Free-living Motor Symptoms Evaluation in Parkinson's patients through Smartwatches: Protocol for defining digital biomarkers

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Table of Contents

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Abstract

Background: Monitoring motor symptoms in patients with Parkinson's disease (PD) presents significant challenges due to the complex nature of symptom progression, variations in medication responses, and the fluctuations that can occur throughout the day. Traditional neurological visits provide only a limited perspective of a patient's overall condition, with challenges in achieving accurate and objective assessments of symptoms. To bridge this gap, extended monitoring in non-clinical settings could play a critical role in personalizing treatments and improving their efficacy. Wearable devices have emerged as potential tools for assessing PD symptom severity; however, studies integrating both in-clinic and free-living conditions, as well as multi-day monitoring, remain scarce. Defining digital biomarkers that provide valuable insights into motor symptoms could enable comprehensive monitoring and tracking of PD in various contexts, facilitating more precise medication adjustments and the implementation of advanced therapeutic strategies.

Objective: The objective of this study is to collect a dataset for the proposal and definition of digital biomarkers of PD motor symptoms using wearable devices. Data will be gathered in a supervised setting and continuously in a remote free-living context during their normal daily activities, including PD patients and healthy controls. The goal is to identify reliable digital biomarkers that can effectively distinguish PD patients from healthy controls and classify disease severity in both supervised and unsupervised free-living environments.

Methods: This article outlines a protocol for an observational case-control study aimed at assessing motor symptoms in PD patients using a smartwatch. The smartwatch will record accelerometer, gyroscope, and physical activity data. Participants will be instructed to perform a series of exercises guided via an smartphone. Measurements will be collected in two settings: a supervised clinical environment, with motor symptoms assessments conducted at the beginning and end of the study, and in an unsupervised free-living context for one week. In both settings, participants will be required to wear the smartwatch while performing the same set of exercises. In their daily routine, participants will be required to wear the smartwatch continuously throughout the day, removing it only at night for charging.

Results: Subject recruitment and data collection started in December 2024 and will proceed until the spring of 2025. The planned sample size includes 15 participants with PD and 15 healthy controls.

Conclusions: This study aims to generate a dataset of accelerometer and gyroscope signal data recorded from PD patients at various stages of the disease, alongside data from a control group, enabling robust comparative and impactful analyses.

Additionally, the study seeks to develop analytical techniques capable of tracking PD symptoms in real-life scenarios, both in everyday settings and clinical environments. Clinical Trial: ClinicalTrials.gov NCT06817772; https://clinicaltrials.gov/ct2/show/NCT06817772

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Abstract (max 450 words)

Background: Monitoring motor symptoms in patients with Parkinson’s disease (PD) presents significant challenges due to the complex nature of symptom progression, variations in medication responses, and the fluctuations that can occur throughout the day. Traditional neurological visits provide only a limited perspective of a patient’s overall condition, with challenges in achieving accurate and objective assessments of symptoms. To bridge this gap, extended monitoring in non-clinical settings could play a critical role in personalizing treatments and improving their efficacy. Wearable devices have emerged as potential tools for assessing PD symptom severity; however, studies integrating both in-clinic and free-living conditions, as well as multi-day monitoring, remain scarce. Defining digital biomarkers that provide valuable insights into motor symptoms could enable comprehensive monitoring and tracking of PD in various contexts, facilitating more precise medication adjustments and the implementation of advanced therapeutic strategies.
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Trial Registration: ClinicalTrials.gov NCT06817772; https://clinicaltrials.gov/ct2/show/NCT06817772
Keywords: Parkinson’s disease; movement analysis; wearable devices; smartwatch; home monitoring; digital biomarkers.

1. Introduction

1.1. Background

In the context of an increasingly aging society characterized by an inverted population pyramid, the treatment and management of neurodegenerative diseases represent a significant challenge. In 2013, the World Health Organization recognized neurodegenerative diseases as *"a global health problem that must be addressed without delay for humanitarian, social, and economic reasons"* [1]. The humanitarian aspect arises from the profound physical, psychological, and emotional toll on patients and their families, which impacts their quality of life as well as their personal, social, and professional development. From a social perspective, these diseases contribute to significant human losses and years of life lived with disability. They also adversely affect productivity, as exemplified in Spain, where more than 50% of caregivers—predominantly wives—are compelled to leave their jobs [2]. Economically, the long-term medical and supportive care required poses a substantial challenge to the sustainability of health systems. A review estimated that the cost of neurodegenerative diseases (combined with mental disorders) in the European Union amounted to €798 billion. Of this, 37% was attributed to direct healthcare costs, 23% to direct non-medical costs, and 40% to indirect costs. [3].
Parkinson's disease (PD) exemplifies this issue, with the number of affected individuals rising by 250% between 1990 and 2015 [4]. In Spain, a new case of PD is diagnosed approximately every 45 minutes, with 15% of these cases occurring in individuals under the age of 45 [5]. PD is a progressive neurodegenerative disorder characterized by the selective degeneration of dopaminergic neurons in the substantia nigra pars compacta, which supports the cortico-subcortical network, which facilitates limbic, associative, cognitive, and motor functions [6]. In early stages, PD often exhibits non-motor dysfunctions, including impairments in working memory, executive function, attention, visuospatial capacity, and semantic fluency, which may eventually progress to dementia [7]. In advanced stages, motor symptoms such as tremor, bradykinesia, postural instability, and rigidity become more pronounced [8].
Currently, PD has no cure. Treatment strategies typically involve pharmacological and surgical interventions, often complemented by non-pharmacological therapies [9]. Pharmacological

treatments focus on restoring dopamine levels to preserve motor function for as long as possible [10]. While effective in managing hypokinesia (loss of movement) and tremor, these therapies remain beneficial within a therapeutic window of 5 to 10 years, after which 50% to 80% of patients develop dyskinesias (involuntary muscle movements). Additionally, certain patients exhibit resistance to these treatments [11].

Non-pharmacological interventions are crucial for enhancing patients' quality of life [12]. These include traditional treatments like physical exercise, physiotherapy, occupational therapy, or cognitive training, among others [13], [14], [15]. Experimental approaches, including non-invasive neurostimulation techniques like transcranial direct current stimulation [16], are also being explored for their potential to improve symptom management.

