruitment script.

- ResearchMatch - a national health volunteer registry that was created by several academic institutions and supported by the U.S. National Institutes of Health as part of the Clinical Translational Science Award (CTSA) program. ResearchMatch has a large population of volunteers who have consented to be contacted by researchers about health studies for which they may be eligible. Individuals identified via this recruitment strategy will be contacted through the ResearchMatch website using a study invitation email (**Appendix36**). Those who are interested will complete a screening phone call with research staff to check for eligibility and will be given the option to complete the non-sensitive screening questions ahead of time via a study-specific redcap link

- UW MS Center Research Participant Pool Registry- We will solicit participation from a UW registry of individuals (UW IRB STUDY00005250) with MS that have expressed interest in participating in research studies.

Recruitment Process Description:

Trained study staff (primarily the Research Coordinator, Research Study Coordinator, and Research Study Assistant) will offer all individuals recruited for this study the option to complete the screening process two ways.

1. Individuals can complete the entire screening process over-the-phone with study staff. This includes all information in the recruitment description (Appendix3) as well as answering all questions on the Screening Form (Appendix4). 2. Individuals will also be given the option to complete the non-sensitive screening questions via a study-specific redcap link. If they chose this method, they will still complete a screening call with study staff where they will answer the mental health questions, the sections that cannot be done online (UBACC Capacity Screen and Cognitive screen), and other questions not answered ahead of time in redcap.

Up to 3 follow-up contacts will be made for email and mail approaches that do not receive a response. Study staff will use the recruitment description and screener to inform individuals about this study and to screen them if interested.

Non-participant demographics **(Appendix 7)**: We would like to track basic demographic information of individuals who are eligible for this study, but not interested in participating. The screening script includes a declined demographics form that we will use to collect the information. Candidates are free to decline to provide the information.

Invitation into Rehab Participant Pool (i.e., Registry): All adult persons approached for this study and who have not been previously invited to the Registry will be asked if they would like to receive information about the UW Rehab Participant Pool. The recruitment script contains text for participants who are being screened for this study. Research staff will provide individuals with approved Participant Pool information if they are interested in learning more about the Pool.

Specific Recruitment Process for Pilot Study: We plan to recruit up to 10 individuals for a pilot test of some of this study's materials and procedures**.** These individuals are members of the Rehabilitation Med Department Participant Pool, who have previously done pilot testing specifically. Because they are familiar with pilot testing within the UW Rehab Department, we would like to directly contact them by phone. Research staff would call them and see if they are interested in participating using our Pilot Study Recruitment Script **(Appendix A; materials used for pilot testing only will be identified by a lettered Appendix).** We will mail or email a Pilot Study Recruitment Letter **(Appendix B)** if we are unable to contact these individuals by phone. Study staff will use the recruitment script to inform individuals about this study and to screen them if interested.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Recruitment materials for Pilot Testing:

- Pilot study recruitment script (Appendix A)
- Pilot study invitation for individuals identified from participant pool (Appendix B)

Recruitment and screening materials include:

- study invitation for individuals identified from participant pool (Appendix 1)
- recruitment materials description-study flyer (Appendix 2)
- recruitment description (Appendix 3)
- screening checklist (Appendix 4)
- study invitation for individuals identified from UW medical records (Appendix 5)
- study invitation for individuals identified from CIL (Appendix 6)
- declined study demographics (Appendix 7)

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[X] **No**
[ ] **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

Payment for Main Study Participants:
After completing each survey, participants will receive a $25 check and a thank you letter (Appendix31).

Given the effort required to track daily outings in a travel log and to charge and wear the GPS device, participants who complete the 7 day GPS and travel diary protocol at two separate timepoints will receive additional payments. We will pay participants $10/day for completing the 1-week protocol at both time points (up to $140 total).

Therefore, individuals may receive up to $100 total for completing the four assessments if not participating in the GPS sub-study and up to $240 for completing the four assessments and the GPS sub-study (if applicable).

Payment for Pilot Study Participants:
Each pilot study participant will be paid a total of $150. This comes to about $25 for reviewing the baseline survey, $70 for completing the 1-week GPS monitoring and travel diary, and $55 for feedback on the study materials and the cognitive interview. This payment breakdown is for IRB information only; payments will not be pro-rated for partial participation. Any feedback that we receive will be valuable to the intervention study.

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

n/a

4.6 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[ ] **No** → If no, you must still answer question **4.7** below.
[X] **Yes** → If yes, describe the consent process.

Consent to screen will be obtained from all participants prior to obtaining any screening data, and will be obtained two ways:

REDCap Screening Consent: Only individuals who use REDCap for the initial screening questions will be asked to document their consent for screening prior to any data collection in REDCap. They will be asked to read a statement about consent and select either Yes or No (corresponding to their decision), along with the date that they are providing consent. Because the most sensitive questions will only be asked by study staff while on the phone with a participant during a follow-up call, individuals who complete the REDCap screening questions will be asked to provide verbal consent again at the follow-up call that includes additional information about the most sensitive questions they will be asked.

