ISU IRB: 22-286-00
Approved Date: 03/08/2023
Expiration Date: N/A

Informed Consent Document

Walk with Ease Study

Principal Investigator: Dr. Greg Welk, Ph.D.

This is a research study. Please take your time in deciding whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please feel free to ask questions at any time.

OVERVIEW

The purpose of this study is to evaluate the effectiveness of the Walk with Ease program for improving physical function, improving balance and reducing risks of falling in older adults. You have may have been referred by a physical therapist or a physician because they feel that you may benefit from participating in a structured physical activity program. Alternately, you may have requested to join the program for guidance and support since you may want to reduce your risk of falling in the future. Regardless of how you became interested in the program, all participants are required to be cleared by a clinician prior to participation to ensure all participants are safe to engage in light to moderate physical activity, and so that health care providers are aware of your participation. Participation in the group walking program being studied is a supplement to other medical treatment you may be receiving, not a replacement. Please note you must be at least 65 years old, speak either English or Spanish, and be able to stand for 10 minutes without increasing pain to enroll in this study. Individuals that are already physically active for 15 or more minutes per day or that are not considered to be at risk for falls are not eligible for this study. This study is funded by the Centers for Disease Control and Prevention, and linked to the National Center for Injury Protection.

DESCRIPTION OF PROCEDURES

The study is designed to test the effectiveness of different exercise and behavior change strategies for improving function and balance in older adults. The Walk with Ease program is an established, evidence-based program that is available to the public. We are interested in evaluating ways to further enhance the effectiveness. If you agree to participate in this research project you will be randomly assigned into one of two exercise conditions and one of two online support conditions to facilitate behavior change.

Overview: All participants will be guided through the same group-based Walk with Ease program. You will be asked to complete group sessions three times per week for six weeks (18 total sessions). Each walking session will involve a warmup and stretching exercises, self-directed walking, as well as cool-down and additional stretching activities, and will take about one hour. You will be asked to wear a pedometer during each walking session, which will count your steps. We will get you enrolled in the online Walk with Ease portal and get you access to the associated guidebook. Each week you can access resource links, goal-setting prompts, and activity logging tools through the portal. Please let researchers know if you have limited or unstable internet access so we can make sure you receive these materials.

Exercise Conditions: The only difference between the two exercise conditions are with the type of exercises that you will perform during the warm-up and cool down periods. Participants in Condition 1 will follow the standard exercise recommendations that are included in the Walk with Ease program. Participants in Condition 2 will be asked to meet with a licensed physical therapist prior to starting the program. Researchers will pay physical therapy appointment fees. Physical therapists will conduct an evaluation and develop customized exercise recommendations for you. Participants in Condition 1 will receive a similar physical therapy evaluation and similar customized exercise recommendations at the end of the project.

Online Support Conditions: All participants will be guided through Walk with Ease with the assistance of an online portal system that provides access to an eBook, resource pages, goal setting activities and exercise tracking tools. Each week, the online dashboard will provide new information and links to support the theme for the week. The only differences between the exercise conditions are with the type of video content that you will receive and with the degree of coaching that you will have. Participants in Condition 1 will follow the standard Walk with Ease training model while participants in Condition 2 will be receive some different information and resources.

In addition, participants in Condition 2 will be connected with a virtual health coach who will help you make and track goals. If assigned to this group, you will choose how often you want to talk with your coach – you can connect either by phone or video. Health coaching conversations usually take less than 30 minutes. Participants in Condition 1 will have the option of working with a health coach at the end of the project.

To assist in evaluating the program, you will also be asked to complete other study procedures.

Physical testing: You will be asked to complete a lab visit before beginning Walk with Ease. During this session researchers will collect your height, weight, blood pressure, body fat percentage, and heart rate. In addition, you will be asked to answer some questions and complete some fitness tests related to your mobility and strength/endurance.

When the six week Walk with Ease intervention ends, you will be asked to return for another lab visit to repeat the same measurements and testing.

Surveys: Throughout the study you will be asked to complete four surveys. These will occur when you first join the study, at the end of the Walk with Ease program, six months after completing the program, and again in another six months (twelve months after completing Walk with Ease). In these surveys you will be asked to answer basic demographic questions as well as provide information about your health. Specific sections will ask you about pain, fatigue and physical limitations, physical activity habits, and a basic health history. The surveys will take about 20 minutes to complete.

If you decide to join this research project, the following information will be used as study data:

- Information collected during physical testing
- Survey responses
- Information you enter into the Walk with Ease online portal, such as activity logs, goals and self-reported progress
- Data collected through the pedometer you wear during walking sessions
- The number and duration of your health coaching sessions
    - Please note – researchers will never use the content of your conversations with health coaches as study data.

Medical Records: You will be asked to release the following information about you from your medical records for use as study data:

- The custom exercise recommendations developed by the physical therapist at McFarland Clinic or Mary Greeley Medical Center, including any relevant notes such as issues impacting the way you walk.
- Beginning on the date you sign this form, annual fall data from your medical record will be obtained for research purposes. Example: the number of falls, if any, that appear on your medical record during the prior year. For each reported fall researchers will receive information about related injuries. This information will be collected annually from Mary Greeley Medical Center and/or McFarland Clinic for up to three years after you finish the Walk with Ease intervention.

