DARE

DIGITAL LIFELONG PREVENTION

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Spoke 1 Deliverable

S1.D4.3
Report on the development and integration of wearable/portable solutions

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S1.D4.3 Report on the development and integration of wearable/portable solutions

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Publishable summary

This Deliverable presents an overview of the studies carried out within the DARE project which leverage wearable and portable devices to support the development of innovative digital health solutions. This document reports the status of the activities conducted by the various partners involved in Spoke 1 and is structured according to application context. Within each context, individual contributions from the partners are presented, including the study objectives, adopted methodologies, developed strategies, and key findings.

While the activities conducted so far have primarily focused on individual study goals, they provided a solid foundation for understanding the capabilities and limitations of different wearable systems in various real-world and clinical contexts.

Future efforts will be mainly address at increase and promote cross-pollination and collaboration between different partners, with the aim of harmonizing protocols, unifying data processing and analysis workflows, and fostering interoperability across studies addressing similar objectives.

1. Introduction

This Deliverable reports on the status of the studies within the DARE project, where wearable and portable devices are employed to design innovative solutions for digital health applications. Within Spoke 1, research groups affiliated with different organizations have been contributing to the development and evaluation of wearable-based approaches tailored to the specific goals of the pilot studies. These activities address a wide variety of health-related goals, including areas such as lifestyle and physical activity monitoring, motion analysis, chronic disease prevention, and fall prevention, all contributing to the overarching goal of improving health and quality of life, aligned with the primary objectives of DARE.

The Deliverable is organized as follows.

- In Section 2, an overview of the wearable solutions employed across DARE pilot studies is presented.
- In Section 3, the status of the studies carried out by the partners of Spoke 1 is reported. The application scenario and specific goals of each study are described along with the adopted solutions. Preliminary results reached up to Month 36 are also presented.
- In Section 4, conclusions are drawn along with future directions.
- In Section 5, references of interest are reported, including conference and journal articles published as part of DARE project.

2. DARE's Selected Wearable Solutions

The overview of wearable sensors employed across DARE pilot studies, as well as the activities carried out to identify and recommend the most appropriate solution for each pilot, has been finalized (Figure 1). This process was led by the research group from UNIBO (L. Palmerini, L. Chiari). In particular, the selection process for each study was driven by specific requests outlined by the proposing partners. At the first stage, this process required a detailed description of the intended use of the candidate device and its operational context, including the specific setting (e.g., laboratory-based, free-living monitoring), the relevant health domain (e.g., cardiology, oncology, metabolic health, neurology, or rehabilitation), and the primary monitoring objectives, such as the specific physiological parameters to be measured and tracked. Then, a comprehensive technical evaluation was conducted to determine the suitability of potential wearable devices, assessing their technical specifications (e.g., recording modalities, measurement accuracy, battery duration, physical burden, connectivity capabilities). The accessibility of raw data generated by the considered wearable devices represented a key factor in the selection process, since this aspect is crucial for enabling advanced post-processing analyses through customized algorithms tailored to specific research questions. Another significant technical criterion concerned interoperability, ensuring that the selected devices could address various research needs while seamlessly integrating with existing data pre-processing and data analysis frameworks, which typically require *raw* data as input. Potential constraints were also systematically addressed during this process, including relevant regulatory requirements for medical device certification, organizational challenges, such as workflow integration complexities and training requirements for clinical and research personnel, and financial considerations encompassing the cost of device acquisition and ongoing maintenance. Finally, the candidate devices were carefully screened and recommended with the aim of maximizing harmonization across different DARE pilot studies.

