mHealth-based just-in-time adaptive intervention (JITAI) protocol to improve physical activity levels of individuals with spinal cord injury

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Abstract

Background: The lack of regular physical activity (PA) in individuals with spinal cord injury (SCI) in the United States is an ongoing health crisis. Regular PA and exercise-based interventions have been linked with improved outcomes and healthier lifestyles among those with SCI. One of the facilitators that can promote PA is to provide people with an accurate estimate of their everyday PA level in the community. Researchers have validated sensor-based activity monitors in laboratories and free-living conditions to quantify PA and exercise interventions. PA tracking can be combined with mobile health (mHealth) technology to provide a just-in-time adaptive intervention (JITAI) for individuals with SCI in the community.

Objective: The overarching goal of this study is to investigate the benefits of combining a mHealth-based JITAI with a 14-week web-based PA intervention (WI) program towards increasing and sustaining moderate-intensity (or higher) PA levels among individuals with SCI in the community. This protocol outlines the study design for investigating the impact of integrating a JITAI with the WI program via a randomized controlled trial that integrates a two-arm trial and a micro-randomized trial. The primary aim is to investigate the long-term benefits of adding a JITAI to WI (WI + JITAI). The secondary aim is to investigate the benefit of just-in-time PA feedback on proximal PA. Proximal PA is defined as moderate-intensity PA within 120 min of a PA feedback prompt.

Methods: Individuals with SCI (N=196; ages 18 to 75) will be randomized to a WI arm or a WI + JITAI arm. Within the WI + JITAI arm, a micro-randomized trial will be used to randomize participants several times a day to various types of tailored feedback and PA recommendations. The study has three phases: 1) baseline (weeks 1 and 2), 2) WI program with or without JITAI (weeks 3 to 16), and 3) PA sustainability (weeks 17 to 24). Participants will be loaned an Android-based smartphone and smartwatch. Participants will provide survey-based information at various time points during the 24-week study and are asked to wear the smartwatch every day for 12 hours or more.

Results: The study was approved by Temple University's Institutional Review Board, and recruitment and enrollment began in May of 2023. Data analysis is expected to be completed within six months of ending participant data collection.

Conclusions: The JITAI has the potential to achieve long-term PA performance by delivering tailored, just-in-time feedback,

based on the person's actual PA behavior rather than a generic PA recommendation. New insights from this study may help to design engaging PA interventions for individuals with disability in the community. Clinical Trial: NCT05317832; https://clinicaltrials.gov/study/NCT05317832

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Conclusions: The JITAI has the potential to achieve long-term PA performance by delivering tailored, just-in-time feedback, based on the person's actual PA behavior rather than a generic PA recommendation. New insights from this study may help to design engaging PA interventions for individuals with disability in the community.

Trial Registration: NCT05317832; https://clinicaltrials.gov/study/NCT05317832

Keywords: Spinal cord injury; Physical activity; Just-in-time adaptive intervention; Mobile health; Randomized controlled trial; Micro-randomized trial; Wearable sensors; Ecological momentary assessment; Community

Introduction

Physical inactivity is a significant concern among the over three-hundred thousand individuals living

with spinal cord injury (SCI) in the US [1], who are at an elevated risk of mortality due to cardiovascular diseases, diabetes, and lung disease [2–4]. Low levels of physical activity (PA) in individuals with SCI have also been associated with secondary conditions such as pain, fatigue, and depression [5–7]. Research studies have found varying percentages of SCI populations that perform regular PA [8–10]. On the higher end, Rauch et al. found that 48.9% of 485 participants with SCI in Switzerland met World Health Organization recommendations of 2.5 h/week of moderate-intensity or higher PA, and 18.6% were physically inactive [8]. On the lower end, Tasiemski et al. found that only 20% of 985 people with SCI in the UK performed regular PA of 2 h/week, and 53.3% reported no regular PA [10]. Furthermore, several other studies have indicated that the majority of individuals with SCI do not perform regular PA [11–13].

Regular PA and exercise interventions in individuals with SCI have been linked with improved cardiorespiratory fitness, quality-of-life, and functional independence, as well as reduced risk of cardiometabolic disease, depression, and shoulder pain [11,12,14,15]. While there are significant health and quality of life benefits with regular PA, various barriers limit individuals with SCI from performing PA regularly [16]. To address some of these barriers, the National Center on Health, Physical Activity, and Disability (NCHPAD) has developed a free web-based PA program for people with mobility limitations, chronic health conditions, and physical disabilities [17]. Web-based PA programs can lead to an increase in PA level and duration of PA performed by individuals with SCI [18–21]. One of the facilitators that can promote PA during PA intervention programs is to provide people with an accurate estimate of their everyday PA level in the community [18,22–24]. This information can empower individuals with knowledge about their regular PA levels, which in turn can help develop a physically active identity [16].

The PA of individuals with SCI is frequently assessed through samples of individuals who provide self-reports [8–10], which may suffer from recall bias and social acceptability bias. To address these limitations and to better quantify PA and exercise interventions, researchers have validated sensor-based activity monitors in laboratories and community-dwelling environments [22,23,25]. PA tracking can also be combined with mobile health (mHealth) technology to provide a just-in-time adaptive intervention (JITAI) for individuals with SCI in the community. A JITAI uses mHealth technology to deliver the intervention at appropriate times and contexts to support individuals' health behaviors [24,26,27]. For example, Klasnja et al. used a JITAI to provide a real-time feedback intervention aimed at improving step count in individuals without disabilities [27]. Our team tested a pilot JITAI for its feasibility and acceptability in individuals with SCI [24]. Results from our pilot study indicated that participants wished to have the system provide customized messages to help them further increase their PA levels. These customized messages combined with web-based PA intervention programs have the potential to impact factors such as intent to increase PA, awareness of PA benefits, reminders, and encouragement that are related to increased PA levels in individuals with SCI [11,12,18,28].

The overarching goal of this study is to investigate the benefits of combining a mHealth-based JITAI with the NCHPAD's 14-week web-based PA intervention (WI) program for increasing and sustaining moderate-intensity (or higher) PA levels among individuals with SCI in the community. This protocol outlines the study design for investigating the impact of integrating a JITAI with the WI program via a randomized controlled trial that integrates a two-arm trial and a micro-randomized trial (MRT). Specifically, individuals with SCI (N=196) will be randomized to either a WI program or a WI program combined with the JITAI (WI + JITAI). Within the WI + JITAI arm, an MRT [27,29,30] will be used to micro-randomize participants several times a day to various types of feedback and PA recommendations. The primary aim is to investigate the long-term benefits of adding a JITAI to WI. We hypothesize that the integration of a JITAI to WI will result in significantly higher PA levels

compared to WI alone. The secondary aim is to investigate the benefit of just-in-time PA feedback on proximal PA. Proximal PA is defined as moderate-intensity PA within 120 min of a PA feedback prompt. The exploratory aim will investigate time-invariant moderators such as biological sex and level of injury and time-varying moderators such as prior PA and engagement with the JITAI to help identify subgroups of individuals with SCI who are likely to benefit the most from the integration of a JITAI with WI.

Materials and methods

Research design

Temple University's Institutional Review Board has reviewed and approved this study. The trial was registered on clinicaltrials.gov (NCT05317832). Participants will take part in the study from their home environment in the community. The study has three phases: 1) baseline (weeks 1 and 2), 2) WI program with or without JITAI (weeks 3 to 16), and 3) PA sustainability (weeks 17 to 24). Participants will provide survey-based information at various time points during the 24-week study and are required to wear a smartwatch for the duration of the study. The PA intervention for this study is informed by the capability, opportunity, and motivation (COM-B) model, which highlights that these three constructs should be considered when developing a behavioral intervention [31]. To our knowledge, this is the first study to optimize a JITAI that has the potential to boost PA level using real-time feedback for individuals with SCI.

