Investigating Changes in the Brain After Using a Wearable Healthy Lifestyle Intervention: A Mixed-Methods Protocol

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Abstract

Background: Wearable technologies, such as the Apple Watch, are rapidly transforming the healthcare landscape by enabling the tracking of real-time physiological and behavioral data used in healthy lifestyle interventions. Despite their widespread adoption in the consumer market, scientific validation of their impact on the brain remains limited, and factors influencing adherence and effects on cognition are not fully understood. This gap is critical as consumers, healthcare providers, and researchers depend on this data to unlock the potential of wearables for cognitive support.

Objective: In this study, we aim to assess the cognitive and behavioral effect of a commercially available wearable technology, the Apple Watch, on the brain, while exploring user experience (UX) factors influencing adherence, engagement, and acceptability of wearable healthy lifestyle interventions. Our goal is to provide comprehensive guidelines to evaluate the effect of wearable technologies on the brain, which could potentially shape the future of brain health interventions.

Methods: Healthy adults aged 18-40 with a sedentary lifestyle (n=72) will be recruited in the Vancouver Metropolitan Area, BC, Canada. Participants will be randomized into an intervention group following a healthy lifestyle intervention using an Apple Watch or a control group following standard physical activity guidelines without an Apple Watch over a period of four weeks. We will employ a convergent parallel mixed methods design to investigate three constructs of a wearable healthy lifestyle intervention: effectiveness, engagement, and acceptability. This design integrates pre-, during, and post-intervention assessments combining quantitative and qualitative approaches. Effectiveness will be evaluated with quantitative assessments including perceived health (SF-36), behavioral performance (Go/No-Go task) and cognitive activity (EEG-based ERPs and resting-state activity). Engagement and acceptability will be assessed using questionnaires (goals completion and System Usability Scale, respectively). Qualitative assessments will include weekly check-ins and semi-structured interviews to capture UX factors influencing the acceptability of the intervention. Secondary outcomes include descriptions of possible interactions between the three constructs.

Results: The study received funding by the AGE-WELL Network Centres of Excellence (April 2020–March 2023) and the Pacific Economic Development Agency of Canada (April 2022–March 2025) and was approved by Simon Fraser University's Research Ethics Board. Enrollment for the study is ongoing. The data collected from participants who have successfully completed the intervention is currently being processed and analyzed. The first results are expected to be published by the end of 2025.

Conclusions: This study outlines a foundational framework for evaluating the effect of wearable health interventions on the brain. Further, we hope our mixed methods approach will inform the design and development of effective, engaging, and friendly wearable brain health technologies.

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Protocol

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Keywords

wearable technologies; human-computer interaction (HCI); digital health; user experience (UX); cognitive function; EEG; behavioural performance; mixed methods; engagement; acceptability; healthy lifestyle intervention; brain health; adherence; smartwatch; digital health interventions; physiological data; behaviour change; real-time tracking

Introduction

Every year, hundreds of commercial brands develop new wearable devices for the consumer

market [1]. The global wearable technology market had an estimated worth of US $40.65B in 2020 and is projected to triple in value by 2028 (US $118.16B) [2]. Advances in wearable sensors over the last decade have enabled the gathering of real-time physiological and behavioural data in an increasingly precise and unobtrusive way [3]. The sensors embedded in wearables gather movement, physiological, and biochemical data for a variety of tasks such as tracking steps, measuring heart rate, and monitoring glucose, respectively [4]. This data provides a wealth of information on people's behaviours, emotions, and lifestyles, ultimately providing users with personalized health data for health-monitoring and behaviour change [5]. It also allows researchers and clinicians to explore and obtain keener insights into brain health [3,6], and could be key towards designing effective multi-modal personalized interventions using technologies already familiar to users [7]. Technological advances in wearable sensors may also reduce the gap between medical and non-medical grade devices [8], advancing digital interventions to better support brain health [2,7], and potentially extending its range to hard-to-reach populations such as rural and low-resource locations [3,4]. Research in wearables holds the potential to revolutionize the next generation of brain health interventions [6].

Wearable devices have changed the health technology industry by empowering users to become active and responsible drivers for their own care, but these benefits will only materialize if people continually use and adopt these products [9,10]. Benefits such as early health issue prediction will only be realized through the continuous collection and analysis of comprehensive sets of data, which could also be used to identify and promote positive lifestyle habits [10]. However, designing a wearable associated with a healthy lifestyle, and providing scientific evidence to support this assumption, while keeping up with the rapid nature of the field, is often challenging [5,11]. Studies report different outcomes for continual use of wearables over long periods of time [5,11], with a key study providing evidence that 32% of users abandon wearables after six months of use [5]. Continual use of wearables is impacted by user experience (UX) conditions such as comfort [12], effort [7], gamification [11], confidence [5,6], and social observability [9], as well as the type of goal pursued by the user. Some researchers have categorized these goals as intrinsic and extrinsic. Intrinsic goals are satisfying to pursue and include the innate psychological needs for autonomy, relatedness, competence, and growth. Extrinsic goals are focused on obtaining rewards and positive evaluations from others, sometimes leading to stressful behaviour with unsatisfactory outcomes [9,13]. Exploring UX factors that influence adherence and long-term efficacy, including the role of intrinsic and extrinsic goals in outcomes, is essential towards the increased viability of wearable-based brain health interventions [14].

While there are some positive indications that using wearable trackers improves overall health [1], evidence of the effect of wearables on the brain still needs to be established with scientific validation. It is common to find unsubstantiated scientific claims on company websites and marketing materials which could set a dangerous precedent if misinterpreted [4]. Similarly, single-subject, subjective reports available from Quantified Self movements are scientifically unreliable. It remains unclear how young adults regularly exposed to a constant stream of behavioural and physiological wearables feedback experience brain impacts [5]. Wearable technologies' complex, rapidly evolving nature, presents challenges in evaluating its impact. For example, users' context and lifestyle could produce different outcomes in various scenarios [15]. These are important factors that must be explored in the scientific community.

With the goal to evaluate the impact of wearables in brain health interventions, we propose a study to measure the functional impact of a commercially available wrist-worn wearable tracker

on the brain. We also plan to explore subjective UX factors particular to our study that might influence adherence and long-term efficacy. Our research methodology was inspired by previous work in the field, specifically the studies conducted by Moreno et al. (2011) [16], Antle et al. (2019) [17], Bevan Jones et al. (2020) [18], and Kiaei Ziabari et al. (2022) [19].

Methods

Study Design and Population

Recruitment and Consent

Seventy-two healthy adults (n=72: control=36, intervention=36) will be recruited in the metropolitan area of Vancouver, BC, Canada. The sample will be above common sample sizes in the context of Human-Computer Interaction (HCI) [20], and are above typical sample sizes for Event-Related Potentials (ERP) data collection [21].

A recruitment poster with study details, contact information, and a link to the pre-screening survey will be distributed both physically and digitally for its use in physical channels such as local bulletin boards and displays. Study personnel will also contact prospective participants through snowball recruitment, local universities mailing and recruitment lists (Simon Fraser University, University of British Columbia), newsletters, and known contacts. Initial contact will be made by email. Individual contact with prospects will be made by email and phone call to schedule in-person research activities.

All participants will provide written informed consent before any assessment. Participants and prospects will be instructed to not consume alcohol or drugs 24 hours before assessments. They should also have dry hair, and avoid using hair products and make-up, as they may interfere with electroencephalogram (EEG) recording procedures [21].

Inclusion Criteria

We will recruit healthy adults aged 18-40 interested in improving their lifestyle to participate in our intervention. Participants must have a sedentary lifestyle indicated by self report of one day or less of weekly moderate exercise. They must have normal or corrected-to-normal vision and no color vision deficiency. They must own and actively use an iPhone Xs or later with iOS 17 or later, due to compatibility restrictions with the smartwatch used for the intervention. Apple Watch was selected due to its widespread adoption [22]. This provides a more comprehensive representation of the current impact of wearable healthy lifestyle interventions on the brain. They must also be available to attend all remote and in-person study sessions required for the intervention in a designated lab space. Lastly, participants must be right-handed due to differences in the laterality of brain activity [21].

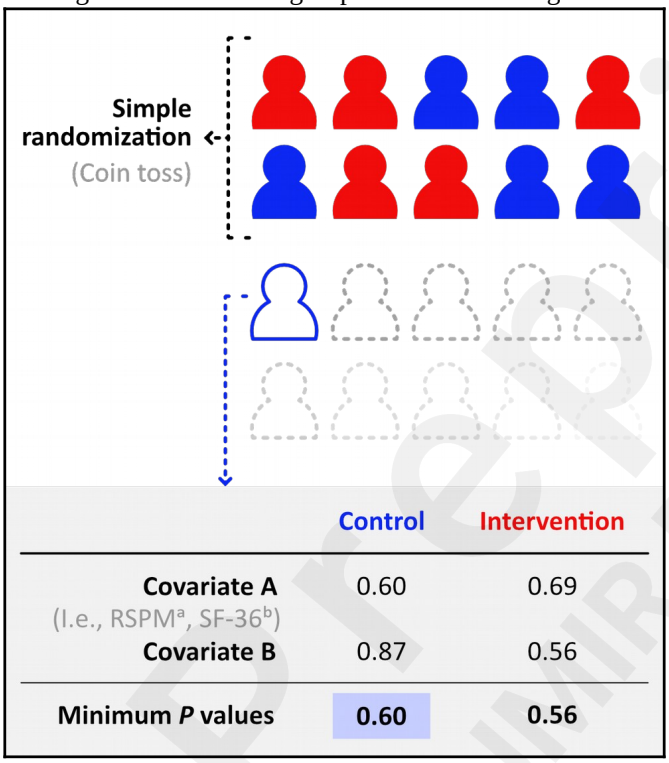
Exclusion Criteria

We will exclude prospects who report significant health problems, currently participate in a health intervention, currently use a smartwatch with healthy lifestyle features, or have used one in the past year. Prospects will undergo the first pre-test assessments for a final screening. Participants with an IQ score of Grade IV or lower (lower 25 percentile group, using the Ravens Standard Progressive Matrices (RSPM) scale) will be excluded. We will request prospects and participants to report medication use, and will exclude them if these could affect any of the assessments.

Randomization

To reduce differences between groups before the intervention, participants will be assigned to either an intervention or a control group using a pseudo-randomization method [16]. To control and balance the influence of covariates, and to facilitate the continuous enrollment of participants, we will use covariate adaptive randomization [23]. New participants will be temporarily assigned to both groups, and their covariates will be analyzed to determine the most suitable group assignment based on statistical criteria. P values will be calculated for each covariate. The group assigned is determined by the highest minimum P value for each group. To prevent predictability, the first ten participants will be randomly assigned into groups before covariate adaptive randomization is applied [23]. See **Figure 1** for more details.

Figure 1. Example breakdown of the first 11 participants group assignments. In this case, the 11th participant will be assigned to the control group because of the higher minimum *P* value (0.60 > 0.56).



