Title of the study: Daily Weight Feedback for Wheelchair Users to Promote Weight Loss

NCT number: 03264248

Date: June 5th, 2018

University of Pittsburgh

Human Engineering Research Laboratories

School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology

School of Medicine
Department of Physical Medicine and Rehabilitation

Executive Faculty:

Rory A. Cooper, Ph.D.
Director
Distinguished Professor and FISA/PVA Chair
Rehabilitation Science and Technology
Professor
Physical Medicine and Rehabilitation and Bioengineering

Brad E. Dicianno, M.D.
Medical Director
Associate Professor
Physical Medicine and Rehabilitation

Michael L. Boninger, M.D.
Senior Associate Medical Director
Professor
Physical Medicine and Rehabilitation
Professor
Rehabilitation Science and Technology and Bioengineering

Alicia Koontz, Ph.D., ATP, RET
Associate Director for Research
Associate Professor
Rehabilitation Science and Technology

Jon Pearlman, Ph.D.
Associate Director for Product Innovation and Translation
Assistant Professor
Rehabilitation Science and Technology

Annmarie Kelleher, MS, OTR/L, ATP, CCRC
Assistant Director for Clinical and Regulatory Affairs
Instructor
Rehabilitation Science and Technology

Garrett Grindle, MS
Assistant Director for Engineering

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Daily weight monitoring and weight loss for wheelchair users.

PRINCIPAL INVESTIGATOR:
Jonathan Pearlman, PhD

CO-INVESTIGATORS:
Jonathan Duvall, MS
Patricia Karg, MSE
Elizabeth Casey-Gold, MS

Department of Rehabilitation Science & Technology
Human Engineering Research Laboratories
Bakery Square, Suite 401
6425 Penn Avenue
Pittsburgh, PA 15206
(412) 822-3700

SOURCE OF SUPPORT: Paralyzed Veterans of America

One or more of the investigators conducting this research has a financial interest in **FURNITURE-INTEGRATED WEIGHT MESAUREMENT SYSTEM AND LOAD CELL FOR SAME** being evaluated in this research study. This means that it is possible that the results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Human Subject Protection Advocate of the University of Pittsburgh (866-212-2668).

You are being asked to participate in the research because we would like to evaluate the usability and feasibility of the E-scale system and the impact of the E-scale system coupled with a standard behavioral weight loss protocol. The results of this study will be useful for further refining the E-scale to make it more useful for wheelchair users and identifying if more accessible weight monitoring devices could help lower the prevalence of obesity among wheelchair users. The E-Scale is a bed-integrated weight scale being developed at the University of Pittsburgh's Department of

Rehabilitation Science and Technology. Weight sensors are installed under each foot of the bed. They supply weight data of each sensor that allows us to calculate the person's total weight. We will be recruiting 15 people as participants in this study.

We are asking you to take part in this research study because:

- You use Wheelchair as primary means of mobility
- Your bed has 4 legs
- Your BMI is ≥27 and <40.0
- You are between 18 – 80 years of age
- You have daily access to Internet to access LoseIt website and/or app and weekly chat meeting
- You currently own or are willing to use an android device
- You are able to provide physician's clearance to participate in a weight loss intervention.
- You have recorded your diet for 3 days to become familiar with what we will be asking you to do during the study

If you decide to take part in this study, you will be asked participate in a 13-week weight loss study which requires monitoring your diet and exercise using the LoseIt! and weighing yourself daily using the Nexaware E-scale. You will also be asked to participate in weekly chat sessions. After you have been consented, we will do the following:

- Your weight will be measured using a roll-on scale
- Measure your height and waist with a tape measure while you are lying on a mat table
- Your body-fat percentage will be measured with a hand-held BIA inductance measuring tool You will complete questionnaires about your mood and eating habits (CES-D and EDDS) as well as your ability to participate in healthy activities (SRAHP) and a demographics questionnaire.
- The LoseIt! (diet and activity journal) and E-scale apps will be installed on your phones/android devices or you will be provided with an android device with the apps already installed to use during the study. Login and passwords will be provided for you to use during all of the study procedures
- Some training on use of the E-scale and LoseIt! apps will be presented to you as well as the first lesson of the 13-week curriculum.
- Over the next few days, the study team will schedule a time to come to your home to install the E-scale under your bed.