Behavioral intervention model

The proposed intervention approach builds on the COM-B model [31] – an organizing framework for designing behavior change interventions [32–34]. An individual's capability, opportunity, and motivation interact to generate behavior (e.g., PA) that in turn influences these three constructs (Figure 1) [31]. Capability is the individual's psychological and physical capacity to perform the desired activity, including having the necessary knowledge and skills. Motivation is the individual's internal drive or energy that directs behavior, including conscious/analytical decision-making, as well as habitual processes and emotional responses. Opportunity captures environmental (social and physical) factors external to the individual that facilitate or undermine behavior. The solid arrows in Figure 1 represent potential influence between these constructs [31]. For example, opportunity can enhance (e.g., a supportive environment) or inhibit (e.g., an adverse environment) motivation and capabilities [31]. It is also possible that enacting a behavior can alter capability, motivation, and opportunity. This framework incorporates context naturally through the 'opportunity' construct [31]. For individuals with SCI, the context is characterized by physiological and environmental barriers to participate in PA [16,35] and stigma [36], which can hinder motivation and capability to engage in PA.

Conceptual framework of the JITAI

The framework used for this proposed study (Figure 2) is adapted from Nahum-Shani et. al. [26], which highlights four components including decision points, intervention options, tailoring variables, and decision rules. JITAIs often provide an intervention through a smartphone and/or a wearable activity monitor. The system automatically determines which intervention option, such as prompting an individual to set a goal to perform PA or prompting feedback about PA, could be helpful or especially effective. Engagement with the JITAI, i.e., effort invested in the JITAI [37], is critical for intervention effectiveness [26], therefore JITAI components should be selected and designed to

promote engagement [27].

NCHPAD's WI Program

Our proposed JITAI will be offered along with NCHPAD's 14 Weeks to a Healthier You Program [17,38,39], modified to be accessible on a smartphone or tablet. This 14-week WI (web-based PA intervention) program was launched in 2011 by NCHPAD with funding from the Centers for Disease Control and Prevention [38]. Since its launch, the program has been used by more than 45,000 people with various physical disabilities. It is the most widely recommended online PA program across various disabilities and state disability programs [40]. The program's uniqueness lies in its ability to offer tailored exercise that matches the participants' functional capabilities. The WI program was developed with guidance from literature and practice in health behavior change and internet-based health promotion programming. Additionally, preliminary evaluations by individuals with disabilities were used to update the WI program. Table 1 presents the key features and content of the program [39].

Table 1: Content and features for the NCHPAD's 14-Week WI Program.

Week#	Motivational Resource	Updated Weekly	Customizable Features
1	Goal setting	• Introductory video • Exercise resources • Motivational resources • Recipes • Nutrition resources	• My schedule • Initial assessment • Badge reward system • My goals • Daily reminder
2	Overcoming barriers		
3	Benefits of activity		
4	Weight management		
5	Self-monitoring		
6	Keep it fun!		
7	Rewarding yourself		
8	Building social support		
9	Stimulus control		
10	Preventing injuries		
11	Self-advocacy in recreation		
12	Activity in daily life		
13	Avoiding overtraining		
14	Keeping it up!		

Integration of JITAI with WI

The integration between the WI and JITAI is designed to blend multiple evidence-based components aimed at prompting capability, motivation, and opportunity for engaging in PA among individuals with SCI (Table 2). Capability will be enhanced by not only providing tailored information and advice for individuals with SCI via the standard WI, but also by using self-regulatory techniques, operationalized by setting goals, monitoring progress, and providing timely feedback via the JITAI [24,26,31]. To enhance motivation to engage in PA, the JITAI will reinforce progress by providing just-in-time feedback about the minutes of moderate-intensity PA achieved or remaining to be achieved towards the daily goal. Opportunity will be enhanced by identifying specific types of goals (tailored, standard, or goal not presented) and PA feedback (achieved, to-go, or feedback not presented) that will be most beneficial in promoting daily and proximal PA, respectively. While the standard goal encourages the individual to perform 20 min of moderate-intensity PA for the day based on PA guidelines for adults with SCI [41], a tailored goal is based on average minutes of moderate-intensity PA performed by the individual over the last seven days. The choice of the last seven days is based on PA guidelines for adults with SCI [41] and our pilot study [24] in which

participants had lower PA for a day or two during the week. While the achieved PA feedback message focuses on the PA level the person has accomplished untill that moment in the day; the to-go message focuses on the remainder of the PA level the person has to accomplish to meet their designated goal. Prior research has indicated that the gain-framed messages were more likely than loss-framed messages to encourage prevention behaviors such as PA [42]. In this study we are interested in evaluating whether participants prefer achieved PA message (gained) or to-go message (to gain) to accomplish their goal. Additionally, the participants will be reminded to engage with the WI on a regular basis.

Table 2: Components of the COM-B model targeted by the WI and WI + JITAI arms.		
	WI	WI+ JITAI
Capability	• Tailored information and advice • Weekly goal setting • Monitoring weekly progress	• Tailored information and advice • Weekly goal setting • Monitoring weekly progress *JITAI* • Goal setting for the day • Just-in-time tailored PA information
Motivation	• Badges for completing weekly modules on WI • PA progress over the last seven days	• Badges for completing weekly modules on WI • PA progress over the last seven days • Goal attainment at the end of day *JITAI* • PA recommendations during goal setting • Just-in-time tailored PA feedback messages • Availability of real-time PA information
Opportunity	• Daily reminder to complete WI program	• Daily reminder to complete WI program *JITAI* • Just-in-time specific type of feedback to encourage proximal (within 120 min) PA achievement • Just-in-time feedback to encourage more distal (daily goal) PA achievement

PA Intervention components

The PA intervention components include either the WI program or the WI program combined with JITAI for individuals assigned to the WI or WI +JITAI arms, respectively.

WI program

Participants will access the 14-week WI program and answer questions related to their interests, needs, and abilities (Table 1) which will be used to tailor the content (exercises and videos). Participants can monitor the WI program use on their dashboard. From this point forward, program content automatically updates every week to introduce new exercises, and a weekly motivational and educational topic. Participants will receive a daily reminder, except for the day off, on the smartwatch to access the WI program (Figure 3). Furthermore, participants will have access to the minutes of moderate-intensity PA performed over the last seven days on the study smartphone (Figure 4).

JITAI components

Participants in the WI + JITAI arm will have access to the JITAI components. In addition to WI program access, participants will receive just-in-time feedback and PA recommendations informed by the guidelines for adults with SCI [41]. Participants will have access to the minutes of moderate-intensity PA performed over the last seven days on the study phone. In addition, they will have near-real-time access to minutes of moderate-intensity PA performed over the day on their smartwatch.

During the 22-week intervention period, the PA feedback and recommendation messages will be delivered using micro-randomization, which involves random selection of intervention options at each possible time of delivery [29,43]. The micro-randomizations will assess the proximal benefits of just-in-time (Figure 5 and Figure 6): 1) *PA recommendations* by randomizing the participant with a 33% probability to a standard, tailored, or no goal within 1-2 hours of waking up (Multimedia Appendix 1), and 2) *PA feedback prompts* by randomizing the participant with a 50% probability to a JITAI message or no message twice a day (Multimedia Appendix 2). The first and second PA feedback prompts are randomized between 2-4 hours after wake-up and 6-8 hours after wake-up, respectively. Table 3 shows the type and number of messages participants will receive during the intervention period. Within the *PA feedback prompts*, the participant will be randomized to an achieved or to-go message with a 25% probability per day. The participant can acknowledge seeing the JITAI message by pressing a "Got it" pop-up button that appears on their smartwatch. Furthermore, since the smartwatch's accelerometer sensor can detect movement-based PA and not the intensity of the strength exercises, participants will respond to a short ecological momentary assessment, presented on their smartwatch at the end of the day to confirm whether they performed exercises (aerobic and/or strength) or not (Multimedia Appendix 3). The choice of two randomizations/day for *feedback prompts* was based on our pilot study [24], in which the participants felt that five interruptions per day were reasonable and not distracting. The other three interruptions include goal-type message, WI reminder, and a short ecological momentary assessment at the end of the day.