The diagnosis of PD is primarily clinical, relying on a detailed anamnesis based on information from the patient and their family, combined with a physical examination [17]. These consultations serve to conduct clinical assessments, adjust medications, and prescribe exercises or therapies, thanks to several scales, with the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) [18] being the most widely used. However, the time allocated per patient during these visits is limited [19]. Reflecting this constraint, numerous resources, including guidelines, websites, and individualized workshops, have been developed to help patients and caregivers prepare effectively for their neurologist appointments [20], [21], [22], [23].

Recent studies have highlighted the suboptimal accuracy of clinical diagnoses for PD, because the techniques are inadequate for capturing the nuanced and fluctuating nature of PD symptoms, which can vary significantly throughout the day [24]. Clinical assessments, conducted infrequently during brief consultations, fail to provide a comprehensive understanding of patients' conditions in their everyday lives [25]. This limitation underscores the need for continuous monitoring tools to complement periodic clinical evaluations.

To enhance diagnostic resources for objective monitoring, digital health technologies—particularly wearable devices—offer significant potential for optimizing health management [26]. These technologies can serve as complementary clinical tools, supporting tasks including early diagnosis and the objective monitoring of PD symptoms over time [27]. Wearable devices offer a discreet and user-friendly solution for patients that not only alleviate the burden on patients to recall and manually record symptom information but also can offer systematically organized data on symptom evolution [28]. This can be achieved using digital biomarkers [29], which enable the objective assessment of disease progression and the impact of treatments or therapeutic interventions in chronic conditions like PD.

1.2. BioCliTe Project

Digital BIOmarkers for the assessment of motor status in Parkinson's disease patients with CLInical and ThErapeutic application (BioClite) is a project funded by the Ministry of Science and Innovation of Spain (No. PID2021-123708OB-I00) that aims to enhance PD monitoring using wearable technology.

The BioClite project responds to the growing need for objective assessment tools to improve the management and long-term monitoring of PD using wearable devices, specifically smartwatches. By employing this technology, the project aims to improve the accessibility of medical care and eliminate physical barriers between patients and healthcare providers.

The project employs a dual-monitoring approach: guided exercises conducted in controlled environments, where participants perform specific tasks to capture motor patterns associated with PD, and free-living activities, where data is collected from participants during their daily routines. By including free-living monitoring, this methodology allows for continuous data collection without interrupting patients' everyday activities, providing a more natural and unobtrusive experience compared to traditional methods.

Data labelling plays a crucial role in the project, using two main methods: algorithmic tagging, where custom-designed algorithms automatically analyze collected signals to identify significant motor events, and the use of external beacons and markers to link time points with contextual information, improving the accuracy of the tagging process. The combination of these approaches can support the collection of a comprehensive, annotated dataset that supports the development of algorithms for PD detection, predict PD status, and personalized therapeutic strategies.
Through the collection of motor activity data, primarily in real-world environments, the project aims to develop digital biomarkers that provide valuable insights into PD symptoms, particularly tremors and bradykinesia.
The BioClite project contributes to more precise symptom tracking and the advancement of wearable technology in PD management by enabling continuous and unobtrusive monitoring, ultimately enhancing patient care and advancing scientific research in the field.

2. Methods

2.1. Inclusion and Exclusion Criteria

For the PD cohort, the main inclusion criterion is a diagnosis of Parkinson's disease (PD) based on the UK Brain Bank criteria. All subjects in this group were recruited from individuals affiliated with Asociación Parkinson Madrid (APM), ensuring access to a well-defined population actively engaged in PD care and support.
The control subjects are not selected regarding age alignment with the PD patients, as both groups are recruited and analyzed concurrently. While this design choice may introduce variability, age will be included as a covariate in statistical analyses to account for its potential impact on the results. Additionally, prioritizing inclusivity over strict matching allows for a broader understanding of how the proposed biomarkers may generalize across diverse populations.
The common inclusion criteria established for participants with PD and control groups require participants to:

- Wear the study devices on the hand most affected and dominant by the condition (for PD patients) or the dominant hand (for controls), which must also be the hand primarily used in free-living activities.
- Be capable of performing prescribed exercises independently.
- Maintain daily functioning without dependence on caregivers.

To ensure a representative sample, efforts will be made to achieve a gender balance across the study population. Additionally, participants must meet an age requirement ranging from 30-80, reflecting the study’s focus on middle-aged and older populations typically affected by PD [30].
Specific inclusion and exclusion criteria for the PD group have been designed to enhance the homogeneity of the sample:

- Eligible participants must have minimal or mild disease severity, defined by a Hoehn and Yahr scale score of ≤ 2.5.
- Participants must not experience motor symptom fluctuations throughout the day.
- Individuals who have undergone deep brain stimulation, used dopamine infusion pumps, or have conditions mimicking PD symptoms (e.g., progressive supranuclear palsy, Lewy body dementia, multiple system atrophy, or other parkinsonian syndromes) are excluded.

2.2. Recruitment Process

The recruitment of new participants begins with an initial contact, conducted either in person or by telephone, during which a concise overview of the study's purpose and procedures is provided. If the prospective participant expresses interest and meets the inclusion criteria, they are invited to proceed

with the next steps.
For participants in the PD group, an appointment is arranged at the APM, while control group participants attend a meeting at the Escuela Técnica Superior de Ingenieros Industriales at Universidad Politécnica de Madrid (ETSII-UPM). During these sessions, the study's objectives, procedures, and expectations are thoroughly explained to ensure participants have a comprehensive understanding of their role and responsibilities.
To formalize their participation, individuals are asked to review and sign an informed consent form, in compliance with ethical guidelines and regulatory standards.

2.3. Study Design

This study comprises one week of free-living monitoring of 15 participants with PD and 15 healthy control subjects. The proposed number of participants in this study is comparable to those found in the literature for defining biomarkers in PD [29] or for remote monitoring of PD motor symptoms [31]. All participants will undergo the same experimental protocol, which includes:

1. A baseline assessment to establish initial measures.
2. A one-week period of unsupervised free-living activity monitoring to capture naturalistic data.
3. A final evaluation to reassess clinically and compare with baseline results.

The study schema is illustrated in Error: Reference source not found, providing an overview of the structured protocol and its key phases.

