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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: **Tamara Vos-Draper**

Study Title: **Interface Pressure Mapping to Improve Weight Shift Performance in Spinal Cord Injured Wheelchair Users**

Protocol version number and date: **Version 1, 09/16/2016**

Research Question and Aims

Aims, purpose, or objectives:

This study will examine two interventions to increase weight shifts, overall trunk movement, and self-efficacy related to pressure ulcer prevention in wheelchair users with a spinal cord injury (SCI). First, the participants will use a mobile seat interface pressure mapping system that gives them live, real-time, visual feedback on the distribution of pressure between them and their seat cushion. This type of feedback works as a compensatory strategy for lack of sensation and allows the individual to visually observe pressure distribution they aren't able to feel. Additionally, the participants will be provided with structured pressure ulcer prevention education, grounded in the principles of social cognitive theory, regarding pressure ulcer risk and use of weight shifts. The pressure mapping system, which will be used during training, provides virtual modeling of the desired outcome (reduced pressure) and is an important part of the education module.

The findings of this study will inform clinicians and investigators whether use of mobile seat interface pressure mapping as a compensatory-based intervention has a positive impact on trunk movement and self-efficacy for completing weight shifts in wheelchair users who lack sensation. Another contribution of this work is an exploration of the relationship between self-efficacy and movement in wheelchair users.

Primary Aim. Trunk movement in seated wheelchair users with SCI will increase when the user has access to a mobile seat interface pressure mapping system to self-monitor pressure distribution on their wheelchair seat cushion.

Secondary Aim. Self-efficacy for use of weight shifts as a pressure ulcer prevention strategy in wheelchair users with SCI will increase through structured education and with access to the mobile seat interface pressure mapping system to self-monitor pressure distribution on their wheelchair seat cushion.

Hypotheses:

Hypothesis 1. Weight shifts (counts of forward and side leans) will be higher with access to the mobile seat interface pressure mapping system than without it.

Hypothesis 2. Overall trunk movement (counts of vector magnitude) will be higher with access to the mobile seat interface pressure mapping system than without it.

Hypothesis 3. Self-efficacy rating immediately after education for weight shifts will be higher than self-efficacy rating taken prior to education.

Hypothesis 4. Self-efficacy rating during access to mobile seat interface pressure mapping at home will be higher than rating after education for weight shifts and higher than rating during phases when there is no access to the pressure mapping system.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc.*):

Pressure ulcers in individuals with spinal cord injuries (SCIs) are one of the most dangerous secondary health problems encountered throughout the lifespan (Krause, 1998; McKinley, Jackson, Cardenas, & DeVivo, 1999). At any given time, up to 46% of the 300,000 people with SCI (National Spinal Cord Injury Statistical Center, 2015b) in the United States will have a pressure ulcer related to sitting (Fuhrer, Garber, Rintala, Clearman, & Hart, 1993; Krause, 1998; Raghavan, Raza, Ahmed, & Chamberlain, 2003). With recurrence rates as high as 79% (Bates-Jensen, Guihan, Garber, Chin, & Burns, 2009; Mawson et al., 1988; Niazi, Salzberg, Byrne, & Viehbeck, 1997) and mortality rates as high as 48% when sepsis is present (National Spinal Cord Injury Statistical Center, 2015a; Staas & Cioschi, 1991), there exists a critical clinical need to target prevention of ulcer development to avert serious complications and death. Despite the prevention efforts implemented over the years, pressure ulcers continue to occur at a high rate of incidence in the SCI population. This is true even though the

National Pressure Ulcer Advisory Panel estimates that 80% of all pressure ulcers are avoidable (Black, 2011).

A key component for the prevention of pressure ulcer development is education to minimize pressure under the sacral, ischial, sacral and coccygeal areas (Consortium for Spinal Cord Medicine, 2014; Staas & Cioschi, 1991; Thietje et al., 2011). Weight shifts are movements that change pressure distribution and can mitigate harmful magnitudes and durations of pressure that accumulate under areas of the skin that are most at risk for pressure ulceration. Skin health in SCI requires persistent attention to a specific set of behaviors on a daily basis, including frequent weight shifts to offload pressure between the buttocks and seat cushion of the wheelchair.