Phone/Verbal Screening consent: Verbal Consent to screen will be obtained from all individuals prior to asking any questions when completing the phone screening call. Verbal consent will be obtained from everyone, regardless of whether they completed any of the screening via REDCap because it includes new information about the most sensitive questions that were not asked on REDCap.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

[X] **No** → If no, describe the information you will provide during the consent process and for which procedures.

We request waiver of written documentation of consent in order to ask the screening questions (Appendix 4 and embedded in Appendix A). We will inform individuals that the questions will take about 2-3 minutes to answer, possible risks or discomforts (with an example of the most sensitive questions being asked), how answers will be stored with respect to confidentiality and identifiability, and who to contact with questions or concerns.

Although we are requesting a waiver of written documentation of consent for recruiting and screening procedures, we will be asking individuals who complete the REDCap screening questions to document their consent by selecting either "Yes" or "No" and by filling out the date they provide their screening consent.

[ ] **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

4.7 **Data and specimens for recruiting and screening**. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain for recruiting and screening (prior to obtaining consent) and whether you will retain it as part of the study data.

Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time.*

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

Individuals will be asked eligibility questions during screening. Responses to the screener questions primarily consist of yes/no answers (eg, Do you have access to a telephone?) or responding to a prompt ("Say the months of the year in reverse"). Basic demographic questions about sex, race, and ethnicity will be asked at screening due to NIH demographic reporting requirements. This data will be retained as part of the study data, both to indicate eligibility and to track the reason(s) that individuals screen out of the study. The screening eligibility questions will take about 2 to 3 minutes to answer, depending on the person's responses.

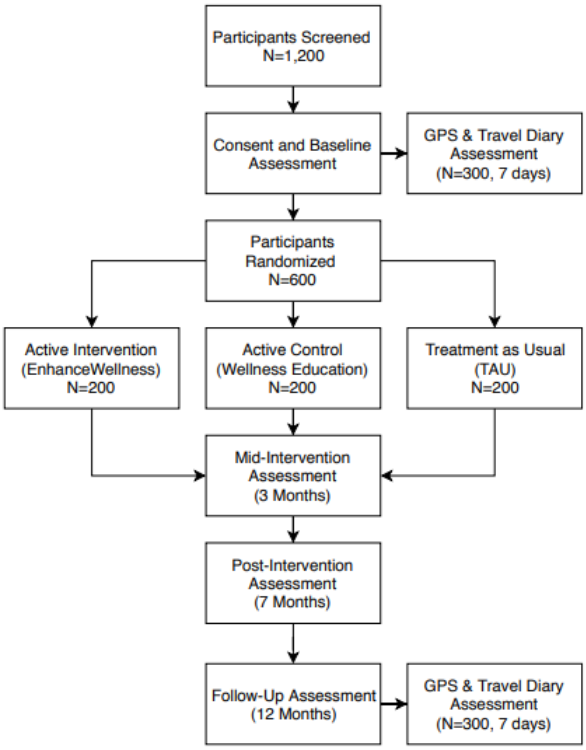
5 PROCEDURES

5.1 **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB ***POLICY: Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*

Overview: This is a 3-arm randomized clinical trial of 600 individuals with LTPD. Self-report survey assessments will be conducted at baseline, 3 months, 7 months, and 12 months. Study participants will be randomly assigned to one of three conditions, each lasting 6 months: (1) The intervention (EW-D), (2) a wellness education control, or (3) treatment as usual (TAU). A subset of participants will provide GPS/diary data about their community activities. See Figure 1 for study flow.

Figure 1. Participant Flow Diagram (Version 3)



Individuals who are both eligible and interested in participating in this study will complete informed consent using: a) Electronic signature via a DocuSign account set-up by the University of Washington OR b) By mailing the consent form, a cover letter, and a return envelope to the participant. The procedures associated with the study group will start once we receive the individual's signed electronic or paper consent and once they have completed the baseline survey.

Study Arm Randomization: After completing the baseline survey, individuals will be randomized into one of the three study arms. Participants will be randomized using a randomization script (Appendix 23).

Before initiating the intervention study, up to 10 pilot participants will provide feedback on the recruitment and enrollment process and materials, the baseline survey, and the GPS/travel diary procedures and materials (procedures described in more detail below).

Description and procedure for each study arm:

GROUP 1: Adapted EnhanceWellness-Disability (EW-D) Intervention

What is the EnhanceWellness-Disability (EW-D) intervention? EW-D is a collaborative, patient-centered program designed to work across disease types. It is used in King County by Sound Generations (formerly Senior Services) to target older adults. In EW-D, participants work one-on-one with the study Wellness Coach (the coach will be UW study staff typically a master's level social worker or registered nurse who will be trained bySound Generations, the legal owner of the EnhanceWellness intervention). The participant and wellness coach will work together to identify health self-management problems, consider options, develop goals and an action plan, and make adjustments to that plan over time. Goals are participant selected. They may include any aspect of wellness, participation, or health the participant wishes to address, including (but not limited to) health behavior change, changes in physical activity, specific disease or symptom self-management, reduction in health risk factors, plans to increase meaningful socialization, addressing workplace accommodations, parenting stressors, retirement planning, new declines in physical function, involuntary retirement, and emergence of new chronic medical comorbidities. The Wellness Coach works with the participant through a combination of motivational interviewing, problem solving, and referral to community resources as needed. The program is designed to last 6 months.