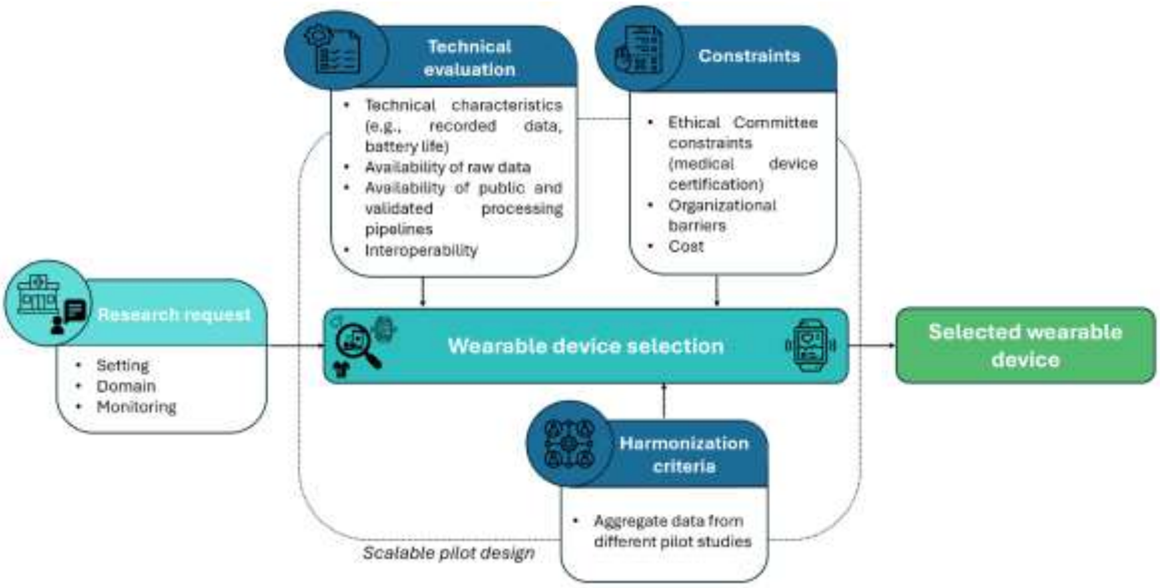

Figure 1. Workflow for a wearable selection for each DARE pilot study.

Overall, 16 pilot studies involved in DARE decided to include wearable sensors in their protocol (Figure 2) to monitor physical activity, joint mobility, sleep, heart rate variability, nutrition, and glucose homeostasis across diverse health domains, including healthy aging, chronic disease prevention, and lifestyle modification programs targeting over 20000 participants.

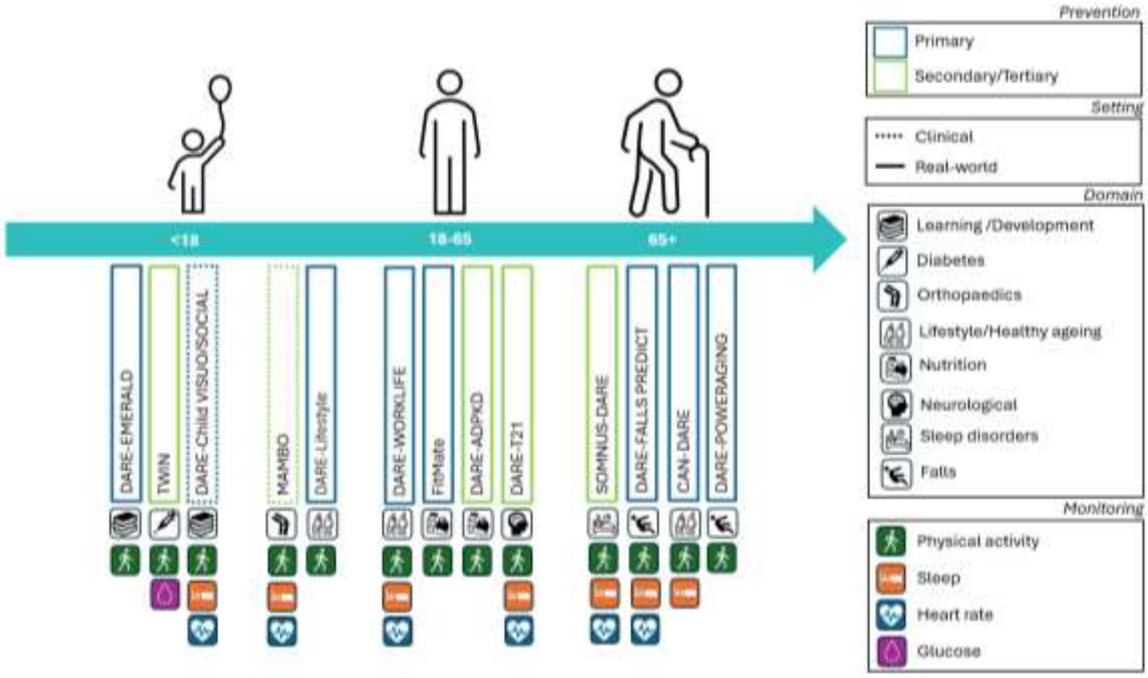

Figure 2. Overview of the DARE pilot studies across the life course, categorized by age group, type of prevention, setting, domain, and monitoring focus.

