

Interactive Telehealth and Biofeedback Sensor System for Pressure Ulcer Prevention after SCI

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Overview and Rationale: Pressure ulcers (PUs) are a frequent and serious secondary complication after SCI with an annual incidence of 31% and a lifetime incidence of up to 85%. PUs are linked to increased morbidity and mortality. As medical or surgical repair of established PUs is difficult and costly, the preferred approach is prevention. Traditional prevention recommendations included intermittent relief of interface pressure, such as performing wheelchair (WC) pushups every 30 minutes for 30 seconds or once an hour for 60 seconds. Alternatives to the push-up maneuver, including forward and lateral trunk leans, have been recommended to reduce the demands of weight bearing on the shoulders. One approach to address inadequate PR is to provide a simple reminder (i.e., an alarm) at set intervals. However, this approach is inadequate because patients who attempt PR maneuvers often do not achieve an adequate magnitude or duration of PR for tissue unloading. In addition, compliance with PR performance can be negatively impacted by unanticipated life circumstances. A system to measure PR maneuvers in the home and community and provide reminders and feedback on frequency and success of individual attempts of this important preventative activity could reduce the incidence of PUs. In our collaborative module project, we will establish the efficacy of a sensor and feedback technology system for promoting effective pressure relief behaviors and reducing risk of pressure ulcer development among wheelchair users. In collaboration with the participating SCIMS centers, we will conduct a randomized clinical trial of education and goal setting alone compared to education and goal setting combined with the biofeedback system (sensor and smartphone app) that we developed and validated as part of our current module project in the SCIMS. The fully functional system is unobtrusive and simple. The system attaches to any WC (without modification) and generates automatic reminders via a Smartphone app. Biofeedback, also delivered via the Smartphone app, indicates in real time when a PR maneuver has been completed successfully. The display also tracks the user's daily PR activity as he/she works towards a customizable daily goal. Each collaborating site will receive wireless WC sensors and Smartphones with pre-installed app.

Specific Aims: Primary: Compare PR behavior (daily PR frequency and average duration of uninterrupted sitting) between participants who receive education and four weeks of biofeedback training with the monitoring system (intervention group) and those who receive education but no system feedback (control group). **Secondary:** Compare the incidence of ischial PU development at one year post-intervention between groups.

Hypotheses: 1) Biofeedback from the monitoring system will increase PR frequency and decrease uninterrupted sitting time compared to that achieved by education and goal setting without feedback. 2) Improvements in PR adherence will be retained after two weeks of wash-out (no feedback). 1) Incidence of ischial PU development will be lower in participants who receive feedback training with the telehealth monitoring system than in the control group.

Methods: Participants will be at least 18 years of age, between 2 and 6 months post SCI, full-time WC users for community mobility (AIS A-C), able to perform PR maneuvers without assistance, and have no current or prior history of a PU. A total of one hundred (n=100) manual WC users from all collaborating centers will participate in an 8-week monitoring trial with a one-year follow-up to assess PU development. All participants will complete two weeks of recording PR behavior by the monitoring system without feedback. Following baseline assessment, participants will be randomized into one of two groups: an intervention group that will receive an education session on PU prevention with goal setting for PR frequency and duration followed by four weeks of biofeedback via the smartphone app component of the monitoring system, or a control group that will receive only the education and goal setting session, but will not receive biofeedback and will have the WC sensor system for measurement only. After four weeks, the biofeedback feature in the intervention group will be turned off. The system will continue to monitor activities for another two weeks. We will assess whether improvements in PR adherence are retained after the 4-week bout of biofeedback (washout). Participants will return one year following the 8-week intervention to assess whether they have developed a PU. Participants will be queried and their medical record reviewed regarding PU occurrence since the intervention. A physician, nurse, or other clinician will examine participants' skin visually and record presence of any PUs (stages 1-4) in the ischial region.

Proposed Outcomes: To establish the efficacy of the wheelchair seat sensor and app-based biofeedback for establishing healthy self-management behaviors (pressure relief maneuvers) and reducing incidence of pressure ulcer development in individuals with recent SCI.