Procedures: Prior to starting their EW-D sessions, participants will complete the baseline study survey for the first time (completion time is about 45 minutes; **Appendix 8**) as well as the baseline GPS week (if randomized to the GPS). As part of the EW-D intervention, participants in this group only will respond to another set of questions that are a feedback tool designed to help the Wellness Coach tailor the intervention sessions (completion time is about 20 minutes; **Appendix 9**). Then, we will connect the participant with their Wellness Coach to schedule their first session (all sessions will be conducted over the telephone or Zoom HIPAA compliant video call and each session is expected to last about 1 hour). The first session or two will consist of an overview of the program, review of these EW-D questionnaire responses, and determining their health or behavior related goal with the

Wellness Coach. Once this goal is decided, a health action plan will be set in place and the intervention will begin, except for participants who choose a goal related to increased physical activity. Any participant who chooses a goal related to increased physical activity will be asked to complete two health screening calls with a UW Rehabilitation Medicine Physician **(Appendix39**). The first call will be completed before the participant start working on their health action plan, and the second call will be completed 3 months into the study. The purpose of these calls is to assess for risk due to increased physical activity and are not considered to be a part of the intervention itself (i.e. will be in addition to the 8-10 intervention calls). Goal topics are varied and can include: health self-management, social activity, alcohol use, smoking, memory, falls prevention, incontinence, depression, anxiety, exercise, nutrition or weight control, or medication management. The Wellness Coach will utilize the principles of motivational interviewing to promote self-efficacy in participants, encourage them to manage their own symptoms and to utilize community resources. A sample of the Intervention manual that the Wellness Coach will follow is attached (**Appendix 10**, sections 7-1 thru 10-20). We are currently in the process of supplementing the manual for people with disabilities (see **Appendix 11** for draft of manual supplement). As part of the program, the Wellness Coach may ask the participant for consent to share their action plan with their primary care physician, to encourage accountability and collaboration, at the participant's prerogative. The consent form outlines this information so that participants understand what information may be shared with their physician.

Although the expectation is a total of 8 calls over a six-month period (2 in each of the first 2 months, one per month thereafter), participants may request up to 2 additional calls if they require support with a particular challenge (up to 10). The number of follow up visits will vary depending on the participant's desires and his or her program goals. These visits will involve a review of the health action plan and discussing progress toward reaching goals. To monitor for fidelity to the intervention, a random selection of sessions will be audio-recorded and reviewed (with participant consent) by the study PI, designated study staff, and/or an EnhanceWellness Master Trainer at Sound Generations.

Participant's Valued Outcomes	**Action Plan Goals (established with coach)**	**Action Steps for Participant**	**Wellness Coach Roles**
"I want to eat better, lose some weight and become more physically active"	1. Improve nutrition 2. Increase exercise to 30min, 3x/wk 3. Lose 5% of body weight in 6 months	1. Ask MD for referral to nutritionist 2. Call insurance company regarding referral to Physical Therapy for exercise training 3. Attend an adapted exercise program at the YMCA 4. Purchase bathroom scale	1. Work on development of Action Plan 2. Provide letter to participant's physician stating involvement in program and asking for any additional target areas 3. Provide participant with community resources for increased physical activity 4. Provide participant with support in making step by step plans to achieve complex goals (for example, what to ask insurance company re: physical therapy) 5. Help participant identify and overcome barriers to goals 6. Help participant identify social support resources to achieve goals 7. Provide feedback to participant on progress
"I want to get better control of my pain."	1. Decrease pain interference 10%	1. Attend a local pain self-management support group 2. Ask MD for pain and medication information 3. Attend adapted yoga class	

GROUP 2: Wellness Education To control for expectancy effects and Wellness Coach contact time, we will include an educational time control condition based on eight 45 minute sessions of telephone or Zoom-based wellness education, also delivered over 6 months. These sessions will also be administered by a UW study Wellness Coach (called the social worker for this study arm). The session timing is designed to match the EW-D group (2 sessions in the first month, one per month thereafter). For this control condition, participants will discuss material presented in the CDC's "10 Keys to Healthy Aging" program, developed by the University of Pittsburgh

(see manual: **Appendix 22**). These sessions provide participants will health information in 10 key areas, 8 of which have been selected for this trial. These 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. In addition to the 8 sessionswith the interventionist, participants will be provided with informational material by mail or email.

Procedures: Prior to starting their wellness education sessions, participants will complete the baseline study survey (Appendix 8) and GPS baseline (if randomized to the GPS group). Then, we will connect the participant with the social worker to schedule their first session (all sessions will be conducted over the telephone or Zoom HIPAA compliant video call). During each session, the social worker will review the health topic selected for that session (Appendix 22). The participant will receive the handout included for that topic in the manual, but they will not be asked to complete the homework listed in the manual. If the participant does not have any issues with the topic selected for that session (eg, they have normal blood pressure), the social worker will review information on how to maintain their blood pressure. To monitor for fidelity to the intervention, a random selection of telephone sessions and Zoom HIPAA compliant video calls will be audio-recorded and reviewed (with participant consent) by the study PI and/or designated study staff.