An article presenting the overview of the wearable sensors used across DARE pilot studies was submitted to the NPJ digital medicine journal in September 2025 and the preprint is currently available online [R1]. In this work, we meticulously detail the methodological characteristics of these study protocols, explicitly outlining the technical specifications, functional capabilities, and inherent limitations of 18 distinct wearable devices (sourced from 12 manufacturers) employed across these trials (Figure 3). This work was further disseminated in a presentation to clinical experts, which was also open to normal citizens. The event was held in Rome in June 2025, during the DARE's event "Prevention Atelier: Technologies for prevention" (https://www.eventbrite.com/e/atelier-della-prevenzione-tickets-1371290289169?aff=oddtdtcreator). The participants were able to try in practice the use of wearable technology.

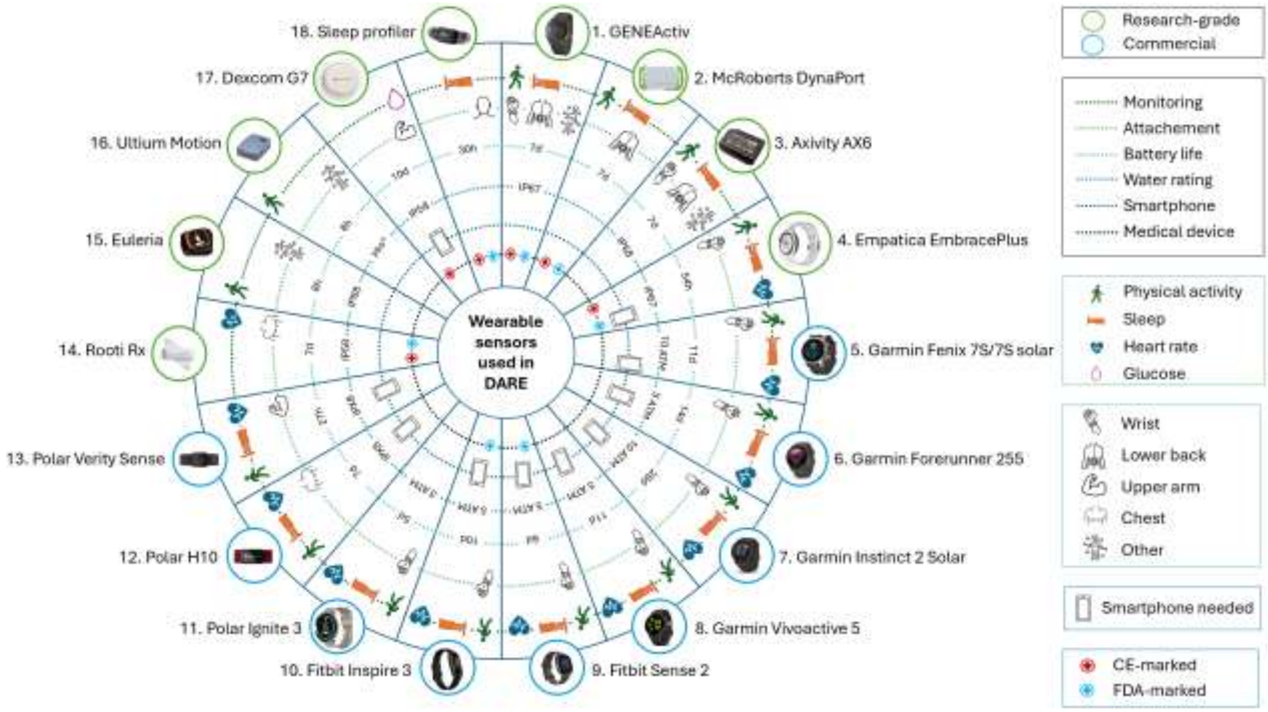

Figure 3. Overview of wearable devices used in the DARE initiatives, categorized by monitoring domains, attachment site, battery life, water resistance, smartphone dependency, and medical certification status.

