University of Pittsburgh | School of Health and Rehabilitation Sciences

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Effectiveness of the On the Move Group Exercise Program to Improve Mobility in Community-Dwelling Older Adults

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Why is this research being done?
The overall goal of this study is to test a community-based group exercise program to improve walking in community-dwelling adults.

Who is being asked to take part in this research?
Adults aged 60 years or older, who are able to walk household distances without the help of another person, do not have plans to leave the area for an extended period of time, do not have any acute or

unstable illness or medical condition, and can participate in a group exercise program are being asked to participate. We plan to enroll up to 600 adults in this research study.

What procedures will be performed for research purposes?

If you consent to participate in the study, we will collect information that is based on your performance of various tasks or information that you report to us by answering questionnaires. The approximate time to complete these assessments is indicated in parentheses. All testing will be administered by trained research staff and will be completed at the community-based organization.

<u>If you consent to participate, we will collect the following information:</u>
A screening examination (10 minutes), which will include:

- Basic information about your age, education, and social situation.
- A review of your health history and readiness to participate in physical activity. A measure of your ability to walk independently for short distances.

<u>Based on the screening examination, if you are eligible for the study, you will undergo some additional measures (see below) of walking and physical function. If you are not eligible for the study based on the screening physical examination, you will not be able to participate in the exercise program. The additional measures that you will undergo if eligible are:</u>

- Measures of your walking speed. (5 minutes)
- Questionnaires about your perception of your ability to function in everyday activities and your perception of your health.(15 minutes)
- Several questions about how confident you are in your ability to walk. (5 minutes)

The initial testing will take approximately **25 minutes**. Throughout the testing you will be permitted to take rest breaks as needed. If you become too tired to complete the testing in any study visit, you may be asked to return within the week following the study visit to complete the testing. All study visits for the testing described above will take place at the community-based organization that you attend. The testing will occur in either the activities room or the exercise room.

Experimental Procedures
At the very beginning of this research study, the community-based organizations were randomly assigned (such as flipping a coin) to starting the exercise program immediately or to starting the exercise program after waiting for 12 weeks. **If your community-based organization is assigned to the second session of classes, we will ask you to repeat the 25-minute baseline testing (described above) prior to starting the exercise session.**

All individuals will receive the same exercise program. You will perform warm-up exercises which may include walking and range-of-motion exercises for your legs. You will also perform strengthening exercises for your legs. The exercises will include exercises performed while standing or walking that will challenge your ability to move in different ways. Some examples of the exercises are stepping forward, backward, and diagonally while standing; walking in patterns that include curves, like ovals,

serpentines, and spirals; and walking that includes changing directions.
The exercise programs will be conducted in a group setting (up to 10 people) at the community-based organization which you attend. All exercise sessions will be delivered by a certified exercise instructor trained in the exercise program. There may be as many as 9 other research participants in the group exercise sessions with you. The treatment sessions will be held **2 times per week for 12 weeks**, with each session lasting approximately **1 hour.**

The group exercise classes will be periodically recorded including both video and audio. **Video and audio recording is a requirement to be able to participate in the study**. The video and audio recordings of the exercise classes will be used indefinitely after data collection by the investigators and research assistants, or by other investigators, who have research studies approved by the University of Pittsburgh Institutional Review Board (IRB), who have asked to use the recording information. We do not include information that could identify you such as your name on any of the recordings, but you can be identified by the image. If you agree to participate in this study you are agreeing to permit the use of the recordings by the investigators named on the cover of this consent form, and by investigators in the future who have approval from the University of Pittsburgh IRB to use the recordings in research and for educational purposes.

After you complete the 12-week exercise program, you will be asked to return for a visit to repeat the testing measures that you completed during the initial visit. These will include the walking test and the questionnaires described above. We estimate that the post-exercise session testing will take **approximately 25 minutes.**

At the end of the exercise program, we will ask you for feedback about the exercise program. Feedback about your experience with the exercise program will be obtained through a brief satisfaction survey. Some exercise classes will be asked to provide additional feedback through a focus group. The focus group discussion will be audio recorded and may be video recorded if conducted via zoom. We anticipate the focus group to last **60 minutes**.

If your community-based organization is assigned to the first session of exercise classes, you will be asked to return 12 weeks after the completion of the exercise classes (i.e., 24 weeks after baseline). At this final visit you will be asked to repeat the testing measures including the walking test and questionnaires that you completed at the previous testing sessions. We estimate that the final testing session will take approximately **25 minutes**.

The total number of visits for this exercise study is 28 visits in about 24 weeks. The timing of the sessions will vary depending on which exercise session your community-based organization is assigned to. If your organization is assigned to the first session your visits will include: 1 visit for testing prior to starting the exercise program, 24 visits for the exercise program, 1 visit for testing after the exercise program, potentially 1 visit for the focus group, and 1 final testing session 12 weeks after the conclusion of the exercise program. If your organization is assigned to the second session your visits will include: 2 visits for testing prior to starting the exercise program, 24 visits for the exercise program, 1 visit for testing after the exercise program, and potentially 1 visit for the focus group.

What are the possible risks, side effects, and discomforts of this research study?

