Physical Activity Intervention - Stanford University
PI: Marcia L. Stefanick, Ph.D.
Behavioral Scientist: Abby C. King, Ph.D.
Medical Director: Mark Hlatky, M.D.

Data Coordinating Center – FHCRC (WHI CCC)
Multi-PIs: Charles Kooperberg, Ph.D.
Andrea LaCroix, Ph.D. (U.C. San Diego)
Co-investigator: Lesley Tinker, Ph.D.

Consultant, Collaborator: Michael LaMonte, Ph.D.
(University of Buffalo)
Primary Aim: Conduct a pragmatic trial in ~50,000 women enrolled in WHI Extension Study, for whom CV outcomes are available (WHI Medical Records Cohort or CMS linkage), randomized to a centralized physical intervention or “usual activity” (Control).

Primary Hypothesis:
Aerobic physical activity combined with muscle strengthening, balance and flexibility exercises, and reduced sedentary behavior will reduce major CV events (MI, stroke, CV death) in older women, compared to “usual activity” (control) over ~5 years.


Implemented through: National Institutes on Aging (NIA) http://go4life.nia.nih.gov/

Primary Safety Aim: Evaluate whether an intervention based on DHHS recommended levels of physical activity for older adults increases risk of total clinical fracture, hip fracture, falls, or non-CVD mortality over ~5 years.

Secondary Hypotheses PA (vs Control): Lower rates of VTE and PAD – and- Less loss of physical function (by Rand-36 score), including higher rates of ongoing mobility (and independence)

Secondary Aim: selected PA-linked secondary outcomes, potentially ameliorable through regular physical activity, of importance to maintaining independence in older women

Secondary Safety Aim: Evaluate whether the PA intervention (versus control) increases coronary artery bypass graphs (CABG) or percutaneous coronary intervention (PCI)
Randomized Consent Study Design

Based on Zelen. N Eng J Med 1979

~50,000 WHI participants randomized

*Inclusion:
- Alive, WHI Extension Study consent
- CV Outcomes available
  - Medical Records Cohort or CMS,
  - i.e. linkage to Medicare

*Exclusions:
- dementia
- living in a nursing home
- self-reported inability to walk

Eligible based on existing data*

Randomize

Eligible based on existing data*

no
Follow, per original protocol

yes

Randomize

Control

Follow, per original protocol

Intervention

Passive Consent

(no opt out) no
Follow, per original protocol

yes

Physical Activity (Go4Life®) Intervention
Mailings, Motivational Phone Calls (± IVR**), Website, Email, etc. + live advisor, PRN

** Interactive Voice Response System

Accelerometer Sub-study

“Physical Activity Study” Consent

Primary Outcomes: major CV events (MI, Stroke, CV Death)
Accelerometry Sub-study

- 2,350 participants who were part of the Objective Physical Activity for Cardiovascular Health (OPACH) consented to wear accelerometers three times (~months 6, 18, 36) for a week during WHISH trial.
- objective measurement of physical activity levels.

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention</th>
<th>Control</th>
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<tbody>
<tr>
<td>Number consented</td>
<td>1168</td>
<td>1182</td>
</tr>
<tr>
<td>Did not wear</td>
<td>295 (25.3%)</td>
<td>141 (11.9%)</td>
</tr>
<tr>
<td>Data transmitted, not usable</td>
<td>124 (10.5%)</td>
<td>110 (9.3%)</td>
</tr>
<tr>
<td>Wear 2 data usable</td>
<td>750 (64.2%)</td>
<td>931 (78.8%)</td>
</tr>
</tbody>
</table>
Survey 1 (Preference Survey)

11,400/23,900 (48%)

- Top 3 activities:
  - Walking (80%)
  - Gardening (48%)
  - Group fitness (32%)

- Interested in increasing activity:
  - Very interested (41%)
  - Somewhat interested (47%)