RISKS

There is risk for injury when engaging in physical activity, including risk for trips or falls that may result in further injuries such as fractures or joint injury. However, your health care provider has deemed you safe to participate in a light-to-moderate exercise program. This program is supplementary to other medical treatment you may be receiving. You may note some increased muscle or joint soreness following initial walking sessions, and if this is the case, please notify researchers so your program may be modified to help reduce or eliminate this pain.

BENEFITS

It is expected that taking part in this study will build capacity, confidence, and skills needed to maintain a healthy and active lifestyle. In addition to the custom exercise recommendations from a physical therapist, you will also receive a personalized fall prevention assessment report.

COSTS AND COMPENSATION

There are no costs associated with your participation in this study, although you will need to provide your own transportation to research sessions. You will not be compensated for your participation in this study. However, a $25 gift card will be provided to participants that complete the final survey to provide feedback on their participation.

You will need to complete a form to receive payment. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal

resident of the U.S. or another country. If required, taxes will be withheld from the payment you receive.

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time, without impacting your access to health care services or impacting your relationship with your current health care provider. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled. For your own safety, researchers will withdraw you from the study if you can no longer safely participate in physical activity due to injury or illness. During data collection you can skip any questions that you do not wish to answer.

RESEARCH INJURY

Please tell the researchers if you believe you have any injuries caused by your participation in the study. The researchers may be able to assist you with locating emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By agreeing to participate in the study, you do not give up your right to seek payment if you are harmed as a result of being in this study. However, claims for payment sought from the University will only be paid to the extent permitted by Iowa law, including the Iowa Tort Claims Act (Iowa Code Chapter 669).

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, the Centers for Disease Control and Prevention, the National Center for Injury Prevention, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information.

To protect the confidentiality of the study records and data, the following measures will be taken. All data will be stored using a study specific identifier to prevent individual data from being linked to any participant. Identifiable digital and hard copy records and data will be stored on secure university servers, or within locked filing cabinets accessible only to research staff respectively. A key linking identifiable information to the study specific identifier will be kept separately on secured university servers, and will be destroyed upon termination of the program. If you consent to follow-up communication for future research your contact information will be stored in a secured file for future records. To protect your confidentiality when results of the study are reported, we will only publish group level findings and aggregated demographic information. No identifying information or study identifiers will be reported with results.

Information about you collected for this study may be shared with other researchers. It may also be used for other research studies. These studies may be similar to this study or completely

different. We will make sure that your identity cannot be linked to the information we share. We will not ask you for additional permission before sharing the information.

A description of this clinical trial will be available on http:www.ClinicalTrials.gov, as required by U.S. Law. This website 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.

Certificate of Confidentiality

Identifying information gathered about you during this research project is protected by a Certificate of Confidentiality from the CDC. With this Certificate, researchers cannot be forced to share identifying information about you with anyone not connected to the research, even by a court subpoena. The researchers will use the Certificate to resist any court orders or legal demands.

Additionally, identifying information protected by the Certificate will not be shared outside of the research team, except in the following instances:

- If there is a law that requires disclosure (such as to report child abuse or communicable diseases, but not for legal or other similar proceedings);
- If you have consented to the disclosure or sharing of information, including any disclosure or data sharing plans described elsewhere in this consent document; or
- For use in other scientific research, as allowed by federal regulations protecting research subjects; or
- To personnel of the CDC or National Center for Injury Prevention, when information is needed for auditing or program evaluation; or
- To meet the reporting requirements of the Food and Drug Administration, such as for studies of investigational medical devices or drugs; or
- To authorized individuals at Iowa State University if they need to verify that the research is being done correctly.

In addition, the researchers may share information if necessary to prevent serious harm to you or someone else; for example, if the researchers learn of ongoing child abuse or neglect, or the imminent threat of harm to you or others, they may share this information with the appropriate authorities.

You should know that a Certificate of Confidentiality does not prevent you from voluntarily sharing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study.

- For further information *about the study* contact Dr. Greg Welk at 294-3583 (gwelk@iastate.edu).
- If you have any questions *about the rights of research subjects or research-related injury*, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Research Ethics, Iowa State University, Ames, Iowa 50014.

PARTICIPANT CONSENT

By signing this document, you are agreeing to participate in this study. Make sure you understand what the study involves before you sign. If you have any questions about the study after you agree to participate, you can contact the research team using the information provided above. You may print a copy of this form for your files or request a paper copy from the research team.

_____
Signature

_____
Today's Date

Please type your name: _____

_____By checking this box, you are agreeing to allow the researchers associated with this study to keep your contact information (name, address, phone number, email address) to be informed about the possibility of participating in future studies.

How would you like to be contacted for the follow up survey?

_____ Email (Please provide address: _____

_____ Mail (Please provide address): _____

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