MAYO CLINIC

General Study Information

Principal Investigators: Dr. Susan Hallbeck, Ph.D., Dr. Sharon Sonenblum, Ph.D., Dr. Melissa Morrow, Ph.D., and Dr. Tamara Vos-Draper, OT, Ph.D.

Study Title: Development of Technologies to Increase In-Seat Movement to Prevent Sitting-Acquired Pressure Injuries in Wheelchair Users: AIM 3 Evaluation

IRB #: 19-008916

Protocol version number and date: Version 9, 09/15/2022

Research Question and Aims

Aims, purpose, or objectives: SPECIFIC AIM 3: Assess the effectiveness of the Sensoria® Mat Wheelchair Wellness Coach (Sensoria® Mat) and Assisted Weight-Shift© (AW-Shift©) systems for changing the movement behavior of wheelchair users who are at risk for pressure injuries.

Hypotheses: A) Individuals will complete more frequent and more consistent weight-shifts with access to the feedback systems compared to baseline. B) Self-efficacy beliefs for completing weight-shifts will increase with use of the feedback systems.

The key to reducing risk is understanding the factors that contribute to pressure injuries, having the technical ability to measure these factors, and using these measurements to impact users and mitigate risk of seating pressure injuries. The successful completion of this project will make large advancements in optimizing feedback about pressure and movement that will help wheelchair users with spinal cord injuries (SCI) become more effective in managing pressure distribution on an ongoing, daily basis.

Background:

A. SIGNIFICANCE: Pressure-related injuries in individuals with SCI are one of the most dangerous secondary health problems encountered throughout the lifespan [1, 2]. With recurrence rates as high as 79% [6-8] and mortality rates as high as 48% when sepsis is present [4, 5], there exists a critical clinical need to target prevention of pressure injuries. **Despite the prevention efforts implemented over the years, pressure injuries continue to occur at a high rate of incidence.** This is true even though the National Pressure injury Advisory Panel estimates that 80% of all pressure injuries are avoidable [14]. New prevention strategies are needed that focus on modifiable risk factors.

Pressure injuries are localized injuries “to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear” [15]. About 70% of individuals with SCI use a wheelchair as the primary mode of mobility [5] and they spend more than 10 hours/day sitting [11], putting them at risk for pressure injuries at the ischial tuberosities (ITs), coccyx, sacrum, and greater trochanters. Without sensation to guide the need for changes in position to alleviate pressure, individuals with SCI move significantly less than individuals with normal sensory systems. For example, neurologically normal individuals move about 9 times per hour while involved in sedentary task while those with SCI move about 9 times per day when sitting [9-12]. Thus, movement is a potentially robust protective factor to target.

When focusing on movement as a modifiable risk factor, there is evidence that more in-seat movement is protective in wheelchair users [16-23]. Guidelines vary between moving every 15-30 minutes for 30 seconds to 2 full minutes to redistribute pressure [3, 24]. Behaviors, such as weight-shifting to relieve pressure, decay over time [13, 25], which could be attributed to lack of sensation to provide a natural cue to move. Unfortunately, individuals who develop sitting-acquired pressure-related injuries are often labeled non-adherent with clinician recommendations without consideration for the tremendous challenge they face in trying to adhere to the guidelines. More work is needed to understand the types of movement that are most beneficial, and how to empower wheelchair users to move more often.

For almost 50 years, clinicians and researchers have been interested in devices to monitor pressure and weight-shift frequency, send alerts, provide cues, or track movement patterns in wheelchair users. The devices were typically used either to monitor individuals without providing direct feedback to them or to train them to move by providing alarms, and were effective when used. When removed, movement behavior decayed as expected [11, 26-38]. Specifically, there have been no attempts, aside from the AW-Shift©, to show the rich visual display about pressure distribution directly between the body and the seat cushion to a wheelchair user outside of a clinical setting [39, 40]. The Sensoria® Mat is a pre-production system that empowers wheelchair users with knowledge about their preventative pressure relief behaviors. The AW-Shift© and Sensoria® Mat will provide compensatory movement stimulus and reinforcement to improve pressure distribution. Advanced sensor technologies will be placed unobtrusively in a wheelchair user's seat system and displayed on his or her smartphone.