During the next 12 weeks, you will be asked to weight yourself every day with the E-scale app and record your diet, exercise and weight every day with the LoseIt! app. The data that you report on the LoseIt! app will automatically be sent to the LoseIt! database and will be monitored by the study team. The study team will make weekly comments and study materials to you through email encouraging your progress and adherence to the protocol. Every week, a group chat will be conducted with all of the subject's and the research team invited to attend to go over the lesson for that week. The chat room will be hosted using adobe connect with the audio and video capabilities disabled. The link to the chat room for each week will be emailed to you along with the lessons for that week.

During the last week of the study (week 13). You will be asked to come back to the lab in-person where your weight will again be measured using the roll-on scale. Your waist circumference and body-fat percentage will also be measured again. You will again take the SRAHP and you will also be given the final questionnaire which will evaluate how you felt about the E-scale and some aspects of entire study. Any android devices that were loaned to you during the study will be collected and the apps on your personal devices will be deleted if you wish. Over the next few days, the study team will schedule a time to come to your home to remove the E-scale or you can bring it with you to the final assessment.

There may be risks of participating in this study. **There is a risk of damage to your bed, walls, or other items around your bed during installation and removal of the E-Scale.** We will visually inspect the bed and surrounding area in order to try to lessen any risk of damage. We may determine that it is not advisable to continue with the installation and end the study. The E-scale will continuously collect data so when you enter or exit the bed and how much movement there is on the bed may be able to be determined by looking at the data. If there are any problems with the E-scale, you can contact us at 412-822-3700 and we will schedule a time to come to your home to troubleshoot the system. The E-scale should not need new batteries during this length of study, but if it does, we can either walk you through how to replace them or we can schedule a time to come to your home to replace them.

Since you will be using third party applications and websites (LoseIt! and adobe connect), there is a risk of your data being observed or stolen. De-identified login and profile information will be provided to you for you to use for the LoseIt! app while being a part of this study. We will ask you to only use your first name during the adobe connect chat rooms. Therefore, any potential breach of data of these apps or websites will have minimal impact.

As private information is collected about you by the study team as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

There is a risk of falling while transferring out of your wheelchair. You will be asked to transfer out of your wheelchair onto a mat table for weight measurement. This risk is not greater than your usual daily risk of falling during a transfer. Installation of the E-scale under your bed will raise your bed height (by 0.5 inches) which may cause difficulty in transferring into the bed during the study. You reserve the right to discontinue with the study if the increase in bed height or stability is not acceptable.

You may benefit directly from participating in this study as you may lose weight which leads to better health outcomes. What we learn may help us to further refine the E-Scale for use. You will be paid $200 via a WePay debit card for completion of the study. Partial payment may be provided if you do not complete the entire trial. Specifically, 20 dollars for enrolling (passing the phone screening and coming to the lab to be consented) and being determined ineligible or withdrawing after enrolling, 75 dollars for participating for 4 weeks, 125 dollars for participating 8 weeks.

You may be removed from the study if you are admitted to the hospital for more than 5 day or if you have not participated in any study procedures for 2 weeks.

If you believe that you have been hurt as the result of the research study, please contact Dr. Jonathan Pearlman, the principal investigator listed on the first page of this form, as soon as you can. 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. 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 care 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.

To protect your privacy and maintain confidentiality of the information we obtain from you, we will keep all the information about you in a secure location. All records related to your taking part in this research study will be stored in a locked file cabinet and all electronic records will be stored on a secure server. Your identity on these records will be indicated by a case number rather than by your name and the code linking your name to this number will be maintained separately with very limited access to research team members. It is also possible that authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office, or the sponsors of this research study (Paralyzed Veterans of America) may review your data for the purpose of monitoring the conduct of this study.

This study does <u>not</u> involve access to any of your clinical or medical records.

Participation in this study is completely voluntary and your decision whether or not to take part in this research or to later withdraw from it will not affect your relationship with the University of Pittsburgh

If you no longer wish to continue to participate after you have signed this consent form, you should contact the principal investigator listed on the first page. Any information obtained from you up to the point of your withdrawal may be used for our data analysis. The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you are determined to be ineligible.

You may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

****

PARTICIPANT'S CERTIFICATION

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- I agree to participate in this study.

_____
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(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. I further certify that no research component of this protocol was begun until after this consent form was signed

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date