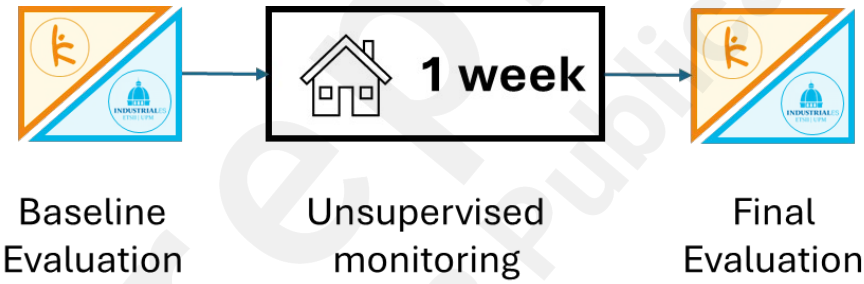

Figure 1: Overview of the experimental protocol of the study..

Participants will engage in a series of standardized exercises and a structured free-living activity conducted at home. The findings from this study will establish a foundation for future research focused exclusively on assessing free-living activities without requiring patients to perform any predetermined tasks.
Upon recruitment, each participant begins the experimental protocol with a meeting at APM (for the PD group) or at the ETSII-UPM (for the control group). During this visit, a baseline assessment of the participant's motor symptoms is conducted using the Monipar set of exercise [32]. This set comprises eight tasks specifically designed to evaluate various motor symptoms of PD.
Seven of these exercises are adapted from the MDS-UPDRS III scale, specifically resting tremor amplitude (item 3.17), postural tremor of the hands (item 3.15), finger tapping (item 3.4), hand movements (item 3.5), pronation-supination movements of the hands (item 3.6), arising from a chair (item 3.9), and gait (item 3.10). The eighth exercise, proposed by the research team, complements the evaluation by addressing additional motor symptoms. These tasks are routinely used by neurologists in clinical settings, and participants are generally familiar with performing them, ensuring ease of implementation.
For the PD group, a specialized Parkinson's physiotherapist performs all the assessments, using the MDS-UPDRS III scale to ensure consistency and reliability across participants.
Also, to facilitate the transition from controlled clinical assessments to unsupervised free-living

conditions, participants are required to perform a specific free-living activity. This activity involves beating eggs for one minute, a common daily task familiar to most individuals. The repetitive nature of this activity makes it particularly useful for evaluating bradykinesia [33], [34] under free-living conditions. The selection of this activity was informed by consultations with nurse practitioners, patients, and therapists, all of whom stated its potential relevance and significance for assessing bradykinesia.

Following the baseline evaluation, participants proceed with the study in free-living, unsupervised conditions, maintaining their normal daily routines. They are required to wear the smartwatch throughout the day for one week, removing it only at night for charging.

The smartwatch records accelerometer and gyroscope data during a designated 4-hour period each day. This recording window, determined by the participants at the study's outset, accommodates their individual schedules and availability. Participants are expected to perform a series of tasks within this defined period, which will remain consistent throughout the 7 days of the study.

In the 4-hour recording period, each participant is asked to perform the Monipar exercises daily under free-living conditions and without supervision. Participants are encouraged to complete the full set of exercises each day, ideally at the same hour of the day.

Completing this set of exercises takes approximately 7 to 8 minutes daily, which does not significantly disrupt patients' daily lives. Incorporating them as a routine task facilitates easier recall and adherence. In addition, participants will be required to perform the specific free-living activity of beating eggs for 1 minute each day. So, the participants will need to set aside 10 minutes each day to perform these two tasks.

Additionally, participants will complete a daily paper questionnaire, to help to contextualize the 4-hour recorded sensor data. This questionnaire captures the timing of key activities such as breakfast, lunch, and dinner; rest periods (useful for assessing resting tremors); and medication intake. Participants are also encouraged to include any relevant comments for each day, such as forgetting to wear the smartwatch or if the device was completely discharged.

As participants are required to wear the smartwatch throughout the day, their physical activities, such as walking, running, or cycling, are automatically recorded and labeled by the device, using the smartwatch's own applications [35]. The physical activities are characterized by step count, distance and calories burnt in each session. This automatic labeling allows any physical activity that occurs during the designated 4-hour signal recording period to correlate with the acquired accelerometer and gyroscope data, enhancing the contextual understanding of the recorded measurements.

After one week of free-living monitoring, participants return to APM for a final evaluation, conducted in the same manner as the baseline assessment. This includes performing the Monipar exercises under the guidance of the Parkinson's physiotherapist (for the PD group), completing the specific free-living activity and filling out a questionnaire to assess the comfort and usability of the smartwatch, report any issues encountered, and provide additional observations or feedback.

2.4. Devices Used in the Study

This study uses two different types of devices: a smartwatch (Samsung Galaxy Watch5) and a smartphone (Samsung Galaxy A14). The smartwatch serves as the primary measuring tool, responsible for recording all generated data throughout the study. In contrast, the smartphone is used to display instructions and label the proposed activities.

Figure 2 illustrates the devices used in this study. The home screen of the smartphone displays two distinct icons representing the applications participants will use to complete the activities. A contact telephone number is displayed on the wallpaper (blurred for privacy purposes). Additionally, the smartwatch screen is intentionally designed to display only essential information —such as the time, date, and battery status—to ensure user-friendliness and minimize distractions for participants.

Figure 2: Devices used in this study: Smartphone (left) and smartwatch (right).

The smartwatch incorporates a LSM6DS0 module, integrating a 3-axis digital gyroscope and a 3-axis digital accelerometer, which facilitate the recording of both acceleration and angular velocity. The smartwatch configuration was set to prevent the collection of unnecessary data, such as location, audio, or video to ensure data relevance and privacy.

Sensor’s data is captured using an Android Wear OS custom application developed by the research team, configured to acquire data at a sampling rate of 50 Hz from each sensor. This frequency was chosen because it is well-suited for analyzing PD motor symptoms, which typically frequency range is 0-20 Hz band [36].

Additionally, this custom application facilitates the scheduling of accelerometer and gyroscope signal recordings. In this study, a period of 4 hours per day is chosen for the free-living monitoring week. Continuous recording throughout the day is avoided for two primary reasons: to preserve participants' privacy—since certain activities could be inferred from these sensor data—and to minimize battery consumption. With these considerations, data from the accelerometer and gyroscope are recorded for a duration of four hours, during which the participants must perform the proposed activities.

In addition, the smartwatch is responsible for collecting data related to the physical activity performed by each subject all day, obtained from the smartwatch's dedicated applications.

