Mindful Movement for Physical Activity and Wellbeing in Older Adults- A Hybrid Effectiveness-Implementation Study (Y-U)

Informed Consent
October 30, 2020

R33AT009110 (U.S. NIH Grant/Contract)

NCT03929393

Informed Consent Form
Y-U Study for Physical Activity & Wellbeing

Please read this form carefully and ask any questions you have before agreeing to participate in the study.

INTRODUCTION
You are invited to participate in this research study, because you are at least 50 years of age and you are interested in improving your health, physical activity and wellbeing.

This study is being conducted by:

- Dr. Roni Evans, a researcher at the University of Minnesota (UMN) in Minneapolis, MN, and
- Staff at the YMCA of the North.
- The study is funded by the National Institutes of Health's, National Center for Complementary and Integrative Health.

STUDY PURPOSE
This study is testing two educational programs: Mindful Movement and Keys to Health & Wellbeing. Our goals for this study are to see:

1. Which program is better for increasing physical activity and wellbeing?
2. What people think about these programs (e.g. what you like and dislike)?

There will be no cost to you to participate. You will have 2 screening visits to see if the study is a good fit for you.

You do not have to attend any study visits in person. You will participate in at least one screening visit and all program visits using Zoom. The Zoom app we use is secure and private. It allows people to see and talk to each other using a computer, tablet or smartphone. We will show you how to use Zoom. If you do not have a computer, tablet or smartphone, assistance may be provided if you qualify for the study.

STUDY PROCEDURES
First Screening Visit (1.5-2 hours) -- Phone and/or Zoom

- We will review this consent form with you and answer your questions.
- We will ask you questions about your access to technology (e.g. computer, tablet, smartphone, Internet). We may set up an additional call to discuss your technology needs.
- You will fill out questionnaires about you, your general health, activity levels and wellbeing. You do not have to answer any questions that are too personal. If you chose not to answer certain questions, you may not be eligible to participate.
- We may ask you about your past medical history. You may be asked to follow up with your medical provider to make sure it is safe for you to participate in this research study.
- You will be asked to wear an activity device every day for 10 days. This device records your physical activity. It will be mailed to you. After you wear the device for 10 days (10

hours per day), you will mail it back using a postage paid envelope we provide. See additional information below.

Second Screening Visit (1-1.5 hours)--Phone and/or Zoom

- We will review the study again and answer your questions.
- You will fill out questionnaires about your general health, activity levels, and wellbeing. You do not have to answer any questions that are too personal. If you chose not to answer certain questions, you may not be eligible to participate.
- We will ask you about your past medical history to see if you qualify for the study.
- We will tell you if you qualify for the study. If you qualify, you will be entered into the study.

Random Assignment and Program Registration

If you qualify for this study, you will be enrolled randomly (like the flip of a coin) to one of two education programs: Mindful Movement or Keys to Health & Wellbeing.

Important things to consider:

- Neither you nor the researchers can choose which program you will get.
- You have an equal chance of getting into either program.
- You will be told which program you get into at your second screening visit.

Both programs last 9 weeks (about 2 months). We will ask you to fill out questionnaires and wear the activity device three additional times (at 2, 6, and 12 months). Your total participation in the study is 12 months (1 year).

YMCA Education Programs (Weeks 0-8)

- You will be asked to commit to an orientation session (Week 0) and 8 educational program sessions (weeks 1-8) for a total of 9 sessions.
- All sessions are 90 minutes long (1 hour, 30 minutes) and will take place using Zoom.
- These are group programs. Other people in the community will participate in the sessions with you at the same time.

You will receive general information about increasing your physical activity and suggestions for activities you can do at home and in your community. You will participate in group discussions and be asked to practice what you learn at home. You will be given a workbook to record your goals and monitor your progress. You will also be given access to online materials. You will participate in only **one** of the following programs:

Mindful Movement Program

This group program will teach you how to manage your thoughts and emotions with different techniques and tips. These are also known as ‘mindfulness practices’. This program will also address how to overcome barriers to exercise. You will learn how mindfulness can help your overall health and wellbeing. You will be introduced to different forms of mindfulness practices done while sitting, walking, and doing gentle movements.

Keys to Health & Wellbeing Program

This group program will teach you about different things you can do to improve your health and wellbeing. You will be introduced to different health-related topics important for people 50 years of age and older. This will include things you can do to prevent and care for common health conditions and ways to maintain your overall health.