Effective self-management strategies are needed to facilitate consistent daily engagement in use of weight shift maneuver with the ultimate goal to reduce pressure ulcer risk. Sustaining attention on weight shift movements when there is a lack of sensation to provide a natural cue to move is a challenge in wheelchair users with SCI. A new intervention strategy grounded in health behavior change theory provides a framework within which to implement and assess the intervention. The social cognitive theory (SCT) is commonly used when designing and assessing new interventions designed to impact health behavior and is focused on how individuals learn and apply new behaviors (Albert Bandura, 1997). Self-efficacy is a key concept of social cognitive theory and it will be assessed in relation to performance of weight shifts in this study (Glanz, Rimer, & Viswanath, 2008). Seat interface pressure mapping is one strategy used in a clinical setting to determine the distribution of seated pressures for wheelchair users (Akins, Karg, & Brienza, 2011; Crawford, Strain, Gregg, Walsh, & Porter-Armstrong, 2005; Davis & Sprigle, 2008). Currently, pressure mapping technology can only be performed in the clinical setting, limiting the ability of wheelchair users to benefit from the rich visual information about pressure distribution in their daily routines, at home. Monitoring seating pressures at home has great potential to reduce pressure ulcer risk by allowing wheelchair users to make time-sensitive changes in their position and subsequently validates that they have indeed alleviated higher pressures. The pressure map values are displayed in colors on a screen, similar to a weather map. Higher pressure is shown in warm colors, so we can readily visualize areas that area at highest risk. Other interventions have implemented technology to provide reminders or warnings as a training system to teach wheelchair users how to shift their weight, but none have been designed or evaluated for use as a long-term compensatory strategy for the missing sensation. Use of pressure mapping in a home environment is largely untested, but has significant potential as a viable compensatory aid.

This research study addresses pressure ulcer prevention through introduction of a novel compensatory approach to improve weight shifting movements and self-efficacy in achieving the goal of preventing pressure ulcers. It is proposed that use of an on-demand, real-time, visual display of seat interface pressure (T. Vos-Draper, 2013; T. Vos-Draper, Rindflesch, & Morrow, 2013) will provide key feedback that allows wheelchair users with poor or absent sensation to immediately see the results of weight shifting and thus feel more confident in their ability to manage the build-up of pressure by using weight shifts effectively. Use of seat interface pressure mapping throughout one's typical daily routine has the potential to impact self-efficacy for managing skin health and also to improve weight shift adherence over time. This purpose of this study is to explore the potential benefit

of seat interface pressure mapping as a compensatory intervention strategy for impaired sensation in spinal cord injured wheelchair users.

Study Design and Methods

Methods: *Describe, in detail, the research activities that will be conducted under this protocol*:

This is a longitudinal, within-subject, repeated (A-B-A-B) measures design. Two interventions will be provided: structured education regarding pressure ulcer prevention through weight shifts at start of study and use of a mobile seat interface pressure map (IPM). Outcome measures include self-efficacy (SE) for weight shift movements and a measure for trunk movements. Figure 1 provides an overview of the design and sequence of measurements.

