

Community-based Intervention Effects on Older Adults' Physical Activity

NCT03326141

October 31, 2023

Consent

Title of Research Study: Ready~Steady

Researcher: Siobhan K. McMahon

Supported By: This research is supported by the National Institute of Health/National Institute of Nursing Research (NIA/NINR)

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions about research appointments, the study, research results, or other concerns contact the researchers. You may ask any questions you have now, or if you have questions later, **you are encouraged** to contact them:

Researcher Name: Siobhan K. McMahon
Assistant Professor,
School of Nursing
University of Minnesota
Phone Number: 612-625-3225
Email Address: skmcmaho@umn.edu

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or give feedback online at www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

The purpose of this research is to evaluate different ways to promote physical

activities recommended for older adults. Although there is strong evidence that identifies which physical activities benefit people over 65 years of age, there is no evidence that describes how to help people include these in their everyday lives. Thus, in this study, we will compare four versions of a wellness course that include different ways to help people begin to practice these physical activities on a regular basis.

How long will the research last?

We expect that you will be in this research study for approximately 1 and one-half years, or 18 months.

How many people will be studied?

We expect about 310 people will participate in this research study.

What happens if I say “Yes, I want to be in this research”?

If you agree to be in this study, we would ask you to do the following:

Before the Ready Steady course:

1. You will meet with a researcher, at a community center private meeting room or your home, per your preference. The appointment will be about 60 minutes. The appointment will involve interview questions (A-H) and observations of your balance (I).
 - A. Your contact information.
 - B. Your marital status, education level and monthly income.
 - C. Your health and fall risk.
 - D. Medications and supplements you take on a regular basis.
 - E. Your level of pain.
 - F. The support you have (or don't have) from family, friends, and the community to stay active
 - G. Strategies you use to stay physically active.
 - H. Physical activities in which you typically participate in, how often you participate in them, and for how long.

- I. Your leg strength and balance, as you walk, sit, and stand in different positions.
2. We will ask you to wear a physical activity monitor for approximately 10 hours over the course of 10 days. This will help researchers measure your activity patterns before and after the study. The monitor is called a Fitbit™. When you wear this, we ask that you be yourself and try not to increase or decrease the activities you usually do.
3. You may be assigned by lottery (chance) to one of four types of wellness programs. However, depending on the number of potential volunteers and the study schedule, there is a chance your name will not be assigned to a wellness program. If this happens, we will ask for your permission to contact you at a later date to invite you to participate in a follow-up interview and another chance to participate in the study.

During the Ready Steady course

4. You will keep your physical activity monitor (Fitbit) throughout the study, to use as you wish. You can use it to help you track your own activities, such as steps or miles walked each day.
5. You will receive information about the 8 meetings to which you have been assigned with other a small group of additional research participants. These meetings are held once weekly over 8 weeks (approximately 90 minutes each). You will be given a calendar that highlights the times, dates and location of these meetings. Each group meeting will involve:
 - A. Practicing light physical activities that build balance and leg strength. These activities will be adjusted according to your preferences, strength and abilities. The types and number of physical activities practiced will be gradually increased. Following is a list of physical activities that will be practiced by week:
 - Weeks 1-2: gentle ankle, head, neck trunk and back stretching movements, movements that strengthen and

improve coordination in feet, ankles, and legs and walking

- Weeks 3-5: gentle ankle, head, neck trunk and back stretching movements, movements that strengthen and improve coordination in feet, ankles, and legs, walking, plus movements that strengthen and improve coordination your hip muscles
- Weeks 6-8: gentle ankle, head, neck trunk and back stretching movements, movements that strengthen and improve coordination in feet, ankles, and legs, walking, plus movements that strengthen and improve coordination your hip muscles

B. In addition to the physical activities, weekly meetings will also involve discussions. Each group will discuss safely practicing different types of physical activities and how falls can be prevented. Also, additional topics will be discussed according to the group to which you were randomly (by lottery) assigned. Additional topics that may be discussed in your group include:

- A.** The give-and-take of social support for physical activity within & outside the small group
- B.** Being a role-model
- C.** The level of your physical activity over time
- D.** Goals that are personally meaningful to you
- E.** Action plans to support your goals
- F.** Including physical in your personal and/or social routines
- G.** Identify and problem-solve personal, social & community resource barriers to physical activity
- H.** Friendly comparisons of how and where physical activities are practiced
- I.** Health and Age topics such as sleep, supplements, common changes in hearing.