Findings from this research will inform clinicians, investigators, and wheelchair users about whether use of mobile seat interface pressure monitoring and feedback about movement performance patterns as compensatory-based interventions have a positive impact on in-seat movement.

B. INNOVATION:

Interface Pressure Mapping (AW-Shift©): Seat interface pressure mapping (IPM) is a tool used in specialty seating clinics to evaluate individuals for most appropriate cushion choices and to educate on effective use of pressure relief maneuvers [41, 42]. IPM consists of a flexible, thin mat with 256-1028 pressure sensors placed directly between the body and the seat cushion, and shows pressure distribution in a gradient of colors that represent the values, allowing patients to visualize high-risk areas. There are no existing commercially available seat interface pressure mapping systems designed for daily use by wheelchair users, but preliminary data from our prototype AW-Shift© system which shows IPM information on a smartphone display demonstrates feasibility for use within a daily routine by wheelchair users [39]. There is strong evidence that use of IPM at the acute-care bedside as a compensatory strategy for nurses to observe effects of repositioning their patients significantly reduced pressure ulcer incidence and improved nurses sense of confidence about moving their patients far enough to redistribute pressure [43]. A significant strength of our AW-Shift© system is that it was initially conceptualized and designed by clinicians with expertise in the area of SCI and seating, based on feedback from patient experiences. The development proposed in this research project will improve the pressure mat design toward a new and novel design not available on the market to meet these specifications while ensuring that it continues to interface with the mobile application.

Movement Behavior (WiSAT): The WiSAT is a research tool that measures preventative pressure relief behaviors during everyday lives of wheelchair users. The WiSAT will not impact the use or operation of users' cushions or wheelchairs and is designed for independent use.

Currently, researchers are hampered by the lack of tools to investigate the relationship between pressure injury occurrence and preventative or healthy behaviors [50, 51]. In the proposed study, the WiSAT will be used as a research tool to evaluate the effects of feedback from the Sensoria® Mat and AW-Shift© on in-seat movement.

Study Design and Methods

Full Study (Clinical Trial):

Study Design: This aim of the study will be a multi-site clinical trial conducted at Mayo Clinic, University of Minnesota (UMN), and Georgia Tech (GT). Mayo Clinic will serve as the Reviewing IRB, and UMN, UTMB, and GT, will be relying institutions. We will be assessing the effectiveness of the Sensoria® Mat and AW-Shift© systems (seat mat and mobile app) for changing the movement behavior of wheelchair users at risk for pressure injuries. Two different types of feedback (from the Sensoria® Mat and AW-Shift© respectively) will be provided separately, through the use of a cross-over design.

A longitudinal, within subject, cross-over study design will be implemented. Changes in movement behavior will be compared between baseline and two intervention phases (AW-Shift© and Sensoria® Mat). A third system, the Wheelchair In-Seat Activity Tracker (WiSAT) will collect movement data passively in the background throughout the duration of the entire study period. This system is being used for collecting the movement data only and is not part of the study interventions. Each permutation of the two interventions will be tested across two groupings, with 30 participants in each (Figure 2). Participants will be in the active study intervention phases for a total of 8 weeks and overall study participation will last about 13 weeks. If one of the phases of the study needs to be paused or delayed (due to equipment delays/malfunctions, participants/study staff scheduling, etc.), the duration of the study may be longer than 13 weeks, but will be no longer than 21 weeks. Participants will not be actively participating in the study during equipment repair downtime.

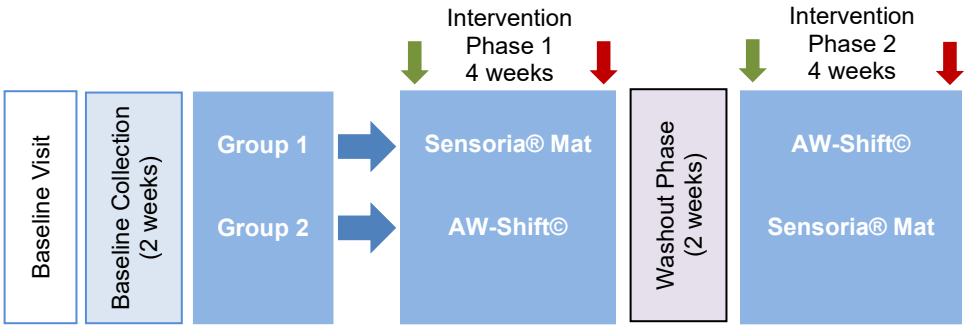

Figure 2. Aim 3 full clinical trial study design. Groups are arranged horizontally. Green arrows are pre-intervention calls and red arrows are post-intervention calls.