GROUP 3: Treatment as Usual (TAU) To establish a baseline comparison for treatment effects, participants in the TAU arm will not receive contact with a study social worker, will not receive education or fact sheet information, and will be asked to continue with their lives as they normally would. Similar to groups 1 and 2, TAU participants will complete the self-report surveys as described below.

Additional study information:

Outcome Data (GPS/diary): To objectively measure community activity and participation behavior, we will collect a combination of Global Position System (GPS) data, in conjunction with daily self-report travel diaries from a sub-set of participants (**Appendix 27, 38**).

Of the 600 individuals enrolled in the study, a subset of participants (N=100 per arm; 300 total) will be invited to a one week GPS/diary study component at two time points (at baseline and again at the 12-month assessment). Participants will be mailed a cover instruction letter, along with the portable GPS data logger (such as, QStartz BT Q1000XT GPS logger), 1 weeks' worth of paper daily travel diaries (**Appendix 27**), and an additional GPS letter with notes for completing the week of GPS data logging (**Appendix30**). Participants will also be given the option of completing the Travel Log electronically. Participants who wish to complete the travel log electronically will be emailed an excel version of the travel log (**Appendix 38)** in addition to the paper version.

- The GPS device is small (72 x 47 x 20mm; 64.g) and can be attached with Velcro to a belt or wheelchair, or can be placed in a pocket, purse, backpack, etc. This portable device works up to 24 hours on a single charge when set at a 15 sec epoch acquisition. Participants will be provided with a charger and instructed to charge the device nightly, power them on in the morning, wear them during waking hours, and remove them at bed time. Participants will be told to go about their daily routine as they normally would.
- The diaries used for this study modeled after the National Household Travel Survey instrument (**Appendix 27, 38**); we will collect information about each place the participant has visited throughout the day, including travel mode of arrival and purpose of visit (e.g., socializing, shopping, etc). Although electronic diaries might be more efficient for data processing (i.e., no need for transcription), not all participants in this study will have reliable daily internet access, making pen-and-paper a more reliable method. Any participants who are not able to complete pen-and-paper diaries will be given the option to provide diary information electronically using an emailed excel file (**Appendix38)** or verbally over the telephone each day to research staff.

Participants are instructed to contact research staff when they receive their gps in the mail to review the instructions for wearing the device and completing the diary. Participants will be contacted again 3 days later to answer any additional questions and ensure compliance.

Participants will be provided with postage-paid envelopes to return materials to a study-specific address. Research staff will then review the data for completeness and will re-contact participants as needed for additional information, or in the case of the lack of useable GPS data, for device re-wearing.

Outcomes for the proposed GPS analyses will be: (1) total number of trips outside the home; (2) total number of minutes spent outside the home; (3) total "travel path length" (calculated as the summed distance between GPS points included in trips); (4) activity space, quantified as radius of gyration131; and (5) number of activity events occurring outside the home in each of 6 categories, as previously identified in other studies of GPS measured participation: shopping (daily or recreational), social/leisure (visiting friends or doing hobbies), "bring or get" activities (errands, such as getting a package from the post office), personal care (including medical care), and other. Use of the travel diary will be important in identifying specific places and activities associated with non-home locations recorded with the GPS. For example, an individual may go to a library, and the GPS will show this, but without the travel diary the investigators will not know if this was to get a book, to meet friends, or to use the internet.

Per sponsor request, we will have a Certificate of Confidentiality (CoC) in place prior to beginning GPS/diary data collection.

Outcome Data (Self-report Surveys): All 3 groups will complete a baseline (prior to intervention), 3-month (mid-intervention), 7-month (post-intervention), and 12-month survey (See **Appendix 8** for Survey and **Appendix 13** for baseline cover letter and **Appendix 14** for follow-up cover letter). The survey will be available online. It will also be available on paper if the participant prefers or administered via telephone if there are accessibility issues (**Appenix8**).

EW-D Survey Data: Participants in the EW-D arm (group 1) will complete an additional survey designed to assist the Wellness Coach with tailoring the intervention sessions (**Appendix 9**). Participants will complete it at baseline (prior to intervention), 3-month (mid-intervention), 7-month (post-intervention), and 12-month survey. Participants will complete the survey on paper and the de-identified survey responses will be entered and stored on the Sound Generations network (the data will allow Sound Generations to accrue supporting data for their intervention). It may also be administered via telephone if there are accessibility issues.

Missing data/survey: For both the self-report survey and the EW-D survey, after research staff receive the completed survey, they will review it and contact the participant if there is any missing data using the missing data script (**Appendix 15**). Research staff will attempt to contact the participant up to 3 times for missing data. This script will also be used to remind participants about unreturned surveys and consent forms.

Withdrawal from study:
*Participants who are withdrawn by study staff***:** We will withdraw enrolled participants who are unreachable after multiple attempts. Participants who have been non-responsive (attempted to contact them (via phone or email) no fewer than 3 times and no more than 6 times over a 4-week period) to attempts by research staff and the wellness coach to schedule visits or follow up on survey mailings will be withdrawn from this study (**Appendix 12**). During our last few contact attempts, we will let participants know that we'll conclude their participation if we do not hear back within 2 weeks. They will also be notified that if they would like to re-join the study, then they can contact us at their convenience.