	Control	Intervention
Covariate A (I.e., RSPM[a], SF-36[b])	0.60	0.69
Covariate B	0.87	0.56
Minimum *P* values	**0.60**	**0.56**

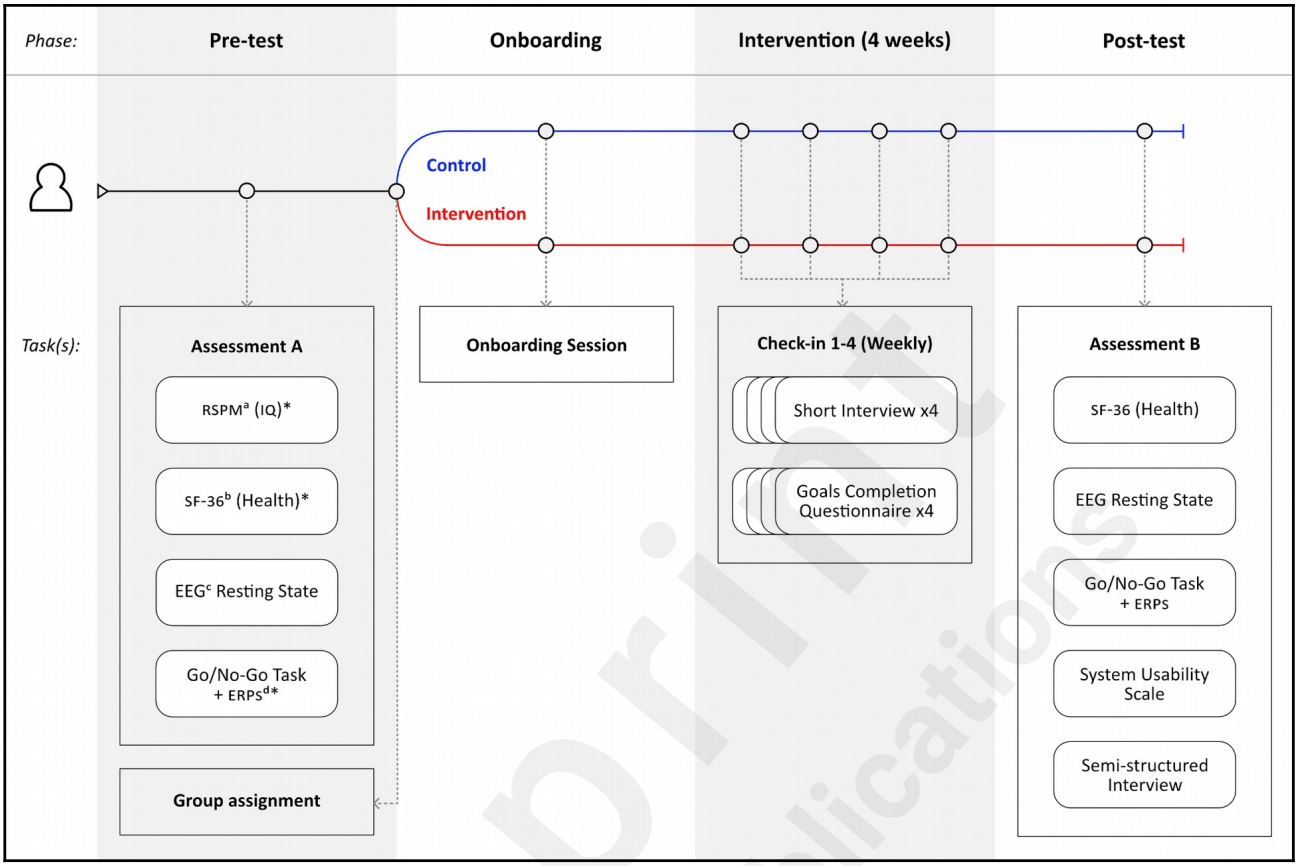
[a]RSPM: Ravens Standard Progressive Matrices.
[b]SF-36: Short Form Health Survey.

Covariates controlled between groups (t-test: *P*>.05) will include age, sex assigned at birth, pre-intervention measurements of IQ (RSPM), perception of their own health (Short-Form (SF-36) Health Survey) [24], behavioral performance (reaction time, accuracy), and cognitive measurements (ERPs).

Procedure

The study will consist of four phases: pre-test, onboarding, intervention, and post-test. All phases are scripted (Multimedia Appendix 1) and will be led by a team of two research assistants. **Figure 2** illustrates an overview of the study procedure.

Figure 2. Overview of the study protocol, including all four phases (pre-test, onboarding, intervention, and post-test), tasks, and assessments considered for each task.



*Outcome measures used for group assignment in addition to age and sex assigned at birth.
[a]RSPM: Ravens Standard Progressive Matrices.
[b]SF-36: Short Form Health Survey.
[c]EEG: Electroencephalogram.
[d]ERPs: Event-related potentials.

Pre-test

This session will last approximately 60 to 90 minutes. When the participants arrive, they will be greeted and asked if they need to use the bathroom to minimize disruptions during the assessment. They will also be requested to silence their phones or any device that could distract them. Then, participants will be asked to sit down comfortably in front of the computer screen with procedure slides where the assessments will be performed. We will adjust the chair to a predefined position, ensuring the same distance between the screen and the heads of all participants. We will also adjust the screen height so that its center is vertically leveled to their eyes. Then participants will be asked to read and sign a consent form containing the study design and goals, specifying the personal health information that will be compiled, and the tasks they will be requested to do. This form will also specify potential benefits, and their rights including confidentiality and the capacity to withdraw from the study at any time. The research team will answer any questions or concerns they might have before they agree to participate and sign the consent form. After consenting, we will request basic contact information including a phone number to follow up with any topic related to the intervention. All personal information will be destroyed after the intervention results are published. Finally, a numeric ID will be assigned to the participant. This ID will be used to store and de-identify their personal data throughout the intervention and data analysis.

After signing the consent form and being assigned a participant ID, the pre-test will begin.

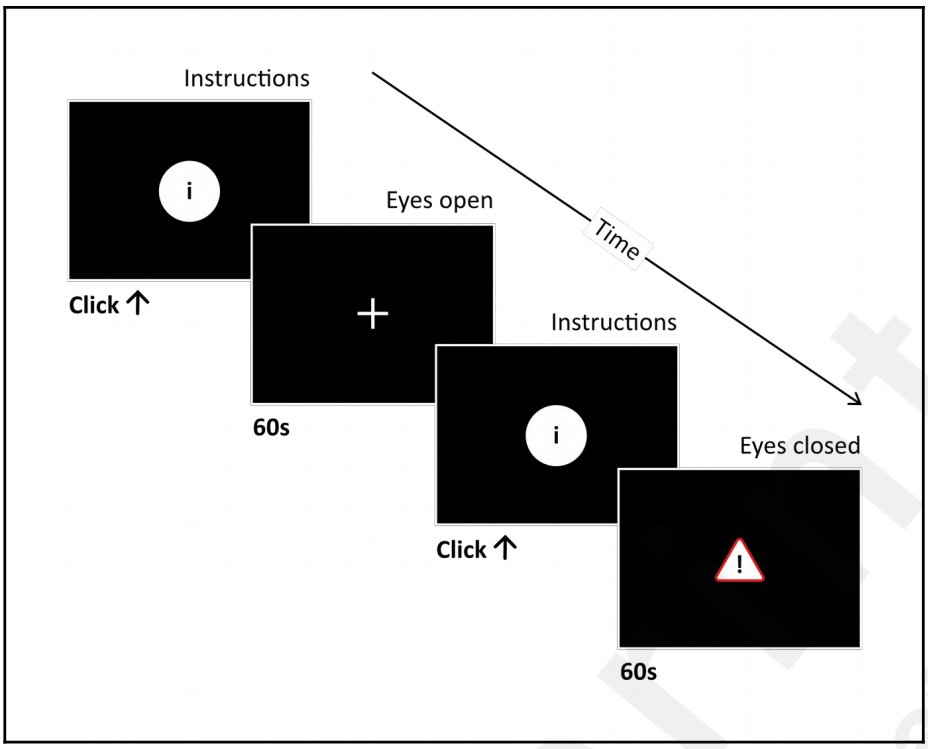
Participants will begin by answering an IQ assessment (RSPM) on the computer. In this IQ assessment participants will be shown a pattern with a piece cut out. They must think about the piece needed to complete the pattern correctly, choosing the right piece from six options. The research team will guide participants through a sample exercise and answer any questions before starting the IQ assessment. There will be no time limit for the test, but participants will be encouraged to finish as fast as they can. We will record their completion time. Finally, we will exclude participants who do not satisfy the IQ assessment criteria.

Selected participants will then be guided through the EEG set-up. We will use a BioSemi Active Two for the EEG assessments. The BioSemi allows real-time visualization of the electrical signal of the brain during tasks and recordings. A cap with 64 electrodes will be used, in addition to CMS (Common Mode Sense) and DRL (Driven Right Leg) electrodes, as well as five external electrodes to track eye and muscle movement (two electrooculograms (EOG) on the temples, one EOG beneath the left eye, and two on the mastoids). The skin area where the external electrodes are to be placed will be cleaned using alcohol swabs, and the head will be measured (from the nasion to the inion) to select a well-fitted cap. After conductive gel is applied to the external electrodes to improve signal and the electrodes are secured in place with electrode collars, the cap will be placed on the participant's head, tested for correct placement and fit, and secured using a chin strap. Then, conductive gel will be applied to each of the 64 electrode locations using a plastic syringe with circular motions to get the hair out of the way and improve the connection between the electrode and the scalp, followed by the insertion of the pin-type electrodes. Finally, the connection of each electrode will be tested and adjusted for connection flaws (impedance ±25mV, and visual inspection of noisy signal) on a separate EEG acquisition computer before the recording.

While the EEG system is being set-up by the research team, participants will be asked to answer the SF-36 Health Survey [24] on the computer. The SF-36 captures the self-perception of health and well-being. The survey has 36 items grouped in 8 dimensions: physical functioning, physical and emotional limitations, vitality, social functioning, bodily pain, general, and mental health. It also includes a health change dimension evaluating the perceived improvement of health after a period of time. The research team will state that the survey is not a test, inviting participants to choose the response that best represents how they currently feel, remaining available for any questions while the participant completes the survey.

