Sustainability of MOVE UP Lifestyle Intervention (MOVEUP-S)

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University of Pittsburgh
Center for Aging and Population Health
Prevention Research Center
Pitt Public Health 130 N. Bellefield Avenue, Pittsburgh, PA 15213

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: **MOVE UP- Sustainability: Mobility & Vitality Lifestyle Program**

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SOURCE OF SUPPORT: The Centers for Disease Control and Prevention

STUDY OVERVIEW:
In prior research, we showed that a 13-month long intervention called the Mobility and Vitality Lifestyle Program (MOVE UP) was effective in producing a mean loss of about 5% body weight, with increased physical activity and reduced fatigue among older adults. Starting in 2019, Dr. Steve Albert and his research team from Pitt Public Health will pilot a streamlined version of this program in a research study called **MOVE UP-Sustainability** to see if it will be similarly effective.

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In this pilot study, we will examine how a 12-week group-based healthy aging and lifestyle change intervention program led by trained Community Health Workers might impact diet, activity, weight, physical function, and psychosocial measures.

Purpose of the Study:

Obesity is a major threat to mobility and independence in older adults. It is a risk factor for diabetes, arthritis, hypertension, stroke, many cancers, and heart disease. Obesity is increasing more than in older adults than in any other age group. We know from many intensive long-term studies that behavioral lifestyle interventions with goals of modest weight loss (5-7%) and increased physical activities (such as walking and/or strength, balance, and flexibility exercises) can help to improve physical function among older adults. However, for such programs to be adopted widely and sustained in many community-based settings, practical group programs need to be tested. By conducting this study, we hope to inform the design and translation of future public health programs for aging adults.

Study Intervention Description:

The goal of the MOVE UP-Sustainability study is to improve healthy eating and physical activity behaviors to support weight management and mobility. In this intervention, you will be asked to attend 12 weekly, in-person group sessions lasting about 60-minutes each. We encourage you to come to as many of these sessions as you can. Groups will have no more than 15 participants. All sessions are based on best practices for healthy aging and lifestyle behavior change. The intervention procedures have been shown to be generally safe and effective for older adults. Sessions will be held at a community site, led by a trained Community Health Worker. This group leader will be someone with prior training and experience working in a public health or social service setting with older adults.

MOVE UP group sessions are designed to be a supportive place to help you achieve weight management goals by decreasing caloric intake, adopting healthy eating patterns, increasing your physical activity (aerobic, strength, balance and flexibility), and coping with barriers to achieving weight loss and mobility goals. Over a period of several weeks in MOVE UP, the activity and mobility goals will include the following; (1) a minimum aerobic goal of walking, or other preferred activities, for 30 minutes, 5 days per week, and (2) adding simple strength, balance and flexibility exercises about 2 times per week (as recommended by the National Institute on Aging in their Go4Life® campaign). We will briefly introduce you to a sample program; handouts and other resources will be provided to help you learn ways to build these activities into your lifestyle. However, you will work on reaching these activity goals on your own (i.e., we will not be conducting a supervised exercise program).

You will be weighed at each session. Both you and the study will keep a record of your weekly weights. Beginning with the first session, you will be asked to complete a Lifestyle Log—a food and activity diary—in which you record what you eat, your physical activity, and your weight. We ask you to turn these into your group leader at every session, and you will receive helpful feedback on your log when you get it back at the following session. We are interested in how you use the logs, and whether they help you achieve your healthy lifestyle goals.

Healthcare Provider Permission to Participate:
To inform your health care provider about the nature of this study and to confirm that you are safe to work on the activity and weight loss goals, we are asking you to get your physician's (or other health care provider) permission to participate. ***This clearance needs to be obtained by the start of the second group session of the program.*** We will give you a simple, one-page description of the study and a clearance form to hand to your physician or doctor's office staff. Your physician, knowing your medical history, will decide if this program is medically appropriate for you. His/her office staff will return the clearance to the study office by mail or a dedicated FAX number. If you do not have a primary care provider, options can be discussed with the study team. If you have a significant health event during the course of the study, you may be asked to go to your provider for permission to return to the study.

Who is being asked to take part in this study?
Men and women who qualify based on the initial telephone screening may be eligible to participate. We would like to enroll enough participants for at least two intervention groups of no more than 15 persons each at two different locations. There is no random assignment in this pilot study; every participant receives the same intervention.