Due to unforeseen issues with equipment and anticipated enrollment/financial timeline constraints, we will update our study design to allow a limited number of participants to complete only one of the intervention periods if necessary. We will alternately choose either the AW-Shift© or Sensoria® for up to 20 participants at each study site (Mayo and GT). The timeline for these participants is shown in Figure 3. **This abbreviated study design will not apply retrospectively to participants already enrolled in the full-length study. Once**

we have determined if the participant will do the full length study or the abbreviated version, it will not change for the duration of the study.

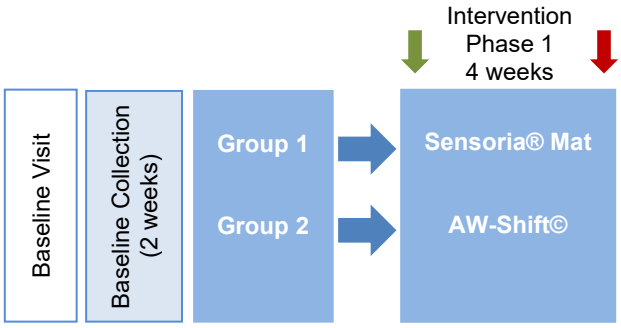

Figure 3. Abbreviated Aim 3 clinical trial study design. Groups are arranged horizontally. Green arrows are pre-intervention calls and red arrows are post-intervention calls.

Study Procedures: Due to the ongoing COVID-19 pandemic, we plan to allow for some or all study procedures/visits to be conducted remotely when appropriate, to provide flexibility to participants who may not feel it is safe for them to come to an in-person visit. This includes the use of Electronic Informed Consent, and video calls for participant visits. In-person visits will occur at Mayo, UMN, or GT campuses. We will use standardized procedures to ensure that uniform instructions are provided to all participants and that recruitment and screening result in the enrollment of appropriate study participants. The data will be entered into an online electronic data program (REDCap) by research staff.

Informed Consent: The consenting process will be conducted by approved study staff in a setting where the participant has ample time to consider the benefits and risks of the study and ask any questions they may have. If any changes are made to the study that require re-consent, participants will be notified in a timely fashion and will be re-consented prior to continuing additional study activities.

Documentation of informed consent at Mayo Clinic will involve the use of the Research Participant Tracking (Ptrax) Digital Signature Capture technology for research informed consent forms. This is an institutionally approved process for obtaining consent only while the subject is in the physical presence of the person authorized to obtain consent. The study team may print a copy of the signed consent form for the subject. The consent form will also be available to the subject via the patient portal for participants at Mayo Clinic. Consent forms at Georgia Tech will be stored in a locked file cabinet.

An alternative approach will be used when consent is done remotely. The informed consent process may be done at the baseline visit, or may be completed separately on Zoom, in which case documentation of informed consent may alternately involve the use of Electronic Informed Consent for research informed consent forms. This is an institutionally approved process for documenting consent using an on-line process. The subject may print or electronically save the consent form, or may contact the study team to provide a copy of the consent.

Note: If the subject or their representative prefers not to use the Digital Signature Capture or Electronic Informed Consent technology, the study team will provide a paper consent form for signature.

Photos: Study staff may take photos of the participant performing various study activities, which will cover identifying features such as the participant's face or identifying tattoos. Participants may grant permission to study staff to take such photos on a separate portion of the informed consent form. Those who do not wish to have photos taken may opt out, but still participate in the study.

Data from previous aims of this grant may be used for Aim 3, which includes study IRBs 17-007956 and 18-009718 at Mayo Clinic.

Skin/Health Checks: Throughout the duration of the study at various timepoints (prior to initial study visit, during pre- and post-intervention calls), participants may be asked to monitor and document their skin health and will be asked questions pertaining to their health, and this information will be retained by study staff.