Participants who chose to withdraw themselves: When a participant chooses to withdraw from the study, study staff will attempt to contact participants (via phone or email) to assess for any Adverse Events or Serious Adverse Events. Study staff will ask participants if their withdrawal was related to any study activities and will collect any information necessary to complete an Adverse Event Report as outlined in the DSMP (**Appendix 19**). Study staff will also ask the participant (via phone or email) if they would be willing to continue completing any aspect of the study going forward, such as the study surveys (**Appendix 32**). If participants request no further contact with study staff when withdrawing, study staff will cease communication with the participant.

Pilot Study: Prior to initiating the main intervention study described above, we plan to run a preliminary pilot study with up to 10 participants. We will ask enrolled pilot participants to complete and provide feedback on a subset of the overall study materials. This will include going through a "mock" recruitment, screening, and consent process while providing verbal and written feedback to study staff (note: pilot participants will have already been recruited, screened, and consented to participate in the pilot study). During the "mock" enrollment, participants will be asked to note any language and processes that are confusing or need to be further detailed. We will also ask pilot participants to complete the full baseline survey (Appendix 8), all components of the 1-week GPS Sub-study (Appendix 21), and travel diary (Appendix 27, 38) and provide written feedback on the forms as they are completed. Finally, we will ask pilot study participants to complete cognitive interviews with study staff about their overall REDCap user experience (**Appendix C**) and about the GPS Sub-study (**Appendix D**). Questions will ask participants things like: "The survey was easy to use", "I am satisfied with the amount of time it took to complete the survey", and "What is one feature of the survey that you didn't like? Why?". The cognitive interview will not be audio-recorded. Participants will be compensated $150 for participating in the pilot study. The pilot study procedures will be completed over a 10-day period (about 3 hours to review the study materials and processes and 1 week to complete the GPS/diary sub-study, with extra time to allow for potential scheduling conflicts). Survey and GPS/Diary data completed by the pilot participants will be excluded from final datasets and analyses.

Database: The self-report outcome survey data will be entered in an online REDCap (Research Electronic Data Capture) database maintained at UW. REDCap is a secure web application designed to support data capture for research studies. It provides user-friendly web-based case report forms, real-time data entry with branching logic and validation (eg, for data types and range checks), audit trails, a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus), procedures for importing data from external sources, and advanced features such as a data quality check module. Access to the data is accomplished through web-based protocols, which helps ensure that queries against the dataset may only be made by authenticated personnel. Furthermore, all browser transmissions including all data and user credentials are transmitted only via HTTPS encryption, which is similar to technologies used by banking or e-Commerce sites. Therefore all transfers of information between the web server and the end user are encrypted with strong technology end to end and never allowed to travel in clear text across the internet at large. All identifiable contact information will be entered into a tracking database only available to UW study researchers.

5.2 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

Self-report outcome survey (Appendix 8)
EW-D-specific survey (Appendix 9, group 1 only)

5.3 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

All data will be obtained from the participants and the GPS (if applicable).

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist at the time when you submit this application)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

All data we will collect will be from participants and therefore are prospective.

5.5 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

Name, address, phone number, email.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

For individuals identified from the Participant Pool, Centers for Independent Living, or medical records, we will be sent a list containing the name, address, phone number, email of potential participants.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

☐ You will store the identifiers with the data. Describe the data to which this applies:

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Name, address, phone number, and email

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

No

5.6 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[X] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

  [ ] **No**
  [ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.

[ ] **No** → If no, skip the rest of this question; go to question **5.8**
[X] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

Research study staff and/or clinic staff may access medical records to pre-screen individuals who may be eligible for this study based on search filters for age and diagnosis of physical disability. Staff may record the individual's name and contact information in order to contact them to inform them about this study.

b. Is any of the PHI located in Washington State?

[ ] **No**
[X] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

Research study staff and/or clinic staff may look at medical records to scan through individuals scheduled for clinic appointments to pre-screen those who may be eligible for this study. Study staff may also access medical records via online platforms such as Leaf to compile a list of potential participants. Staff may record the individuals' name and contact information in order to contact them to inform them about this study.

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

None

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

[X] **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

We are requesting a waiver of HIPAA to access medical records to pre-screen individuals who may be eligible for this study.

Provide the following assurances by checking the boxes.

[X] The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

[X] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

[X] There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will you obtain or generate genomic data (as defined at *https://gds.nih.gov/13faqs_gds.html*)?

[X] **No**
[ ] **Yes** → If yes, answer the question below.

a. Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

[ ] **No**
[ ] **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.9 Data and specimen sharing/banking. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**

[X] **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

We will store all data (survey, subject contact information, GPS, travel diary) on our password protected UW servers.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Study data may be shared with the funding agency (NIH) upon request. De-identified data may be made available for secondary data analyses to researchers at UW and other institutions; no direct identifiers will be shared.

c. Who will oversee and/or manage the sharing?