You may be eligible if you:

- Are able and willing to consent to participate in most group sessions and in the data collection
- Are 60-89 years of age
- Have a body mass index (BMI) of 27.0 - 45.0 (this will be confirmed at your baseline visit)
- Are able to walk (with or without a cane or walker)
- Are able to read materials written in English

You may be excluded from participating if you:

- Were already a MOVE UP participant
- Were hospitalized for an overnight stay in the past six months
- Are in active treatment for cancer
- Have hearing, vision, cognitive or psychiatric problems that would make it hard for you to participate in the program
- Are already in another research study (now or in the last 12 months) that could interfere with either study's outcomes
- Are currently enrolled in another weight loss program
- Have lost 10% of your body weight or more in the past year
- Had bariatric surgery, or taken prescription medications to lose weight, in the past year

Overview of Enrollment and Eligibility Confirmation:
After we review the consent form today and answer your questions, you may choose to proceed with enrollment. Once enrolled, we will measure your height and weight to confirm your eligibility (BMI of 27-45 kg/m^2). If you are not BMI eligible, we will not include you in this study. However, we will offer information about other healthy lifestyle programs we know about in the community.

Health Assessments:
If eligible, we will ask you to complete two research assessment visits (baseline and post-intervention), located at the same site as your group sessions, each lasting about one hour. We will schedule your baseline health assessment at a time that is acceptable to you. You may choose to proceed with your baseline assessment today or within the next few weeks before the group sessions start. The health assessments take about one hour to complete. The assessment visits are important to our study and we value your time and outcomes. Assessments will be conducted by well trained, respectful research staff at the same site where the program is hosted, or another convenient location.

During the baseline and post-intervention assessment visits, the following measures will be completed:

- Height and Weight - We will ask you to remove your shoes and step onto a digital scale, placed privately within the room. We will perform this measurement twice. With your shoes still removed, we will ask you to stand with your back and heels as close to the wall as possible, as we align a wooden height ruler at the top of your head. Your height will be measured twice, at the baseline meeting only.

- Physical Function- As you are able, we will ask you to (a) demonstrate three different standing balance positions; (b) walk four meters at your usual pace, two times; and (c) rise from a seated to a standing position five to six times.

- Questionnaires- At your baseline assessment, study staff will ask you to respond to a series of questionnaires and rating scales. You will be asked questions about the duration and frequency of your physical activity, typical food and eating patterns, medical history, mental and physical health, and beliefs about how well you can manage your weight and physical activity in different situations. For your post-intervention assessment, you may elect to have the questionnaire packet mailed to your home so that you can complete it prior to coming to your visit.

POSSIBLE RISKS AND DISCOMFORTS:
Although there are minimal risks involved in this study, we have outlined them below:

Assessment Procedures:

Height and Weight

- There is some risk of embarrassment when taking body measurements. Study staff can mitigate these discomforts by measuring you without other participants present, or by discussing options with you.

Physical Function

- There is some risk of falling, lightheadedness, imbalance, muscle strain or soreness when performing these procedures. You may choose not to do some of these movements.

Questionnaires

- Some questions may feel sensitive. Feel free to talk with research staff if you have concerns about answering them.

Intervention Procedures:

Weight Loss

- Modest weight loss, including among older adults, is associated with few risks. There are risks associated with losing weight too quickly so precautions are taken to monitor your weekly weight loss. Rapid weight loss may be related to hair loss and gallstone formation. This program emphasizes plant-based foods, a regular pattern of healthy meals and snacks (consistent with national dietary recommendations), and a 1-2 pound weight loss per week to minimize these risks.

Physical Activity

- Risks associated with physical activity including among older adults occur occasionally. One to ten people out of 100 experience muscle soreness, fatigue, and injury such as ankle sprains or pulled muscles. We reduce these risks by (1) following national physical activity guidelines, which recommend a slow and safe progression to 150 minutes per week of aerobic activity such as walking, (2) following evidence-based, Go4Life® strength, balance and flexibility movements designed for older adults to do about 2 times per week, and (3) demonstrating proper muscle warm up and cool down techniques.

- There is a rare risk of heart problems for those who have a chronic disease or experience symptoms with exercise. This risk is extremely small given the intensity of the recommended activities, i.e., walking, gentle strength, balance and flexibility exercises. The level of activity that we will recommend for you is thought to be more helpful than harmful, but there is a very small risk of heart attack or sudden death during exercise. Heart attack has been estimated to occur less than once out of 500,000 hours of exercise in people without known heart disease. The risk is greater in people with heart disease. We will ask your health care provider to approve of your participation in MOVE UP-Sustainability and remind you to contact your doctor 1) before beginning any physical activity program and/or 2) if you experience any new symptoms or related health problems during the study.

