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TITLE: Development of the Wheelchair In-Seat Activity Tracker (WiSAT)

PRINCIPAL INVESTIGATOR: Stephen Sprigle

CONTRACTING ORGANIZATION: Georgia Tech Research Corporation, Atlanta, GA

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14. ABSTRACT

Pressure ulcers remain a critical problem for persons with spinal cord injury (SCI), with negative consequences on nearly every aspect of their lives. Research and clinical experience suggests that weight shifts are an important part of promoting tissue health. This project seeks to design a commercially-viable system to inform wheelchair users about their weight-shifting activity as a means to promote healthy behaviors and prevent pressure ulcers. Termed the WiSAT (Wheelchair In-seat Activity Tracker), it will have impact on wheelchair users, their clinicians and researchers. Such a product can empower wheelchair users with knowledge about their behaviors associated with pressure ulcer prevention

15. SUBJECT TERMS: pressure ulcer; wheelchair; weight shift; spinal cord injury; behavioral change; interactive technology

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INTRODUCTION:

Pressure ulcers remain a critical problem for persons with spinal cord injury (SCI), with negative consequences on nearly every aspect of their lives. Research and clinical experience suggests that weight shifts are an important part of promoting tissue health. This project seeks to design a commercially-viable system to inform wheelchair users about their weight-shifting activity as a means to promote healthy behaviors and prevent pressure ulcers. Termed the WiSAT (Wheelchair In-seat Activity Tracker), it will have impact on wheelchair users, their clinicians and researchers. Such a product can empower wheelchair users with knowledge about their behaviors associated with pressure ulcer prevention

- KEYWORDS: pressure ulcer; wheelchair; weight shift; spinal cord injury; behavioral change; interactive technology

ACCOMPLISHMENTS:

- **What were the major goals of the project?**

	Timeline
Task 1. Develop WiSAT hardware and mobile app	1-12
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Task 3 Engage wheelchair users in usability studies	13-20
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- **What was accomplished under these goals?**

Task 1. Develop WiSAT hardware and mobile app

WiSAT System can be described as having three goals:

1. Measure In-Seat Activity
2. Process and classify data into in-seat activity metrics
3. Provide users with reporting of in-seat activity

To achieve these goals WiSAT has 3 functional subsystems: a hardware module, classification algorithms, and a mobile phone application. Status of each subsystem will be presented in this section.

Hardware module design

Over the past year, multiple hardware modules were deployed in usability trials and pre-clinical trials with full-time wheelchair users. Testing during usability trials revealed that the memory cards used to store raw sensor data in the modules were susceptible to sudden failure. Tests run in the lab under controlled conditions of loading and charging did not reproduce the issue, and the failures were deemed intermittent. Simulated use tests were deployed to identify any potential failures pre-deployment and troubleshooting steps were subsequently amended to enable quicker replacements of faulty modules in the field.

The overall hardware (pressure mat and module) design was considered final and no further changes were made during this reporting period. The current specification table is included in the Appendix.

Mobile phone app development

The iOS app was released on the Apple App Store during Year 3. All subsequent updates were pushed to the App Store. Downloading the app from the App Store was the sole method of deploying the app in usability and pre-clinical trials.

Over the previous year, some key features of the app were updated:

1. **Bluetooth reconnect capabilities and instructions**: Based on user feedback from usability trials, Code changes and UI updates in Q1 and Q2 of this year led to a number of changes including: 1) The app's auto-reconnect functionality was updated. 2) Bluetooth disconnect prompts through push notifications were reworked to for content and timing; and 3) The app's screen flow leading a user through the manual reconnect process was also reworked for clarity and brevity.
2. **Active Goal notifications:** Active notifications are push notifications that inform the user about how well their in-seat activity compares to their self-selected goals. Following an update to the app's database service, regression tests in the lab revealed issues with timing and content accuracy of the notifications, which were corrected by introducing additional sorting of the user's outputs. An app update was released in Q2 with this fix after internal testing.
3. **Data timestamp issues:** An intermittent issue with timestamps' unit conversion was found during usability trials and fixed in Q1 of this year.
4. **Switch to production API environment:** The database used to sync user data from the app to the cloud was switched to its production (final) version before the system was deployed in trials. This database was used throughout the usability and pre-clinical trials by researchers at Georgia Tech and at Pitt to identify and troubleshoot issues. This database was also the source of all user outputs, such as occupancy data, in-seat activity data, and weight shift data. This data was used for investigations into behavioral changes through usage of the system.

The data flow diagram for the mobile phone app is listed in Appendix 2. Examples of the UI screens and notifications from the app are shown in Appendix 4.

Task 2: Develop classification algorithms

At the end of Year 3, classification algorithm development was in its final stages, and subsequent updates were dependent on issues with fixing bugs in the app's implementation of the algorithm and handling of its databases.

In Q1 of this year, the ability to skip a lean during app initialization was implemented and tested. A manuscript describing validation of the algorithm was submitted in Q1 and published in Q3.

No further development of the algorithm was completed during Q2, Q3 or Q4.

Task 3 Engage wheelchair users in usability studies

Usability evaluation was done in a multi-stage process. A review of the user interface (UI) screens was done in Year 3, which led to the finalized screens in the app that have stayed constant apart from changes to Bluetooth reconnect screens as described above.

System-level usability trials were conducted during the current reporting period. Recruitment was adversely affected by the COVID-19 pandemic, and participant setups were done remotely. Procedures for setup were modified to reflect this change, and would be used for pre-clinical trials in Q2 and Q3. 11 full-time wheelchair users, aged 18 years or older, and who had some prior experience with mobile applications, were recruited. 8 participants were provided with a WiSAT for trial use of up to a month after obtaining consent. After up to a month of use, each participant completed a modified version of the Software Usability Measurement Inventory (SUMI) to gauge user satisfaction with the app, and provided open-ended feedback on the system as a whole. Each participant's app outputs were monitored through the API database to help diagnose and troubleshoot issues. Feedback from participants from these trials was used to improve app features (as described above in the App Development section), as well as setup steps and training procedures concerning logger placement and charging. This feedback was also incorporated into design considerations for the next version of WiSAT. Participants' in-chair activity such as occupancy, activity score and weight shifts were used to evaluate behavioral change through use of WiSAT.

