

Informed Consent Document

‘Walk with Ease in the Worksite’ enhanced with the CARROT Wellness app

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

This worksite wellness programming is part of 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 by emailing wellnessworks@iastate.edu.

OVERVIEW

The purpose of this study is to determine the effectiveness of a physical activity program called Walk With Ease (WWE) for employees of worksites within the state of Iowa. WWE is an evidence-based behavior change and walking program developed by the Arthritis Foundation to help participants walk more. Programming is delivered through an Iowa State University outreach program called Wellness Works that is managed in the Department of Kinesiology. WWE is a 6-week program designed to help participants learn skills to become more physically active.

DESCRIPTION OF PROCEDURES

If you agree to participate in this program, you will receive the 'self-directed' version of WWE. This version of the program is delivered completely virtually using solely email communications. If you agree to participate, the researchers will ask for your email address to send weekly newsletters to. The standard WWE curriculum will be followed for the six weeks but the programming will be enhanced with a mobile app called "CARROT Wellness" that will help to automatically track participants' daily steps and physical activity. The use of the CARROT app is supplemental to the program and participants have the option of whether to use it or not. Through the mobile app, participants also have the option to enroll in a group challenge with two other coworkers to see which team of three employees can improve their average daily step counts from the beginning of the program compared to the end of the 6-week program.

Program details are included below:

- **Prior to the start of the program:** An initial survey is conducted to collect baseline data, which includes basic demographic information such as gender, age, etc. The survey will also include a physical activity recall survey, a pain, fatigue and limitations survey, as well as habit strength, self-efficacy and barriers towards exercise and motivations to exercise and expectations of exercise surveys as well as your use and relationship to technology. The baseline survey is expected to take approximately 45 minutes.
- **During the program:** Participants will receive a total of eight emails: 1 email welcoming them into the program, 1 email each week for the duration of the 6-week program, and a final email at the completion of the program. The 6 weekly emails will include helpful information on forming exercise habits and overcoming barriers. The six weekly emails also include a link where participants can self-report the amount of active minutes they completed the prior week.

- **Post participation:** Several surveys completed at baseline will be physical activity recall survey, a pain, fatigue and limitations survey, as well as habit strength, self-efficacy and barriers towards exercise and motivations to exercise and expectations of exercise surveys, as well as a program satisfaction survey. The post-participation survey is expected to take approximately 45 minutes to complete. Participants will also have the opportunity to provide feedback regarding the perceived effectiveness of the WWE program and the CARROT Wellness Mobile App.

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. 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

You will receive no additional benefits, other than the resources provided as part of your participation. The goal is that you can implement the habits and skills learned through participation in the study to help maintain your physical abilities, and reduce any pain you may feel, as well as improve health indicators.

COSTS AND COMPENSATION

There are no costs to individuals associated with your participation in this study. You will not be compensated for your participation in this study.

PARTICIPANT RIGHTS

This program is supplementary to other medical treatment you may be receiving. 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, your participation will be terminated if, during the course of the study, you can no longer safely participate in physical activity due to injury or illness.

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. Eligible Iowa State University students may obtain treatment from the Thielen Student Health Center. 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, Food and Drug Administration (FDA), 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. De-identified data may be shared with other researchers, however private information will not be shared. Information about you collected for this study may also be used for other research studies. We will not ask you for additional permission before sharing the information as described in this section.

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. When reported, only group level data and demographic information will be reported. No identifying information or study identifiers will be reported with results. If you consent to follow-up communication for future research your contact information will be stored in a secured file for future records.

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 50011.