At the end of the study (after 1 year), you will have access to information provided in both groups.

Follow-Up Activities
3 separate times: 1). At the end of your education program, 2). 4 months after your program, and 3). 10 months after your program we ask you to do the following:

Wear an Activity Device

- You will be mailed an activity device and instructions on how to wear it.
- You will indicate you received your device by responding to a short survey sent to your email.
- The activity device is the same one you wore earlier in the study.
- You will wear the activity device for 10 days (10 hours per day).
- You will receive email reminders to wear the device.
- When you are done wearing the activity device, you will mail it back to the University of Minnesota in a postage paid envelope we provide.

Fill Out Questionnaires

- You will complete a questionnaire (via email or phone).
- You will be sent reminders to complete the questionnaire by email.
- The questionnaire will be similar to the ones you completed earlier in the study. It will ask you about your general health, activity levels, and wellbeing.

Compensation

- We will compensate you for your time once we receive your activity device and completed questionnaires. See below for more information.

LOANED ACTIVITY DEVICE

- The University of Minnesota will loan you an activity device to use. The activity device is not for you to keep. It is the property of the University of Minnesota.
- You are required to mail this device four times using a postage paid envelope we provide: during the screening phase, after your program ends; 4 months after your program, and 10 months after your program.
- If you lose the device, damage it (aside from normal wear and tear) or it is stolen, you must pay to replace the device. The device has an approximate replacement value of $225.00.
- If the device is lost or stolen during the course of the study, please contact the study team immediately.
- The device only measures your physical activity. It does not measure your heart rate, sleep patterns, location or any other health related or personal information.

IMPORTANT DATES:
You will be given a calendar that includes important dates for the study. These include:

- Your educational program visits
- Dates when you can expect to complete questionnaires and wear your activity device (after your program, 4 months and 10 months after your program).

RISKS OF STUDY PARTICIPATION
Risks associated with the Mindful Movement and Keys to Health & Wellbeing education programs are considered minimal and are rare.

- Some people may experience minor discomfort while performing mindfulness practices in certain positions (e.g., sitting, walking, gentle movements). Some people don't like to participate or get anxious in group activities

- Mindfulness practices may aggravate symptoms associated with Post Traumatic Stress Disorder (PTSD). Also, these practices may lead to seizures in persons with known seizure disorders.

- Participants might also experience muscle and joint soreness from physical activity; this is expected to be mild and short lasting.

- Very rare but serious risks can occur with increased physical activity. These include heart arrhythmias (changes in your heartbeat), sudden cardiac arrest (heart stops beating), and myocardial infarctions (heart attack). There is no known risk for sudden cardiac (heart) issues when persons who do not exercise, gradually increase to moderate-intensity activity (which is what is recommended in this study). Rare cardiac (heart) events occur most often when people progress from doing no activity to vigorous activity (e.g., shoveling snow).

We may require a note from your medical practitioner that confirms it is safe for you to participate in the study. If so, we will need to receive this note signed and dated by your medical practitioner no later than your Second Screening Visit. Without it, you will not qualify.

BENEFITS OF STUDY PARTICIPATION
There may be no direct benefit to you from participating in this study. Some participants may experience health benefits from increased mindfulness, including decreased stress and increased wellbeing. Also, you may learn new information about how to stay healthy as you get older. Additionally, there is strong research evidence that regular physical activity is associated with a decreased risk of early death, heart disease, stroke, hypertension, type II diabetes, colon and breast cancer, falls, depression, and cognitive decline. The benefits of participation are likely to exceed the risks.

STUDY COSTS/COMPENSATION
All program fees are paid for by the study. You will be compensated for your time and effort in the form of a UMN MasterCard gift card. The gift card will be mailed to you when you complete the educational program, and it can be used at any retailer that accepts gift cards.

To receive the full amount ($210), you must do the all of the following:

- Attend all study sessions (a total of 9) during Weeks 0-8
    - You will be given $10.00 for attending each session → up to $90.00
    - You will not be compensated for missed sessions.

- Activity device & questionnaire after the educational program (Week 9)
    - You will be given a total of $50 for wearing the device, mailing it back and filling out the questionnaire.

- Activity device & questionnaire 4 months (Week 26) and 10 months (Week 52) after your program
    - You will be given a total of $35 for wearing the device, mailing it back, and filling out the questionnaire at each time point → up to $70.00

RESEARCH RELATED INJURY
Care for research related injuries will be billed in the ordinary manner, to you or your insurance company. If you suffer an injury in this study, please report this to the lead researcher, Dr. Roni Evans and/or the Project Coordinator as soon as possible. Contact information is listed below. The University of Minnesota and the YMCA cannot provide financial assistance or coverage for any associated medical expense or other costs.