Task 4: Pre-Clinical Trial to assess acceptability, usability and impact of WiSAT

The pre-clinical trial was designed to assess three important constructs: acceptability, usability and impact. The first objective of the trial was to improve the acceptability and usability of the WiSAT prototype by engaging users during and after a long-term user trial. The second objective was to assess whether WiSAT can change the behavior of wheelchair users at risk for pressure ulcers by increasing in-seat movement activities (i.e., volitional pressure reliefs and weight-shift activity).

Recruitment and participation in the pre-clinical trial was adversely affected by the pandemic. To reduce the impact, the trial duration was shortened and participants were engaged remotely. The study length was shortened to 2.5 months to optimize recruitment while maintaining a balanced and reasonable follow up period. During Q1, University of Pittsburgh submitted IRB modifications and received approval to set up all aspects of the trial remotely. Hines VA received approval for the same in Q2. Georgia Tech was planned to be a third clinical site, but complications with the SmartIRB process imposed additional administrative burdens and Georgia Tech was not added as a site.

Data management updates were implemented during Q3, a participant tracking system was identified and implemented to allow for a quick review of the entire cohort of participants. The participant tracking system condensed API endpoint information and study enrollment information, including participant study stage (such as baseline, passive, or active notifications), weeks remaining, number of

days of available data from the past week (to identify issues with charging or connectivity), and change in occupancy and weight shifts from baseline.

During Q3 and Q4, , University of Pittsburgh enrolled 8 participants and Hines VA enrolled 2 participants. After the last participant completed the study, all data was collected from the API and compiled for analysis. Three participants were removed from analysis due to not having enough valid baseline and/or intervention data. A total of seven subjects with a combined 305 days of data were included in analysis.

Analysis. Behavioral change can be embodied by comparing weight shifts and in-seat activity during baseline and intervention phases. Ordinal classification was performed. A 'Change Threshold' was defined for each subject as the baseline mean +/- baseline std eddor of the mean. If a subject's intervention mean fell within this threshold they were categorized as having no change between baseline and intervention. If their intervention mean fell above the threshold they were categorized as increased behavior and if it fell below, as decreased. Four participants experienced an increase in weight shifts during intervention (Table A) and three experienced an increase in in-seat movement (Table B). Two participant saw a decrease in both weight shifts and in-seat movement during intervention.

Subject ID	Baseline Mean +/- SE Mean	Intervention Mean	Behavior Change
WSH001	3.43 +/- 0.328	5.68	Increase
WSP001	6.43 +/- 0.794	10.0	Increase
WSP002	11.4 +/- 0.611	5.88	Decrease
WSP003	1.63 +/- 0.457	1.20	No change
WSP006	6.89 +/- 0.809	8.03	Increase
WSP007	1.49 +/- 0.163	5.07	Increase
WSP008	0.51 +/-0.0526	0.429	Decrease

Table A. Average daily number weight shifts per hour of occupancy during baseline and intervention. If a subject's intervention mean fell within their baseline mean +/- SE mean they were categorized as having no change between baseline and intervention. If their intervention mean fell above this threshold they were categorized as increased behavior and if it fell below, as decreased.

Subject ID	Baseline Mean +/- SE Mean	Intervention Mean	Behavior Change
WSH001	50.15 +/- 5.17	53.48	No change
WSP001	145.3 +/- 18.5	156.9	No change
WSP002	121.2 +/- 5.47	102.1	Decrease
WSP003	78.96 +/- 2.40	87.72	Increase
WSP006	93.10 +/- 4.11	108.9	Increase
WSP007	144.5 +/- 6.90	185.6	Increase
WSP008	71.50 +/- 7.24	60.53	Decrease

Table B. Average daily activity score per hour of occupancy during baseline and intervention. If a subject's intervention mean fell within their baseline mean +/- SE mean they were categorized as having no change between baseline and intervention. If their intervention mean fell above this threshold they were categorized as increased behavior and if it fell below, as decreased.

A repeated measures general linear model was run to determine if there was a significant change in weight shift or in-seat movement behavior during app use. Neither weight shifts nor in-seat movement changed significantly from baseline behavior ($p = 0.131$ and $p = 0.174$, respectively).

Participants had autonomy to set their weight shift and activity score goals throughout the study. Goals ranged from 3-5 weight shifts / hour and 60-105 movements/hour, with most participants setting a goal of 4 weight shifts per hour and 60 in-seat movement per hour.