Table 3: The type and average number of messages participants will receive during the intervention period.

Goal-type message (number of days in a week)	Number of JITAI or No message for each goal-type (randomized)		Number and type of JITAI messages per goal-type (randomized)		Ecological momentary assessment
	JITAI Message	No Message	JITAI - Achieved	JITAI - To Go	
Standard goal (2)	2	2	1	1	2
Tailored goal (2)	2	2	1	1	2
No goal (2)	2	2	2	0	2
Day off (1)	0	0	0	0	1

Personalized PA threshold identification

A multifaceted approach of utilizing self-reported PA data with sensor data from the smartwatch during the baseline period will help identify personalized PA thresholds. These personalized PA thresholds are then used by the JITAI to determine if minutes of moderate-intensity PA per day for each participant have been achieved each day for the rest of the study period. Baseline PA data are quantified using a motion summary measure that is computationally feasible on the smartwatch for real-time computation. Area under the curve (AUC) values obtained from high-pass-filtered triaxial accelerometer signals are summed each minute to obtain a single motion measure per minute, which

is then further summed through the day. The AUC values provide a quantitative and cumulative measure of PA over time because they integrate the intensity of motion activity over time. The choice of a relatively simple measure of PA intensity is due to its low computational demands on the central processing unit, resulting in a reduced impact on the battery life of the smartwatch. Additionally, self-reported PA data is collected through the Physical Activity Recall Assessment for people with SCI (PARA-SCI), which provides subjective insights from the participants [44]. After the baseline data collection, we will meticulously compare the self-reported PA data with AUC data to determine a new threshold value for each participant (Figure 7) to gain a more comprehensive understanding of their actual PA levels and intensity. The rationale for this process is due to various functional deficits resulting from complete or incomplete SCI at different neurological levels (cervical, thoracic, lumbar, and sacral) [45]. These functional deficits, in turn, lead to large biomechanical variations of upper extremity use during exercise and mobility. Moreover, developing person-specific models that are trained to recognize the types of activities each person with SCI can perform would be burdensome. Our approach of using movement data from a wrist-worn smartwatch allows us to generalize the intervention to persons with SCI without requiring them to come to a laboratory for extensive measurements.

Sample size determination

Sample size calculation for the primary aim (a two-arm randomized controlled trial) indicated that 82 participants are needed per group to detect at least a standardized mean difference of 0.44 [46] (considered small to moderate) in the primary outcome, with 80% power (assuming a two-sided test with an alpha level of 0.05). Based on prior research [47,48] and our pilot study [24], we anticipate a 20% dropout rate. Thus, we plan to recruit a total of 196 participants with SCI (98 participants per group). In addition, power analysis for the secondary aim (an MRT) based on two randomizations/day indicated that a sample size of 69 is needed to detect a difference between JITAI message and no message on the proximal PA achieved for the WI+JITAI arm [30,49]. We assumed an average proximal treatment effect for message vs. no message of 0.10 (considered small), that starts with 0.12 (i.e., a small effect) and decreases linearly over the 16 weeks, an alpha level of 0.05 and 80% power [30]. We will have sufficient power for the MRT as we plan to recruit 98 individuals for the WI + JITAI arm to ensure that the primary aim is powered.

Recruitment

Our collaborative research team will work with co-investigators from Magee Rehabilitation Hospital, MossRehab Hospital, Thomas Jefferson University Hospital, and Good Shepherd Rehabilitation Network to recruit participants for this study. We have an established collaboration for the past six years. Participants will be recruited through a multi-pronged approach including: 1) the clinicians identifying patients with SCI at their clinics who are eligible for the study and providing them with study flyers, 2) flyers being placed in the common areas of the outpatient clinics, and 3) flyers being distributed through their listservs. In addition, we will also send flyers to local and national support groups for individuals with SCI in the US to increase the visibility of our study.

Eligibility criteria

Participants will be included if they: 1) are 18-75 years of age, 2) have a traumatic (neurological level of injury at cervical level 5 and below) or non-traumatic SCI, 3) are at least 6-months post-SCI, 4) use a manual or a power wheelchair as their primary means of mobility (>80% of time), 5) show readiness to PA as assessed by the Physical Activity Readiness Questionnaire, 6) can use their upper

arms for exercise, 7) are able to use a smartphone including interacting, recharging, and carrying it with them, and 8) are able to use a smartwatch including interacting, recharging, and wearing it. Participants will be excluded if they: 1) have any secondary complications such as pressure injuries, contractures, and infections that medically restrict their activity in any way, 2) are diagnosed with traumatic brain injury, and 3) have a history of cardiovascular disease.

Screening

Participants who contact us and indicate an interest to participate in the study will be informed about the inclusion and exclusion criteria. Participants will verbally indicate if they meet the criteria. If they meet the criteria, we will schedule a first meeting with them. If they do not qualify then we will not record or store any data.

Protocol and Assessments

Participant meetings

All study procedures will be performed at Temple University or in the community. Our team can work with the participants remotely via Health Insurance Portability and Accountability Act compliant video conference meeting software such as Zoom to obtain study-related information; we will send participants an Android-based smartphone and a smartwatch through postal mail. The research team can also meet with participants for a 30-minute face-to-face meeting if they prefer and are located within the greater Philadelphia region. All precautions will be taken to minimize the risks to participants and the research staff during the face-to-face meeting. Recruiting individuals who wish to remotely participate in the study will help improve the chances of including individuals with SCI who face transportation barriers, boost recruitment, and enhance retention.

The initial meeting will allow individuals with SCI to provide informed consent and answer questions about their demographics, SCI, wheelchair, and health and activity history. From prior research studies, the investigators estimate that the questionnaires will take about 60 to 90 min to complete (Table 4). Participants will also answer questionnaires 4 to 12 indicated in Table 4 at the end of weeks 2, 8, 16 and 24.

Table 4: Questionnaires answered by the participants.	
1	Demographics (e.g., age, biological sex, gender, race, ethnicity, and marital status)
2	SCI and level of injury (SCI Core Data Set Form, SCI Spinal Column Injury Basic Data Set Form, Non-traumatic SCI Data Sets Version 1.0 Form, and American Spinal Cord Injury Association Impairment Scale)
3	Mobility (Assistive Mobility Devices and Orthoses Form)
4	Pressure injuries (Pressure Ulcer Scale for Healing Tool 3.0), if applicable
5	Pain (International SCI Pain Basic Data Set Version 2.0 Form)
6	Fatigue (Neuro-QOL Item Bank Version 1.0 Fatigue Short Form)
7	Function (Spinal Cord Independence Measure III)
8	Quality of life (Quality of Life Basic Data Set Version 1.0)
9	PA history (PARA-SCI Survey and Leisure Time Physical Activity Questionnaire for People with SCI Survey)
10	PA Behavior (SCI Physical Activity Behavior Survey)
11	Barriers to PA (Barriers to Physical Activity Questionnaire for People with Mobility Impairments)
12	Participants' motivation (Physical Activity and Leisure Motivation Scale)

Allocation and blinding

After the baseline data collection, participants will be randomly allocated to one of two study arms (WI arm or WI + JITAI arm) based on the randomization schedule established by the project biostatistician. Participants will be block randomized based on their level of injury: tetraplegia (higher-level injury) vs. other (lower-level injury).