STUDY RESULTS
No study results will be shared with you directly.

PROTECTED HEALTH INFORMATION/CONFIDENTIALITY
Protected Health Information created or received for the purposes of this study is protected under the federal regulation known as HIPAA. We try to limit the use and sharing of your information, including research study records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview
If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. Your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes. We will not include any information in publications or presentations that will identify you. We will not access your private medical records.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?
Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☒ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- National Center for Complementary and Integrative Health (NCCIH)
- Westat (external auditing agency)

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

VOLUNTARY NATURE OF THE STUDY

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota or the YMCA. If you decide to participate, you are free to withdraw at any time without affecting these relationships. If you decide to withdraw from the study, we ask that you let Dr. Evans know in writing. You will be asked the reason(s) for not wanting to participate, but you are not required to provide this information.

CONTACTS

If you have any questions related to the study, please contact the research team. You may ask any questions you have now, or if you have questions later, you are encouraged to contact us:

Principal Investigator: Roni Evans, DC, MS, PhD
Mayo Memorial Building, C504
420 Delaware Street SE
Minneapolis, MN 55455
Office Phone: 612-301-9004
Email: evans972@umn.edu

Project Coordinator: Linda Hanson DC, MS, CCRP
Mayo Memorial Building, C504
420 Delaware Street SE
Minneapolis, MN 55455
Office Phone: 612-626-2224
Email: y-u@umn.edu

This research has been reviewed and approved by an 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 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. 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.

STATEMENT OF CONSENT

I have read the above information in this Informed Consent Form and have been given an opportunity to ask questions. By signing this, I agree to participate in this study. I have been given a copy of this signed consent document for my own records. I understand that I can change my mind and withdraw my consent at any time without affecting or jeopardizing my future relationship with the participating institutions. By signing this consent form I understand that I am not giving up any legal rights.

_____ _____

Study Participant Signature Date

_____ _____

Signature of Person Obtaining Consent Date

Addendum - Informed Consent Form
Y-U Study for Physical Activity & Wellbeing

Please read this consent addendum carefully and take your time making your decision. Please ask questions about this addendum and the study prior to signing the form.

PURPOSE OF THIS ADDENDUM

The purpose of this addendum is to provide additional information about devices (e.g. computer, tablet or smartphone) that will be provided to you so you can participate in the study. Except for the activities described in this addendum, the terms of your original consent form remain in full effect.

LOAN OF DEVICE

The University of Minnesota will loan you a device (computer, tablet or smartphone) to use for the screening process if you do not have one. If you do not qualify for the study, you are required to return the device to the University of Minnesota in a postage paid envelope we provide. If you lose the device, damage it (aside from normal wear and tear) or it is stolen, you must pay to replace the device. The device has an approximate replacement value of $150-$250. If the device is lost or stolen during the course of the study, please contact the study team immediately. If the device is damaged during the study, we are not required to, and may not be able to repair or replace it.

TRANSFER OF OWNERSHIP

If you qualify for the study, you can keep the computer, tablet or smartphone provided to you.

You may use the device for your own private use during the study and after the study ends. However, the University of Minnesota is not responsible at any time for your use of the device including illegal purposes and illegal (unsafe) disposal.

QUESTIONS

Please contact the following with any questions or concerns:

Roni Evans, DC, MS, PhD	Linda Hanson DC, MS, CCRP
Principal Investigator	Project Director
Mayo Memorial Building, C504	Mayo Memorial Building, C504
420 Delaware Street SE	420 Delaware Street SE
Minneapolis, MN 55455	Minneapolis, MN 55455
Phone: 612-626-2224	Phone: 612-626-2224
Email: evans972@umn.edu	Email: y-u@umn.edu

STATEMENT OF CONSENT

I have read the above information in this Addendum Informed Consent Form and have been given an opportunity to ask questions. By signing this, I agree to the above. I have been given a copy of this signed addendum document for my own records. I understand that I can change my mind and withdraw my consent at any time without affecting or jeopardizing my future relationship with the participating institutions. By signing this addendum I understand that I am not giving up any legal rights.

_____ _____

Study Participant Signature Date

_____ _____

Signature of Person Obtaining Consent Date