After the Ready Steady course

- 6.** After the 8 weeks of small group meetings, you will be asked to:
 - A.** Continue practicing the physical activities you have mastered during the 8-week program.
 - B.** Make appointments with the researchers, approximately:
 - a. One week after 8-week program is over
 - b. Six months after the 8-week program
 - c. 12 months after the 8-week program

Please note: The procedures during these appointments are the same as you will go through during the appointment you will have before the 8-week course. Procedures are outlined above in the section titled, “**Before the Ready Steady Course**”.

- 7.** Finally, you may be invited to make another appointment with the researchers for an interview with questions about:
 - A.** Your thoughts about the Ready~Steady wellness research
 - B.** Your thoughts about the technology used in the research (Fitbit™)
 - C.** Suggestions you have for improving the Ready~Steady wellness program

What happens if I do not want to be in this research?

Participation in this study is voluntary. Your decision about whether or not to participate will not affect your current or future relations with the University of Minnesota or with the community center. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

What happens if I say “Yes”, but I change my mind later?

You can leave the study at any time and it will not be held against you. If you decide to leave the research, contact the investigator so that you and the investigator can discuss that extent of your withdrawal. That is, the investigator will ask you if you wish to withdraw from the 8-week meeting portion of the study, but are willing to undergo one or more of the follow-up appointments with researchers. This will also ensure that the investigator communicates your plans with the research team.

Is there any way being in this study could be bad for me?

The study has several risks. The first risk is that your muscles may feel stiff or sore at the beginning of the course. This is expected and will improve over time. The second risk is that you may injure a muscle. This risk is very small. Less than 1 in 10,000 people injure a muscle. If you feel discomfort, please stop the physical activity and tell the researcher. The third risk is mental or social discomfort when talking to others in the interview appointments or small group meetings.

What happens to the information collected for the research?

The records of this study will be kept private. Your record for the study may, however, be reviewed by the National Institutes of Health, and by departments at the University with appropriate regulatory oversight. We will not include any information in publications or presentations that will make it possible to identify you. Your responses to questionnaires and your monitor data will be transmitted via the internet. Our procedures for transmitting this data will protect your privacy by keeping it password protected and separating your data from personal identifiers such as your name. To these extents, confidentiality is not absolute. All study data will be encrypted according to current University policy for protection of confidentiality.

Group meetings and interview appointments may be audiotaped, at random, to verify that interviews and small group meetings proceed as planned. Audiotapes will be stored in a secure, password protected computer database.

Will I have a chance to provide feedback after the study is over?

The Human Research Protection Program may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team for the Human Research

Protection Program (HRPP). See the “Who Can I Talk To?” section of this form for study team and HRPP contact information.

Will I be compensated for my participation?

You will receive payment. As a token of appreciation for your time and efforts in this study we will pay you \$20.00 immediately after each interview appointment that you complete. We will also pay you \$50.00 immediately after the physical activity data is collected. There are total of four such time points during the 15-month study, over the course of 12 months. Thus, if you participate in each interview and physical activity data collection time point, you will receive a total of \$280.00.

You may also be invited to an additional interview (see item 7 above). You will be given a payment of \$20.00 immediately after this interview.

Optional Elements

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

_____ _____ The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

_____ _____ The researcher may photograph, audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

_____ _____ The researcher may contact me in the future to see

whether I am interested in participating in other research studies by the principal investigator of this study.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent

You will be given a copy of this information to keep for your records.

Ready-Steady Contact Information

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