Study PI

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

De-identified data may be made available for secondary data analyses to researchers at UW and other institutions; no direct identifiers will be shared.

e. Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

[ ] **No**
[X] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 6.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

[ ] **No**
[X] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

The consent forms contain information on how to contact study staff in case a participant wishes to withdraw. If the link between identifiers and study data is destroyed, we would no longer be able to withdraw a specific participant's data from sharing.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

[X] **Confirmed**

5.10 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

After enrollment, participants may receive initial and reminder emails, texts, and/or phone calls about completing their surveys, their scheduled sessions, and instructions about using the GPS and completing the travel diary.

5.11 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[X] **No**

[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.12 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[X] **No**

[ ] **Yes** → If yes, describe the alternatives.

5.13 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

n/a

5.14 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

[ ] All of your research procedures → Go to question **6.2b.**

[ ] None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission	Reason why you will not obtain parental permission	Will you inform them about the research?[2]	
			YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then skip to question 7.5.
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups → Use the table below to provide your justification, then go to question 7.4.a.

☐ All of your research procedures and child groups → Go to question **7.4.a**, do not complete the table

☐ Some of your research procedures and/or child groups → Complete the table below and then to go question 7.4.a

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented	Reason why you will not document assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.5 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.6 Other regulatory requirements. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.

WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

[X] Adult subjects

[ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

[X] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

Consent Process for Main Study:
After individuals are determined to be eligible for this study, they will be given the option to complete informed consent via:

a) **ELECTRONIC CONSENT FORM**: participants will be emailed an electronic copy of the consent form (**Appendix 25**) through a University of Washington DocuSign account approved by UW IT. The electronic consent form will have placeholders in the consent form for the participant to add: i) First/last name ii) Check the checkboxes iii) Signature iv) Date signed. The participant will also be emailed the Baseline Cover Letter (in a separate email from UW staff). After a participant has been emailed the consent form, they will schedule a time to review the information with research staff over-the-phone prior to signing through DocuSign. In this phone call, staff will review all information in the consent form with the participant, give the participant the opportunity to ask questions, and ensure all questions and concerns have been addressed before consenting through DocuSign. Once the consent discussion has finished and all questions have been sufficiently answered, the participant will be instructed by research staff to provide their electronic signature on the consent form and click 'Finish' in DocuSign. Research staff will then automatically receive an email with a copy of the consent document containing the participant's signature. Research staff will electronically sign/date the consent form and then print the final completed consent form containing the participant and staff signature and store the form in a locked file cabinet at UW. The staff member will also email the participant a copy of the signed consent form.

b) **PAPER CONSENT FORM:** participants will be mailed two copies of the consent form (**Appendix 25**), Baseline cover letter (Appendix 13) and a prepaid return envelope. The Baseline cover letter will instruct the participant to call research staff when the participant receives the consent form packet, so that the research staff can review the consent form with the participant over the telephone. In this phone call, staff will review all information in the consent form with the participant, give the participant the opportunity to ask questions, and ensure all questions and concerns have been addressed before the participant signs the consent. The participant will be instructed to sign the consent form and return it in the provided envelope. The participant will keep the 2nd copy of the consent for their records.

***NOTE:** For both electronic and paper consent methods, research staff will not be witnessing the participant sign the consent form and **we are requesting a waiver of verifying the identity (i.e. via video call) of the participant signing the consent form**. We believe this waiver is justified because there are no legal/financial risks to UW, safety risks to the participant, or scientific risks to the study if someone other than the participant who is not an intended signatory signs the consent form. If a participant informs study staff that an unintended signatory signed the consent form, study staff will shred that participant's consent form and request a video call with the participant to witness the participant sign the paper or electronic consent form.

After Completing Consent: Once the participant completes informed consent, they will be sent their Baseline survey and GPS/Travel Diary (if applicable). After completing the baseline survey, the participant will be randomized to a study arm. Because individuals will be consented prior to randomization into a study arm, the consent form has detailed information about procedures involved in all three study arms.

Consent Process for Pilot Study:

After an individual is recruited for the pilot study, research staff will send them the study information statement (**Appendix E**) in a packet along with the intervention study materials they will be asked to review. The individual will be asked to read the information sheet and contact the research team with any questions. Prior to starting the pilot procedures, study staff will ask the participant if they have any questions about the research and/or the procedures.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

We will answer any questions that participants may have about the study. When responses appear inappropriate or inconsistent (eg, individual's responses contradict their previous responses) during screening, staff (in consultation with the PI) may decide to exclude them from the study. To ensure the participants understand the purpose of the research, we included 3 questions from the UBACC Decisional Capacity Questions in the Recruitment Script (Appendices 3 and A).

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[X] **No**

[ ] **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

Any new information that may impact a subject's decision to participant (or how they participate) in the study will be reported to the individual promptly. Active participants will be made aware of any changes that directly impact their participation via an IRB-approved letter, email, or phone call (depending on participant preference) (Appendix 37). As applicable, participants will review changes to study information with study staff. Study staff will confirm the participant's understanding of the changes via verbal or written (including email) confirmation from the participant. All participants will be provided with a copy of the updated consent (as applicable).

Participants will be told that they may stop being in this study at any time.