Initial/Baseline Visit: This visit may be completed in-person, or virtually. The subject will receive standard guidelines/education on weight-shift frequency for pressure injury prevention, and may have their skin health reviewed by the study team. Research staff will provide a basic overview of all systems and mobile apps. The WiSAT mat will be installed underneath the participant's wheelchair cushion to monitor in-seat movement, and will remain under the cushion throughout the study. A mobile app associated with the WiSAT mat may also be installed on participants phone, or provided with a separate mobile device. This app will remain in the background and be used to maintain the clock on the WiSAT data logger. Users may open the app to determine if the WiSAT device needs to be charged, but the app will not provide any weight-shift feedback or information. The participant will perform three leans to initialize the WiSAT mat and ensure accurate monitoring,

Baseline Collection: During the 2-week baseline collection, the in-seat movement behavior will be continuously and passively (no interaction required by the participant) measured with the WiSAT mat installed underneath the wheelchair cushion to determine how much movement the participant performs.

Pre-Intervention Phase Calls/Visits: Before each intervention phase, study staff will meet with the participant via phone, video call, or in-person to assist the participant in setting up the correct system for the phase. Study staff will help the participant download the correct mobile app onto their phone. They will be instructed on how to properly fit and secure the correct system to their wheelchair cushion. Participants will be directed to set personal weight-shifting goals within the app that will generate customized weight-shift reminders (or to leave the default setting). Questions regarding use of the intervention will be answered at this time, skin/general health may be assessed, and the WiSAT leans will be performed again. There will be two pre-intervention calls/visits at beginning of weeks 3 and 9.

Intervention Phases: During the intervention phases, the participants will have full access to their designated system (Sensoria® Mat or AW-Shift©) and data from their interactions with each system will be recorded remotely. No PHI is collected through either system. Participants may be asked to perform regular tasks or weight-shifts throughout the intervention phases. Study staff will be able to see the participant's interactions with the systems and may contact them during this time regarding technical difficulties.

Post-Intervention Phase Calls/Visits: Immediately after each intervention phase, study staff (who are not masked to the participant IDs) will meet with the participant via phone, video call, or in-person to check-in on their skin/general health, and prepare them for the washout phase. They will complete questionnaires by phone,

electronically/via email (REDCap), or they may be mailed a hard copy. There will be two post-intervention calls/visits at the end of weeks 6 and 12.

At the 2nd post-intervention call/visit, the participant will be instructed on how to return the study equipment and study apps will be deactivated/removed from their phone.

Washout Phase: The Sensoria® Mat and AW-Shift© apps are deactivated during the washout phase. The WiSAT mat will continue to passively monitor in-seat movement, and the system used in Intervention Phase 1 will be removed from their wheelchair.

Study Timeline:

					Intervention Phase 1			**Intervention Phase 2**	
	Screening Call	**Informed Consent**	**Baseline Visit**	**Baseline Collection (2 weeks)**	**Pre-Intervention Call/Visit**	**Post-Intervention Call/Visit**	**Washout Phase (2 weeks)**	**Pre-Intervention Call/Visit**	**Post-Intervention Call/Visit**
Visit No.	**0**		**1**		**2**	**3**		**4**	**5**
Visit Week	**-2**		**0**		**3**	**6**		**9**	**12**
Allowable window (in days)			±7		±1	±1		±1	±1
Inclusion/Exclusion	X		X						
Informed Consent*		X*	X*						
Demographics/SCI and Medical History			X+						
Skin/Health Check	X		X+		X	X		X	X
Pressure Injury/Weight-Shift Guidelines			X						
WiSAT System Installation			X						
Leans for WiSAT Initialization			X		X		X	X	
System Training/Set-Up			X		X			X	
PUK Questionnaire			X+						
SE Questionnaire			X+			X			X
Early Detection and Action: Pressure-Related Concerns Questionnaire			X+			X			X
SUS Questionnaire						X			X
Usability Questions						X			X
Structured Interview Questions						X			X
Return Equipment						X			X

*Informed consent discussion may occur via phone or Zoom prior to the baseline visit or during the baseline visit (in-person).
+Participants may complete some portions of the baseline study visit during the informed consent call after they have signed the consent form.

Questionnaires: Participants will complete questionnaires at various timepoints during the study. These questionnaires may be sent electronically using REDCap, completed via phone with study staff, or the participant may complete a paper copy.

Pressure Ulcer Knowledge Questionnaire (PUK): A 6-item questionnaire that measures a person's perception of their own pressure ulcer knowledge.