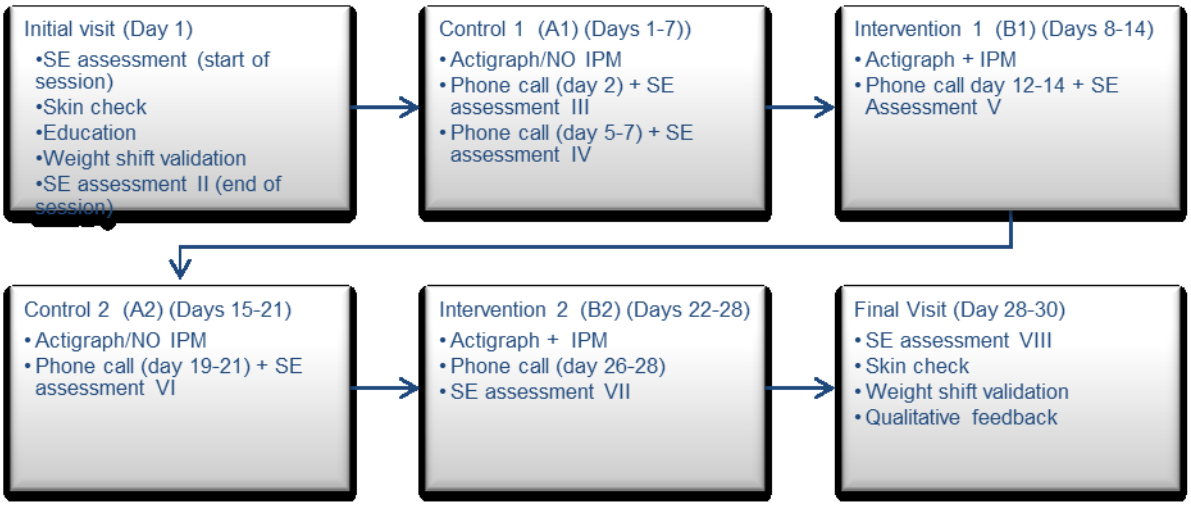

Figure 1. Details of study design.

Independent variables (IV). There are two independent variables in this study.

1. ***Access to the mobile seat interface pressure mapping system (IPM) as a visual feedback system.*** This mobile IPM system was designed to provide visual information about seat interface pressure distribution to compensate for lack of sensation on the sitting surface. This variable will be toggled on and off between the A and B phases of the study. The participants will have access to the visual feedback while learning how to complete weight shift maneuvers at the initial visit and then again at home during the A phases (weeks 2 and 4). During the B phases (weeks 1 and 3), they will not have access to the visual feedback from the pressure map. The pressure mapping system consists of a commercially available pressure mat by Vista Medical, and a mobile web-application developed by the research team through a CoDE award provided by the Center for Innovation in 2012 to display the pressure map information on a smartphone screen. The pressure mat connects to the smartphone via Wifi. The smartphone accesses the web application via the phone's data plan while connected to

the mat to display the pressure readings to the user on the phone. No information about the individual, except for the research participant ID number is transmitted to the web application. Each research participant will have a unique password associated with their own ID to use when they log into the web application. The web application resides on a Mayo Clinic server.

2. ***Education about pressure ulcer risk and how to perform weight shift movements.*** **Structured** education for performance weight shift maneuvers and pressure ulcer prevention will occur during the initial visit. The education method used aligns with principles of the social cognitive theory to facilitate learning. The purpose in providing the education is to ensure all of the participants receive uniform instruction in how to perform weight shifts and to facilitate understanding of the importance of completing them as a protective measure against pressure ulcer development. Because each participant will come into the study at varying levels of understanding about pressure ulcer risk and knowledge of how to complete weight shift maneuvers, the education component is critical to ensure all participants are provided with the same information in the same way.

Dependent variables. There are two dependent variables in this study: overall trunk movement (vector magnitude and weight shift count) measured through a single tri-axial accelerometer and self-efficacy for performing weight shifts to prevent pressure ulcers measured with four items on a self-efficacy assessment written specifically for this study.

1. ***Trunk movement***. Trunk movement will be measured using a single tri-axial accelerometer attached to the participant's sternum with a chest strap. The accelerometer used in this study is the Actigraph GT3X+ (Culiolo & Shaw, 2016). The GT3X+ measures accelerations within a dynamic range of +/- 6 units of gravity (G) in three planes of trunk motion, the vertical, anteroposterior, and mediolateral. The accelerometer will be worn throughout the study while the individual is in their wheelchair and taken off at night when sleeping. Trunk movement will be reported in two ways: vector magnitude for counting total movements of the trunk and counts of specific weight shift movement magnitudes based on offset angles of the accelerometer measures. Frequency of data collection will be 30Hz. When measuring continuously for 24 hours/day at 30Hz, the published battery life is 22.5 days and memory limit is 42.5 days. This will require that the participants charge the battery midway through the study. A more detailed description of the specific variables follows.

    a. **Vector magnitude***.* A total count of trunk movements in the form of vector magnitude will be averaged across each phase for each participant. The Actigraph GT3X+ provides raw values in each of the three axes. A composite vector magnitude of these three axes (VM) in a specific period of time is a "count" of movement. VM is the square root of the sum of each axis squared. VM will be calculated per second of wear time. For each of the 7 days in a phase, there will be a total VM, which will be graphically portrayed by day for visual analysis of trends for movement within each phase. The overall VM for each phase will be the average VM across the 7 days. This average VM per phase (A1, B1, A2, B2) will be used as the dependent variable for overall trunk movement.