On the other hand, the smartphone functions as a user interface, facilitating participants' execution of both the Monipar activity and the specific free-living activity. This was achieved through two dedicated applications designed to display and playback the instructions necessary for performing these tasks effectively.

While the applications were identical in functionality, each was designated for a specific task—one for the Monipar activity and the other for the specific free-living activity. This differentiation served two purposes: providing participants with the flexibility to perform each activity at their convenience and accommodating the additional preparation required for the specific free-living activity.

Figure 3 illustrates the interface of the Monipar application, while Figure 4 depicts the layout of the application for the specific free-living activity.

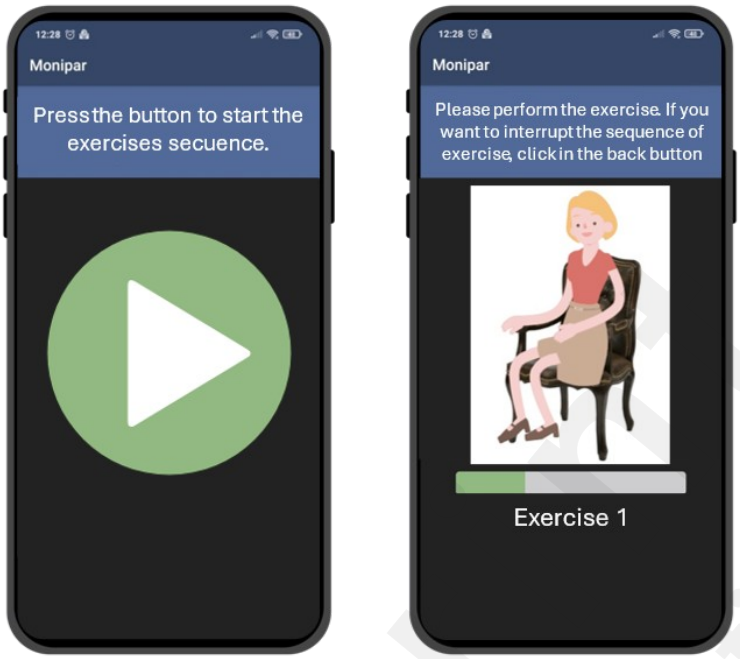

Figure 3: Interface of the application related to the Monipar activity: (left) Start screen, (right) Activity screen.

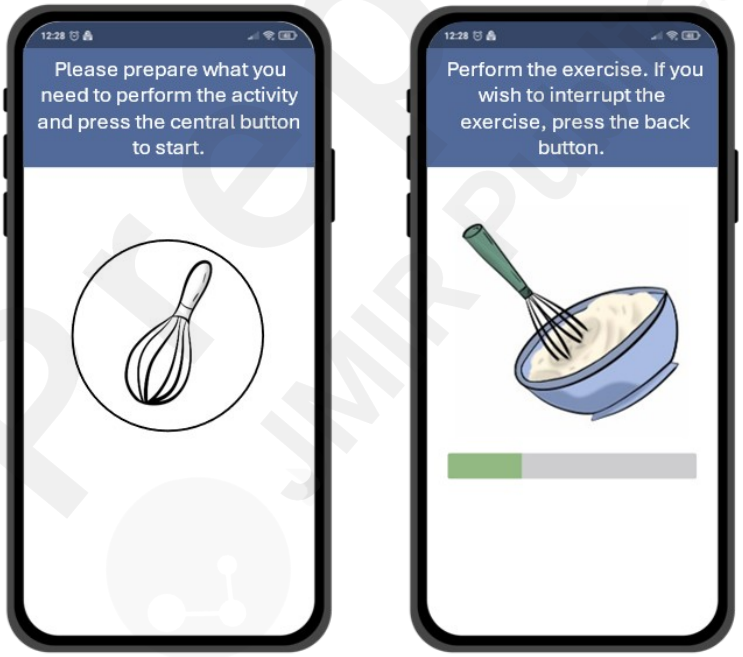

Figure 4: Interface of the application related to the specific free-living activity: (left) Start screen, (right) Activity screen.

The smartphone synchronizes with the smartwatch, tags each activity performed and, upon completion of the study with each participant, integrates the data recorded by the smartwatch with these labels. This process ensures accurate data labeling, aligning the sensor measurements with the corresponding activities for subsequent analysis.

The smartphone is set up to prevent the collection of unwanted data, such as location, audio, or video. Additionally, participants are restricted from making calls or accessing applications unrelated to the study. To address potential participant inquiries, a contact phone number for one of the researchers is set as the device's wallpaper.

2.5. Data Collection

The proposed system is designed for dual functionality, allowing use in both supervised clinical settings and unsupervised daily life scenarios. Although all devices involved operate independently, they are temporally synchronized via Bluetooth, ensuring simultaneous data collection and seamless integration of information from multiple sources.

The smartwatch serves as the primary device for recording data, while the smartphone facilitates the capture of time stamps for activity labeling. Data extraction and processing will occur post-study using a desktop computer. Figure 5 illustrates the architecture of the data acquisition system during and post the study.

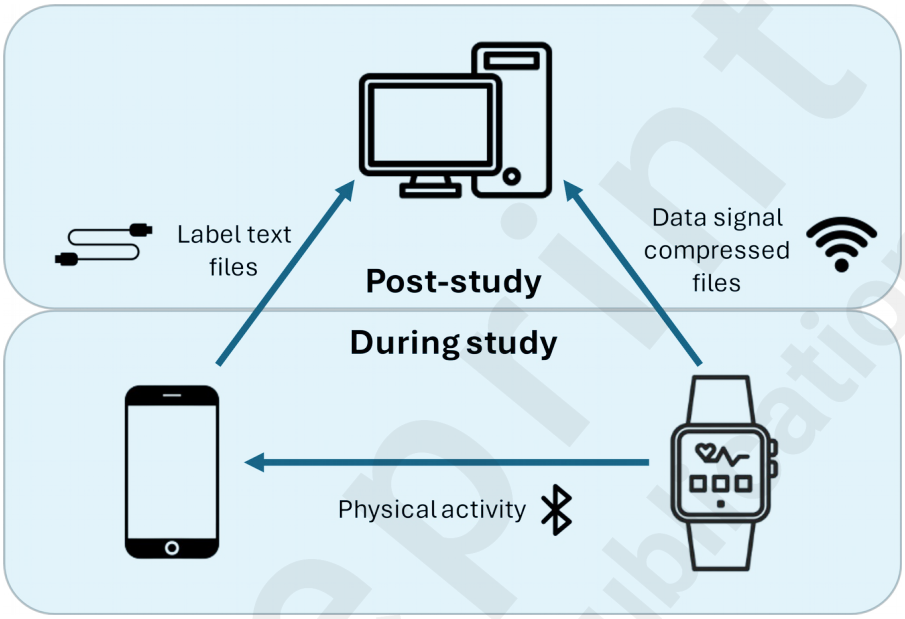

Figure 5: Structure of the data acquisition system.