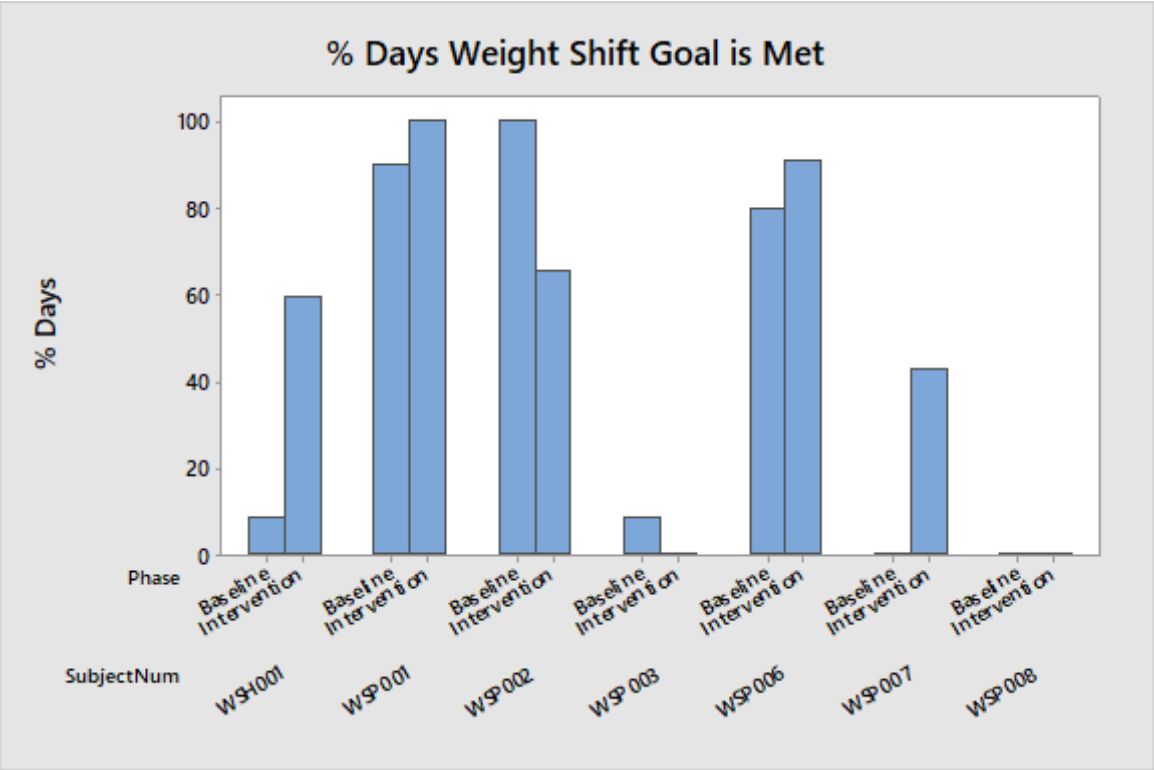


Figure 1. Percent of days where weight shift goal was met on average. Four participants shows any increase in the percent of days where goals were met between phases, while two participants showed a decrease the percent of days where goals were met and one participant showed no change.

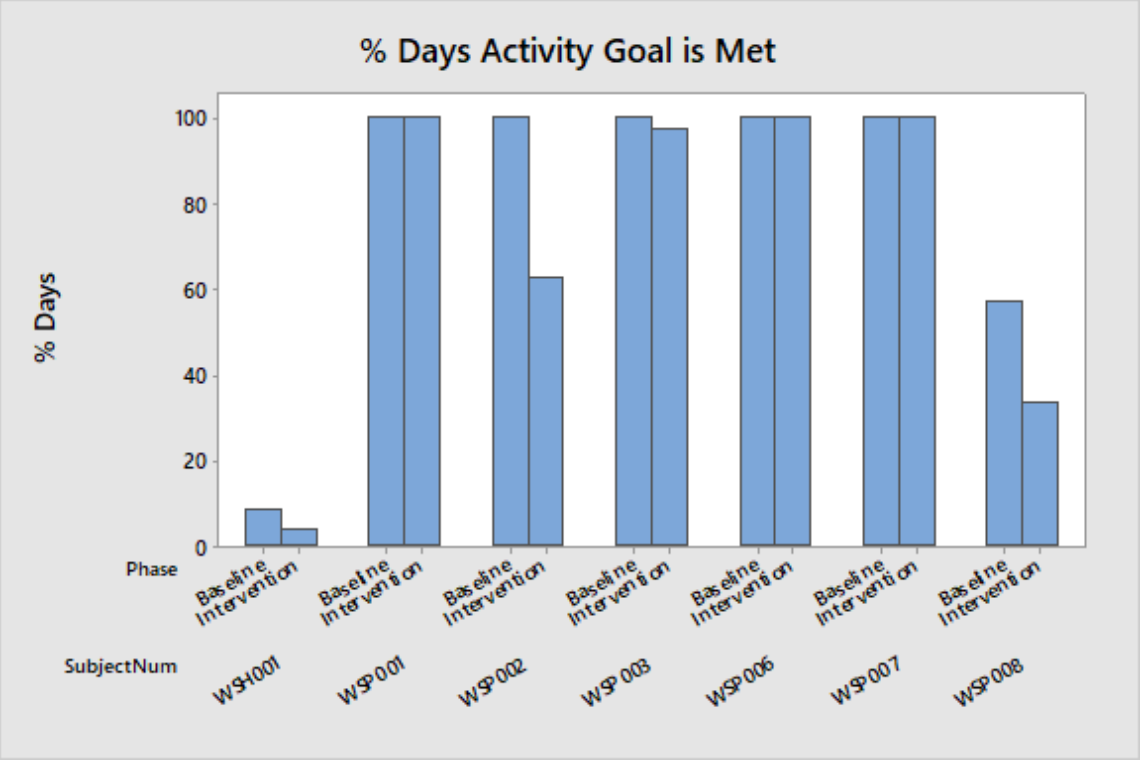


Figure 2. Percent of days where activity goal was met on average. No participants increased the percent of days where they met their activity goal during the intervention, however, many participants were meeting their goal frequently prior to intervention.

A Wilcoxon Signed Rank test for the change in % days of meeting goals for both weight shift and activity showed no significant change in meeting goals. However, as mentioned, many people were meeting their activity goals prior to intervention so change was difficult to obtain. Furthermore, it is interesting to note that the people most likely to be missing their weight shift goals were the ones with a goal of 5 weight shifts per hour. Those with a 3 weight shift per hour goal were more likely to be successful.

Day-level analysis

An alternative means to assess goal attainment is at the day level, not the subject level. This has validity as it accommodates higher baseline levels that create a ceiling and places the focus on daily activity.

Overall probability of meeting daily Weight Shift goal: 48%
Probability of meeting Weight Shift goal without feedback: 34%
Probability of meeting Weight Shift goal with feedback: 54%
Odds ratio: 2.33 On a given day, when using feedback, one has a 2.3x greater odds of meeting weight shift goals

- **What opportunities for training and professional development has the project provided?**

Not applicable

- **How were the results disseminated to communities of interest?**

  Because we have been measuring weight shift behaviors for several years, we are able to report findings and from the current project in combination with results from prior work. Conference presentations, attended primarily by clinicians and researchers, have included aspects of the current project.

- **What do you plan to do during the next reporting period to accomplish the goals?**

  As detailed below, we will be reconfiguring a new trial; the next reporting period is expected to entail ramp-up activities, including modification of the IRB protocols and establishing updated participant engagement activities.