3. Application Scenarios and Partner Contributions

3.1. Parkinson's Disease and Motor Disorders

In the context of motion analysis to assess clinical conditions related to typical neurological disorders, such as the Parkinson's Disease (PD), wearable sensing technologies have gained increasing interest in the last years, thanks to their main characteristics, including ease of use, portability, lightweight design and unobtrusiveness. Inertial Measurement Units (IMUs) have emerged as cost-effective solutions for the reliable monitoring of motion of individuals with motor disabilities.

3.1.1. Gait analysis

Within this framework, the research group from UNIPR (G. Ferrari) worked on developing effective solutions to assess the PD from gait signals acquired from wearable IMU-based systems. As a first study, a custom-made IMU sensor, named *move2i®*, was validated in characterizing common gait metrics extracted from vertical acceleration signals acquired by a single *move2i®* node positioned on the lumbar area of the involved participants. The benchmark validation of the *move2i®* device was performed against the *XSens MVN motion capture system*, considering the full-body configuration, which consists in 17 fully connected wireless wearable sensors. The back view of the placement of both systems is shown in Figure 4.

Figure 4. Placement of the *move2i®* and XSens MVN Awinda system. The MVN Awinda sensors are attached with velcro straps on specific body locations, and the *move2i®* device is placed on the lower back.

Four healthy subjects (2 males and 2 females, age 25 ± 4.5, height 182 ± 13.3 cm) were involved in this validation study. The gait of all participants was assessed during test sessions consisting in a Straight line Walking (SW) test, performed in an indoor environment, along a free hallway covering a distance of 12 meters. The participants were asked to walk at a self-pace back and forth on the designated path for approximately 90 seconds, turning by 180 degrees when reaching the endpoints. Each test was performed three times by each participant, equipped with both monitoring systems (*move2i*® node and XSens MVN Awinda motion capture system), at the beginning of each test session.

In order to properly process the data extracted by the two systems, two different procedures were implemented. Regarding the XSens MVN Awinda system, he MVN Gait Report tool, hosted on a secure cloud platform, named MotionCloud, was exploited to generate reports, in PDF format, containing gait metrics of interest, such as the mean speed and cadence of the gait, as well as spatial and temporal parameters. On the other hand, the SKDH Python library (publicly available at https://github.com/pfizer-opensource/scikit-digital-health) was used to store in Comma Separated Values (CSV) files reporting gait metrics extracted from vertical acceleration signals recorded by the *move2i*® device. A direct comparison of the employed devices was finally drawn considering 10 common gait features obtained by the two processing procedures.

The results obtained from the comparative analysis of the two monitoring systems are shown in Figure 5 in terms of the relative error between the outcomes obtained from the *move2i*® device and XSens MVN Awinda motion capture reference system for the four participants.