To determine wear time, two approaches will be used. First, the participants will be asked to document time up to chair and out of chair each day on a daily log (Appendix C). Second, raw accelerometer data will be analyzed for a specific change in orientation based on offset angles and lack of accelerations for a time period of 15 minutes. By asking participants to invert the device on the table, and because this position would be difficult for the device to be in while worn on the chest, it allows for easier detection of the non-wear periods. When there is a question about wear time, the daily logs will be compared with the raw data.

b. ***Weight shift count*****.** Trunk angle offsets from upright will be derived from the raw accelerations. When starting from an upright orientation, an offset angle will be measured in both the anteroposterior and in the mediolateral planes. To determine each participant's trunk angles while performing the prescribed weight shifts, the accelerometer will record while each participant performs a specific sequence of the weight shift maneuvers. From the initial recordings, an algorithm will be adapted for each participant to detect weight shifts in the field-collected accelerometer data. Movements reaching the defined threshold for partial and full weight shifts will be counted. A total count per day and an average count per phase will be recorded. The total daily count, when graphed, can be visually analyzed for trends during each phase. The average phase counts can be compared across control versus intervention conditions.

2. Self-efficacy for performing weight shifts*.* The second dependent variable, self-efficacy, is measured with a series of four individual questions about self-efficacy for weight shifts for pressure ulcer prevention (Appendix A). Each question is answered by choosing a number from 0-100 to indicate confidence level. This assessment includes an initial question that targets an individual's outcome belief about whether they believe that completing weight shifts will prevent pressure ulcers. This is followed by three questions about their own judgement of their immediate capability to complete weight shift maneuvers based on three criteria: effectiveness (moving enough to impact pressure distribution), consistency (completing weight shifts every half hour), and duration (holding weight shifts for two minutes). The items were written following principles outlined in Albert Bandura's guide to developing self-efficacy assessments (A. Bandura, 2006).

The score for each of the four items will allow preliminary analysis of any change in self-efficacy for specific components of performing weight shifts with the outcome of pressure ulcer prevention. The self-efficacy questions (SE) will be administered in person or by phone a total of 7 times: at start of initial session before any education, at end of session when education is completed, on day 2 when participant has been home for 1 day but no other intervention has been provided (test-retest), and at the end of each of the four phases. The self-efficacy survey will be given twice during the initial visit, 4 times over the phone when participant is called each week, and 1 time during the last visit for a total of 7 times.

Additional demographic information will be obtained from existing medical records and will include date of onset of spinal cord injury, date of birth, history of pressure ulcers on sitting surface, history of pressure ulcer repair surgery, level of spinal cord injury and severity of injury.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*:

This research project will be conducted by the Primary Investigator (Tamara Vos-Draper) and her co-Primary Investigator, Melissa Morrow as part of their NIH R21 award. There is sufficient FTE allocated to each for completion of the work. The subjects will be seen in a clinical exam space within Physical Medicine & Rehabilitation, on Mayo 14, where the Seating and Mobility Clinic practice is.

☐ (1a) This is a multisite study involving Mayo Clinic and non Mayo Clinic sites. *When checked, describe in detail the research procedures or activities that will be conducted by Mayo Clinic study staff.*

☐ (1b) Mayo Clinic study staff will be engaged in research activity at a non Mayo Clinic site. *When checked, provide a detailed description of the activity that will be conducted by Mayo Clinic study staff.*

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: 30

Subject population (children, adults, groups): Participants with an existing spinal cord injury who use a wheelchair as their primary means of mobility will be invited to participate in this study.