- **IMPACT:**
  - **What was the impact on the development of the principal discipline(s) of the project?**

    This project represents translation of prior research into technology development. As a result, the technology development activities will extend clinical capabilities and will represent new technology innovation. Because the activities up to this point were formative, impact on disciplines was not a goal.

  - **What was the impact on other disciplines?**

    Nothing to Report

  - **What was the impact on technology transfer?**

    The objective of the project is to develop a commercial product, the WiSAT.
    After lack of progress with GT's Office of Industry Engagement, the investigators requested the release of the technology in order to pursue more effective technology transfer activity. This request is currently within the DoD process so has not been completed.

    What was the impact on society beyond science and technology?

  - Nothing to Report
- **CHANGES/PROBLEMS:**
  - **Changes in approach and reasons for change**
  -

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  - The pre-clinical trial was delayed due to suspension of all human subject activities as a result of the pandemic. The DoD offered a 12-month no-cost extension for projects affected by the pandemic and we were provided with this extension through June 2021.
  - In addition, we altered the timeframe of the pre-clinical trial and established protocols for remote subject engagement in an attempt to collect data while recognizing that the timeframe for returning to subject recruitment and enrollment was unknown
  - A 2nd extension with supplemental funds was submitted and approved. This will permit technology evaluation through the 2021-2022 year. This Revised Pre-clinical trial maintains the same focus on behavioral change but has a few key differences. The description is appended to this report
- **Changes that had a significant impact on expenditures**
  - Suspension of human subject research activities has adversely impacted the budgets of Georgia Tech and the clinical sites. The nature of sponsored projects does not permit furloughing of employees due to suspension of research. Certainly there was no mandate to do so from the sponsor. As such, the project incurred personnel costs despite the suspension of the pre-clinical trial, and reduced ability to re-start it. The supplemental funding will allow us to re-initiate the trial in the upcoming reporting period.
  - **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents** Nothing to report
- **Significant changes in use or care of human subjects:** none
- **Significant changes in use or care of vertebrate animals.:** N/A
- **Significant changes in use of biohazards and/or select agents:** N/A

- **PRODUCTS:**
  - **Publications, conference papers, and presentations**: none
    - **Journal publications.** *none*
    - **Books or other non-periodical, one-time publications.** None
    - **Other publications, conference papers, and presentations.**
  - **Website(s) or other Internet site(s);** None
  - **Technologies or techniques:** None
    - **Inventions, patent applications, and/or licenses**
      Wheelchair in-seat activity tracker US Patent number 10,357,186, July 23, 2019
    - **Other Products:** none

- **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**
  - **What individuals have worked on the project?**

Name	**Stephen Sprigle**
Project role	**PI**

Research ID (ORCID)	0000-0003-0462-0138
Annual Person-month effort	**2.0**
Contribution to project	**Overall project management include liaison between DoD, Georgia Tech and clinical sites; design duties include project management and design team coordination.**

Name	*Sharon Sonenblum*
Project role	**Senior Investigator**
Research ID (ORCID)	0000-0003-0462-0138
Annual Person-month effort	**3.0**
Contribution to project	**Lead investigator on developing detection algorithms; other design activities include WiSAT module and seat sensor**

Name	*Yogesh Deshpande*
Project role	**Research engineer**
Research ID (ORCID)	
Annual Person-month effort	**4.0**
Contribution to project	**Project management; mobile application development; hardware and firmware development**

Name	*Kathleen Jordan*
Project role	Program Support Coordinator
Research ID (ORCID)	
Annual Person-month effort	**3.0**
Contribution to project	**sensor characterization and validation; human subject data collection and analysis**

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  - Nothing to Report
- **What other organizations were involved as partners?**
  - **Organization:**

    University of Pittsburgh, School of Health and Rehabilitation Sciences
    Forbes Tower, Suite 5044
    Pittsburgh, PA 15260

Partner PI: Patricia Karg

- **Partner's contribution to the projec**t
  Pitt will continue its collaborative role within the Revised Pre-Clinical Trial. As defined in the scope of work, YR4 effort from the University of Pittsburgh focused on amending the trial protocol to accommodate for the pandemic. They also assisted the Hines VA on completing IRB submission and approval as well as recruitment approved under the new pandemic restrictions. Finally, Pitt deployed the system on seven additional participants, providing valuable information to improve the data collection and app delivery.

- **Financial support** : YR4 funding : NCE from Yrs 1-3
- **In-kind support**: none
- **Facilities:** no specialized facilities required for effort in YR4
- **Collaboration** (forward)**:** Partner staff will participate in the planning and implementation of the Revised Pre-Clinical Trial. This aactivity is consistent with prior effort which developed detailed protocol for Pre-clinical trial, developed data collection instruments and processes, tested protocol and hardware, and reinstated recruitment and ran several participants.
- **Personnel exchanges**: none

- **Organization:**

  VA Center of Innovation for Complex Chronic Healthcare (CINCCH)
  Edward Hines, Jr. Hospital
  Hines IL 60141
  Partner PI: Marylou Guihan

- **Partner's contribution to the projec**t: Within the original Pre-clinical trial, partner secured amendment approval of local IRB for protocol changes related to the pandemic restrictions. They also recruited and initialized two participants for the study.
  - **Financial support :** YR4 funding : NCE from Yrs 1-3
  - **In-kind support**: none
  - **Facilities** *none in YR4*
- **Collaboration** (forward) Hines VA is not involved in the Revised Pre-clinical trial, so its effort has sunset.
  - **Personnel exchanges** *none*
  - **Other.**