Other Potential Risks:

- If you indicate your willingness to be contacted by the research staff through text messaging, these messages are not encrypted or secure which means there is a risk the messages could be intercepted.

POSSIBLE BENEFITS OF PARTICIPATION:

Benefits from participating in the MOVE UP intervention may include maintaining or losing weight, maintaining or improving your physical function, and increasing your healthy behaviors. Your participation may help the Centers for Aging and Population Health to better understand the public

health care needs of your community, as well as to promote and encourage you and other adults to take charge of their health. It will also lead to a greater understanding of how adults aged 60-89 can safely lose weight. These potential benefits are not guaranteed. There are no direct benefits from participating in the health assessments.

COSTS OF PARTICIPATION:
There are no costs to you for participating in this study. However, you may incur cost traveling or parking at your site location, which are not covered by the study.

PAYMENT FOR PARTICIPATION:
There is no payment for your participation in this study. Participants will each receive program materials in a binder, and a gift such as a tote bag or pen.

NEW INFORMATION:
You will be promptly notified if any new information arises during this research study that may change your mind about staying in the study.

ACCESS TO PERSONAL INFORMATION:
Taking part in this research may involve providing information that you consider confidential or private. Efforts such as coding research records, keeping research records password secure, having computer firewalls installed, and allowing only authorized people to have access to research records, will be made to keep your information safe.

We do ask that you provide contact information for two individuals in case of emergency, or in the event that we have difficulty reaching you, so please notify them that you are in the study and could be contacted. However, information from your research records will not be shared with these individuals.

Although we ask you to obtain clearance for participation in the study from your health care provider, none of your health assessment records will be placed in your medical files unless you choose to share this information with your provider. We will not communicate with your provider unless you give us permission to do so.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov, if required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to the principal investigator listed on the first page of this consent form and their research staff, the following individuals will or may have access to your identifiable information related to your participation in this research study:

- ✓ Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable information for the purpose of monitoring the appropriate conduct of this research study.

- ✓ Authorized representatives of the sponsors of this research study, Centers for Disease Control and Prevention (CDC), may review and/or obtain your identifiable information for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. Authorized representatives of the CDC may also be present during your participation in certain research procedures.

- ✓ The investigators involved in the conduct of this research study may receive funding from the CDC to perform the research procedures and to provide the CDC with identifiable research information related to your participation in the study.

At the end of this study any records that personally identify you will remain stored in locked files and will be kept for a minimum of seven years. Your identity will not be revealed in any description or publications of this research.

COMPENSATION FOR ILLNESS OR INJURY:
The University of Pittsburgh investigators and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. We will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that research procedures have resulted in injury to you, immediately contact the Principal Investigator listed on the first page of this fosrm. Emergency medical treatment for injuries solely and directly relating to your participation in this research study will be provided to you by the hospitals of the UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical treatment beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

PARTICIPATION IS COMPLETELY VOLUNTARY:
You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators and/or study staff listed above will be available to answer your current and future questions. You may refuse to take part in this study, or you may stop participating at any time, even after signing this consent form.

Your decision will not affect your relationship with the University of Pittsburgh or the University of Pittsburgh Medical Center. Your participation in this research study is entirely voluntary. 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.

WITHDRAWAL FROM THE STUDY AND FUTURE CONTACT:
You can, at any time withdraw from this research study; you can also withdraw your authorization for us to use your identifiable medical information for the purposes described above. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above. To formally withdraw from 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.

You may also be withdrawn from the study at any time by the investigators; for example, if you were found to meet any of the study criteria that would exclude you from participating, did not receive your physician's clearance to participate at any point during the program, or if the study investigators felt that participation might be harmful to you. If you are withdrawn from the study, you will not be able to continue to participate in the program. If you choose to discontinue the program, we will still contact you and invite you to participate in post-intervention assessments.

VOLUNTARY CONSENT:
All of the above has been explained to me, and all of my current questions have been answered. A copy of this consent form will be given to me. I understand that I am encouraged to ask questions about any aspect of this research throughout the study and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the Human Research Protection Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
*Printed Name of **Participant***

_____ _____
***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, and I have discussed the potential benefits and possible risks of study participation. Any

questions the individual has 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*