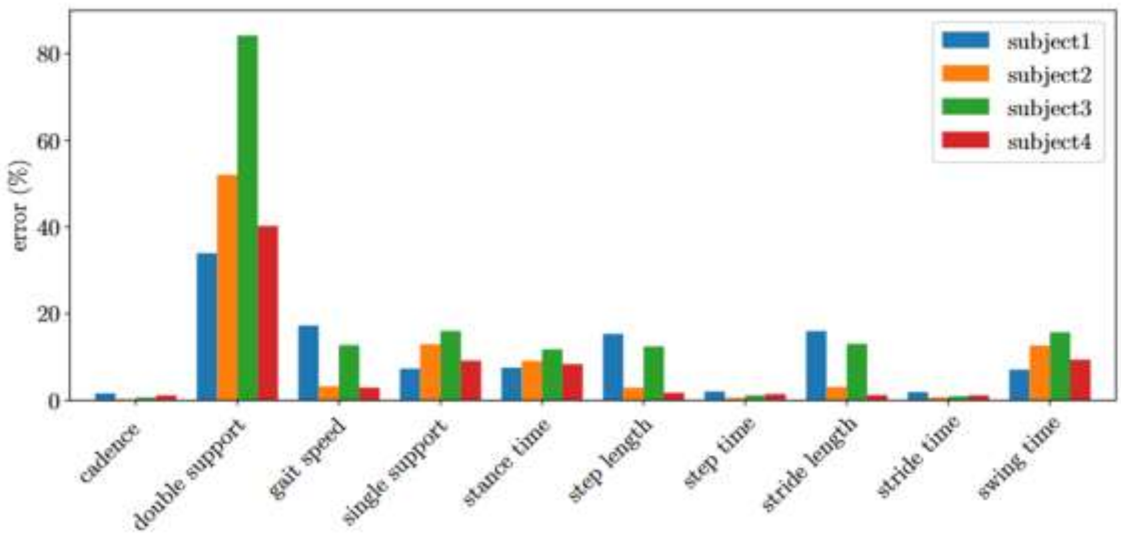

Figure 5. Comparison of the gait features obtained from MVN Awinda system and *move2i*® device in terms of relative error computed for each subject.

Low relative errors were obtained for most of the considered gait metrics. In particular, cadence, step time, and stride time produce the lowest error, e.g., around 0.3%. The error produced by the double support metric is likely due to heuristic methods internal to the MVN Gait Report tool. This metric is, indeed, strongly correlated to the total step time and to the single support metric, which are both associated with small errors, demonstrating the reliability of the presented *move2i®* device. This work was presented at the Workshop on "Biomedical Applications, Technologies and Sensors" (BATS), held in Rome in October 2025 [R2].

3.1.2. Automated classification of Parkinson's Disease severity

As a second study concerning the PD characterization from gait signals acquired through wearable devices, an automated pipeline for the objective classification of PD severity, leveraging different Deep Learning (DL) architectures, was implemented. The proposed pipeline is composed of two main modules, denoted as *Walk Detector* and *Clinical Classifier*, aimed at signal segmentation and final severity classification, respectively. The motivation behind this work arises from the wide variety of DL models available in the literature, which makes it challenging to select the most suitable architecture for this research context, considering factors such as the size and quality of avalable dataset, as well as the specific objectives of the application scenario the application scenario. For this reason, the research group from UNIPR (G. Ferrari) conducted a comparative performance analysis, evaluating the accuracy of five classification models in discriminating different stages of severity of the PD.

In order to conduct this study, the WearGait-PD dataset, associated with data collected from 58 PD patients and 65 healthy subjects, was exploited to properly train the *Walk Detector* and *Clinical Classifier* modules. The WearGait-PD dataset is publicly available and contains motion data registered by wearable sensors and clinical information of the patients annotated during medical inspections. In particular, the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III score, specifically aimed at motor examination, was annotated for each PD patient and the distribution of the disease severity among the enrolled subjects is shown in Figure 6.

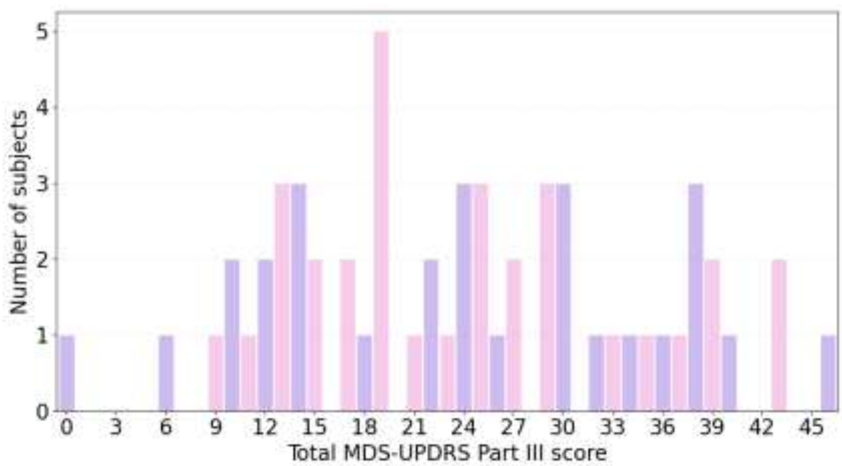

Figure 6. Distribution of the severity of PD patients within the WearGait-PD dataset according to the total MDS-UPDRS Part III score.