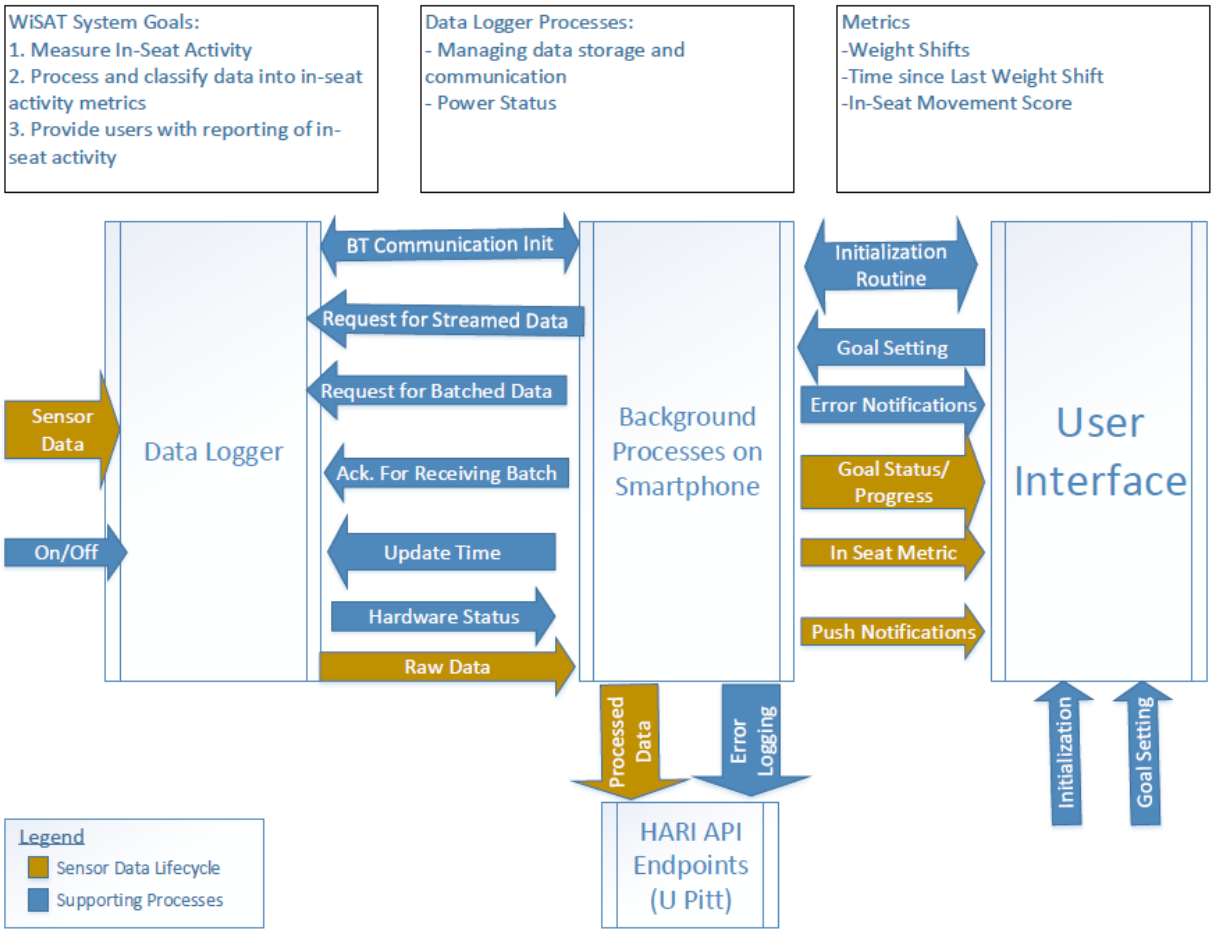
- **APPENDICES:**

Appendix 1. Hardware Specification Table

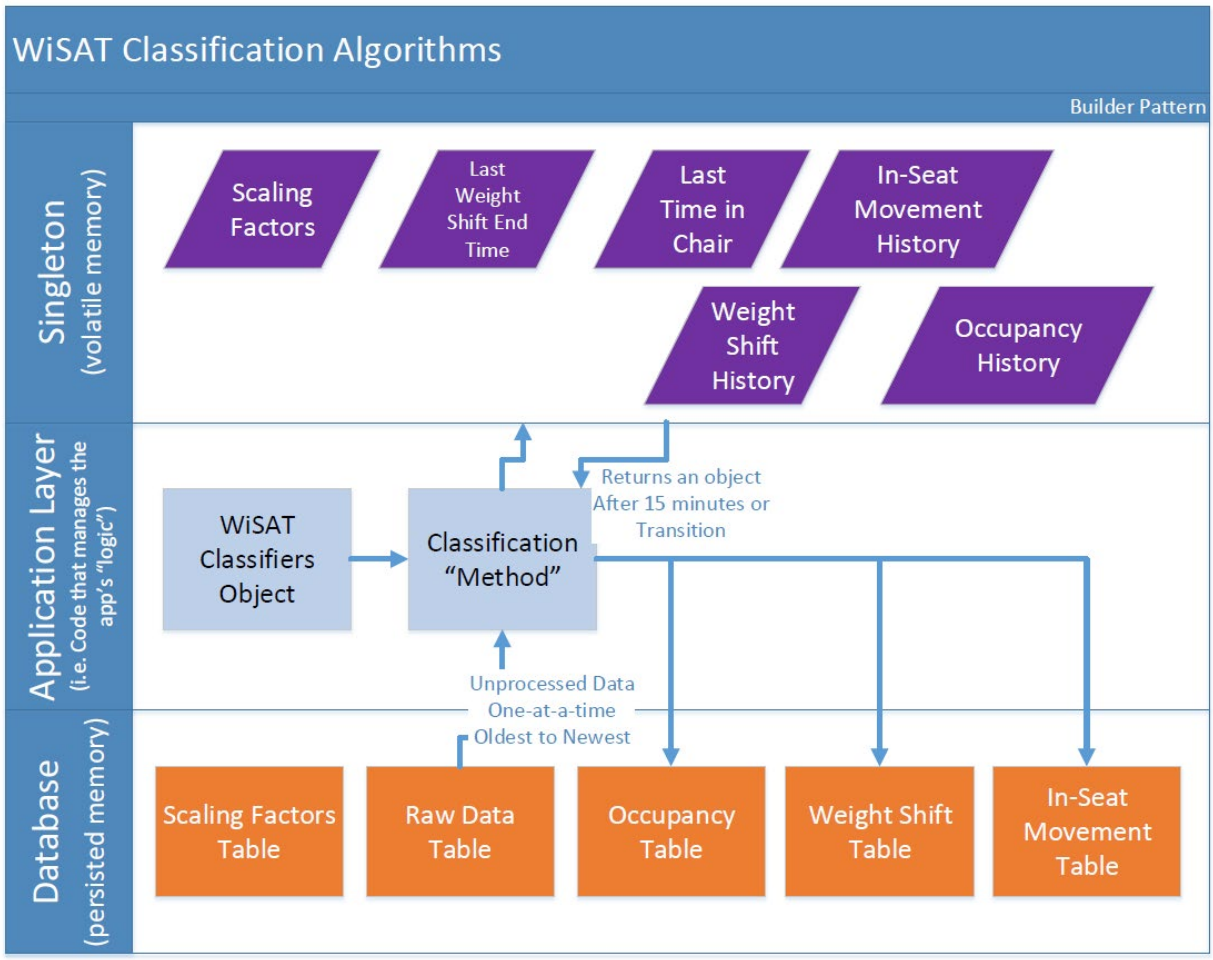
	Requirements
Form factor	2.5in x 1.75in x 0.8in
Case and connectors	Case contains openings for microUSB and seat mat connector. Also contains LED indicators and on/off switch. Connector to inductive charging receiver: microUSB Connector to seat mat: 8-pin output Clincher 67516-208LF "Pig-tail" extension will be made of https://www.digikey.com/product-detail/en/parlex-usa-llc/PSR1635-08/AF08-100-ND/127259 The inductive charging module's receiver is mounted externally to the datalogger case using a plate with magnets embedded at 2 corners to ensure pairing and alignment with transmitter across a cushion cover.
Processor	Cortex-M4 Processor
Battery life	Approx. 2 days
Indicators and on-off switch	* on-off switch * power indicator * data collecting / transmitting indicator
Pressure Sensors	* Custom mat produced by Tekscan, FFC material, Six pressure sensors (comparable performance to Flexiforce A502 https://www.tekscan.com/products-solutions/force-sensors/a502) positioned on a mat with cut-lines to allow for users with cushions ranging from 14.5" to 20"
Battery Charging	Primarily via inductive charger connected to data-logger's microUSB port with a USB type-B connector. Alternatively using type-A or type-B USB connector plugged into a wall socket. The inductive charging receiver is mounted on the logger as specified above. The inductive charging transmitter attaches to the receiver through the cushion cover using magnets attached to the custom-made transmitter casing. With an estimated 2 day life, instructions will be for user to charge daily.
Communication	Bluetooth 4.0 Low-Energy (Telit 53330-02)
Data storage	Collecting data for up to 4 months at 4 Hz sampling, storing all data for recovery at end of study. 8 GB of flash memory
Data Access/Transmission	Current app receives data as flat JSON files. Data can be accessed for post-processing by connecting the logger to a computer via USB.
System Status communication	System status gets transmitted to the mobile app upon request. App receives info about current timestamps, data being logged, and battery life.