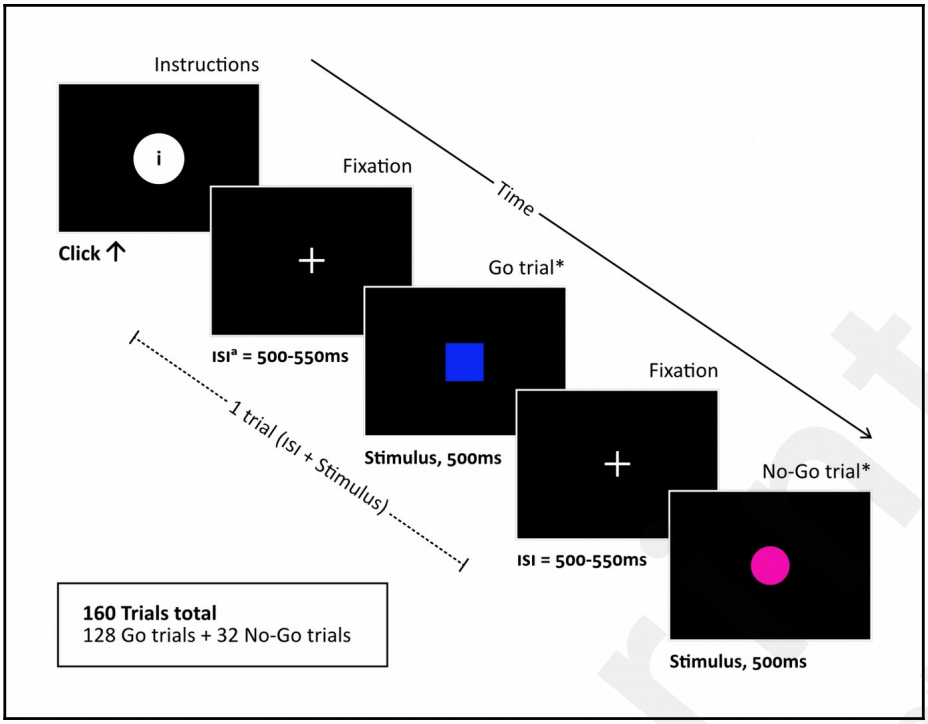
After completing the survey and finishing setting-up the EEG system, we will record the participant's brain activity at rest. Instructions will be provided both verbally and visually on the computer screen (**Figure 3**). Participants will be asked to focus on a fixation cross for one minute and to avoid moving or blinking. The research team will ensure communication between the stimulus and recording computers and then begin the recording. The participant will initiate the one minute task when they are ready by clicking on the screen. After completing this task, instructions for a second one minute task will be provided. This time, participants will close their eyes and avoid moving while not focusing on anything in particular. The participant will click on the screen when they are ready. The research team will let them know when the task is over, and stop and save the recording on the EEG system.

Figure 3. Schematic of the sequence of prompts for the resting state task.



Next, participants will perform a Go/No-Go task while the EEG is recorded. The Go/No-Go task is used to assess the efficiency of response inhibition. Specifically, it measures the capacity to control responses and sustain attention [16]. The task will consist of two stimuli differing in colour and shape, for which the participants will either respond (clicking a mouse button) or withhold a response (not clicking a mouse button), depending on whether a go or no-go stimulus is displayed on the screen (**Figure 4**). The task will consist of 160 trials. 80% of the trials will present the go stimulus (128 trials), while the rest (20%: 32 trials) will present the no-go stimulus. The order of trials is randomized for each Go/No-Go task, decreasing the chances of predicting the no-go stimuli. The roles of the stimuli will be randomized for each participant. After a task is defined and the signal is tested, instructions will be provided both verbally and visually on the computer screen. Participants will be asked to respond as fast and as accurately as they can, while they avoid moving or blinking. They will do a short practice task (10 trials) to ensure comprehension of the instructions. After the practice is complete, the research team will start the recording and ask the participant to click on the screen when they are ready to begin the main task. When the Go/No-Go task is completed, the research team will remove the EEG electrodes and cap, and explain the next steps of the intervention to the participant.

Figure 4. Schematic of the sequence of stimuli in the Go/No-Go task.



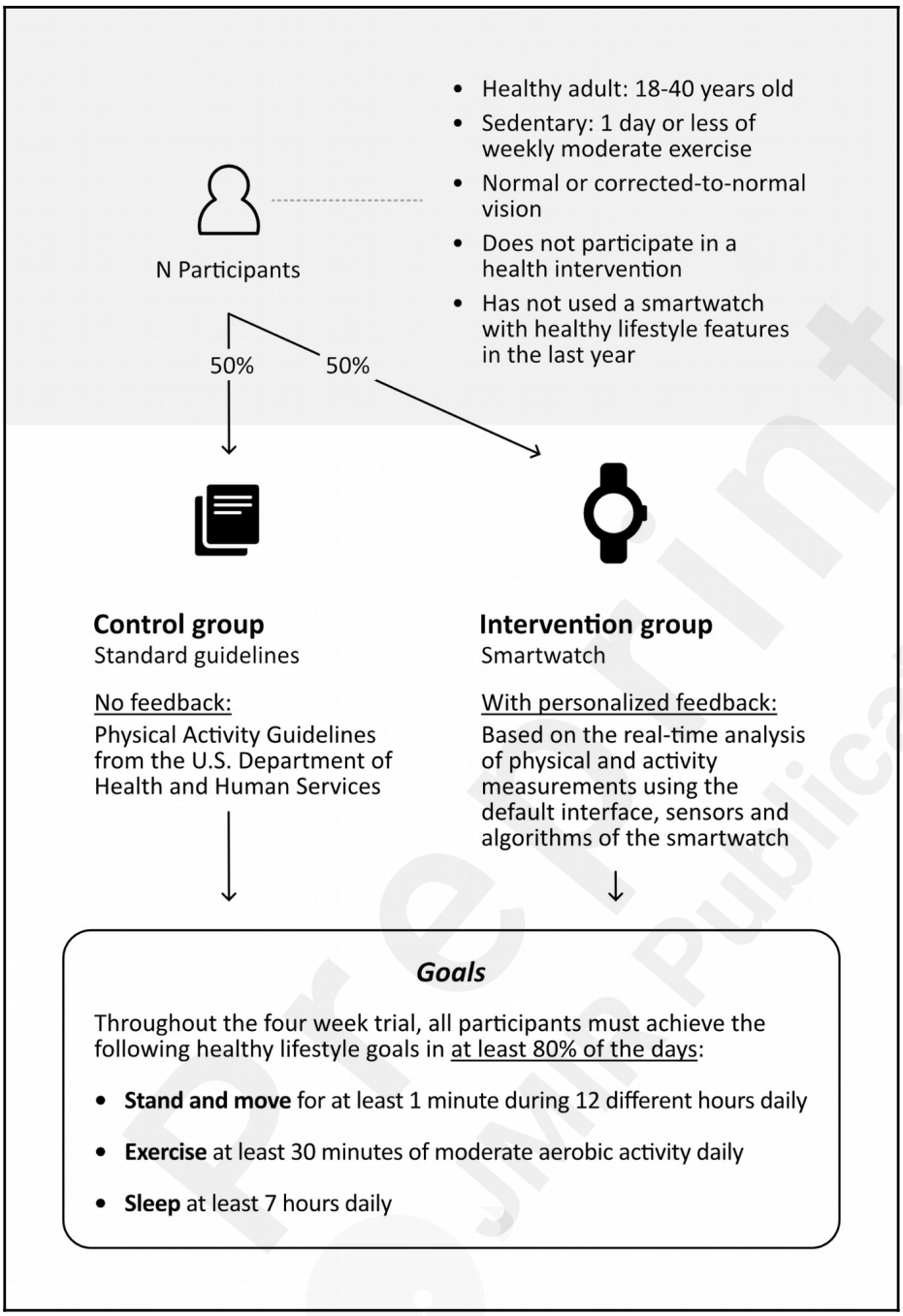
[*]The order of go and no-go trials will be randomized, and stimuli (color and shape) will be reversed in the post-test.
[a]ISI: Inter-Stimulus Interval.

Onboarding

Participants will be pseudo-randomized into either an intervention or a control group using the pre-test measurements of IQ (RSPM), perceived health, behavioral performance and cognitive measurements, to reduce differences between groups before the intervention (see details under Participants: Randomization).

After the participant is assigned to a group, the research team will schedule a 30 minute in-person onboarding session with the participant. In this session participants will be instructed with the goals, expectations, and criteria for success in the healthy lifestyle intervention. Participants in the intervention group will be lent an Apple Watch Series 8 or 9 (Apple Inc., Cupertino, CA) to be used throughout the intervention and returned when the intervention ends. Participants in the control group will receive a copy of the Physical Activity Guidelines (PAG) from the U.S. Department of Health and Human Services (**Figure 5**).

Figure 5. Overview of intervention procedure including goals.



The onboarding for the intervention group will include steps inherent to the smartwatch use and set-up: signing a complementary consent form, pairing their phone with the smartwatch, ensuring proper fit (use on non-dominant arm, correct strap size, snug fit, and how to tighten during workouts), configuring goals, activating health and activity notifications, and sharing of data with the research team. Participants will be allowed to increase the goals configured, but not to reduce them to a lower value than the initial set-up. Participants will also be able to customize all other aspects of the smartwatch as if it was their own.

The control group will be guided through the outline of the PAG executive summary and they will be asked to read it in full and to ask any questions they might have. The PAG provides evidence-based advice for adults on how physical activity can help promote health, including specific guidelines that set the standard goals for our intervention. Participants in the control

group will receive a printed copy of the executive summary and a digital copy of the full 118 pages document with an in-depth analysis and explanation of the guidelines. Participants will not be required to read the full document, but will be encouraged to do so if they want to learn more about the intervention standards.

To be considered a successful intervention, both groups must achieve each of the following goals in at least 80% of the days:

- **Stand and move** for at least 1 minute during 12 different hours daily.
- **Exercise** at least 30 minutes of moderate aerobic activity daily (i.e. activities that increase the heart rate such as brisk walking).
- **Sleep** at least 7 hours daily.

Participants must commit to achieving these goals. After the goals, expectations, and criterias are understood, we will schedule four weekly remote (video conference) check-ins with all participants. These check-ins will be scheduled on the same day and time for each week. After scheduling, participants will start the intervention.

Intervention

The healthy lifestyle intervention will last 4 weeks. To validate the intervention success, all participants must achieve the required healthy lifestyle goals during this phase. They are also expected to complete each of the weekly check-ins. These remote check-ins will help us understand their experience with the intervention at different time points, track the completion of goals, and ask for significant issues they might be facing. Each check-in consists of a short semi-structured interview and a questionnaire, and will be 10 to 15 minutes long. Check-ins will be audio-recorded and transcribed unless the participant requests us not to, in which case, notes will be taken. In the short interview, participants will be asked questions about their experience with the intervention, including issues, workarounds, helpful factors, their discoveries or usages, as well as any change(s) or customization they made to the intervention. The questionnaire consists of six questions to measure their progress towards completing the intervention (Multimedia Appendix 1). Two questions will be made for each goal (stand and move, exercise and sleep). The first question asks how many days in the past week they successfully completed their goal. The second question asks for an average of how much of the goal they achieved on days when they were unable to complete it. At the end of the third check-in, the last in-person post-test assessment will be scheduled right after the end of the intervention.