Self-Efficacy (SE) Short Form Questionnaire: A 4-item form addressing common issues related to performing weight-shifts.

Early Detection and Action: Pressure-Related Concerns Questionnaire: A 12-item questionnaire that focuses on awareness and early detection of skin/pressure-related problems.

System Usability Scale (SUS): The System Usability Scale is a 10-item questionnaire with five response options for respondents. This questionnaire will be administered after each intervention period.

Usability Questions: A 14-item form addressing specific usability questions with regards to the intervention systems.

Structured Interview Questions: After each intervention phase, participants may be asked structured interview questions regarding the seating system.

Study Equipment: Equipment for the WiSAT system, Sensoria® Mat, and AW-Shift© may be given to participants via mail or in-person at study visits. Participants will be provided with adequate mailing supplies and instructions on how to return the equipment.

Participant Tech Support: To provide timely and efficient technological support to study participants while using the seating pressure systems, we may send text messages at regular intervals throughout the study to check-in on the function of the systems. We will use an approved service/method of sending these communications, and none of these messages will contain PHI. Only participants who have given specific permission will receive these text messages.

Primary Outcome Measure:

Change in in-seat movement between baseline and intervention: The difference in average weight-shift frequencies per hour of wheelchair occupancy between the baseline phase and the intervention phases will be calculated to determine if having an intervention increased in-seat movement. Weight-shifts will be measured by the WiSAT mat, where a weight-shift is defined as a partial unloading lasting more than 15 seconds, and a pressure relief is a specific weight-shift that completely unloads the buttocks for more than 15 seconds. The number of weight-shifts is calculated for each day as the number of events divided by the number of hours spent in the wheelchair. The daily values are averaged across days with at least 4 hours of wheelchair occupancy to define the value for the study phase.

Secondary Outcome Measures:

Self-efficacy: A self-efficacy for weight-shift performance scale is being developed and psychometrically tested as part of related study at Mayo Clinic, Development of this scale follows Albert Bandura's guidelines for creating self-efficacy scales [84]. Items are self-scored by the participant on a scale of 0-100. Item analysis will allow comparison of the different compensatory techniques across the various sub-tasks related to shifting weight or moving more frequently. This level of analysis may allow clinicians to eventually screen individuals for specific challenges and, based on areas where self-efficacy is low, recommend the most appropriate type of compensatory strategy. Self-efficacy is assessed during the baseline visit, during each post-intervention video call, and during the follow-up visit.

Comparison of systems: The difference in average weight-shift and pressure relief frequencies per hour of wheelchair occupancy between the baseline phase and the intervention phases will be calculated and compared across the systems to determine whether there is a difference across systems' effectiveness.

Change in consistency/distribution of weight-shifts: Consistency of weight-shifts is measured by two metrics of the distribution of weight-shifts across a day: 1) The longest daily duration the participant is seated without performing a weight-shift, and 2) The coefficient of variation of the time between weight-shifts. An effective system will reduce the longest daily duration without a weight-shift, and may reduce the coefficient of variation of time between weight-shifts.

Mobile app interaction and goal setting: Log data will be stored on a HIPAA compliant server known as the Sensoria® Health Cloud Based Solution, developed by Sensoria® using Microsoft Azure. This will allow researchers to observe wheelchair use and in-seat movement through a research portal. Additionally, we will track whether the users met their self-selected movement goals in each system.

Usability of system (SUS): The System Usability Scale is a 10-item questionnaire with five response options for respondents. This questionnaire will be administered after each intervention period.

Exploratory Outcome Measure:

Incidence of pressure injury: Participants will be monitored for changes in their skin during the post-intervention video calls. They will be asked about changes to their skin and whether they have needed medical attention for any skin changes. Participants may have an existing pressure injury when they enroll in the study. The information collected regarding presence of a pressure injury, size and staging, will allow researchers to track improvement or worsening of any injuries and compare it with movement data collected throughout the study period. While there isn't a control arm that does not use a compensatory strategy, using the information about pressure injuries throughout the study will allow us to begin making a connection between movement and real changes in skin health over time in wheelchair users.