APPENDIX 2

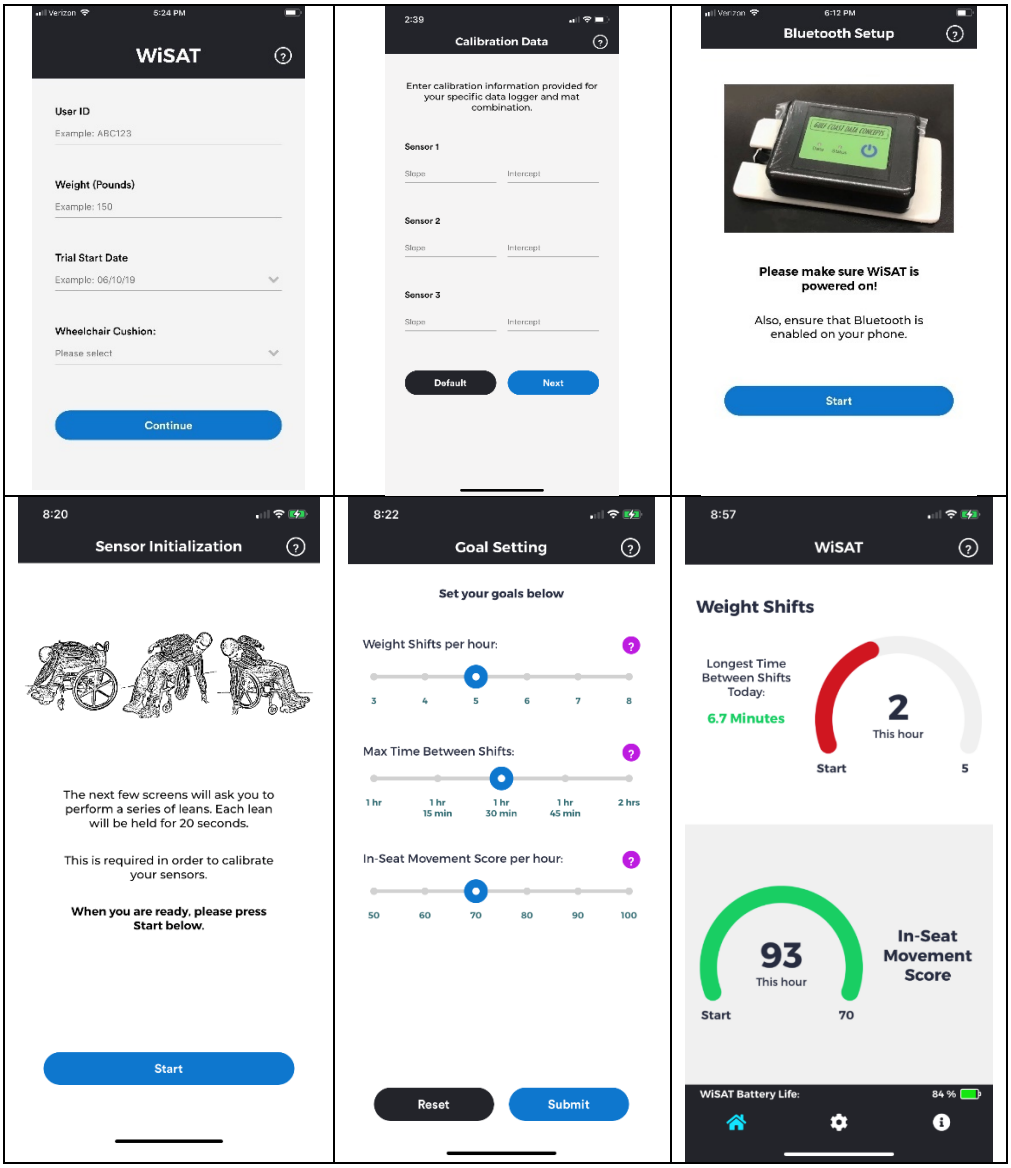
Mobile Phone App Flow Diagram



Appendix 3. WiSAT Classification Algorithm

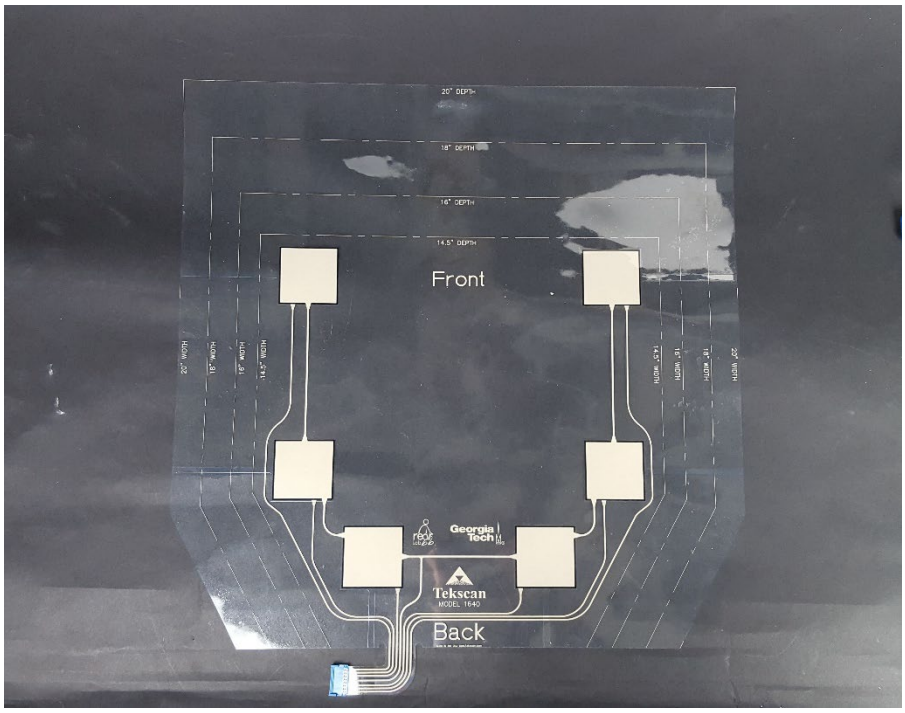


APPENDIX 4: Several examples of the UI screen from mobile phone app, including initial set-up screens, Home Screen, activity score data screens for Day, Week and Month, and notifications from the app.




2:08
In-Seat Movement Score
DAY
WEEK
MONTH
Apr 23, 2020
Hourly Activity Scores
GOAL: 100
6 AM
8 AM
10 AM
12 PM
2 PM
4 PM
6 PM
Hourly Goal: 100
Hours in Chair Today: 8.3
Average Movement Score Per Hour: 153.7
WiSAT Battery Life: 38 %
Apr 14, 2020 - Apr 20, 2020
Average Activity Scores Per Hour
TUE 14
WED 15
THU 16
FRI 17
SAT 18
SUN 19
MON 20
Hourly Goal: 100
Average Hours in Chair Per Day: 2.6
Average Daily Movement Score Per Hour: 52.5
WiSAT Battery Life: 38 %
April 2020
Days Where Average Hourly Activity Score Meets Goal
Hourly Goal: 100
Average Hours In Chair Per Day: 4.5
Average Daily Movement Score: 182.5
WiSAT Battery Life: 39 %
1:15
Thursday, April 23
WiSAT
now
Try to shift more often
You averaged 147 hourly Movement Scores in the past 5 seated hours, but only 1 Weight Shifts.
Swipe up to unlock
10:19
Tuesday, April 21
WiSAT
now
Unplugged Cable
It appears your WiSAT mat may be unplugged. Please check your connection. Contact your research team if you need help.
9:35
Tuesday, April 14
WiSAT
now
Bluetooth Disconnected
Tap here to reconnect.
Swipe up to unlock

Appendix 5. WiSAT Seat sensor



Appendix 6. Revised Pre-clinical Trial (text copied from supplemental request)

Scope of work

Specific Aim 4. Pre-clinical trial: Clinical Effectiveness of the Wheelchair in-Seat Activity Tracker (WiSAT) for changing the behavior of wheelchair users at risk for pressure ulcers

We propose to complete a pre-clinical trial with the same objectives, with one important change: use of the Sensoria pre-production prototype as the testbed. This change has both practical and functional benefit. The pre-production prototype has been engineered and fabricated at a much higher level of fidelity that our prototype. Use of production techniques results in a much smaller and robust technology. One challenge in assessing usability of prototypes is that their form factor and function are not optimized. Use of the Sensoria Tracker overcomes this limitation. That being said, we are focusing this trial on all tracker technology and will share results as a means to improve this new technology for all manufacturers and better position it for adoption by users.

The first objective of the trial is to improve the acceptability and usability of the tracker by engaging users during and after a long-term user trial. The second objective will assess whether the tracker can change the behavior of wheelchair users at risk for pressure ulcers by increasing in-seat movement activities (i.e., weight-shift activity). This objective positions trackers to be used in a future clinical trial to investigate whether informing users of their PR and WS activity can prevent pressure ulcers.

Human subject engagement will be organized and administered at the University of Pittsburgh and Georgia Tech with Georgia Tech also serving in a technical role. This

approach leverages the extensive expertise at Pitt to collect and manage data using the previously established infrastructure. Dual enrollment sites will support a geographically diverse cohort and increases the potential for more diversity in participant demographics. Georgia Tech will undertake a higher level of technical support to help the sites manage a new technology. We will also be charged with data management, including cleaning and creation of an analyzable dataset.