The motion data included in the WearGait-PD dataset were collected by different sensing devices, such as sensor insoles and a pressure walkaway. However, this work focuses only on data acquired by the *XSens MTw Awinda* motion capture system, composed of a set of 13 wearable nodes, which communicate wirelessly at 100 Hz with one of two receiving stations, properly connected to a Personal Computer (PC) provided with the dedicated MT Manager 2019.1.1 acquisition software. The *Xsens MTw Awinda* overall sensor configuration is shown in Figure 7, along with an insight of the lumbar-mounted unit. In order to minimize the intrusiveness of the proposed approach, only inertial data acquired by the lumbar node are, indeed, considered in this work to train the proposed classification model. As a first step, the *Walk Detector* module was designed as a mono-dimensional Residual Network (1D-ResNet) specifically trained on the inertial signals of interest, properly preprocessed and segmented, and the corresponding annotations provided within the dataset. The output computed by this first module is the probability that a given segment of the input signal represents a *walking* or *non-walking* phase (e.g., a static phase or transitions), thus enabling the automatic segmentation of the gait signal. The subsequent *Clinical Classifier* module aims at finally classifying the PD severity and was implemented on the basis of five DL architectures: mono-dimensional Convolutional Neural Network (1D-CNN), Long Short-Term Memory (LSTM), 1D-ResNet, CNN-LSTM, and CNN-Bidirectional LSTM (BiLSTM) with Attention Mechanism. In order to assign more relevance to walking phases during the training, the *Clinical Classifier* module is fed with the probabilities computed by the *Walk Detector*.

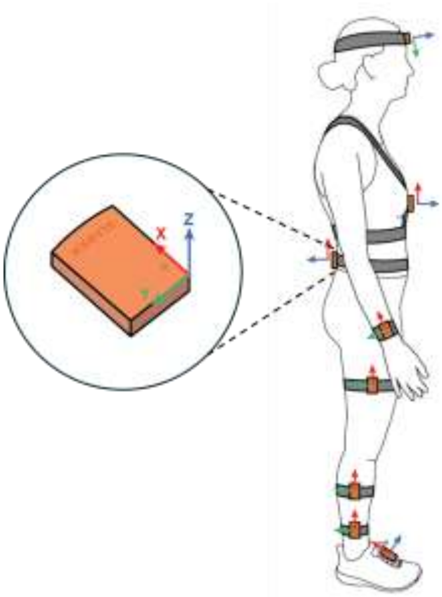

Figure 7. Xsens MTw Awinda overall sensor configuration and insight of the lumbar-mounted unit.

To evaluate the performance of the different DL architectures, various configurations were adopted in terms of signal segmentation and classification strategy. In particular, the following classification strategies, leveraging different partitioning of the distribution of the MDS-UPDRS Part III scores in Figure 6, were considered:

- Binary classification: the distribution is partitioned on the basis of the median value of the total MDS-UPDRS Part III score of the considered dataset, discriminating between two stages of severity (i.e., mild and severe).
- Ternary classification: the distribution is partitioned into three severity levels (i.e., mild, moderate, and severe).
- Quaternary classification: the distribution is partitioned into four quartiles, reflecting a realistic clinical rating scale divided into four stages of severity (i.e., mild, mild/moderate, moderate, and severe).
- Regression: the model directly predicts a continuous MDS-UPDRS Part III score instead of discrete labels.

The best-performing configuration was returned in the case of ternary classification performed over signals segmented into 6-second windows interlaced by 25%, reaching an overall classification accuracy of 90%.

Regarding the regression task, the obtained results were analysed in terms of Mean Absolute Error (MAE) between the predicted regression outcomes and the true classification values. The MAE was computed for each DL model according to different demographic and clinical categorizations (i.e., gender, age, and PD severity). The corresponding results are shown in Figure 8, revealing that:

- Higher average errors are obtained for the female group for all architectures. This is possibly due to the nature of the dataset, since a smaller number of women is included.
- Lower MAE values are obtained for the older age group (70+).
- Intermediate clinical MDS-UPDRS Part III scores (15-24) are better predicted (i.e., with a lower average error) than extreme score ranges (1-14, 25-30, 31+).