Participant Retention: To compensate participants for time spent in the study, all participants will receive remuneration. Following the baseline collection, participants will receive $50. After completion of each intervention phase, participants will receive an additional $100, and after completing the study, participants will receive an additional $150, totaling $400 in remuneration for the study. Participants may be given parking passes and reimbursement for valet parking when they attend in-person study visits. All participants will receive the same amount of remuneration, but the frequency of payments may differ by site. This will be outlined in the informed consent form. The study coordinator will maintain a contact management database in REDCap. REDCap is a secure, web-based application for managing an online database that is supported by Mayo Clinic IT staff free-of-charge. A dedicated line will be set-up at Mayo Clinic and GT for participant calls to the study coordinator.

Resources: This portion of the study is part of a multi-aim, multi-site study funded by the National Institute of Health (NIH) through an R01 grant. This aim (Aim 3) will be conducted at Mayo Clinic, UMN, UTMB, and GT. Dr. Susan Hallbeck will serve as a Co-Principal Investigator at Mayo Clinic. Dr. Tamara Vos-Draper will serve as a Co- Principal Investigator at UMN, Dr. Melissa Morrow will serve as a Co-Principal Investigator at UTMB, and Dr. Sharon Sonenblum will serve as a Co-Principal Investigator at GT. Dr. Vos-Draper is a licensed Occupational Therapist and will provide clinical perspective and assistance to the study team. Study

coordination staff at Mayo and GT will be responsible for any work involving the IRB and carrying out general study activities. They will also be responsible for all study recruitment for all three sites. The University of Minnesota will not do any site-specific recruitment, but study visits may occur at UMN facilities. Mayo and GT's study teams also include engineering staff who will provide oversight of the study devices and hardware.

All study staff will be adequately trained to their roles on this study which may include but is not limited to: on-site hardware and mobile app training, human subjects training (if applicable), and study protocol training. Study staff at each site and also across all three sites will meet regularly to ensure they receive timely study updates.

Facilities available for participant visits include the Mayo Clinic Clinical Research and Trials Unit (CRTU), which provides inpatient and outpatient research facilities with trained nursing, technology, and nutrition staff. We will also be able to conduct study visits at the Delaware Clinical Research Unit and the OT Program Research Lab at the Children's Rehab Building at the University of Minnesota. Facilities at Georgia Tech include the Rehabilitation Engineering and Applied Research Lab (REAR Lab), which includes private room space where study visits may occur.

☒ (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.*

Mayo Clinic staff will be responsible for subject recruitment, participant study visits and associated data collection, and remuneration for participants seen at the Mayo Clinic or UMN sites.

Subject Information

Target accrual: We plan to accrue a total of 60 adult individuals who use a manual or power wheelchair for their primary form of mobility may be at risk for pressure injuries. Enrollment will be split between the Mayo Clinic (n=30) and GT (n=30) sites.

Subject population: Participants will be recruited from the Mayo Clinic Spinal Cord Injury Registry (IRB #16-001004), the electronic medical record (EPIC), clinician/staff referrals, other related studies, and from previous aims of this project (IRB #s: 17-007956, 18-009718). Recruitment methods may include email, letter, flyer, social media, business card, and phone call.

Inclusion Criteria: Potential eligible subjects must:

1. Currently be age 18 years or older;
2. Be able to come to the Mayo Clinic, UMN, or GT campuses for study visits, or participate in virtual (video) study visits;
3. Qualify for or use a skin protection or skin protection and positioning wheelchair cushion;
4. Be able to perform weight-shifts independently without assistance of another person (by moving themselves or using of power tilt);
5. Own and be able to operate a smartphone with Apple or Android operating system; and
6. Are willing to download and use the mobile app on their phone.

Exclusion Criteria: Subjects will be excluded if:

1. They are scheduled for flap surgery;
2. There is an active stage 3, 4, or unstageable pressure injury as defined by the National Pressure Injury Advisory Panel definitions anywhere on their sitting surface at time of enrollment;
3. They use a custom molded or alternating air wheelchair cushion;
4. Have/use the recline function on manual or power wheelchair;
5. They have a prescribed or limited sitting time of less than 5 hours per day;
6. They live in a long-term care facility or group home and require 24 hours/day assistance; or
7. They have a known history of any condition or factor judged by the investigator to preclude participation in the study or which might hinder adherence.