- Current activity level:
  - Sit more than walk (41%)
  - Move/walk more than sit (37%)

- Limitations:
  - None (47%)
  - Balance difficulties (26%)
  - Difficulty walking (23%)

Survey 2 (Intervention Survey)

11,479/21,651 (53%)

- Materials that helped to increase activity:
  - Pedometer (38%)
  - Calendar (22%)
  - Go4Life® Exercise & Physical Activity Book (20%)

- Physical activity level since WHISH started:
  - Increased a lot (8%)
  - Increased somewhat (31%)
  - Stayed the same (42%)
  - Decreased somewhat (13%)
  - Decreased a lot (6%)

- Top two reasons to be physically active:
  - Personal health (81%)
  - Maintain independence (56%)
What Motivates You?

Many of you told us that being physically active is important for maintaining or regaining your health and independence. But, what actually gets you up and going? Take the What Motivates You Quiz (insert) to get ideas that might work for you. Only you can figure out what helps you move more!

My WHISH Stick-With-It Activity Goal

The WHISH Stick-With-It Activity Goal notepad (enclosed) can help you set specific weekly goals that fit into your daily life.
- Each week, set a personal physical activity goal.
- Be as specific as you can when you fill in the boxes.
- Add detail to your goal by answering: When? What? Where? How?

Imagining yourself actually doing the activity helps you create a realistic and effective goal. Now, post your goal where you can see it to help you stick with your plan.
What Motivates You?

First, mark the ideas below that you are willing to try or that sound interesting. Then, see the other side to learn more about what motivates you.

START HERE!

- Sign up for a group exercise class, like Silver Sneakers
- Make a walk and talk date with a neighbor or friend
- Challenge a friend to see who can get the most steps each day
- Enjoy the crisp air and sun glistening on snow crystals as you walk
- Pay attention to a change in your mood after a brisk walk
- Notice that your resistance band exercise feels easier than last time
- Sign up for a charity walk
- Participate in an environmental “clean up” activity
- Be active on a community or church project
- Post your Stick-with-It notepad where it catches your attention
- Place your resistance band where you watch TV or sit to read
- Rearrange a space in your home for doing physical activity

Understanding Your Motivation

Start on the other side. Motivation is more than willpower! There are many different motivators. We have described four of them for you. The ideas you marked on the other side of the page are grouped in colored boxes that correspond to the colored boxes below. Which strategies seem to motivate you?

Social

- Being active with others, including grandchildren: getting support from and even competing with others.

Senses & Feelings

- Being mindful of your surroundings (smells, sounds, sights), your mood and how your body feels while you are active.

Purpose & Causes

- Doing activities that benefit others, your community, environment, animals, etc.

Cues & Context

- Being reminded to move by cues around you and having your home, yard, etc., arranged to encourage physical activity.

Move More!

Sit Less
**Goal Setting & Motivation!**

In our last newsletter, we talked about goal-setting and motivation, particularly what drives women to stay active. We included a goal-setting sheet (the Stick-With-it notepad, see left) and a quiz (see box below) to help you determine what motivates YOU! Are you using the goal-setting sheet? Are your goals specific and realistic? Have you encountered any barriers? Ask yourself why you did or did not meet your goals and if you want to make any changes. This process can help you achieve your goals.

In the following section, WHISH participants tell us what motivates them to stay active and how they stick to their goals.

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**WHISH Motivation Stories**

**Purpose & Causes**

**Catherine B., 74, Baltimore, MD**

Catherine’s friend, who is a breast cancer survivor, asked her to walk in the Warrior Walk 5K. This gave Catherine the opportunity to be active while supporting her friend and many others who have cancer or who are caregivers of people with cancer.

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**Senses & Feelings**

**Jacqueline M., 84, Centerville, MA**

Jacqueline will be participating in a rehabilitation program using a recumbent bicycle to go riding outdoors where she is monitored by a Physical Therapist or specialist. She loves cycling, most of all because it makes her feel so good and “normal”. She says it is a joy that she will be able to participate in such a wonderful program. Being handicapped does not mean that she can’t do things!