Participants will be masked (single blinding) to the study arm. All participants will receive the same WI program and commercial off-the-shelf technology. Participants in both arms will have access to minutes of moderate-intensity PA performed over the last seven days, which is designed to motivate them to use the smartwatch in the community. Additionally, the participants in the WI+JITAI arm will receive randomized prompts of various types of tailored feedback and PA recommendations over the course of the study.

Participant testing in the community

The research team will conduct a virtual training session for all participants to introduce them to the WI program, and study-related smartphone and smartwatch. Participants will be loaned an Android-based smartphone and smartwatch. Participants will be asked to wear the smartwatch every day for 12 hours or more. Participants are expected to wear the smartwatch for at least six days of the week to assist with good quality data collection for the study. They will be asked to charge the smartphone and smartwatch nightly. Participants can leave the smartphone at home. Once smartphone and smartwatch setup is complete, participants will be instructed to continue with their normal daily routine for two weeks during baseline data collection.

WI Program: Participants will access the 14-week WI program. Participants will receive reminders on the smartwatch to access the WI program. Furthermore, the study team will emphasize features such as badges for completing weekly modules to promote engagement with the WI program.

WI Arm: Participants in the WI arm will take part in the WI program mentioned above. They will

also have access to the minutes of moderate-intensity PA performed over the last seven days on their study smartphone. After the WI program is completed in week 16, the participants will transition to the PA sustainability phase (weeks 17 to 24) which will include participants having continued access to the WI program and PA performed over the last seven days.

WI + JITAI Arm: Participants in the WI + JITAI arm will also take part in the WI program. They will have access to minutes of moderate-intensity PA performed over the last seven days on their study smartphone, just-in-time feedback, and PA recommendations that are informed by PA guidelines for adults with SCI [41] on their smartwatch, and near-real-time minutes of PA performed over the day on their smartwatch. After the WI program is completed in week 16, the participants will transition to the PA sustainability phase (weeks 17 to 24) which will include participants having continued access to the WI program and feedback and recommendations on their study smartphone and smartwatch.

WI and WI + JITAI arms: At the end of the study, the research team will send the participants a return postal packet for them to return the study related smartphone and smartwatch.

Compensation

Participants will receive gift cards for a total value of $160 for completing the study. The participant incentives are provided upon completion of meetings and data collection. The incentives are divided into $20 per meeting for the initial and final meetings of the study, and $20 for every 4-week duration of the study for a 24-week study.

Statistical Analysis

For all aims, descriptive statistics will be obtained to assess distributional assumptions and any transformations will be applied if needed. In addition, we will examine patterns of missingness and handle this appropriately through either multiple imputation or using models that can appropriately handle missingness (e.g., mixed-effects models). We will also examine whether there are any group differences on baseline covariates (e.g., pain, fatigue, health, and activity history) despite randomization, and if so, we will statistically control for these variables in our models. All analysis will be performed with an alpha level of 0.05.

Primary aim analysis

We hypothesize that the integration of WI + JITAI will result in significantly higher PA levels over 14 weeks compared to the standard WI alone. Exploratory outcomes include long-term PA (measured via sensors and self-report) over 24 weeks (~six months). To test our hypothesis, we will fit a mixed-effects model in which the group indicator variable is a predictor, and the outcomes are the PA measurements at two, eight, and 16 weeks. We will include an interaction with time in the model, as we hypothesize that although PA levels may increase in both groups, it will increase more in the WI+JITAI group. We will also include a random intercept and slope for time. To evaluate long-term PA, we will include the PA levels at 24 weeks in the model.

Secondary aim analysis

Data from the individuals with SCI assigned to the WI + JITAI condition will be used to assess the impact of randomly provided just-in-time PA feedback on proximal PA. The analysis will address the question of whether, on average, the just-in-time PA feedback intervention has a proximal effect on moderate-intensity PA within 120 min of the feedback prompt. We will also assess the impact of

randomly provided goal-type message for the day on daily PA level achievement. We will use a generalization of regression analysis specifically developed to ensure unbiased estimation of causal effects of time-varying treatments (e.g., feedback prompts) in mHealth settings [50,51]. Since the treatment is time-varying, potential time-varying moderators, such as pain or fatigue, and potential control variables, such as PA in the 30 min prior to the randomization decision point, may be outcomes of past treatment. Because our randomization probability is constant over the course of the study, we can use generalized estimating equations in which we include availability as weights with an independence working correlation matrix and sandwich standard errors as described in Boruvka et al. [50]. We use an independence correlation matrix because causal effect estimates are biased if off-diagonal elements are present [46,52]. These analyses pool time-varying, longitudinal data across all study participants. There are two possible intervention options at each decision point (PA feedback or no feedback). Thus, the models will include an indicator variable for PA feedback vs. no feedback. In addition, we will include day in the study, as well as the interaction between day and each treatment indicator variable, and potential control variables such as PA in the 30 min prior to the randomization decision point to assess whether the proximal effect varies over the course of the study.

Exploratory analysis

Moderators will include age, biological sex, race/ethnicity, level of injury, function, mobility, pain, and fatigue. The exploratory analysis aims to identify subgroups of individuals with SCI who are likely to benefit the most from the integration of just-in-time PA feedback and recommendations with WI. We will conduct two moderation analyses. First, we will incorporate moderators into our primary aim models to identify subgroups of individuals with SCI who are likely to benefit the most from the integration of just-in-time PA feedback and recommendations with WI. Second, we will address potential time-varying moderators, such as prior PA and engagement with the JITAI, self-reported pain (number and type), and fatigue, which can be incorporated into the model described in the secondary analysis [50]. Engagement with JITAI will be captured by participants' response to the "Got it" pop-up button that appears on the smartwatch when they receive a JITAI message. We will also examine potential time-invariant moderators such as biological sex and SCI level. This analysis will allow us to identify subgroups of individuals who are likely to benefit from particular types of messages (e.g., tailored vs. standard messages).

Results

Overview

This study was funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health (Multimedia Appendix 4). The study was approved by Temple University's institutional review board and registered at ClinicalTrials.gov (NCT05317832). Recruitment and enrollment began on May 25, 2023. As of the submission of this manuscript, participant enrollment is ongoing. Since the research study involves no more than minimal risk, there will be no interim analysis, and data and safety monitoring will occur in accordance with guidelines by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Institutional Review Board of record. Data analysis is expected to be completed within six months of ending participant data collection.

Dissemination policy

We plan to disseminate our findings in the form of interdisciplinary peer reviewed manuscripts, presentations at local rehabilitation hospitals, and presentations at national and international

conferences.

Discussion

Implications

PA interventions paired with mHealth technologies that continuously measure behavior can provide novel insights about PA patterns in the community. Individuals with SCI, although generally stable in the chronic post-rehabilitation phase, are at a higher risk for secondary conditions due to physiological changes associated with injury and due to sedentary behaviors potentially related to the use of assistive technology such as wheelchairs [48,53]. Accurate, real-time measurement of PA using affordable and convenient wearable monitors will not only enable more research on existing behavior and relationships to health outcomes, but also allow insight on innovative JITAIs that may help individuals with SCI become more active in everyday life. To address these needs, we aim to investigate the benefits of combining a JITAI with a WI program towards increasing and sustaining PA levels among individuals with SCI in the community. The JITAI will automatically detect PA levels and provide behavior-sensitive PA recommendations and feedback to increase PA in individuals with SCI. While existing PA-based programs often require individuals to participate in them several times a week, a JITAI can act as a constant companion that encourages individuals and assists them in attaining their daily and weekly PA goals. The JITAI will operate as people go about their everyday lives in the community and provide timely and tailored encouragement, feedback, and tailored PA interventions that assist with people's behavior change [24,27].