Research Activity

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

1. ☒ **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)

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

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

4. ☒ **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)

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) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated 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 __17-007956____

☒ Data ☐ Specimens ☐ Data & Specimens __18-009718____

☐ 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.*

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	X
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X	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	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	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	X	X
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address	X	X
Street address, city, county, precinct, zip code, and their equivalent geocodes	X	X
Phone or fax numbers	X	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

Endpoints:

Primary: The primary endpoint will be the change in in-seat movement frequency (weight-shifts/hour) and consistency (max and COV of time between weight-shifts) between baseline and interventions.

Secondary: The secondary endpoint will be the change in self-efficacy between baseline and interventions.

Tertiary: The tertiary endpoint will be the difference in effectiveness between systems (interventions).

Power Statement: This aim is powered based on the primary outcome measure of in-seat movement behavior, quantified as the change in weight-shifts per hour from baseline to during the use of an intervention. A clinically meaningful change in movement (~50% increase) was defined by preliminary data from the WiSAT system. The data will be analyzed using a mixed effect model with fixed effects for treatment and time trend, and mixed effects for subject and time trend within subject. Power calculations were estimated via simulation. Various scenarios defined by sample size, effect sizes and variances (for error and random effects) were inspected by creating 1000 simulated data sets for each scenario. The response was assumed to be log-normally distributed, with log-transformations employed for modeling. Power was estimated using the percentage of simulated data sets returning a significant result for the hypothesis of interest. All tests are 2-sided with a 0.05 Type I error rate. Table 1 shows the results using a standard deviation of 0.35 (for the log-response), and 0.8 and 0.2 for the random effects of subject and time-subject. Forty-eight subjects will achieve 97% power to detect a 50% increase in weight-shifts and 100% power to detect a 100% increase regardless of sample size (Table 1), as well as sufficient power to detect differences between the 2 interventions (Table 1). Sample size below 48 participants does not allow for sufficient power to detect intervention vs. intervention differences. To accommodate 20% attrition, a total of 60 participants will be recruited into the study.

	Intervention vs Baseline			Intervention vs Intervention		
Sample Size	25% ↑	50% ↑	100% ↑	0% vs 50%	25% vs 50%	50% vs 100%
48	55%	97%	>99%	>99%	67%	96%
54	61%	98%	>99%	>99%	71%	97%
60	66%	99%	>99%	>99%	78%	98%

Table 1. Statistical power at 0.05 significance level for varying sample sizes at standard deviation (error)=0.35

Data Analysis Plan: Interim monitoring and early stopping rules are documented in the Data Safety and Monitoring Plan. The statistician will be masked to the intervention type during data analysis. All tests are 2-sided with a 0.05 Type I error rate. Analysis will be conducted with SAS and R software.

Covariates/Confounding Variables: For all outcome measures, the effect of ***relevant biological variables*** including **sex**, **age,** and pressure injury history will be assessed as covariates in the analysis. Additionally, wheelchair type and level of sensation will be included in the covariate space. Randomization will be blocked by site to reduce any confounding effects of study site. Variables will be transformed as necessary to meet appropriate distributional assumptions for modeling (e.g. normality).

SA3a Hypothesis: Individuals will complete more frequent and more consistent weight-shifts with access to the feedback systems compared to baseline: The change in-seat movement frequency (weight-shifts/hour) and consistency (max and COV of time between weight-shifts) between baseline and interventions will be analyzed using a mixed effect model with fixed effects for treatment and time trend, and mixed effects for subject and time trend within subject. Movement during the washout periods will be adjusted for in the analysis if during washout, the participants do not return back to their baseline movement level.

SA3b Hypothesis: Self-efficacy beliefs for completing weight-shifts will increase with use of the feedback systems: The change in self-efficacy will be analyzed using a mixed effect model as described in SA3a Hyp.

Other Outcome Measures: The difference in effectiveness between systems (interventions) will be analyzed using a mixed effect model as described in SA3a Hyp. The QUEST and SWLS questionnaire and mobile app interaction results will be analyzed using repeated measures ANOVA to determine if there are differences across intervention phases.

Missing Outcome Data: The primary outcome measure is collected passively with no need for the participant to interact with the system (no battery charging needed during this phase). The questionnaires are collected via phone/video call, so we are not relying on returned paper copies. Mixed models handle missing data naturally, so that all available data points may be analyzed, irrespective of whether the subject had some outcome data missing. However, analyses of data with multiple imputation for missing data may be attempted, if the data are likely to be missing at random.

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