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**Cues & Context**

**Patricia A., 75, Sun City, AZ**

Patricia and her husband bought a bike rack with the gift card she received from the WHISH challenge. Now they put their bikes on the car while traveling in their RV and take bike rides when they arrive at their daily destination. She said it has been fun getting rides in. It’s great exercise that she and her husband can do together.

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**Social**

**Sandra L., 74, Monticello, UT**

Sandra (left) and her sisters have been camping and hiking their whole lives. Each year, they get together for an adventure. They motivate each other to stay active by hiking and seeing beautiful places together. The trip up Mt. Kilimanjaro with her sister is one of her highlights.
New WHI Findings

Light Activity Matters!

The Women’s Health Initiative (WHI) has published more exciting findings about physical activity in older women which is shaping national recommendations. Thank you yet again for “being part of the answer!”

About 2,000 of you (WHISH participants) wore a special motion sensor that measured:

SEDENTARY ACTIVITY: sitting while watching TV, reading, doing a jigsaw puzzle.

LIGHT-TO-MODERATE ACTIVITY: washing & drying dishes, laundry, folding clothes, dusting, mopping, and walking (1-2 ½ mph). Intensity may vary depending on fitness level and effort needed to do the task.

KEY FINDINGS:

Just 30 additional minutes of light-to-moderate physical activity per day lowered the risk of death by 12% to 39% compared with women who were sedentary. These findings were true regardless of age, weight, or chronic conditions. Light activity does count!

More information inside and on the WHISH website (whish.org).
Move Throughout the Day

Inactive sitting is bad for your health. Activity is a continuum. No matter where you start on the activity scale, any activity is better than no activity at all. Break up every half hour of sitting with 2 minutes of movement. The more time you spend moving throughout the day, the better.

Do What You Can

Even small increases in daily light activities can reduce risks in older women, even those with chronic medical conditions. Just start where you are, and move more!

More at whish.org

Sit less, Move More

Challenge yourself with activities that take a little more effort. For example, walking slowly for 30 minutes uses nearly the same energy as a brisk 15-minute walk. Both are beneficial, but brisk walking adds more benefit. You can also work harder by adding strength, balance and flexibility exercises. Make these changes gradually and safely.

What's your next step?

Move It or Lose It

To keep your muscles, you need to use them. Getting up and moving keeps you strong. Even simple daily chores can help you maintain your independence and physical function.

Working a Little Harder Adds Benefit
<table>
<thead>
<tr>
<th>Activity Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Active</td>
<td>10%</td>
</tr>
<tr>
<td>Active</td>
<td>36%</td>
</tr>
<tr>
<td>Somewhat Active</td>
<td>42%</td>
</tr>
<tr>
<td>Inactive</td>
<td>9%</td>
</tr>
<tr>
<td>Very Inactive</td>
<td>3%</td>
</tr>
<tr>
<td>Increased a lot</td>
<td>6%</td>
</tr>
<tr>
<td>Increased somewhat</td>
<td>27%</td>
</tr>
<tr>
<td>Stayed the same</td>
<td>47%</td>
</tr>
<tr>
<td>Decreased somewhat</td>
<td>16%</td>
</tr>
<tr>
<td>Decreased a lot</td>
<td>5%</td>
</tr>
</tbody>
</table>
Life Happens
Recovering From Back Injury

Holly J., 72, moved from Chicago to a new home in Florida which had access to fitness classes. As a runner, Holly assumed these would be “easy, old lady” classes; however, she found them challenging because of the variety of activities, such as cycling, stretching, and strength routines.

Unfortunately, a serious back injury left Holly barely able to walk and in significant pain for 6 months. She became depressed. After surgery, she began rehabilitation with physical therapy and short walks throughout the day. Her PT sessions included leg strengthening, stability and flexibility exercises, and the “dead bug” (see top right) to improve abdominal strength.