Regular PA feedback has the potential to make individuals self-aware of their PA levels, which may be effective in a small percentage of individuals who are self-motivated to increase their PA levels [54]. To achieve long-term PA performance required to support behavior change and maintenance, there is a need to tailor PA feedback and recommendations based on an individual's behaviors and goals. This study will focus on understanding the impact of various types of messages on promoting proximal PA performance. Furthermore, use of an MRT study design will allow us to assess the effect of the JITAI components on participants' PA levels over time. MRT designs are new and enable us to investigate the causal proximal effects of just-in-time interventions and test time-varying moderators of those effects [29,30]. Based on the impact of the type of messages on the proximal PA, the MRT will allow us to determine the relative utility of various feedback and PA recommendation strategies.

Anticipated findings

This project investigates a state-of-the-art JITAI-enhanced WI program, which is guided by the COM-B model [31] that highlights the importance of capability, motivation, and opportunity for behavior change. While mHealth is becoming popular in preventive medicine, the impact and efficacy of an intervention is related to the use of specifically designed smartphone apps. JITAI can assist with making the mHealth apps dynamic and engaging to the individual. The outcomes from this study will highlight how PA levels may change with WI and JITAI-based PA recommendations and feedback prompts. The various ways of providing PA recommendations (standard, tailored or no goal) and feedback prompts (achieved, to-go, or feedback not presented) will allow us to test how adding the JITAI to WI may impact PA levels and sustain them over time. Furthermore, the study will allow us to identify subgroups of individuals with SCI who are likely to benefit the most from the integration of JITAI with WI. This information is critical in the design, development, and evaluation of JITAI for future physical rehabilitation intervention studies in individuals with SCI,

and PA interventions for individuals with and without disabilities.

Limitations

One of the potential limitations of this study is that our JITAI has been developed for Android-based smartphones, which provide greater flexibility in research and are used by 53.9% of smartphone users in North America [55]. In addition, we are giving out study-related devices that are not personal devices. If we are able to show the efficacy of the JITAI through this randomized clinical trial, then the approach of using JITAI to provide PA interventions to individuals with SCI can be converted to personal smartphones that use other operating systems (e.g., iPhone with Apple Watch). Use of personal devices has a potential to improve compliance and reduce burden. Our approach is cost-effective and will test the viability of this novel approach of providing PA interventions. The study will recruit adults with SCI between 18 and 75 years old, comprising 89.2% of all those with SCI [2]; children will not be studied due to their use of a variety of wheelchairs during their development, and because children's response to and recovery from an SCI is different compared to adults. However, evaluation of JITAI in children with SCI is a potential avenue for future investigations. Another limitation is that we have a relatively simple measure of PA intensity. Future work might use more sophisticated, person-specific models that are trained to recognize the types of activities each person with SCI can do for obtaining moderate intensity PA.

Conclusions

The JITAI has a potential to achieve long-term PA performance by delivering tailored just-in-time feedback, based on the person's actual PA behavior rather than a generic PA recommendation. New insights from this study may help with designing engaging PA interventions for individuals with disability in the community. Our work could lead to more impactful and sustainable clinical and rehabilitation interventions for this population by using affordable, off-the-shelf consumer devices to create a JITAI that supercharges an existing intervention.

Acknowledgements

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Authors' Contributions

DLC, INS, MT, RJM, SSI, and SVH contributed substantially to the conception and design of the study and intervention. RLC, LB, MSR, MSRL, SAKH, RJM, and SVH contributed substantially to the recruitment design of the clinical trial. HL and SSI developed and optimized the JITAI mHealth application. RLC, HL, CH, SSI, and SVH contributed substantially to the feasibility, testing and evaluation of the JITAI mHealth application, and design and development of data pipeline for collecting sensor data from this decentralized clinical trial. All authors reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Abbreviations

AUC: area under the curve
COM-B model: capability, opportunity, and motivation model
JITAI: just-in-time adaptive intervention
mHealth: mobile health
MRT: micro-randomized trial
NCHPAD: National Center on Health, Physical Activity, and Disability
PA: physical activity
PARA-SCI: Physical Activity Recall Assessment for people with SCI
SCI: spinal cord injury
WI: web-based physical activity intervention
WI + JITAI: WI combined with JITAI

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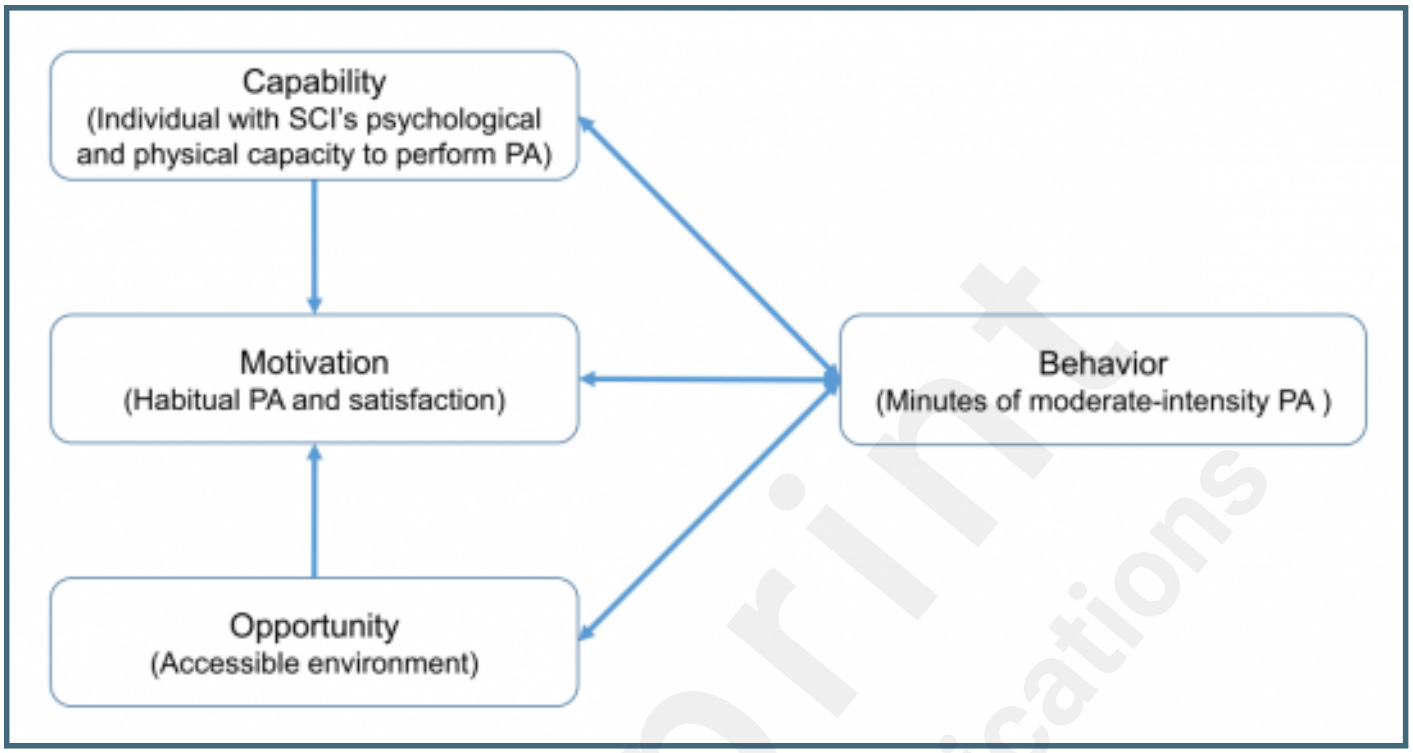
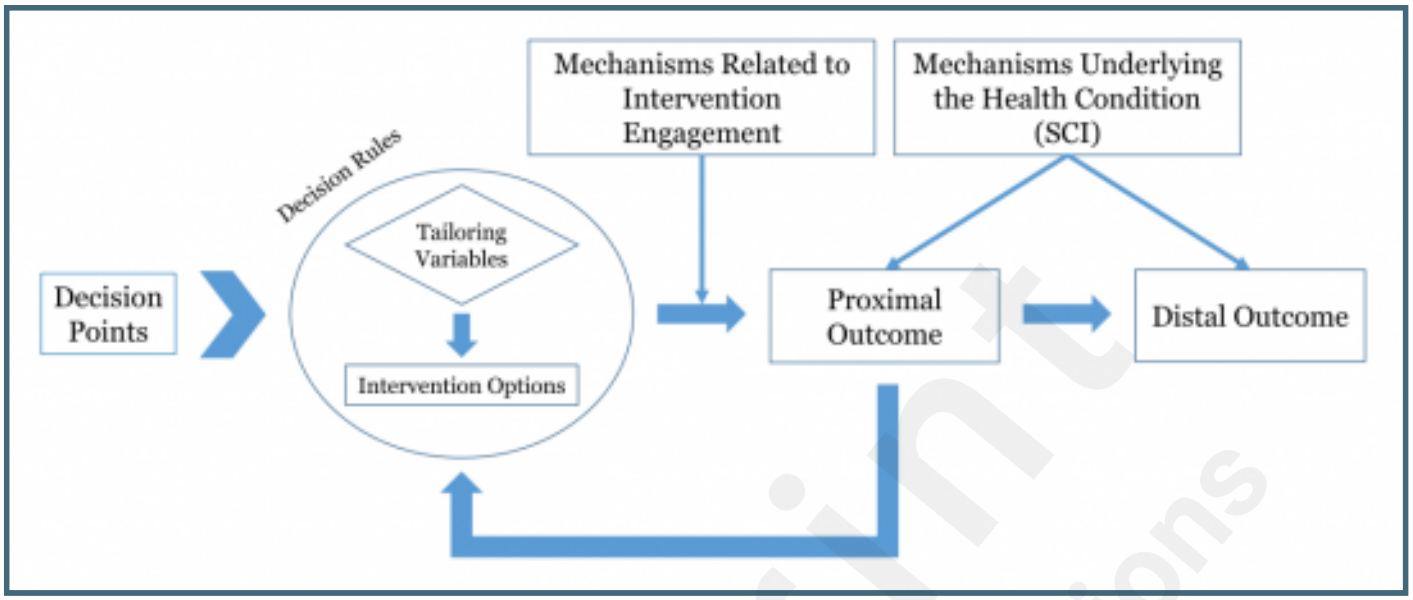
Supplementary Files