As with any experimental procedure, there may be adverse events or side effects that are currently unknown, and certain of these unknown risks could be permanent, severe or life-threatening. The possible risks of this research study are mostly due to the testing of your walking and/or your participation in the exercise program. The risks of participating in the testing and exercise program for walking are minimal. However, there are certain risks and discomforts of which you should be aware.

<u>The possible risks are:</u>

1.) You may get tired during the testing sessions or exercise classes. If you become tired, you can stop the testing or exercise and resume when you are rested.
2.) Side effects from testing or exercise, such as muscle soreness, are expected to be infrequent.
3.) There is a rare risk that you may fall during testing or exercise. However, members of the research staff are trained in exercise testing and supervision of exercise programs. They will be present during all tasks to render assistance in the event of an emergency and will watch you as you walk and stop you from continuing if you appear to be having difficulty or will help steady you if you appear to be falling.
4.) There is a rare risk that you may have heart problems during the testing or exercise. We will conduct a screening to determine if you have any conditions which would put you at increased risk. If you have certain medical conditions you will be unable to participate. The personnel completing the exercise sessions may not be medical personnel. It is important that you report to the research staff or exercise leader any potentially heart related symptoms that you experience such as shortness of breath, heart racing, lightheadedness, etc. From reviewing previous studies reported and our own experience with very similar exercise treatment programs, we do not know of an incidence of serious heart problems in a supervised testing and exercise situation such as this.
5.) There is a rare risk that your confidentiality could be broken. All of the records involving your participation in this study will be kept in locked file cabinets and/or password-protected files. All of the investigators listed on the first page of this form and any additional staff that assist with management of your files are trained in the privacy and confidentiality regulations that govern research.
6.) Because this is a research study, it is also possible that there are risks of participation in this study that are not currently known.

What are the possible benefits from taking part in this research study?

There is the potential for you to benefit from participating in an exercise program. The potential benefits of exercise are general, such as improving your heart and lung function, circulation, and strength and endurance. There may be more specific benefits, such as the potential to improve your walking abilities. However, there is no guarantee that you will receive such a benefit. There is also the potential that information learned from this study may benefit individuals in the future to help improve their walking abilities.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any new information develops during the conduct of this research study which may cause you to change your mind about continuing to participate.

What are alternative treatments I could consider if I decide not to participate in this study?
We would refer you to your physician to consider a referral for physical therapy for treatment to improve your balance and walking abilities. Physical therapists typically treat problems in balance and walking.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?
If you participate in this research study, neither you nor your insurer will be charged for the services done solely for the purpose of the research study. The research study will cover the costs for all procedures and intervention related to the research study. If you participate in this research study, you and your insurance provider will be charged for any routine care you receive not associated with the research study. You will be responsible for any applicable copayments, coinsurances and deductibles associated with routine care not related to the research study.

Will I be paid if I take part in this research study?
You will be paid a total of $60 if you complete all parts of this study. If for any reason you complete part but not all of the study, the terms of this payment will be as follows: $20 for completing each of the 3 testing sessions. If your class is invited to a focus group, you will be paid an additional $30 for participating in the focus group. Payment will be made to you at the completion of the testing session using a University of Pittsburgh "Vincent" credit/debit card. Please note that for payment we need your social security number; if you do not provide your social security number, the University of Pittsburgh must withhold 24% of the total study payment for Federal backup withholding purposes. Since you are being paid for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total payment for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Who will pay if I am injured as a result of taking part in this research study?
University of Pittsburgh researchers and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. You do not waive any legal rights by signing this form.

Who will know about my participation in this research study?
The research staff and study investigators will know about your participation in this study. Other research study participants will know about your participation in this study because the exercise classes will be conducted using a group format. The group exercise program will be held at the community center,

individuals at the community center may see you and know about your participation in this study. Any information about you obtained from or for this research study will be kept as confidential (private) as possible. Forms that identify you by name will be stored in a locked cabinet when not in use by the investigators in this study. You will be assigned a code number that will be used to identify you on all forms that contain research information. The data collected from you will be entered into a computer file by the code number. A separate computer file linking your name to the code number will be accessible only to the investigators named on this proposal. The study sponsor (NIA) will have access to data that includes your name. The safety officer will not have access to data that includes your name. Colleagues within and outside Pitt may be involved in data analysis and data without your name may be shared with them. Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study indefinitely.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your

consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers if, for example, your walking ability worsens and you are at increased risk for injury. You can also be removed from the study if any new medical condition, injury or illness is discovered during the course of treatment that would render you ineligible based on the exclusion criteria. If you are identified by the research staff to have a temporary medical condition that would impact your participation in the research study (i.e. any of the exclusion criteria), you will be required to obtain medical clearance for participation in exercise from your primary care physician prior to returning to the exercise intervention.

Clinical Trial Registration
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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VOLUNTARY CONSENT

All of the above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

Video and Audio Recordings:

_____I understand that video and audio recordings will occur as part of this research study during the On the Move exercise classes.

_____I understand that video and audio recordings will occur as part of this research study during the focus group session.

By signing this form, I agree to participate in this research study and consent to the collection of my video and audio recordings for purposes of this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date