Holly exercised at home. After 6 weeks, she was medically cleared to start back with her fitness routine. The “easy, old lady” classes became her way back to an active life. Her recovery was speedier because she had been in good shape before the injury. She is actually healthier and stronger now than before. Staying active was the best preventive medicine for her!

Tips to Put Some SPRING in Your Step!

- Organize a springtime walking group to meet 2-3 times a week.
- Enjoy your surroundings as you walk through your neighborhood or local park.
- Sign-up and train for a June 21 (Longest Day) walk for Alzheimer’s & Brain Awareness.
- Create a schedule and space at home to do your physical therapy exercises.
- Set spring goals and post your WHISH Stick-With-It Activity Goal where you will see it.

LIFE HAPPENS
Moving Together Through Tough Times

Barbara has been active most of her life. Her family’s culture is one of staying fit through sports and exercise.

Her daughter, who ran track, convinced Barbara to start running as it was something they could share before she left home for college. Reluctantly, Barbara started running— for the next 25 plus years!

A college encouraged Barbara to start yoga and she also began lifting weights. At the suggestion of her son, Barbara began exercising 5 days a week at a local gym after she retired.

Shortly after her husband retired, he was diagnosed with stage 4 cancer. Barbara knew running and exercise were more important than ever. They became her lifeline as she faced the most difficult time of her life, both mentally and emotionally. Life happens, and three years later, her husband of 51 years passed.

Stepping Through the Seasons

- Organize a walking group of friends to meet 2-3 times a week
- Enjoy the sun on your neighborhood walks.
- Sign up and train for an October Breast Cancer Walk
- Do your physical therapy exercises to maintain or regain strength.
- Write down your goal and place it where you will see it.

Barbara C., 77, Ohio

In celebration of her husband’s life, Barbara, her children, their spouses, and five grandchildren took a trip to Machu Picchu. They climbed the 3-hour hike up to the infamous Sun Gate. The guide said she was the oldest person he has had to make the climb.
WHISHful Actions
Every Minute Counts
Women’s Health Initiative Strong & Healthy (WHISH)
Summer 2018

WHISH Summer Challenge
Replace 30 minutes of inactive sitting with active movement.

How can you add small increments of activity to your day?

- Get up and move for 2 min. each half hour to add an entire hour of movement to your day.
- Add 5 min. of movement each hour to get over an hour of extra physical activity.

Even if you exercise for 1 hour a day (and sleep for 8 hrs), how do you spend the other 15 hours of your day?
**STEP 1:** How much time are YOU inactive?

**Inactive time:** any time spent sitting or lying down while awake but not engaged in active movement.

Examples include:
- Reading or writing
- Watching TV
- Working at a computer
- Eating

In each box below fill-in the amount of inactive time (minutes or hours) that you spend.

**MORNING**

**AFTERNOON**

**EVENING**

**TOTAL INACTIVE TIME**

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**STEP 2:** Find activities to replace your inactive time.

Even if you are meeting the physical activity guidelines, sitting for prolonged periods of time can compromise your health. Find ways to add regular activity into your day.

- Take a 2 min. stretch break
- Go for a walk
- Do errands
- Walk up and down the stairs
- Play with children or pets

---

**STEP 3:** Set a goal to add active movement.

Add 30 minutes of activity to your day in large or small increments.

You can make a list of “5-minute activities”, such as:
- walking to the end of the block and back whenever you pick up the mail
- dancing as you wait for your food in the microwave

Replace inactive sitting with light, moderate, or vigorous movement to gain health benefits. Start where you are and safely add effort. Do what you can. Take the Talk Test to find out if your activities are light, moderate, or vigorous.

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**The Talk Test:**
How much effort?