Figures

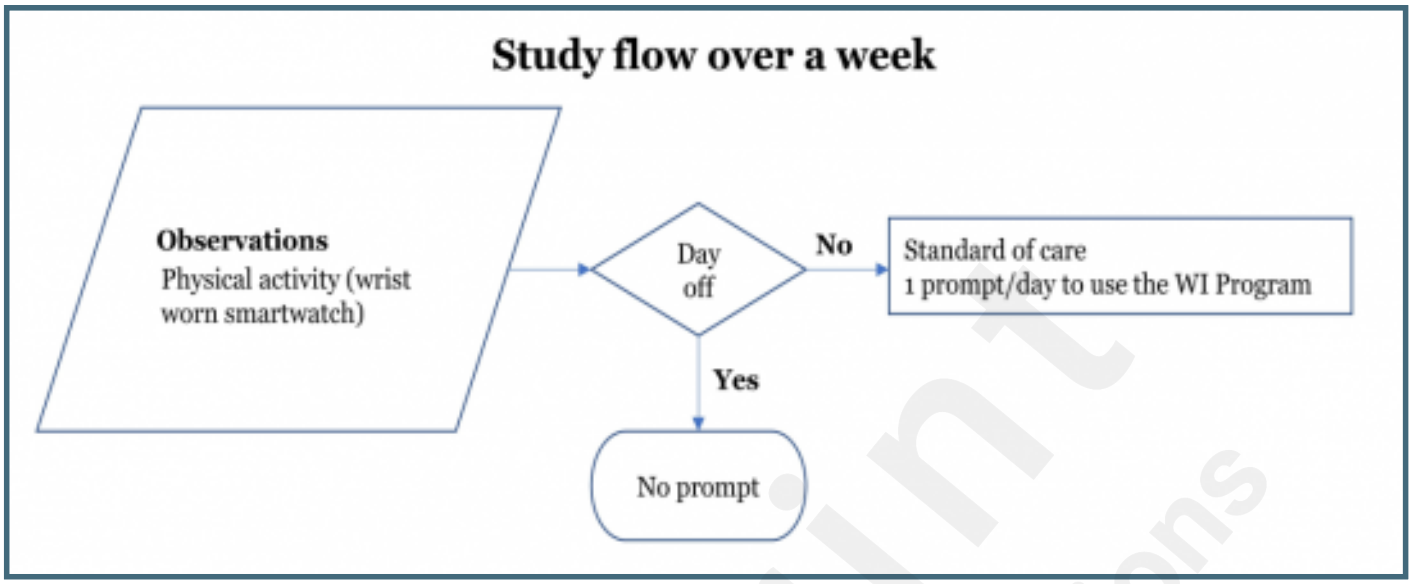
The COM-B model – a framework for understanding behavior (adapted from Michie et al., 2011). The solid arrows represent potential influence between system components.