Post-test

This final session will last approximately 60 to 90 minutes. The post-test follows the same assessment structure as the pre-test, but does not require the participant to provide contact information, complete the RSPM, or sign an additional consent form (**Figure 1**). Additional assessments (not included in the pre-test) are: the System Usability Scale (SUS), a semi-structured interview, and a set-away of the device (intervention group only). The roles of the stimuli during the Go/No-Go task will be reversed for each participant to control for practice effects and color/shape bias from the pre-test.

After completing the SF-36 Health Survey and while the research team continues the EEG set-up, participants will answer the SUS. The SUS is a widely used standardized questionnaire for the assessment of perceived usability [25,26]. The SUS includes 10 items with a likert scale from 1 (strongly disagree) to 5 (strongly agree). Participants will answer the SUS as related to their experience while using the smartwatch (intervention group) or following the PAG executive

summary (control group).
After completing the Go/No-Go task and removing the EEG electrodes and cap, there will be a short five minute break. The research team will then conduct a semi-structured interview with questions about the participant's experience, preferences, and feelings after completing the intervention. The audio of this interview will be recorded and transcribed unless the participant requests not to. The assessment lead will conduct the interview, while the other research assistant will take notes of the participant's answers on a separate computer. The topics included in the interview are: personal background and daily routine, intervention adherence and experiences, perceived benefits, and feedback and future considerations.
If the participant is in the intervention group, a smartwatch set-away is included in the post-test. This set-away includes backing-up and retrieving the health data gathered by the smartwatch, stopping data sharing with the research team, and unpairing the smartwatch with their personal devices.

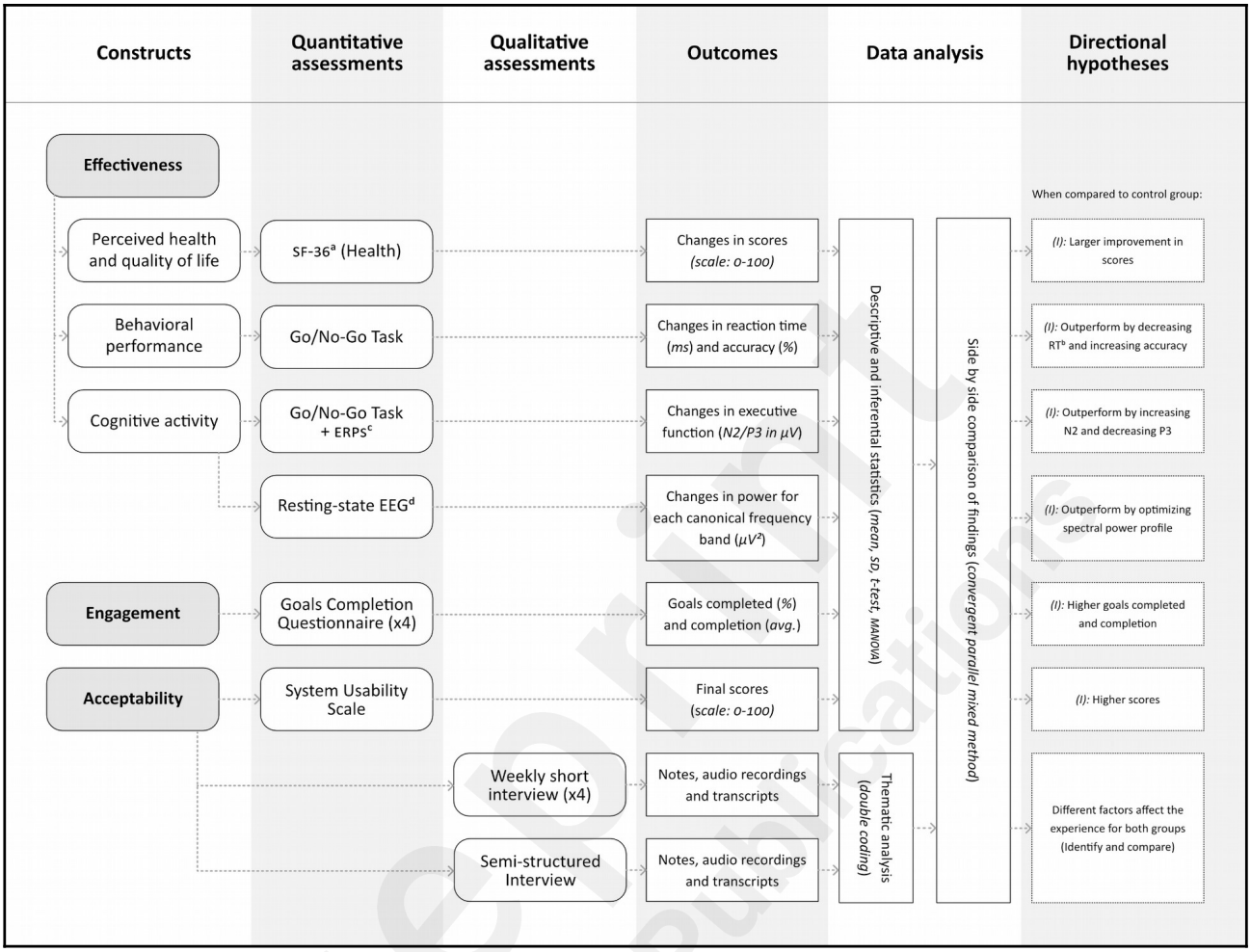
Measurements

Primary Outcome Measures

The overarching purpose of this protocol is to investigate changes in cognition and behavior after using a smartwatch with a healthy lifestyle intervention, and to explore how the experience of the intervention might affect its impact on the brain.
A convergent parallel mixed methods approach (quantitative and qualitative) [27] will be used to investigate three constructs of the smartwatch intervention (**Figure 6**):

- **effectiveness**, which refers to the impact of the intervention on the brain;
- **engagement**, which we define as the participants' interactions and commitment to the intervention;
- **acceptability**, which refers to the participants' subjective perceptions and experiences with the intervention.

Figure 6. Overview of constructs with their corresponding assessments, outcome measures, data analysis and hypotheses.



[a]SF-36: Short Form Health Survey.
[b]RT: Reaction time.
[c]ERPs: Event-related potentials.
[d]EEG: Electroencephalogram.

The constructs of engagement and acceptability are included as binding prerequisites to the effectiveness of the intervention, speaking to the socio-technical complexity of wearable health intervention components [15,28,29]. This approach will provide us a better understanding of what components, such as behavior change techniques included in the smartwatch or unanticipated external factors, might affect the effectiveness and engagement of the intervention [30].

We further operationalize effectiveness in three ways:

1. perceived health and quality of life,
2. behavioral performance,
3. cognitive activity.

The outcome for perceived health and quality of life is indicated by changes in all scores for the SF-36 Health Survey before and after the intervention (Scale: 0-100). The outcome for behavioral performance is indicated by changes in average reaction time of correct go trials (in milliseconds), and accuracy of correct no-go trials for the Go/No-Go task before and after the intervention. Finally, the outcome of cognitive activity is indicated by changes in executive function after the intervention. Executive functions are top-down processes essential for goal-directed coordination of thoughts and behaviour [31]. Inhibition is one of the three core

executive functions, and it is essential for impulse management, focussing of attention, and even the performance of other executive functions [32]. The Go/No-Go task elicits the ERPs N2 and P3, electrophysiological markers of inhibition [16]. Comparative integrity assessments of the N2/P3 before and after the intervention will be used to evaluate changes in inhibitory control. Resting state recordings will be used to obtain the power of each canonical frequency band (delta: 1–4 Hz, theta: 4–8 Hz, alpha: 8–13 Hz, beta: 13–30 Hz, and gamma: >30 Hz) and compare across groups and timepoints.

Engagement outcomes are indicated by the percentage of goals reported as complete at each check-in point, and reported averages of how much of the goals were completed on unsuccessful days. In addition, engagement outcomes for the intervention also will include device-generated logs of the same outcomes provided by the smartwatch.

Lastly, acceptability outcomes are indicated by SUS scores after the intervention (Scale: 0-100), and recorded interviews with notes at each check-in and after the intervention.

Secondary Outcome Measures

In addition to the primary outcomes, we seek to identify interactions amongst the three constructs. Outcomes include descriptions of possible interactions between the constructs of effectiveness, engagement, and acceptability of a smartwatch with a healthy lifestyle intervention throughout the intervention.

Apparatus

Smartwatch

Participants in the control group will use either a GPS-enabled Apple Watch Series 8 or 9 (Apple Inc., Cupertino, CA) during the intervention. Each cohort will use the latest operating system at the launch of the study (i.e., watchOS 11.3.1). To standardize the features in the watch, user interface, and data collected, participants will be instructed not to update the watchOS version after the intervention begins. The smartwatch will facilitate the intervention using features such as real-time feedback and goal completion notifications. WatchOS includes an interface for the completion of goals called activity ring goals comprising three daily goal elements: stand, move and exercise. This interface will be set up using our intervention goals (stand: 1 minute during 12 different hours daily, exercise: 30 minutes daily). In addition, we will set up a goal of 7 hours of sleep in the health app and default visual and haptic notifications related to the completion of these goals will be activated. Apple Watch was chosen because of its widespread adoption [22], which could provide an integral snapshot of the current impact of wearables in the brain.

EEG

The EEG recordings will be conducted using a BioSemi Active Two manufactured by BioSemi B.V. (Amsterdam, Netherlands) with pin-type and flat-type active electrodes. 64 pin-type electrodes will be placed in standard 10-20 international system configuration using a BioSemi headcap. Also, two pin-type electrodes are used for CMS and DRL. Five flat-type electrodes are used for EOG and mastoid locations (See procedure for details). Different headcap sizes will be available for head circumferences ranging from 50 cm to 62 cm.

The system consists of two laptops (one for visual stimuli and another for raw data visualization and recording), respective chargers, mouse, and the BioSemi system. The stimuli laptop will use Presentation (NeuroBehavioral Systems, Inc.), a stimulus delivery and experiment control program for neuroscience. This software allows the coding of the resting state and Go/No-Go tasks, while also

allowing the recording of event codes for data analysis. Event codes are recorded with sub-millisecond temporal precision for stimuli delivery and responses given by the participants. The raw data laptop will use BioSemi ActiView software, a comprehensive acquisition program designed to display all channels and save the data in .BDF format. The sample rate will be set to 512Hz. Finally, the BioSemi system includes an AD-box, a battery box and charger, active electrodes, head caps, USB receiver, cables, conductive gel, plastic syringes, adhesive discs, alcohol wipes and towels.