8.3 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

☐ None of your research procedures	→ Use the table below to provide your justification then go to question **8.4**.
☐ All of your research procedures	→ Do not complete the table; go to question **8.4.**
☒ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
Pilot participants	Individuals will review the main study recruitment and consent materials and procedures, the baseline survey, and the GPS/diary sub-study	☒	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

8.4 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.5 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person; excluding individuals who cannot read and understand the consent form.

Because study procedures require individuals to receive an intervention by an English-speaking Wellness Coach/social worker and to respond to survey questions, individuals who indicate or, in the investigators view, have challenges understanding English will be excluded from participation.

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

- [X] **No**
- [ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

- [ ] **No**
- [ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.7 Cognitively impaired adults, and other adults unable to consent.

a. Cognitively impaired adults and other adults unable to consent. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

X	**No**	→ If no, go to question **8.8**.
	Yes	→ If yes, answer the following questions.

a.1. Rationale. Provide your rationale for including this population in your research.

a.2. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will re-assess decision-making capacity and consent during that time.

a.3. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

a.4. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

a.5. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.8 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

Individuals who are recruited from the Participant Pool or respond to advertisements about this research will have shown an initial interest in participating in research. Individuals approached through clinics, hospitals, and medical records will be assured that their participation will not have an effect on the clinical care that they receive. We will keep all responses confidential. To maintain confidentiality of research data, each participant will be assigned a unique ID number that will be used to track study data. Identifiable data will be stored separately from study data in a secure electronic location accessible only to research study personnel. Participants will be told that they can decline to answer any question or decline to discuss any topic that they wish. They may also stop being in the study at any time.

For participants invited to the GPS/diary data collection, they will be informed that their raw GPS data will be encrypted (using a 7-zip, AES-265 encryption algorithm) prior to storage and transfer, such that in the unlikely case of a data breach, any lost data would be encrypted and unusable. Also, all GPS data will be stored in a database on a secure server accessible only to select study personnel (PI Dr. Molton, co-Investigator Dr. Hurvitz, Research Coordinator, Research Study Assistant, Data Manager) using dual-layer authentication (i.e., a user name and password for accessing the computer itself and a separate user name and password for accessing the database).

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[X] **No**

☐ **Yes** → If yes, will you obtain subject consent for this use?

☐ **Yes**

☐ **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 **State mandatory reporting.** Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

☐ **No**

☒ **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 **Retention of identifiers and data.** Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf***

☒ **Confirm**

9.5 **Certificates of Confidentiality**. Do you have or, are you planning to obtain, a federal Certificate of Confidentiality for your research data?

☐ **No**

☒ **Yes**

9.6 Data and specimen security protections. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

Level 4 for all data

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels.

n/a

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Personal identifiable information about the study subjects will be obtained, including contact information and email addresses, and there is a potential for a breach in confidentiality. Also, to monitor for fidelity of the intervention (groups 1 and 2), all sessions will be audio-recorded, but only a small subset (about 20%) will be randomly selected and reviewed (with participant consent). However, the audio recordings will be paused temporarily during the COVID-19 situation because the interventionists are working remotely, and the recordings cannot be completed securely without UW laptops. Once the research team acquires UW secure laptops and computing equipment, or returns to work on UW Campus, the audio recordings will resume. However, some EW and CDC sessions may not be audio-recorded due to technical difficulties or because the participant does not use Zoom. Additionally, only the audio files will be stored for any participant call that occurs via Zoom. This means that study staff will NOT retain any video recordings from Zoom.

Because the interventionists are working remotely due to COVID-19 (March 2020), this creates the potential for invasion of privacy if the recordings were lost or shared. To minimize this risk, we will pause audio recordings until the interventionists have UW laptops that have been set up by a CTDS IT personnel with proper security measures or until resuming work on UW Campus. The recordings will continue to be labeled only with study numbers and stored on the UW server.

Additionally, subject names and medical record numbers will not be stored with subjects' responses to the demographic questions or interview questions. All contact information collected will be stored in a secure manner and only UW study team members will have access to it.

Research staff are mandated reporters under Washington State Law. In the event research staff learn of any child abuse or elder abuse or that a subject discloses the wish to harm themselves or others, research staff must release certain PHI (first and last name, address, date of birth) to local authorities (such as Adult Protective Services or 911). Participants will be notified of this risk in the informed consent (Appendix 25). Subjects will be offered a call with a research Clinician in the event of any such information is disclosed. Due to safety concerns, it is possible that participants will not be notified that a report has been filed if we learn of abuse. To protect participant's privacy, only the minimum amount of information will be reported, as applicable.

Participants may find that survey questions are personal and request information that they do not want to disclose (e.g., race/ethnicity and income). Participants will be advised they are free to skip any survey questions that they do not wish to answer.

It is possible that the intervention topics could make the study subjects feel uncomfortable. Subjects will be told during the consent process, as well as reminded by trained Wellness Coach during the wellness programs (Groups 1 & 2) that they can skip any topics that they do not wish to discuss or can stop participating at any time. Participants will be encouraged to take breaks during the intervention.