Inclusion criteria. Participants will meet inclusion criteria if they live in the community, are aged 18 or older, male or female, have paraplegia or quadriplegia due to a spinal cord injury that includes sensory loss below their level of injury, and require full-time wheelchair use for mobility. Participants must demonstrate ability to independently access a smartphone and the required pressure mapping application on the smartphone. The participants must be able to tolerate sitting for a minimum of 6 hours per day, 7 days per week, and they must be able to perform weight shifts independently. They also must be able and willing to attend in-person visits at start and end of the study, about 4 weeks apart. No exclusions related to gender or minority mix identified.

Exclusion criteria. Individuals will not be eligible for this study if there is an active stage 3, 4, or unstageable pressure ulcer as defined by the National Pressure Ulcer Advisory Panel definitions anywhere on their sitting surface, if they are not able to independently access the pressure mapping application on a smartphone, or if they are not able to complete an adequate weight shift without help. Individual who use a specific custom-molded seat cushion (Ride Designs Custom Seat Cushion) will not be eligible due to challenges with conformability of the pressure sensing mat to the deep contours of this particular cushion. Individuals will also be excluded if they live in a long term care facility or group home and require 24 hours/day assistance. Participants will be screened by phone or in person when being considered for enrollment into the study for cognitive impairments relating to memory and new learning. If a cognitive impairment is identified by a score of 3 or less on the Six-item Screen for Cognitive Impairment (Callahan, Unverzagt, Hui, Perkins, & Hendrie, 2002), the participants will not be able to participate in this study because there is an expectation of ability to learn new information and be able to recall the information over the study period. Participants must be Mayo Clinic patients for access to the medical record.

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☐ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☐ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☒ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☐ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.)

_____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.)

_____

(3) Prospective collection of biological specimens other than blood:

_____

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) No data will be collected beyond the IRB submission date.

☒ (5b) The study involves data that exist at the time of IRB submission **and** data that will be collected after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☐ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*

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HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name	**X**	
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	**X**	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	**X**	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	**X**	
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers	**X**	
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		

Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☒ None

Data Analysis

Power analyses and study endpoints are not required for minimal risk research, pilot or feasibility studies.

☐ No statistical information. *If checked, please explain*:

Data Analysis Plan:

Post-processing of the Actigraph data will be completed with custom software in MATLAB (Mathworks, Natick, MA).

The ***vector magnitude*** for each second of data during wear-times will be classified as a period of activity or inactivity. Additionally, total vector magnitude of movement for each day will be determined by summing the VM of all active wear-times. Then, for each 7-day phase, the daily values will be averaged for a resulting average phase VM. There will be an average phase VM for each phase A1, B1, A2, and B2.

Weight shifts will be counted as described earlier based on offset angles. The average number of weight shifts for each type of weight shift will be documented by phases A1, B2, A2, B2. The analyses to test the primary hypothesis that overall trunk movement (vector magnitude) and weight shifts will increase in frequency with the use of the mobile pressuring mapping system will be tested using Linear Mixed Effects Regression. When appropriate, post-hoc tests will be performed to test main effects. If a phase x session interaction is present, post hoc tests to analyze and interpret the interaction will be used. Significance is set at α=0.05.

***Self-efficacy* scores** will be analyzed by comparing scores SE #1 vs #2, #2 vs #3 (test-retest), and #4 vs #5 vs #6 vs #7 to determine effect of education and use of mobile IPM on self-efficacy. The analyses to test the secondary hypothesis that the scores for the self-efficacy items will increase after education and will increase again with the use of the mobile pressuring mapping system will be tested using Linear Mixed Effects Regression. When appropriate, post-hoc tests will be performed to test main effects. If a phase x session interaction is present, post hoc tests to analyze and interpret the interaction will be used. Significance is set at α=0.05.

The results will help determine if there is a cause/effect relationship between use of the pressure map and any increase in weight shifts if that is detected and if results are significant, we can conclude that use of the map resulted in increased movement. We can't conclude that there will be a reduction in

pressure ulcers but we can say that weight shifts, a factor known to contribute to reduced pressure ulcer risk, increases when a wheelchair user has access to a compensatory assistive device to accommodate reduced sensation. The same is true for results of the self-efficacy assessments. We would expect the mean score to improve at each subsequent time-point.