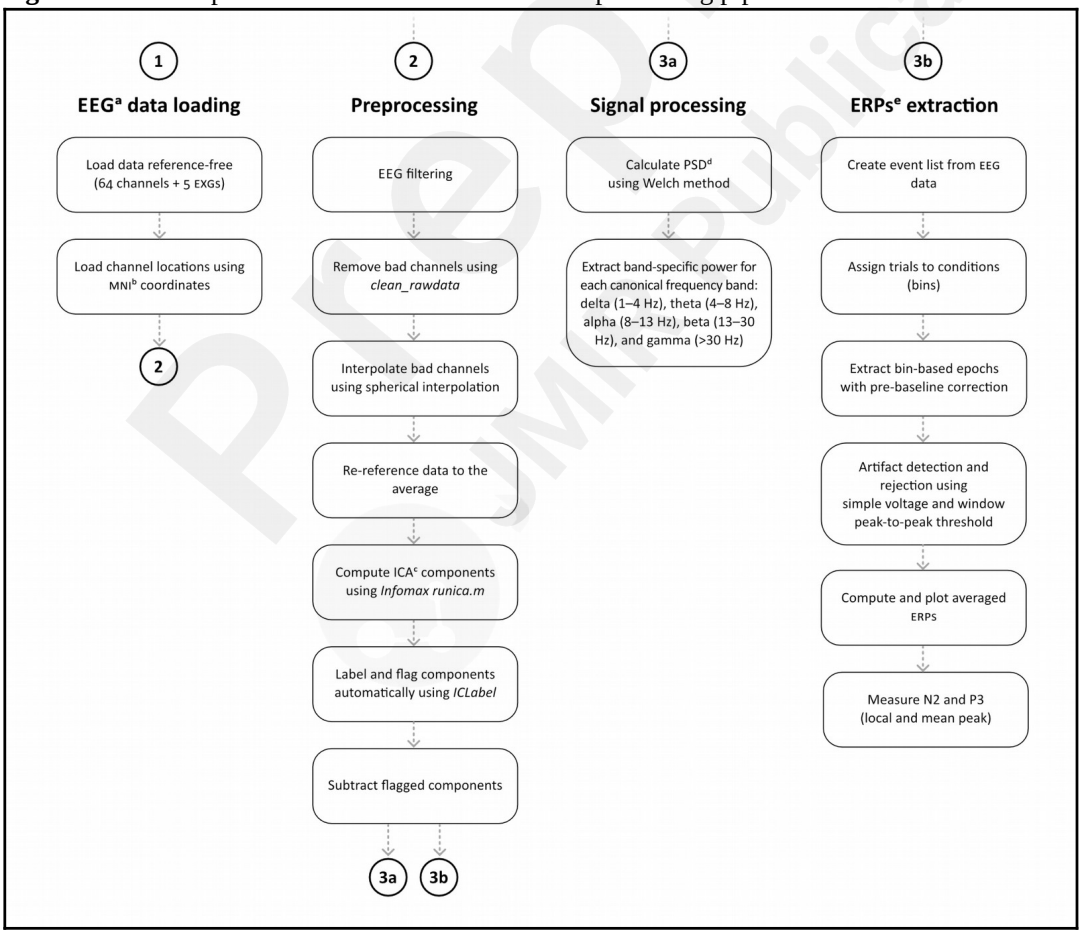
Due to the vulnerability of EEG signals to high noise-to-signal ratio, all data acquisition procedures will be performed in a highly controlled environment [33]. Participants will be isolated in a noise shielded room with controlled lighting conditions. Participants will also be instructed to avoid moving or blinking to reduce discarded data and increase the signal-to-noise ratio.

Data Analysis

EEG Data Processing

Figure 7 shows the EEG-ERP data processing pipeline. EEG data will be preprocessed using EEGLAB [34] (Ver: 2023.0). ERP data will be extracted using ERPLAB [35] (Ver: 9.20). Both toolboxes require the installation of Matlab (The MathWorks, Inc.) (Ver: R2023a).

Figure 7. Visual representation of the EEG-ERP data processing pipeline.



[a]EEG: Electroencephalogram.
[b]MNI: Montreal Neurological Institute.
[c]ICA: Independent Component Analysis.

[d]PSD: Power spectral density.
[e]ERPs: Event-related potentials.

Data Loading

EEG data will be loaded reference-free from the Biosemi .BDF file using the BIOSIG toolbox embedded in EEGLAB. Channel locations will be loaded according to the 64-channel 10-20 system, using corresponding Montreal Neurological Institute (MNI) coordinates.

Preprocessing

EEG signal will be filtered using a low-pass of 30 Hz and a high-pass of 0.5 Hz [36], a roll-off of 24 dB/octave and 4th order IIR Butterworth filter [37]. All 64 scalp channels and 5 ExGs (3 EOGs, 2 Mastoids) will be included. Bad channels will be removed using the EEGLAB plug-in clean_rawdata with a high-frequency noise standard deviation threshold of 4, and channel correlation removal of 0.8 [37]. Removed channels will be interpolated using spherical interpolation. Data then will be re-referenced to the average. Independent Component Analysis (ICA) will be computed using the Infomax runica.m algorithm. We will then use ICLabel for automated component labeling and to flag eye and muscle components with a minimum threshold of 0.9 [37]. Flagged components will be then subtracted from the dataset.

EEG Signal Processing

Spectral power analysis will be conducted on the preprocessed resting-state EEG data. Power spectral density (PSD) will be computed using Welch method for each channel across canonical frequency bands: delta (1–4 Hz), theta (4–8 Hz), alpha (8–13 Hz), beta (13–30 Hz), and gamma (>30 Hz). Band-specific power metrics will be statistically compared across groups (intervention vs. control) and timepoints (pre vs. post-intervention).

ERP Extraction

First, we will create an event list (EventList) from the EEG data. Then, we will assign each trial to one of four predefined bins: 1) correct go trial, 2) incorrect go trial, 3) correct no-go trial, and 4) incorrect no-go trial. After bins are assigned, we will extract bin-based epochs with a time range from −200ms to 800ms after the stimuli was presented, and apply pre-baseline correction. Artifact detection and rejection on epoched data will be done using a combination of a simple voltage threshold of ±200μV to detect large drifts in voltage, and a window peak-to-peak threshold of 150μV to detect artifacts involving sudden voltage changes [38]. The percentage of trials discarded should be lower than 10%. Finally, average ERPs will be computed and plotted. The N2 and P3 components of the ERP will be measured from correct go and no-go trials (bins 1 and 3). Both the maximum voltage (local peak) and the average voltage (mean peak) will be measured for both components between two specific time points. These time points will be defined after a visual inspection of the grand average ERPs from all participants.

Data Analysis Plan

Our convergent parallel mixed methods approach will also involve the analysis of multiple sources of data through quantitative and qualitative methods. Descriptive and inferential statistics will evaluate the hypotheses, while a thematic analysis will uncover factors that might affect the

participant's experience throughout the intervention. This analysis will be done using a combination of tools: JMP, a computer software for statistical analysis (version 16.1, JMP Statistical Discovery LLC), Python scripts for statistical analysis (version 3.13.2, Python Software Foundation), R for statistical analysis (version 4.4.1, R Core Team) using the afex package [39] and NVivo, a computer software for data analysis (version 14, QSR International Pty Ltd).

Primary Criteria Evaluation

Our primary outcomes relate to the intervention's effectiveness, engagement, and acceptability. The research questions (RQs) and directional hypotheses (H) for our primary criteria are the following:

RQ1 (Effectiveness): How does a wearable (with/without) healthy lifestyle intervention impact healthy adults' perceptions of their health, behavioral performance, and cognitive activity over time?

> H1.1 (Health perception): The intervention group will report a larger improvement in SF-36 scores compared to the control group after the intervention.
>
> H1.2 (Behavioral performance): The intervention group will outperform the control group in decreasing reaction time, and increasing accuracy in a Go/No-Go task compared to the control group after the intervention.
>
> H1.3 (Cognitive activity - ERP analysis): The intervention group will show greater improvement of electrophysiological markers of inhibition control by increasing N2 amplitudes and decreasing P3 amplitudes compared to the control group after the intervention [16].
>
> H1.4 (Cognitive activity - Power Analysis): The intervention group will show an optimized spectral power profile post-intervention, compared to pre-intervention spectral power of the intervention group, and spectral power of the control group at all timepoints.

RQ2 (Engagement): How engaging is a wearable amongst healthy adults throughout a healthy lifestyle intervention?

> H2: The intervention group will report a higher number of completed goals, and higher averages of completion on unsuccessful days compared to the control group.

RQ3 (Acceptability): What factors influence how acceptable a wearable is amongst healthy adults during a healthy lifestyle intervention?

> H3: The intervention group will rate the wearable higher in SUS scores compared to the control group guidelines.

Independent samples t-tests will be used to test hypotheses where the primary effect of interest is intervention type (group) on a single dependent variable (health perception for H1.1, system usability scores for H3).

Multivariate analysis of variance (MANOVA) will be used to test hypotheses where the effect of interest includes multiple independent variables (H1.2, H1.3, H1.4, H2). H1.2 will examine the effect of group (intervention or control; between-subjects), assessment (A or B; within-subjects), condition (Correct Go or correct Nogo trial; within-subjects), and electrode (within-subjects) on reaction time and accuracy. H1.3 will examine the effect of group (intervention or control; between-subjects), assessment (A or B; within-subjects), condition (Correct Go or correct Nogo trial; within-subjects), and electrode (within-subjects) on ERP amplitude. H1.4 will examine the effect of group (intervention or control; between-subjects) and assessment (A or B; within-subjects) on canonical frequency band power. Finally, H2 will examine the effect of group

(intervention or control; between-subjects) and assessment (A or B; within-subjects) on goal completion.
Bonferroni-corrected pairwise t-tests will be conducted if the main model is significant, to localize effects. Effect size (eta squared) will be reported.
To identify factors that affect the experience (primary qualitative outcome), a thematic analysis with double coding will be used on the transcripts of recorded interviews and notes at each check-in and after the intervention [40].
An assumption is that if healthy adults in the intervention group perform better in effectiveness tests after the intervention (at post-test) compared to the control group, then the smartwatch had a larger positive impact on their brains. Any other improvement that occurred would have randomly occurred in their everyday activities.

Secondary Criteria Evaluation

Secondary outcomes include interactions between all three constructs. For this, we will follow our convergent parallel mixed methods approach and perform a side-by-side comparison of quantitative and qualitative findings to explore if there is a relation between the constructs of effectiveness, engagement, and acceptability of a smartwatch with a healthy lifestyle intervention throughout the intervention.
In addition, the intervention group's engagement outcomes (goal completion) recorded by the watch will be compared with self-reported goal completion, and differences will be reported.

Data Management

Personal information will be collected but not preserved. Information such as age, gender, job role, test results, EEG data, and interview recordings will be collected and used for analysis. Data retrieved will be de-identified. All the collected data will be coded, and a master list will be used while the study is performed. The master list will be deleted once the data is published. Digital data will be securely stored in firewall-protected servers at SFU. Physical data will be securely stored in a laboratory location with restricted access to personnel involved in this study.