Subjects randomized to the EnhanceWellness-Disability intervention may choose self-directed health goals related to physical activity. Subjects who choose goals related to physical activity such as joining an exercise class, stretching, running, etc. may have increased risk for physical injury. As an example, subjects who choose to run more as their goal may have increased risk for fatigue, falling, muscle soreness, blisters, or other related injuries. These risks vary from person to person and are increased for this study population due to the specific inclusion criteria of having been diagnosed with a long-term physical disability that creates a functional ADL or IADL impairment. To address the risk of physical injury from choosing a physical activity-related health goal, the wellness coach will help design and modify exercise routines (within their scope) to ensure they are safe and sensible for each participant. Additionally, all participants who choose goals that increase physical activity will be asked to complete two, short health screening calls with a UW Rehabilitation Medicine Physician—once before they start working on their goal, and once 3-months later. On each call, participants will be asked basic health questions like "Do you have any active infections?" and "Do you have any balance problems?" (Appendix 39). If the UW Rehabilitation Physician has any concerns about the risk of injury due to physical activity, participants will be asked to talk to their primary care doctor before beginning the goal. The UW Physician may also work with the participant's health coach and recommend choosing a different goal with less risks. While the call is with a UW Physician, they are legally NOT allowed to provide medical advice or care recommendations on the calls, and therefore the call is not a replacement of regular care. Participants will be made aware of this at the beginning of the call.

We believe that the risk of physical injury is small because the EnhanceWellness-Disability intervention is specifically developed for people aging with various levels of mobility and physical function and therefore helps mitigate the risk of physical injury for this trial.

Other self-directed health goals aside from physical activity chosen by participants in the EnhanceWellness-Disability intervention may cause risks. These also vary from person-to-person and goal-to-goal. We believe that these are minimal. For example, goals may include increased socializing, reducing a negative health behavior (stopping smoking), or a home improvement goal (painting the house). Each of these goals presents different risks such as risk from traveling if the goal is to increase socializing in the community (with special acknowledgement and circumstances for this goal given covid-19). For each goal participants choose they will work closely with the wellness coach to evaluate risks and ways to safely address or avoid them. All participants will be reminded they can always choose to work on a different goal.

Individuals who participate in the GPS monitoring group may find this technique intrusive. They may also worry about the confidentiality of the data regarding their movements and the places they go. The belt-mounted GPS unit could potentially cause minor physical discomfort depending on placement. This study procedure is optional and participants will be advised that declining the GPS study will not affect their participation in the main trial study.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[X] **No**

[ ] **Yes** → If yes, identify the procedures.

10.4 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**

[ ] **Yes** → If yes, check all the boxes that apply.

[ ] Administration of any drug for research purposes

[ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes

☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery

☐ Administration of a radio-isotope for research purposes**

☐ Implantation of an experimental device

☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.5 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

DSMP (**Appendix 19**) has been uploaded.

10.6 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

n/a

10.7 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

We will withdraw enrolled participants who are unreachable after multiple attempts. Participants who have been non-responsive (attempted to contact them (via phone or email) no fewer than 3 times and no more than 6 times over a 4 week period) to attempts by research staff and the wellness coach to schedule visits or follow up on survey mailings will be withdrawn from this study (Appendix 12). During our last few contact attempts, we will let participants know that we'll conclude their participation if we do not hear back within 2 weeks. They will also be notified that if they would like to re-join the study, then they can contact us at their convenience.

10.8 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Pilot data have shown that participation in EnhanceWellness for middle-aged adults with long-term physical disability has a variety of positive impacts, including greater satisfaction with social roles and activities, self-efficacy for disability management, and decreases in pain interference and fatigue. Although we do not anticipate that the education control condition will result in any improvements in the outcome variables studied, previous participants report high levels of satisfaction with educational materials, and report that they find the information useful. There is a benefit to others, in that demonstrating the efficacy of this intervention may improve access to health/wellness promotion interventions for people with long-term physical disabilities. There is otherwise no direct benefit of participation in this research.

10.9 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

☐ **No**
☒ **Yes** → If yes, explain whether and how you would share the information with the subject.

It is possible that we may learn of suicidal ideation from participants during their conversations with the Wellness Coach/social worker or other study personnel. We will follow a suicide ideation (SI) protocol should this occur (**Appendix 20**), though we do not believe any study procedures will directly cause suicidal ideation. If a participant reveals thoughts of suicide, study personnel will follow all of the steps outlined in the SI protocol.

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

☐ **No**
☒ **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.10 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

n/a

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

n/a

11.2 Costs to subjects. Describe any research-related costs for which subjects may be responsible (e.g., CT scan required for research eligibility screening; co-pays; cost of a device; travel and parking expenses that will not be reimbursed).

Participants may make lifestyle changes based on their communication with the Wellness Coach/social worker. These will vary from participant to participant and are self-directed, but could involve purchasing items to help with the lifestyle change (such as a scale to monitor weight loss; joining a gym to increase physical activity). Individuals will be informed that these costs will not be reimbursed.

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

none

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

n/a

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

All members of the study team will be or have been trained by the investigators who have extensive experience conducting similar intervention research. We will also conduct regular study meetings to discuss study-related procedures and questions the team may have.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
RDRC	

☐	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

n/a

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.