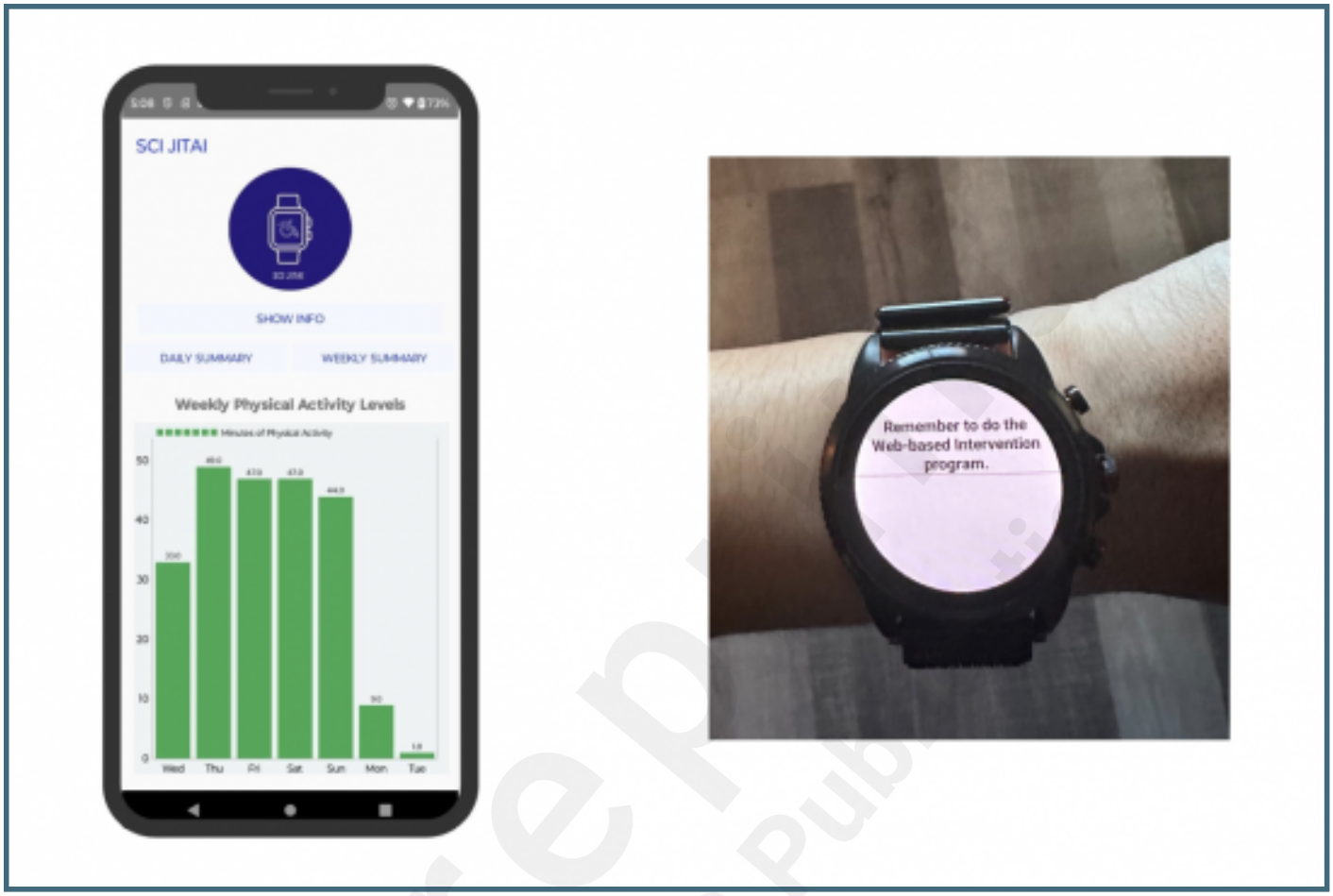
Conceptual framework of JITAI components for our proposed study (adapted from Nahum-Shani et al., 2018).



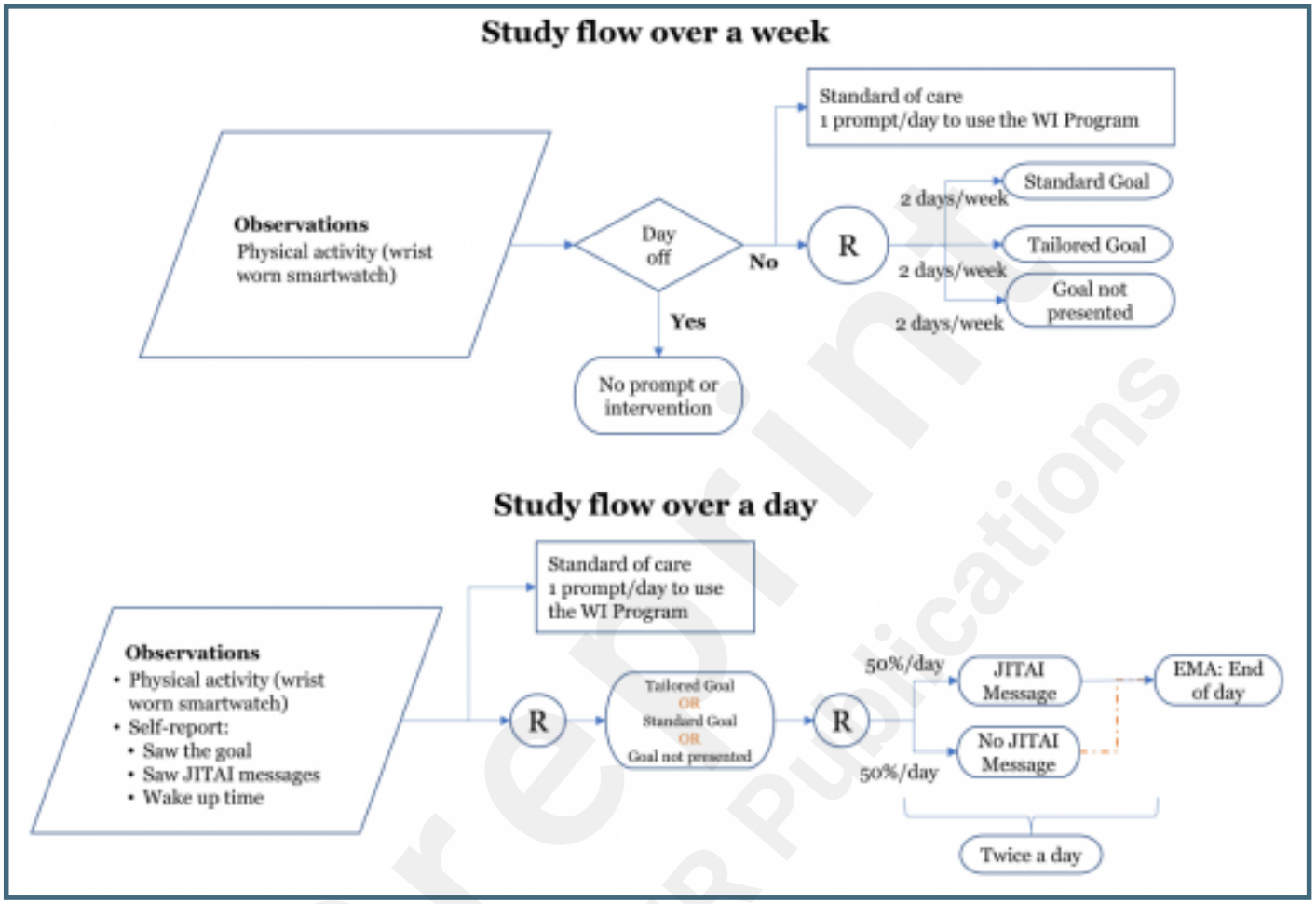
Participants will receive a daily reminder, except for the day off, on the smartwatch to access the WI program.