Results

This study was funded from April 2020 to March 2023 by the AGE-WELL Network Centres of Excellence (Precision Mental Health: A stakeholder-informed, Big Data approach to psychological wellbeing - Core Research Project) and from April 2022 to March 2025 by the Pacific Economic Development Agency of Canada (Development of HQP training in machine learning, data mining, and large databases for the Health Tech Industry). In addition, it was reviewed and approved by the Research Ethics Board (REB) of Simon Fraser University (Study number: 30001509). The study will be conducted following REB regulations. Participants enroll in the study using a continuous enrollment process. The first cohort to evaluate the feasibility of the study was conducted from March 2024 to September 2024, while the second cohort is expected to enroll participants starting June 2025. Currently, data for the first cohort is being processed and analyzed. The first results are planned to be published by the end of 2025.

Discussion

To our knowledge, this protocol is the first study to establish a comprehensive guideline to evaluate the impact of wearable health interventions in the brain. Wearable technologies are

expected to exponentially grow in everyday use [2], and have been found to be as effective as psychotherapy or pharmacotherapy treatments in supporting brain health [41]. Therefore, we anticipate a growth of research on their implementation during everyday activities.
Due to the complex and interdisciplinary task of studying the brain, together with the manifold challenges related to the design, evaluation, and implementation of wearable technologies with health interventions for everyday use [6,42], there is an increased need for frameworks that measure their impact while also considering factors such as acceptability and engagement [28]. In this protocol, we propose a convergent parallel mixed methods study that evaluates the constructs of effectiveness, acceptability and engagement using a combination of quantitative and qualitative measurements and analysis. Our measurements make use of established instruments, questionnaires, tasks, and EEG as a brain imaging method. We detail procedures for implementation and adaptation of EEG, including data processing and statistical analysis.
As suggested by our directional hypotheses, we anticipate that participants using a smartwatch in the intervention group will outperform participants in the control group in all three constructs of effectiveness, engagement and acceptability. Furthermore, we anticipate these results will be affected by the overall experience of the intervention, throughout the intervention [14]. We expect to find and report any relation between these outcomes with our proposed convergent parallel mixed methods approach.

Limitations

We acknowledge inherent limitations to our proposed study design. Our protocol is limited to a four week intervention. Significant changes in cognition and behavior have been demonstrated for this duration [16] and it is fast enough to keep pace with innovation in the field [43], but still could be influenced by a novelty adoption effect [11]. Novelty adoption effects decrease over time and are not indicative of long-term impact [44]. In addition, our implementation of weekly check-ins could affect the commitment of participants compared to regular at-home use, potentially influencing results. Future studies could consider implementing a follow-up stage to evaluate two factors: the intervention’s effect and experience after continued use, or the duration of its effect after no longer having access to the intervention. Finally, our current set-up evaluates the default healthy lifestyle intervention included on a widely commercially available smartwatch, the Apple Watch. Although this approach represents a valuable snapshot of how this specific technology is impacting brain health, it is recommended to proceed with caution when generalizing findings to other wearables as the sensors, algorithms, and user experience are not standardized across devices and evolve rapidly over time [6]. Therefore, the evaluation of different devices, as well as the design and development of applications specifically tailored for brain health based on the findings of this study, is recommended.

Conclusion

Our approach contributes to the field of HCI by implementing robust cognitive measurements (EEG signals) in combination with behavioral tasks, user experience evaluation, and self-report instruments before, during, and after the intervention [45]. This combination could inform the design and development of effective and engaging wearable brain health interventions backed up by scientific evidence of its impact.

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Author Contributions

AS contributed study design, draft and edit of the manuscript, principal investigator in data collection, qualitative data analysis, mixed-methods interpretation, and follow-up to future implementations. JF contributed revision of the manuscript for accuracy, contribution to the EEG data analysis, statistical data analysis, and data collection trials. AD contributed revising and editing the manuscript for accuracy. BR contributed to study design and mixed-methods implementation, revising the study protocol and design, revising the manuscript for content accuracy. SM contributed to supervising the project, revising the study protocol and design, revising and editing the manuscript, providing lab setting, equipment, and funding for the study.

Conflicts of Interest

None declared.

Abbreviations

CMS: common mode sense
DRL: driven right leg
EEG: electroencephalogram
EOG: electrooculogram
ERPs: event-related potentials
H: hypotheses
HCI: human-computer interaction
ICA: independent component analysis
ISI: inter-stimulus interval
MANOVA: multivariate analysis of variance
MNI: Montreal Neurological Institute
PAG: physical activity guidelines
PSD: power spectral density
REB: research ethics board
RQs: research questions
RSPM: ravens standard progressive matrices
SF-36: short-form health survey
SUS: system usability scale
UX: user experience

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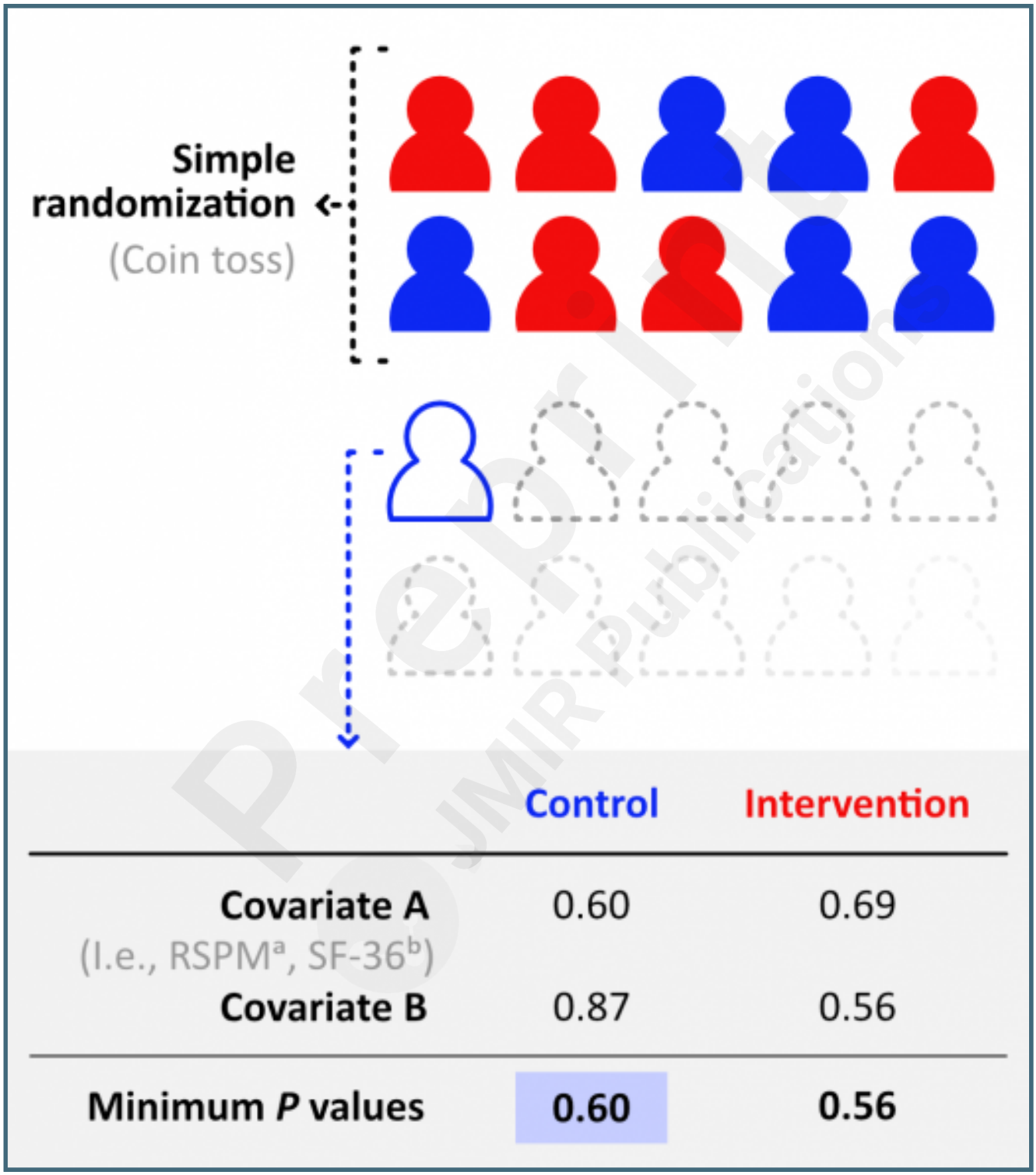
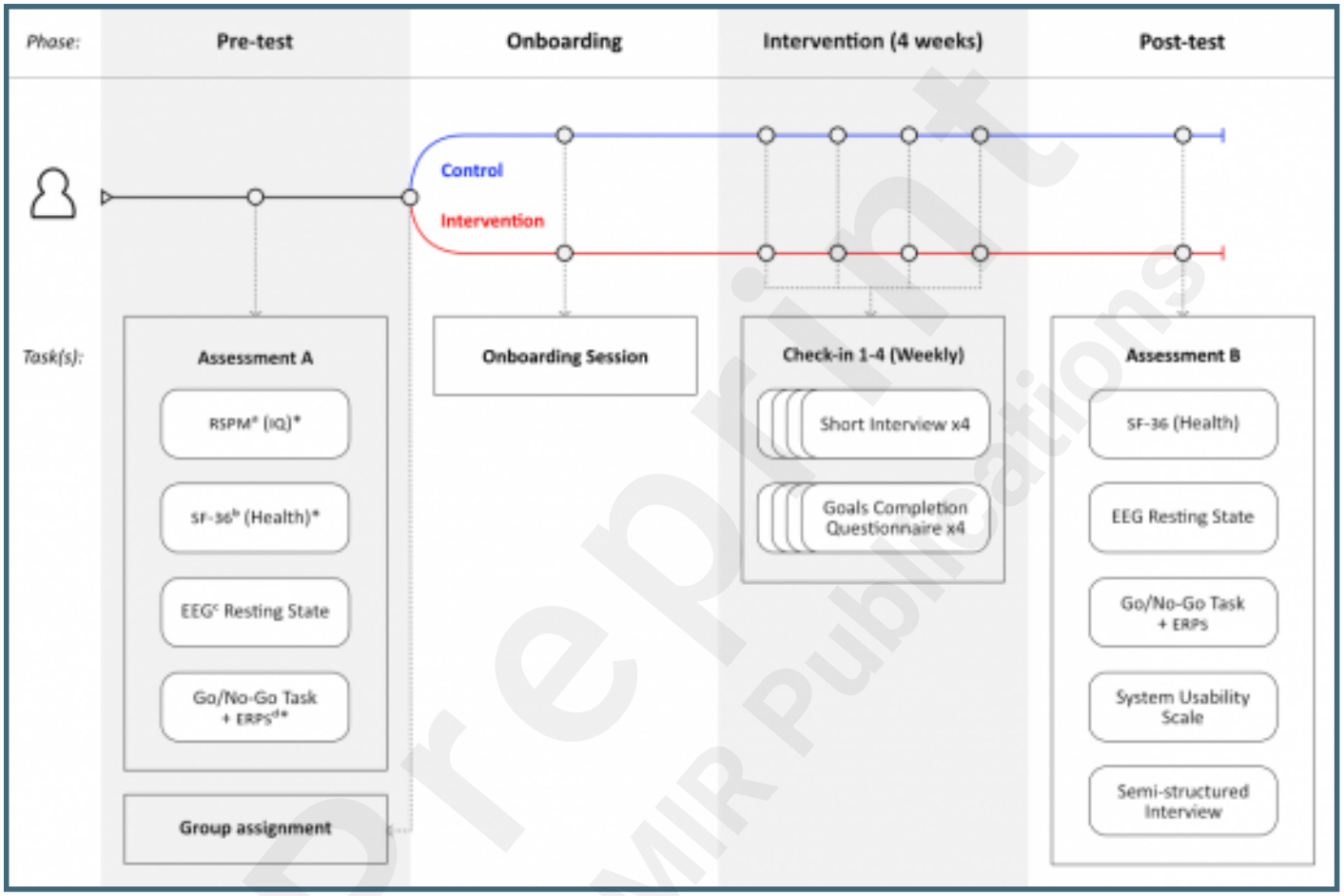
Supplementary Files