The smartwatch worn by the participant acquires data from the accelerometer and gyroscope sensors for a duration of 4 hours each day. The data is recorded at a frequency of 50Hz and stored in a text file in the device memory. Once the specified recording period is completed, the text file is saved in a compressed format (zip), and the original text file is deleted. This compression is done to prevent the risk of memory saturation on the device, as text files take up approximately four times the space of compressed files. This ensures that all daily data files are saved and stored without issue on the device. These compressed files remain on the smartwatch until the device is retrieved at the final study visit.

Physical activity data will gather using the device's built-in applications, temporarily stored on the watch, and periodically transmitted via Bluetooth to the smartphone. The smartphone then retains this information until the study concludes.

The smartphone also generates text files containing timestamps that indicate the start and end of each exercise performed. Since the exercises are tracked using two different applications, two separate label files are generated each day: one corresponding to the 8 exercises of the Monipar sequence and the other to the specific free-living activity. These text files are stored on the smartphone until the end of the study.

Upon completion of the study and the return of the devices by the participants, the collected data is extracted. The extraction process differs based on the type of wearable device, though in both cases it requires the use of a computer. For the smartphone, text files containing the temporary labels are extracted via a direct cable connection to the computer. Conversely, for the smartwatch, the compressed data files from the inertial sensors are retrieved over a Wi-Fi connection, ensuring that both the watch and the computer are connected to the same network.

2.6. Data Analysis

The resulting database from the data collection campaign will comprise signals from the three axes of the smartwatch's accelerometer and gyroscope. This data will be divided into three distinct parts. First, it will include the evaluation of the sequence of 8 Monipar exercises, conducted both in supervised and labelled conditions following the MDS-UPDRS III scale, as well as in unsupervised free-living conditions. Second, it will encompass the performance of the specific free-living exercise, 1 minute of beating eggs, performed under supervised conditions at the association and under unsupervised free-living conditions. Finally, the database will contain the daily recording of 4 hours of free-living activity, accompanied by the physical activities performed during the day.

A comprehensive data analysis will be proposed to identify appropriate indicators and validate their effectiveness. Various application scenarios will be proposed based on the collected data, providing insights into the potential applicability of these biomarkers in diverse clinical and therapeutic contexts.

A set of biomarkers will be defined for the identification of PD patients by comparing their data with that of healthy subjects. Another collection of biomarkers will be calculated to predict MDS-UPDRS scores in PD patients using the labeled sessions, enabling a more detailed understanding of the relationship between the recorded signals and clinical evaluations.

Additionally, a comparative analysis will be undertaken using the previous or new biomarkers between measurements collected in supervised clinical contexts and those recorded in unsupervised, free-living conditions. This will help determine the consistency and reliability of the data across different contexts. Furthermore, the study will explore the correlation between the specific free-living exercise, which is strongly linked to bradykinesia, and the MDS-UPDRS exercises of the Monipar sequence. This correlation will be examined for both data collected at the APM and at the participants' homes, providing insights into how specific activities reflect the motor symptoms in PD patients across diverse settings.

To define these potential biomarkers, data analysis methods are developed and organized according to a data-analysis workflow. Since the entire database is based on the triaxial accelerometer and gyroscope signal, the pipeline will be applied to the whole database. Figure 6 shows the proposed pipeline. All data analysis will be conducted using Python and MATLAB.

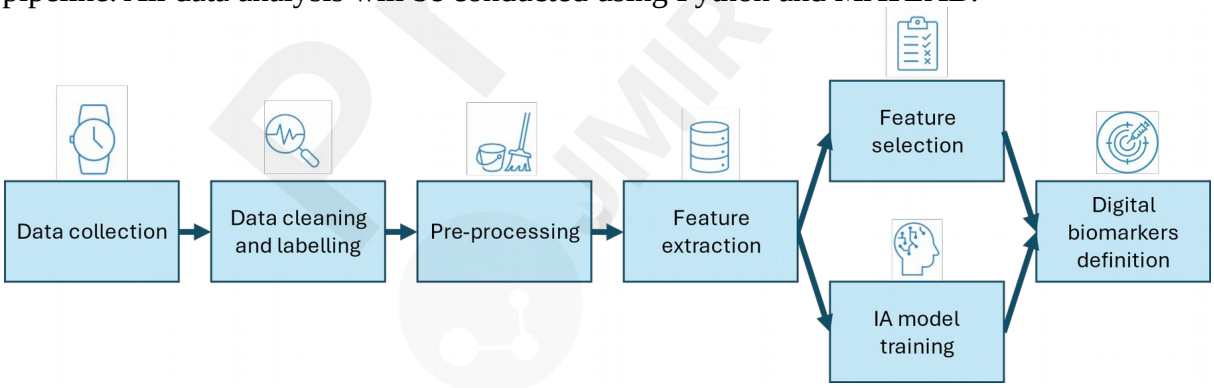

Figure 6: Data analysis pipeline.

Firstly, the correct recording and collection of the expected data for each participant will be verified by ensuring the proper saving of the files. Once confirmed, the data will be labeled by combining the signals collected from the smartwatch with the activity tags generated by the smartphone. The 8 exercises of the Monipar sequence and the specific free-living activity will be tagged, with automatic tagging enabled by the synchronization between the two devices. However, a manual check will be conducted to ensure an accurate synchronization of the start and end times for each tagged activity.

The sessions conducted at the beginning and end of the study for the PD group will also be labelled, as these recordings are accompanied by evaluations performed using the MDS-UPDRS by a physiotherapist specializing in PD.