Hypotheses

Hypothesis 1: The provision of passive feedback (i.e., user views app report) about weight-shift activities will result in a greater frequency of in-seat movement compared to baseline

Hypothesis 2: The provision of active feedback (i.e., reminders) about weight-shift activities will result in a greater frequency of in-seat movement compared to passive feedback

Research Design and Methods

Study population

Twenty-five individuals with SCI who are full time wheelchair users and have a history of pressure ulcers on the buttocks within the past three years will be recruited for the study. These individuals will be adults of any age and gender.

Data is available to inform this sample. Hubli. et al (Spinal Cord (2021) 59:175–184) studied a tracker with SCI/D and compared weight shifts before during and after feedback was provided. The effect size between 'feedback' vs 'baseline' was >2.4 'feedback" vs post feedback' was also very large (>2.0). This was a small and short study, so did not have the duration to allow persons to segue between use and nonuse. Using a means difference of matched pairs, an effect size of 0.6 to achieve power = 0.80 with alpha set to .05, a sample of 19 persons will be required. Note that this effect size is less than 1/3 of that reported in the pilot study, so represents a very conservative estimation. Based upon this estimation, we will enroll 25 participants in the study

Study design

An adaptive treatment strategy will be used to optimize and assess the ability of this system to change movement behavior. The study will prospectively collect in-seat movement activity during everyday life for wheelchair users at risk for pressure ulcers. Each participant will receive education about skin health and personalized feedback on their profile regarding weight-shift activities performed on a daily basis via the Tracker. This information, along with participant goal-setting information results in a measurable individualized intervention. The average movement activity during wheelchair use will be measured to determine if the technology meets the goal to improve in-seat movement behavior of participants.

Intervention

Participants will follow an adaptive intervention process. Each person will have two appointments with investigators to educate and set them up with the Tracker- on in-person and one remote. At the first visit, all participants will receive education about skin health

and pressure ulcer prevention such as pressure relieving techniques in both bed and wheelchair as outlined. A partially-enabled Tracker will be fit to their wheelchairs to collect baseline WS activity. The system will be configured to measure in-seat movement but the mobile phone app will not be enabled. Therefore, subjects' baseline behavior will be monitored to serve as the comparator for the enabled Tracker system

After the 2-week baseline, participants will be instructed to switch the mobile software into 'reporting mode'. This engages the feedback system that is available to the user. The feedback will be provided passively, requiring the user to access the application on their smartphone to review WS activity reports. After four weeks of passive feedback, WS activity will be used as a tailoring variable to categorize participants as meeting or not meeting the movement threshold. Those not meeting the movement threshold will witch to 'active notifications' and receive reminders to move via the mobile phone app.

Each subject will be given the ability to set his or her own goals using the app settings- this will be defined as his or her movement threshold. However, we will require that these goals meet or exceed a minimum WS activity level based upon our data for persons with SCI who have not experienced pressure ulcers. Specifically, the 95% confidence interval across days for these persons are [2.53, 3.39] WS/hr. These values reflect the best evidence –collected to date- on PrU outcomes related to real-world WS behaviors. Based on these intervals, and the need to choose round numbers, we will require that individual goals meet or exceed 3 WS every hour. This approach was chosen to balance the desire to permit individual goal-setting with an objective estimate of minimally acceptable activity.

All participants will be followed for a total of 2 1/2 months: 2 week baseline, four weeks passive visual feedback only, and 4 weeks of passive and/or active feedback. The duration of the intervention and assessment period falls within the ranges of other studies assessing changes in activity.

Data collection and measurement

After participants are recruited and provide consent, they will be scheduled for the initial visit to place the sensing hardware in their cushion for baseline activity measurement. During this visit, demographic information will be collected via self-report, including age, race and ethnicity, marital status, and pressure ulcer history. The second engagement will be done remotely and involves the implementation of the passive (on-demand) visual feedback application on the participant's smartphone and training on the use of the application. During this engagement, each participant will take the Pressure Ulcer Knowledge Test. This 14-item test assesses knowledge about pressure ulcers, skin care and protective behaviors. For all participants, weight-shift activity will be recorded for the entire 2 1/2 months of participation. The in-seat movement data recorded by the sensor will be uploaded by the application for access by the research team. A secure communication protocol and HIPPA-compliant server has been developed by Sensoria using Microsoft Azure to support their other commercial products. They will create a research portal for this project designed for GT investigators to monitor participants.

Data analysis

Linear mixed models will be used to examine the effectiveness of the technology in increasing movement activity over time within each group (passive in-seat monitoring, active app with reminders) and between groups. If the data is not normally distributed, we will switch to a generalized linear mixed model. The mixed modeling approach appropriately

accounts for the nesting within our data and will allow for unequally spaced assessments, fixed and time-varying covariates, estimation of individual and time effects with partitioning of variance and covariance components, and outcome variables with data that are missing at random. Parameter estimates will be generated using the full maximum likelihood approach, which is recommended for data with two levels (i.e., individual and occasion). Model appropriateness will be assessed through a comparison of unconditional and conditional models using the chi-square and likelihood ratio tests. Baseline data will be considered as an assessment point as well as a potential covariate. Other covariates may be included in the mixed models based on association with movement activity. All continuous covariates will be centered prior to model entry to facilitate interpretation of results. The selection of fixed and random effects will also be determined through model comparison.

Design evaluation.

This effectiveness trial will also allow us to examine usability and acceptability of WiSAT after extended use. Usability constructs will be assessed after 4 weeks of use and at the end of the study. Participants will be asked to complete the System Usability Scale and engage in a semi-structured interview about their experiences. The SUS is a simple scale that can be applied to many types of products and covers a variety of constructs related to usability such as perceived benefit, complexity, need for training, and learnability. We've had good experiences with the SUS because it can be used to 'prime' users to think about usability in advance of semi-structured interviews which we will use for more detailed design discussion. Rather than deploying formal statistical analysis, we will be looking for design strengths and design opportunities using SUS and interview data.