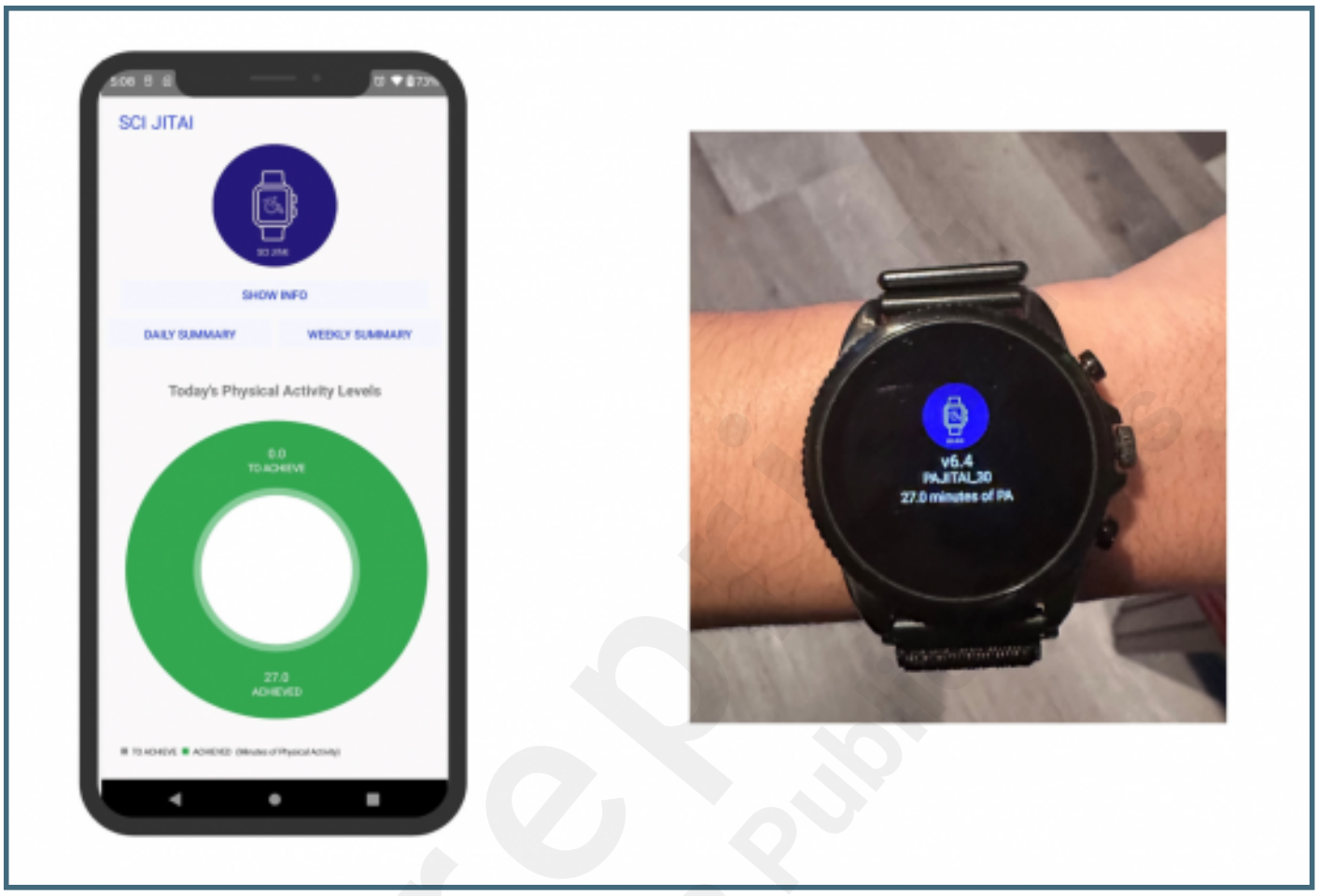
(left) Participants will have access to PA levels performed over the last seven days on the smartphone. (right) Participants will receive a daily reminder, except for the day off, on the smartwatch to access the WI program.



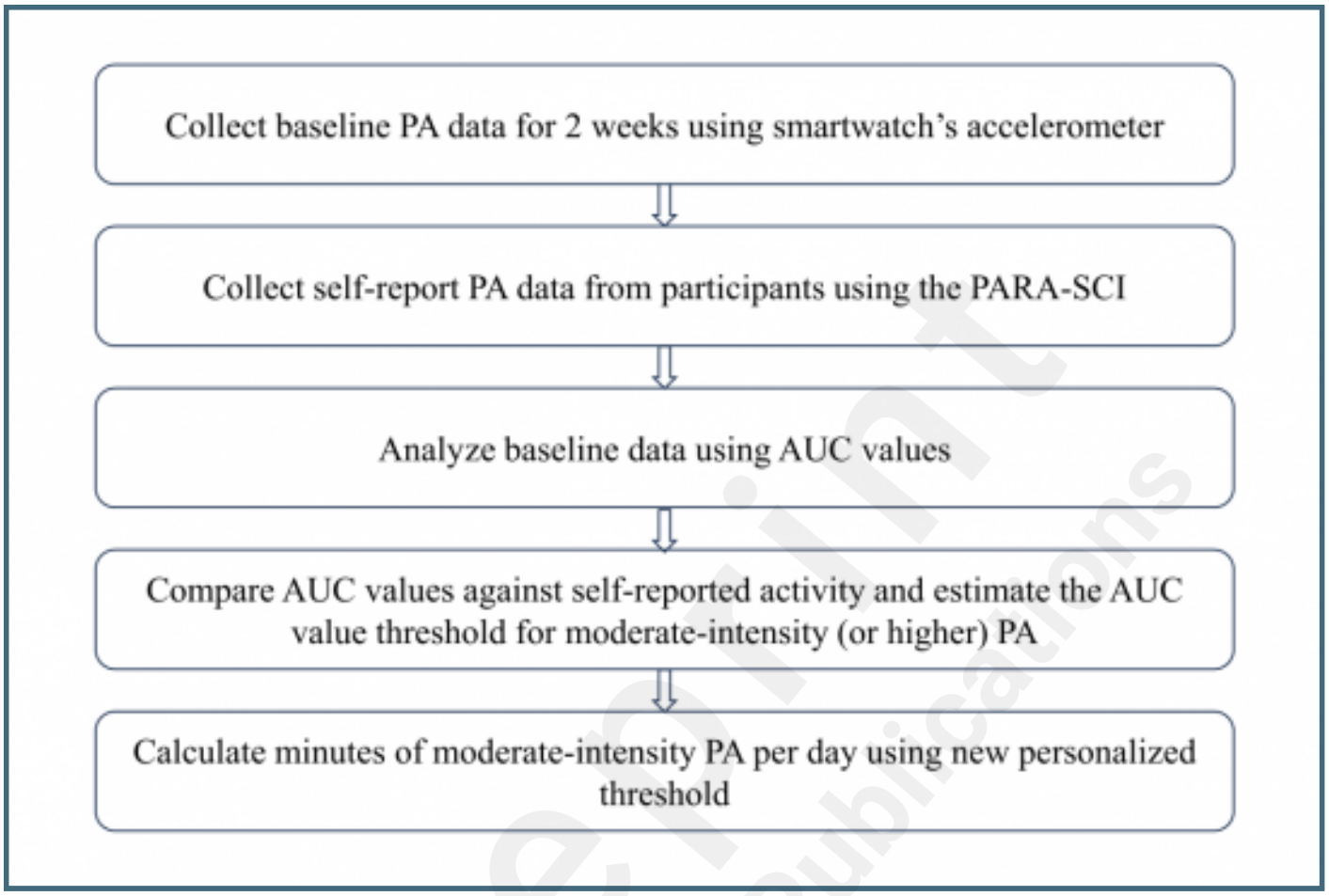
(top) Participants will receive a daily reminder, except for the day off, on the smartwatch to access the WI program. Participants will receive randomized intervention of standard, tailored, or goal not presented for two days each of the week. (bottom) Study flow over a day for the participants in the intervention group.



Participants will receive real-time daily feedback on their smartphone (left) and smartwatch (right). The goal for the day in this example is 27 min of moderate-intensity PA. This is in addition to having access to PA levels performed over the last seven days on the smartphone (Figure 4 left).



Flow chart to identify personalized PA threshold.



Multimedia Appendixes

(top) Goal setting – standard goal. (bottom) Goal setting – tailored goal. The try again screen will be automatically time-out back to the goal screen if the user does not press the Try again button in 3 s. The limit for reprompt is set to three times for all messages.
URL: http://asset.jmir.pub/assets/c64756f0c0477098769cf9de118b73c7.png

(left) JITAI message – achieved. (middle) JITAI message – to go. (right) If the user acknowledges the JITAI message, then they get a fortune cookie message on the smartwatch. An example of a fortune cookie message is: Currently there are 28 paralympic sports sanctioned by International Paralympic Committee.
URL: http://asset.jmir.pub/assets/6da613ba08ab371589ddda33870acc58.png

End of day ecological momentary assessment.
URL: http://asset.jmir.pub/assets/fafb96e2b4f10b5477304e7eec1eda38.png

Peer-review report for the funded grant.
URL: http://asset.jmir.pub/assets/9c508421bbaf14f1f919bb8e146b409f.pdf