Figures

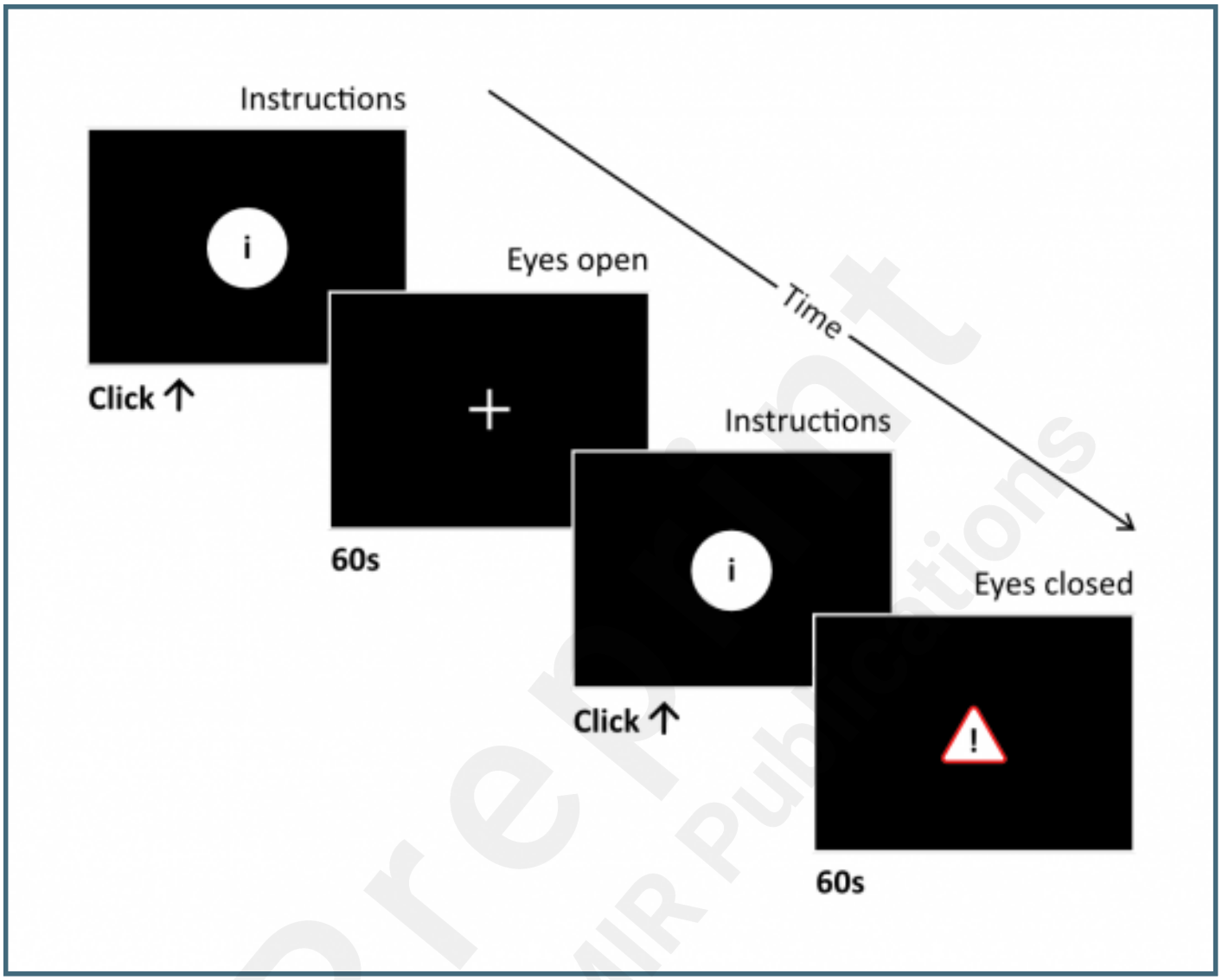
Example breakdown of the first 11 participants group assignments. In this case, the 11th participant will be assigned to the control group because of the higher minimum P value (0.60 > 0.56). aRSPM: Ravens Standard Progressive Matrices. bSF-36: Short Form Health Survey.



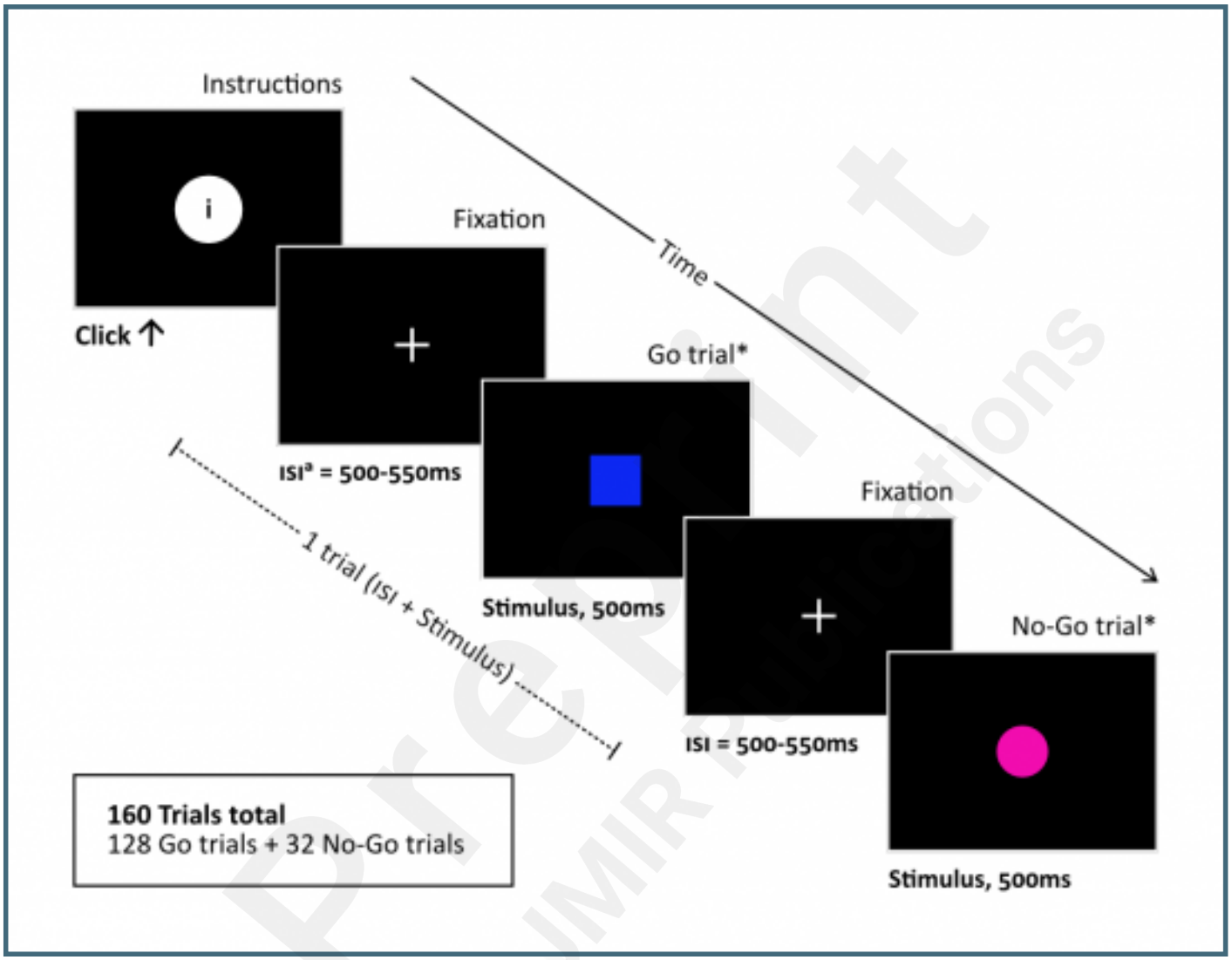
Overview of the study protocol, including all four phases (pre-test, onboarding, intervention, and post-test), tasks, and assessments considered for each task. *Outcome measures used for group assignment in addition to age and sex assigned at birth. aRSPM: Ravens Standard Progressive Matrices. bSF-36: Short Form Health Survey. cEEG: Electroencephalogram. dERPs: Event-related potentials.



