Validation of Treadmill Disturbance Parameters

NCT05333263

23July2020

IRB Minimal Risk Protocol Template

Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at http://intranet.mayo.edu/charlie/irb/

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points , save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Kenton R. Kaufman, PhD, PE

Study Title: Validation of Treadmill Disturbance Parameters

Protocol version number and date: 1.0, July 23, 2020

Research Question and Aims

Aims, purpose, or objectives: The purpose of this study is to evaluate the accuracy with which a programmable treadmill delivers controlled postural disturbances under real world use scenarios (i.e., with a subject on the treadmill belt).

Hypothesis: We hypothesize that the observed disturbance parameters will show acceptable agreement with the command disturbance parameters. In other words, a Bland-Altman plot 95% confidence interval of differences between input and observed characteristics will contain zero.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.): Compensatory step training safely induces a fall by delivering large postural disturbances, in turn requiring subjects to arrest a fall through timely well-placed steps and reduced trunk rotation (Owings et al., *Clin Biomech.* 16:813-9, 2001; Crenshaw et al., *J Biomech*, 45:129-33, 2012). Such training has reduced falls in the laboratory (Grabiner et al., *Med Sci Sports Exerc,* 44:2410-4, 2012) and free-living environment (Rosenblatt et al., *JAGS*, 61:1629-31, 2013, Kaufman et al., *Clin Orth Related Res*, 472:3076-3084, 2014). The ability to respond to a disturbance without stepping (Pai et al., *J Biomech*. 31:1111-1118, 1998) or by taking only one step (Rogers et al., *J*

Gerontol. 56A:M589-M594, 2001; Hilliard et al., *Arch Phys Med Rehabil*. 89:1708-1713, 2008) is reduced for individuals who fall compared to non-fallers. These results suggest that assessments that focus on the ability to respond to external disturbances have utility in prospectively identifying fallers. Such assessments and interventions, however, must use equipment that precisely delivers postural disturbances of various magnitudes. The purpose of this study is to evaluate the accuracy with which a programmable treadmill delivers controlled postural disturbances. The new treadmill (Treadmetrix, Park City, UT) is instrumented with force sensors and has been custom programmed to deliver postural disturbances in a similar manner to treadmills previously validated under IRB 14-000939 from the same PI.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol.*

Subjects will participate for a single 2 hour visit in the Motion Analysis Laboratory. Subjects will be asked to wear comfortable athletic shoes and clothing. Subjects will give written informed consent. A study team member will ask the subject questions about their medical history to see if they qualify for the study. These questions (with required answers) are as follows:

- What is your age? (Age must be between 18 to 45 years)
- Do you have current or chronic pain in your shoulders, elbows, hips, knees, ankles, feet, neck or back? (no)
- Do you have any medical conditions or previous injuries, trauma, or surgeries that reduce your balance, mobility or strength? (no)
- Do you use an assistive device such as a cane or walker? (no)

A study team member will measure the subject's height and mass. The subject's clinic number, birth date, gender, and preferred-kicking limb will be recorded.

The protocol is as follows:

Four reflective markers will be placed bilaterally on the subject's heel and toe. Additional markers will be placed on the treadmill belts. The three-dimensional trajectories of each marker will be recorded with a motion capture system (Motion Analysis Corporation, Santa Rosa, CA). Marker trajectories will be used to determine foot placement. While subjects are on the instrumented treadmill, force sensors in the treadmill will record ground reaction forces.

Subjects will walk on a treadmill for a period of up to 15 minutes. The walking speed will not be greater than 3.0 m/s (Diedrich et al., *Journal of Experimental Psychology*, 21:183-202, 1995). The purpose of this walking trial is to provide a period of warming up and familiarization with the treadmill.

The subjects will respond to external disturbances delivered by treadmill which has been programmed to provide the same disturbances as a commercially available, computer-controlled treadmill that is used clinically (CPT Codes: 97750, 97110, 97112, and 97116) for balance assessments and training (ActiveStep, Simbex, Lebanon, NH, http://activestep.simbex.com/). Before disturbances are delivered, subjects will be securely harnessed to an overhead rail so that the subject's knees and hands cannot

touch the treadmill. These methods are similar to other protocols in progress or in completion (IRB 11-006984, IRB 12-002515, IRB 13-000605, IRB 14-000939, IRB 15-004618, IRB 15-005602, IRB 16-000754, IRB 16-002999, IRB 19-007775). A maximum of 50 disturbances will be delivered.

The testing session will be video recorded as a method of study quality control to help study staff determine if a fall occurred during a treadmill disturbance. If a video clip of the testing will be used for presentation purposes, the volunteer's face will be concealed to protect their privacy.

The dependent variables from this assessment are the treadmill belt displacements, belt peak velocities, treadmill force, treadmill moment, center of pressure, and initial belt accelerations.

Subjects will be allowed to rest at their request. The protocol will be video recorded for documentation purposes.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*: The Motion Analysis Laboratory contains all equipment listed in the protocol. Three engineers are assigned to the project to run the data collection trials, process data, and disseminate the results through presentations and manuscripts.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 20 healthy adults

Subject population (children, adults, groups): Adults aged 18-45

Inclusion Criteria:

- Age 18-45
- Healthy adults with no medical conditions or previous injuries, trauma, or surgeries that reduce your balance, mobility or strength
- Able to follow simple directions
- Willingness to participate in the study
- No restriction will be placed on gender, race, or ethnicity

Exclusion Criteria:

- Current or chronic pain in your shoulders, elbows, hips, knees, ankles, feet, neck or back
- Use of assistive device such as walker or cane

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement: 20 subjects will each perform 50 trials (1000 data points for each treadmill). With 1000 data points, we can accurately estimate the limits of agreement to within +/- 1.96 $\left(\sqrt[2]{\left(\frac{3}{n}\right)}\right)$ s or +/- 0.11 standard deviations (Bland and Altman, *Lancet*, i:307-10, 1986).

Data Analysis Plan: Data will be analyzed using custom software (MATLAB, Mathworks, Natick, MA). The following dependent variables will be recorded for each visit:

- Treadmill belt displacement
- Treadmill belt peak velocity
- Treadmill belt average initial acceleration
- Treadmill force
- Treadmill moment
- Center of pressure location and excursion

Endpoints
Primary: Complete data collection of all subjects and complete statistical analyses
Secondary: Manuscript publication