The Talk Test is a great guide for figuring out how hard you are pushing yourself. As you do an activity, take note of whether you can talk or sing. Keep track of the intensity of your activities. As you slowly add effort, notice the progress you are making over time. Challenge yourself each day to include all levels of activity in your routine.

**Inactive**
- Awake and relaxed while seated or lying down

**Light**
- Can sing and talk while moving

**Moderate**
- Cannot sing, but can still talk

**Vigorous**
- Can only speak a couple of words at a time
Questionnaire 2018

MARKING INSTRUCTIONS
- You may use a pencil or pen (blue or black only).
- To change an answer:
  - If you are using a pencil, clearly erase the incorrect mark.
  - If you are using a pen, mark an X through the incorrect mark.
- Please do not make any stray marks on this form.

During the past 3 months, how active were you, on average:
- Very Active
- Active
- Somewhat Active
- Inactive
- Very Inactive

Over the past 3 months, has your overall physical activity:
- Increased a lot
- Increased somewhat
- No change
- Decreased somewhat
- Decreased a lot

Which of the following are of interest to you? (mark all that apply)
- Home exercise tips or videos
- Latest news on activity and aging
- Improving mood & motivation
- WHISH Challenges by mail
- Team challenges on WHISH website
- Other: ____________________________

How often do you have an ache or stiffness in this body part that interferes with your daily activities (like getting up from a chair or walking 10 feet)?

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back (upper/lower)</td>
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<td></td>
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<tr>
<td>Hip</td>
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<tr>
<td>Knee</td>
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<tr>
<td>Ankle/Foot</td>
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</tbody>
</table>

What could we change or add to the WHISH website (whish.org), to make it a more useful resource for you?

Thank you! We value your feedback. Please note: If you have time-sensitive comments, please contact the WHISH staff at (844) 469-4474 or at whish-team@stanford.edu.
Form 158 – Supplemental Questionnaire 2017

These questions are about memory and changes in mental functioning.

7. Do you feel like your memory is becoming worse?
   ○ No  ○ Yes, but this does not worry me  ○ Yes, and this worries me

This next set of questions asks you to rate any change in your abilities, daily functioning and activities. Fill in the circle for each question that best fits your current ability level compared to 5 years ago.

Select the one best choice for each item and please do not skip any questions.

<table>
<thead>
<tr>
<th>No change</th>
<th>Minimal change</th>
<th>Some change</th>
<th>Clearly noticeable change</th>
<th>Much worse</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Recalling information when I really try:</td>
<td></td>
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<tr>
<td>2. Remembering names and faces of new people I meet:</td>
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<td></td>
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<td>3. Remembering things that have happened recently:</td>
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<td>4. Recalling conversations a few days later:</td>
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<tr>
<td>5. Remembering where things are usually kept:</td>
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<tr>
<td>6. Remembering new information told to me:</td>
<td></td>
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<tr>
<td>7. Remembering where I placed familiar objects:</td>
<td></td>
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<td>8. Remembering what I intended to do:</td>
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<td>9. Remembering names of family members and friends:</td>
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<tr>
<td>10. Remembering without notes and reminders:</td>
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<td></td>
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<tr>
<td>11. People who know me would find that my memory is:</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>12. Remembering things compared to my age group:</td>
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</tbody>
</table>
Funded WHISH Ancillary Studies

**WHISH-2-Prevent Heart Failure**
PI, Charles Eaton, MD, Brown University
[1R01HL130591-01]
-- evaluating incident HF and HF burden (HF hospitalizations and CVD death in women with HF)

**WHISH-Silent Atrial Fibrillation Recording Study (WHISH STAR)**
PI, Marco Perez, MD, Stanford University
[1R01HL136390-01]
-- assessing clinical and asymptomatic forms of atrial fibrillation in WHISH trial, using loop recorders

A statistical methods proposal developing advanced methods for accelerometry data, motivated by WHISH (PI, Dr. Chongzhi Di).