Once the data has been labeled, a pre-processing step will take place. These preprocessing steps aim to prepare the data for further analysis, ensuring that the signals are in the optimal format for extracting meaningful insights.
Following the pre-processing phase, feature extraction will be conducted to identify and compile characteristics from the processed signals for further analysis. Extracted features may encompass statistical properties of the signals or may be derived from mathematical computations or based on biomechanical analyses of the movements performed, targeting specific motor symptoms, including resting tremors, bradykinesia, or gait abnormalities.
Furthermore, artificial intelligence models will be developed using the proposed features. Given the medical context of this application, it is crucial that the models are interpretable and explainable. The evaluation of the classification models will be assessed through a confusion matrix, alongside metrics such as sensitivity, specificity, or accuracy. Other performance measures could be considered to offer a more thorough evaluation of the model's effectiveness. The most relevant features will be extracted from the models to identify biomarkers.
All relevant features, both before and after model training, will be examined and utilized to define the biomarkers. These biomarkers will serve several purposes: differentiating PD patients from healthy participants, assessing the MDS-UPDRS stage in both supervised and free-living conditions, evaluating the ability of free-living activities to correlate with the disease stage of each patient, determining the relationship between the MDS-UPDRS assessment and free-living activities.

2.7. Technical Support

At the beginning of their participation in the study, each participant receives a detailed set of instructions designed to facilitate understanding and adherence during the week of free-living monitoring. These instructions primarily consist of image-based guidelines to ensure clarity and ease of comprehension. These visual instructions are provided to each participant in printed paper for convenient reference throughout the study. Additionally, participants are given a contact telephone number of a member of the research team, which is prominently displayed on their smartphone wallpaper and included in the instruction materials, allowing them to reach out with any questions or concerns during the study.

2.8. Ethical Consideration

2.8.1. Ethical Approval

The study protocol performed was approved by the Universidad Politécnica de Madrid's ethical committee. The ethical guidelines established clear procedures and responsibilities for managing data protection prior to the processing of any personal data, ensuring full compliance with legal regulations and adherence to best practices in research. Personal data, including participants' names and contact details, will be recorded on paper and securely managed by the designated Data Controller for the project. The Data Controller will pseudo-anonymize these records by substituting identifiable information with an alphanumeric code, according to the Spanish data protection agency.
This unique code will be used to log all other participant information—such as gender, age, educational level, profession, handedness, clinical data, and additional comments—into the project's digital database. Researchers will have access only to this anonymized digital database and not to the original paper records containing identifiable information.
Additionally, the database will include sensor data collected through a custom application developed by the research team, as well as health indicators obtained via smartwatch and smartphone applications. These measures ensure the secure and ethical handling of sensitive participant data throughout the study.

2.8.2. Informed Consent

Before the initiation of the study, all participants were thoroughly informed about the details, and a written informed consent was obtained from each participant in accordance with Good Clinical Practice guidelines and International Conference on Harmonization standards.

2.8.3. Withdrawal of Participants

Participation in this study is completely voluntary. Participants can withdraw at any time without providing a reason, and their decision will not affect the quality of care or services they receive from the organization. Upon withdrawal, any data previously collected from the individual will be excluded from the analysis, and no replacement participants will be recruited.

3. Results

Recruitment for the study commenced in December 2024 and will continue until spring 2025. The findings from this study are anticipated to be published by late 2025 or early 2026. Furthermore, the results will be disseminated to national and international patient organizations, as well as shared with the public. The database generated will be published at European public repositories.

4. Discussion

This paper presents the research protocol for the BioCliTe project at APM, a study focused on monitoring PD using smartphones and smartwatch sensors. The study aims to compile a dataset comprising 15 PD participants and 15 healthy controls for assessing motor symptoms in individuals diagnosed with PD.

The BioCliTe study aims to bridge this gap by transitioning from controlled clinical assessments to follow-up in non-supervised free-living environments, as high variability in motor symptoms associated with PD necessitates the evolution toward continuous patient monitoring. This approach involves evaluating participants through the MDS-UPDRS exercise sequence and the specific free-living activity of beating eggs by analyzing accelerometer and gyroscope signals from a commercial smartwatch. These activities are performed in both supervised clinical settings and unsupervised free-living conditions. This dual approach ensures a comprehensive assessment of motor symptoms under controlled conditions and in the context of participants' daily lives.

The ultimate goal of the study is to facilitate the definition of digital biomarkers for assessing motor symptoms in PD patients. These biomarkers will be designed for application in both supervised clinical context and unsupervised free-living environments, enabling neurologists and PD specialists to evaluate symptoms and monitor their progression across both contexts.

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Conflicts of Interest

The authors declare that they have no conflicting financial interests or personal relationships that could have influenced the work presented in this paper.

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Abbreviations

APM: Asociación Parkinson Madrid
PD: Parkinson's disease
MDS-UPDRS: Movement Disorder Society-Unified Parkinson's Disease Rating Scale
ETSII-UPM: Escuela Técnica Superior de Ingenieros Industriales at Universidad Politécnica de Madrid.

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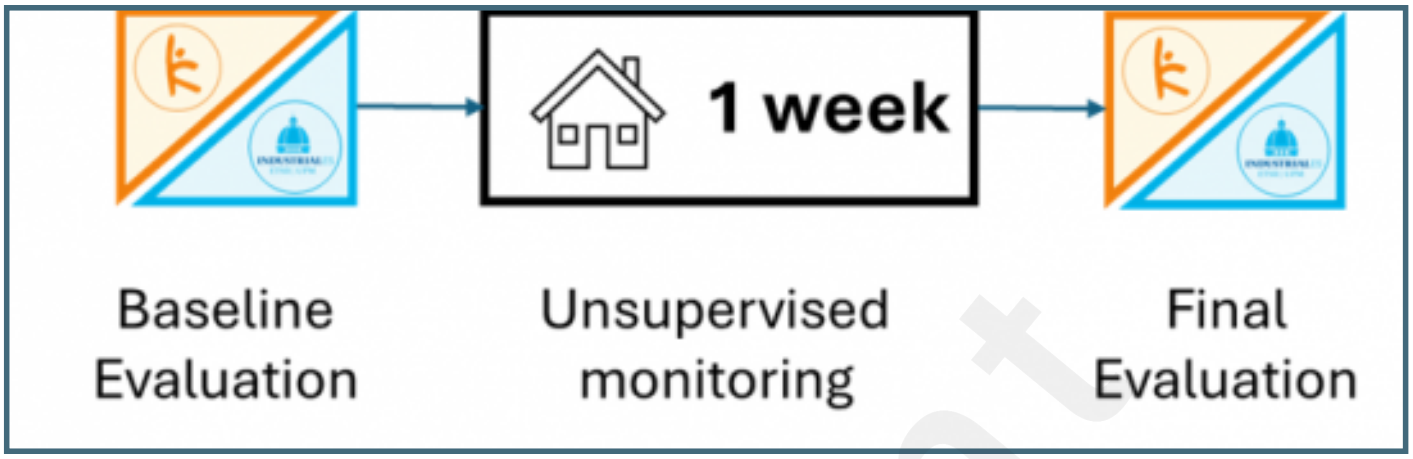
Supplementary Files