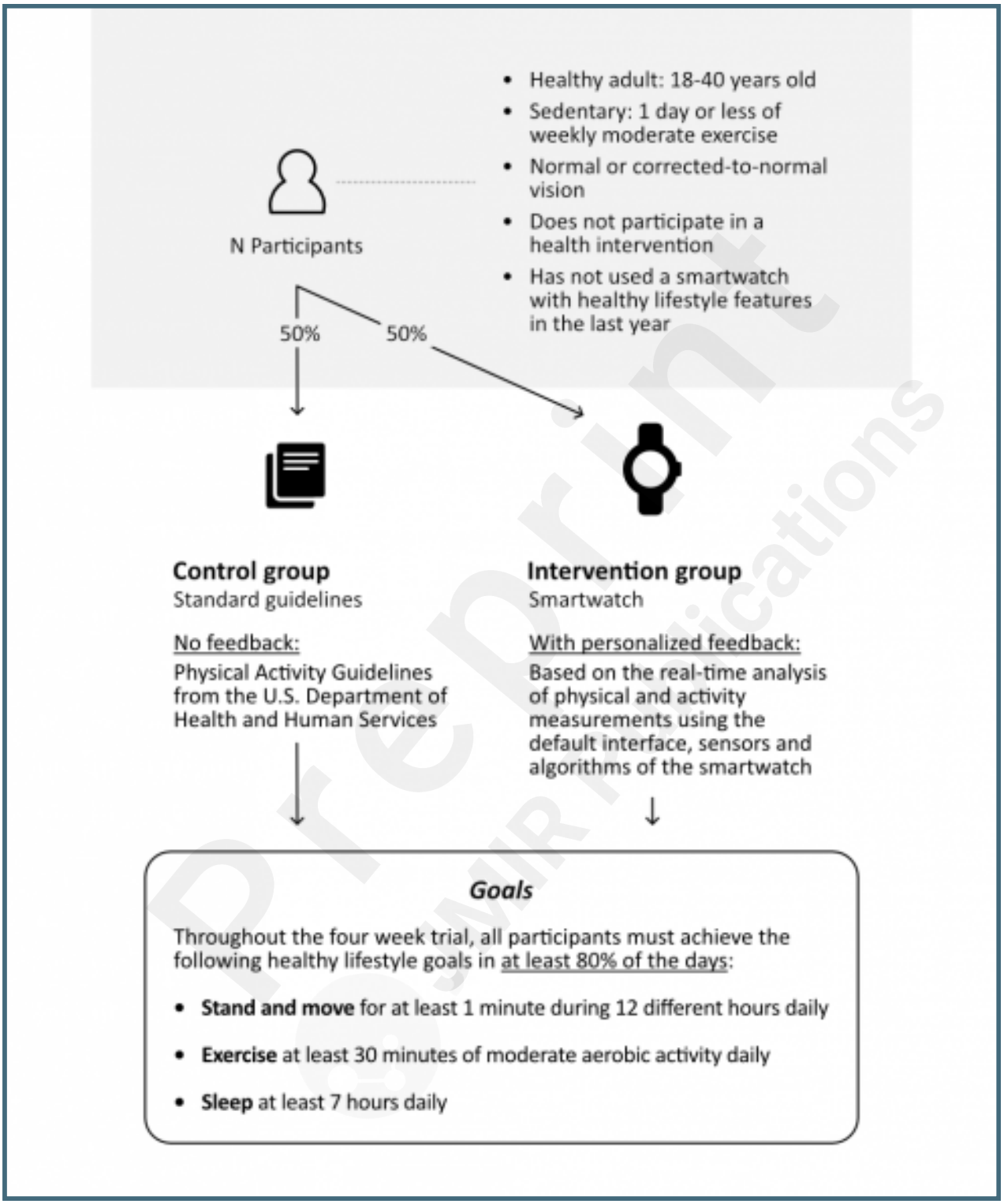
Schematic of the sequence of prompts for the resting state task.



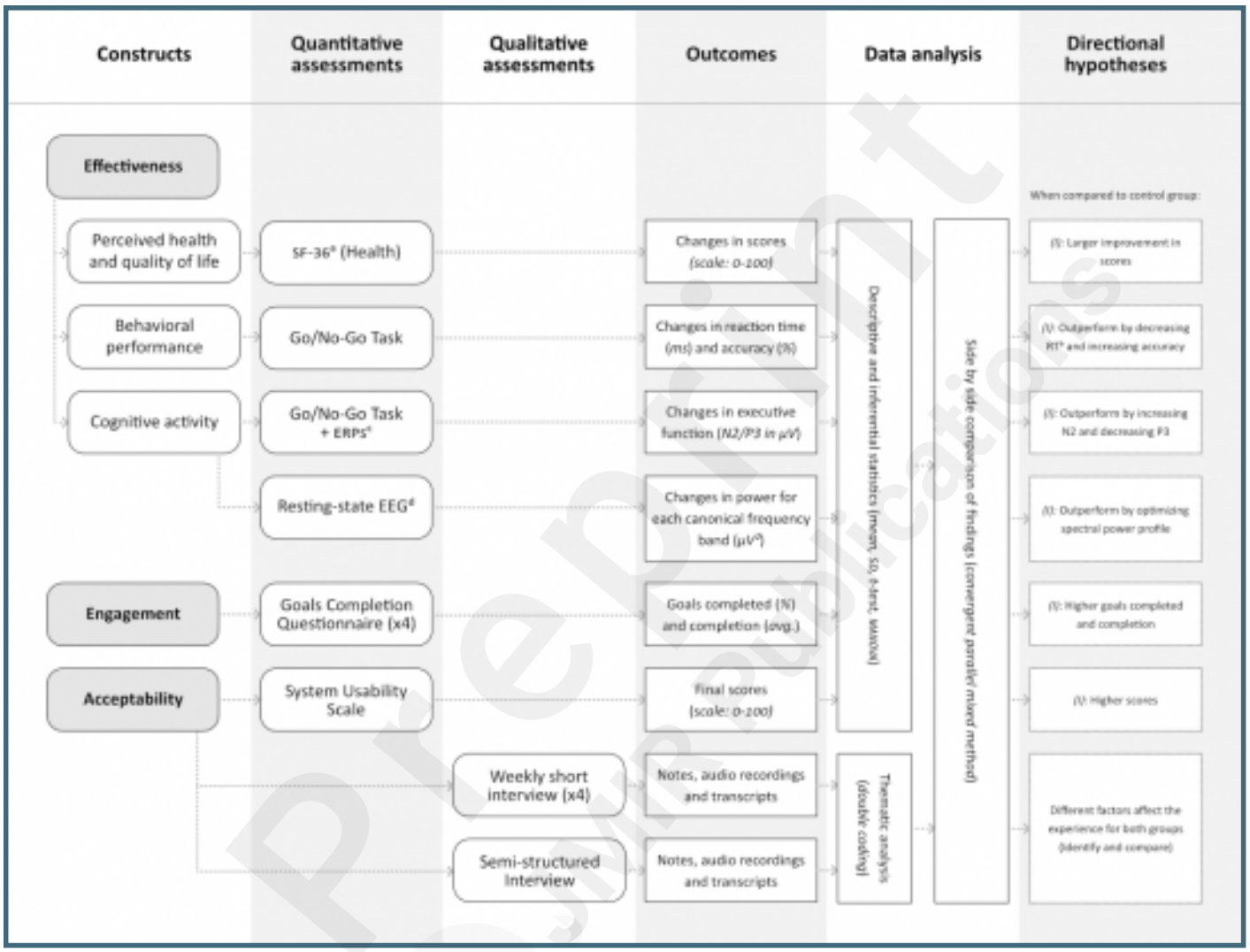
Schematic of the sequence of stimuli in the Go/No-Go task. *The order of go and no-go trials will be randomized, and stimuli (color and shape) will be reversed in the post-test. aISI: Inter-Stimulus Interval.



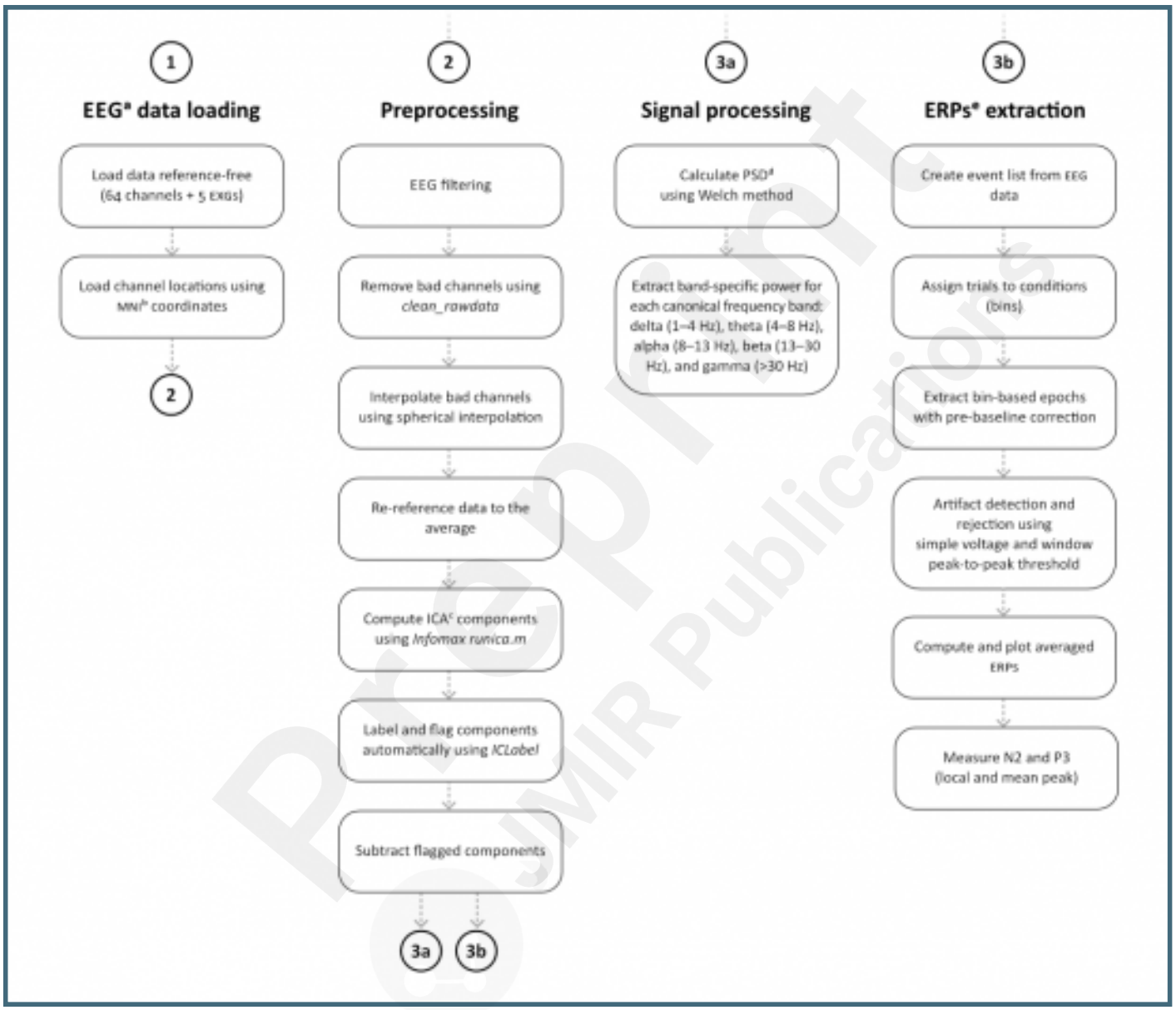
Overview of intervention procedure including goals.



Overview of constructs with their corresponding assessments, outcome measures, data analysis and hypotheses. aSF-36: Short Form Health Survey. bRT: Reaction time. cERPs: Event-related potentials. dEEG: Electroencephalogram.



Visual representation of the EEG-ERP data processing pipeline. aEEG: Electroencephalogram. bMNI: Montreal Neurological Institute. cICA: Independent Component Analysis. dPSD: Power spectral density. eERPs: Event-related potentials.



Multimedia Appendixes

Script for all protocol phases: pre-test, onboarding, intervention, and post-test.
URL: http://asset.jmir.pub/assets/26a2a217c52ccfa32ce3696d20bbb374.pdf