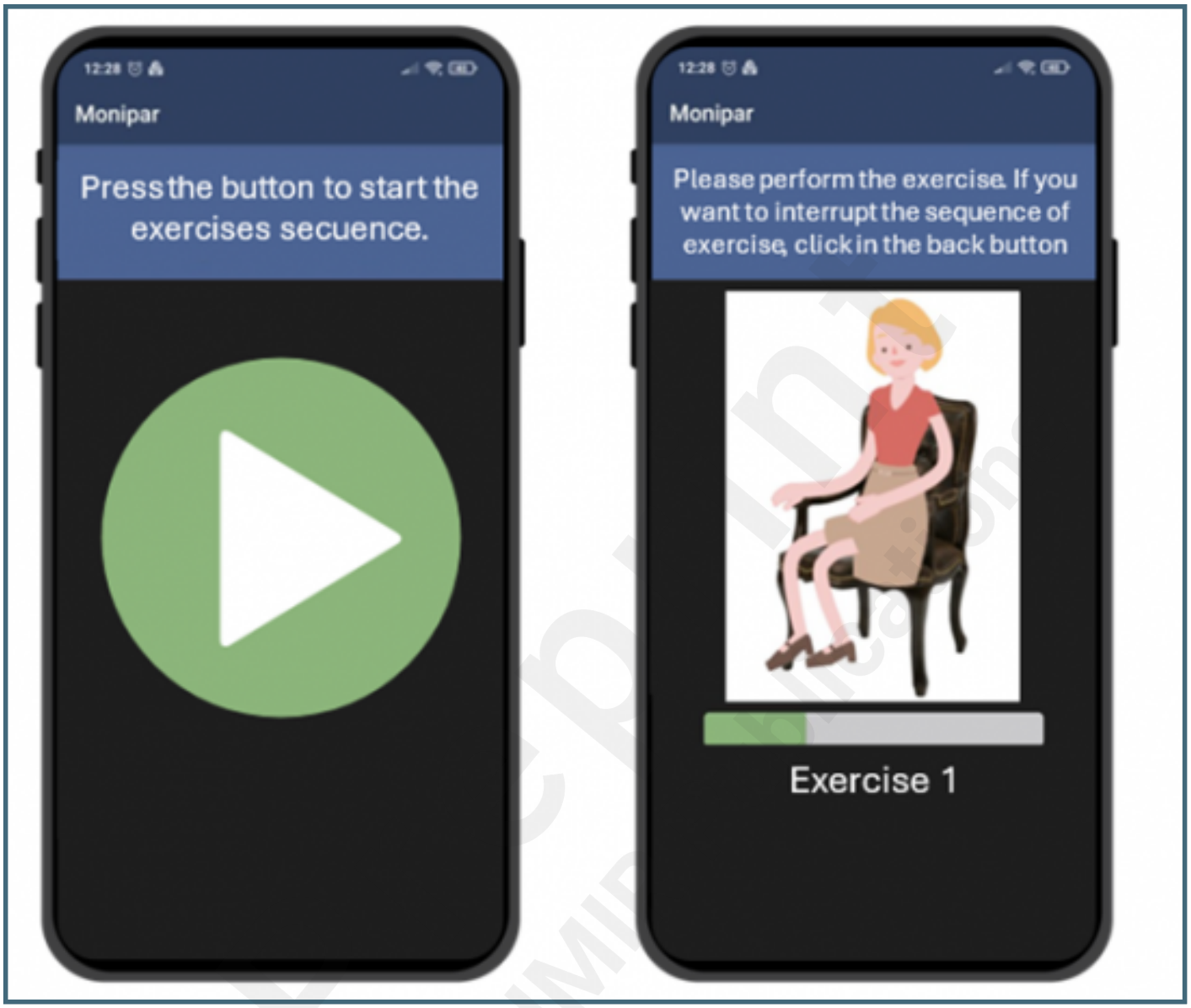
Figures

Overview of the experimental protocol of the study.

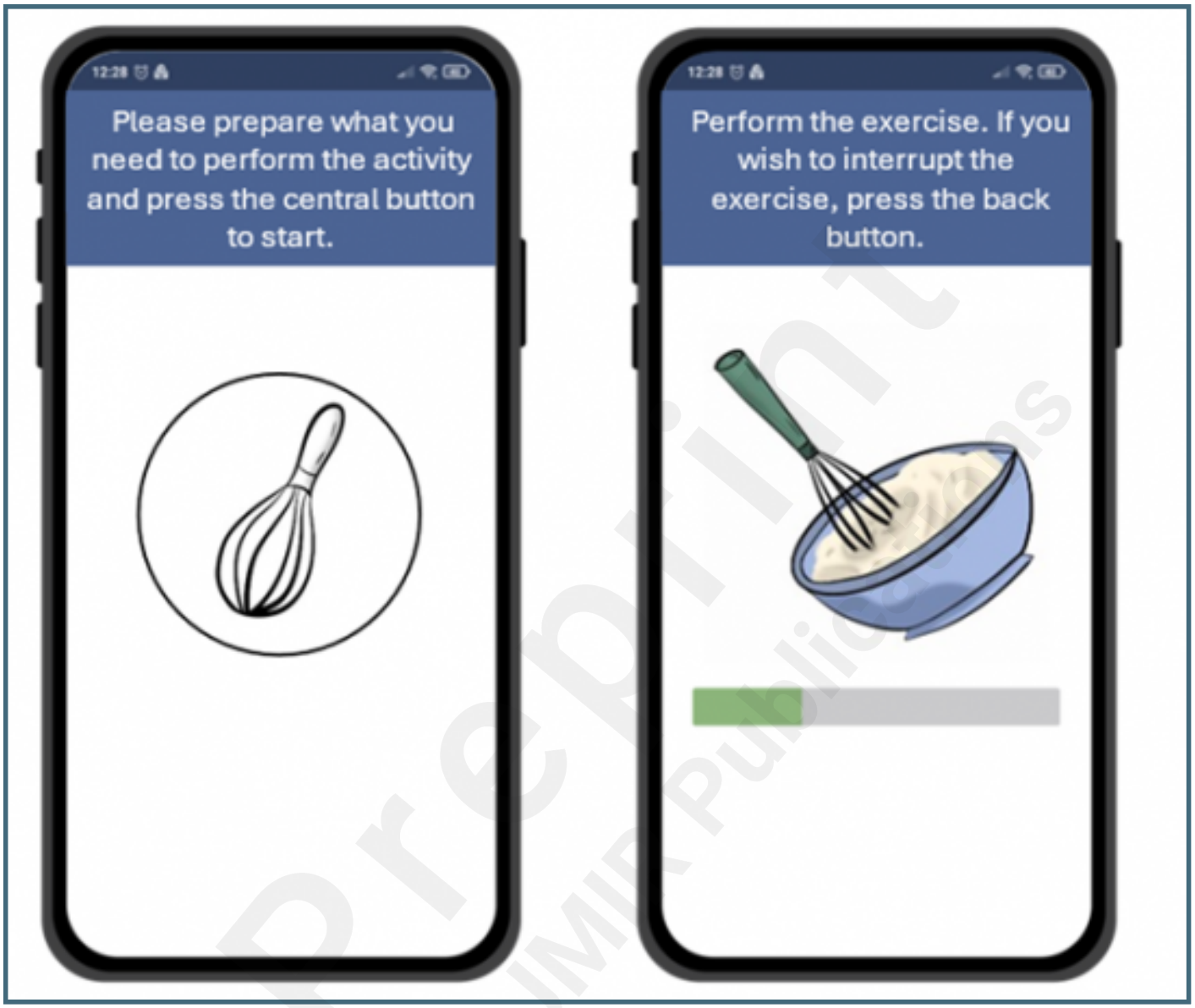


Devices used in this study: Smartphone (left) and smartwatch (right).

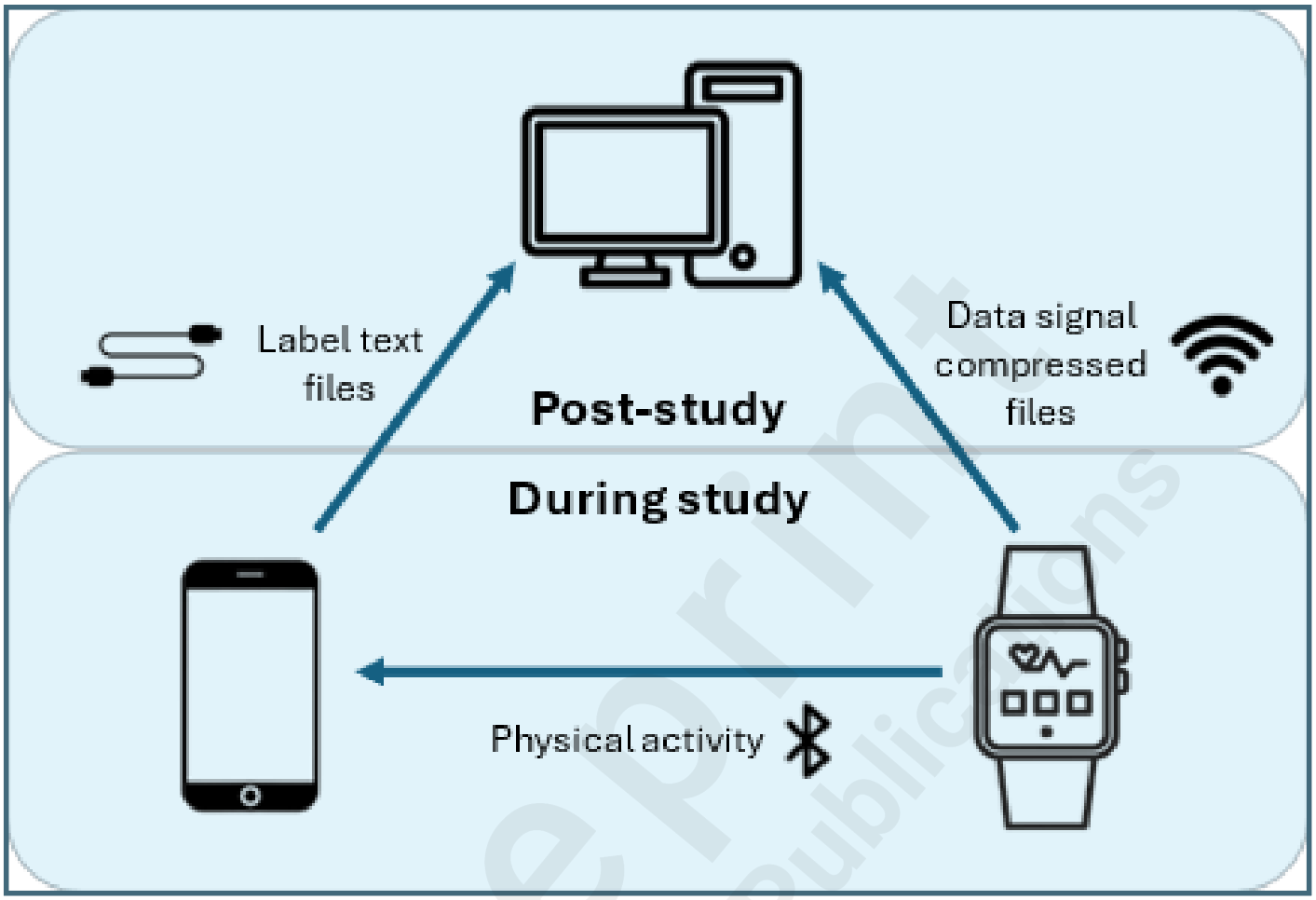
Interface of the application related to the Monipar activity: (left) Start screen, (right) Activity screen.



Interface of the application related to the specific free-living activity: (left) Start screen, (right) Activity screen.



Structure of the data acquisition system.



Data analysis pipeline.