An article presenting the results obtained in this study was submitted for possible publication to the IEEE Transactions on Neural Systems and Rehabilitation Engineering (TNSRE) in December 2025.

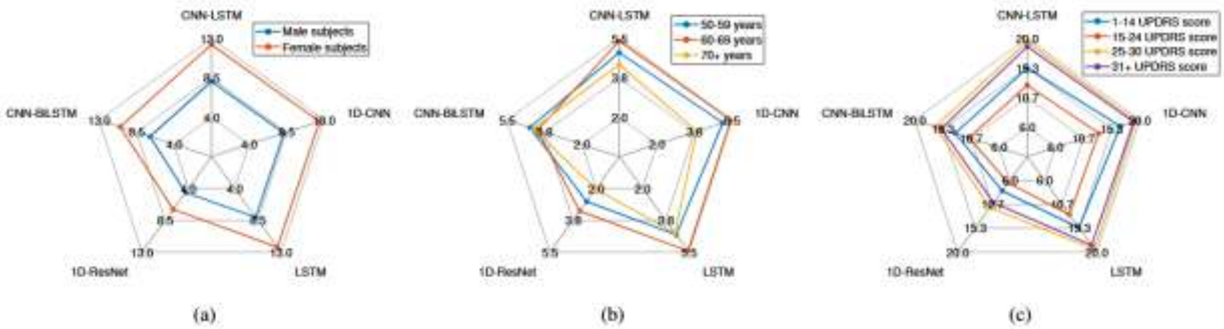

Figure 8. MAE obtained for each DL model applied to the regression task performed on 6-second

windows interlaced by 25% considering different demographic and clinical categorizations according to: (a) gender, (b) age, (c) PD severity.

3.2. Sleep posture monitoring with smart bed

Gaining insight into sleep patterns and positions is crucial for evaluating one's general health and well-being. The correct sleep position is not only crucial for getting a good night's sleep, but it is also essential for reducing many health issues. Studies indicate that various sleep positions can affect how we breathe, our spine's alignment, and our overall comfort while sleeping. As a result, these postures can impact our physiological processes and overall health. Individuals with obstructive sleep apnea (OSA) frequently display postural preferences that can worsen their disease. Identifying and tracking these preferences can assist in the control of OSA and provide valuable information for individualized treatment strategies. Likewise, particular sleep positions may be required to alleviate symptoms and ensure ideal comfort for medical disorders such as acid reflux, discomfort associated to pregnancy, and musculoskeletal concerns. Sleep posture detection is essential in clinical settings and relevant in sports medicine and rehabilitation.

In this context, the research group from UNIPR (G. Matrella) has developed a low-cost contactless system that is able to achieve sleep posture recognition with the acceleration sensor mounted under a smart bed [R19]. The time-series acceleration sensor data is grouped as temporal windows. Each window contains 125 samples. Subsequently, 42 input features are computed from the windows to be fed into the proposed ML models. The K-fold cross-validation technique is used to compare the accuracy of 9 candidate models. The three best models are passed to the next round, where further analysis is applied, as illustrated in Figure 9.

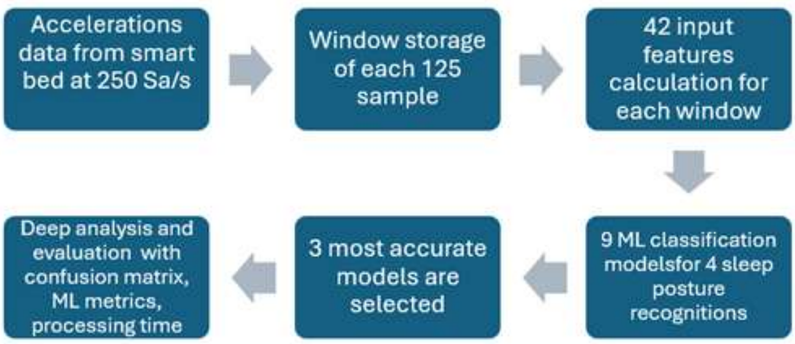

Figure 9. System operation diagram.

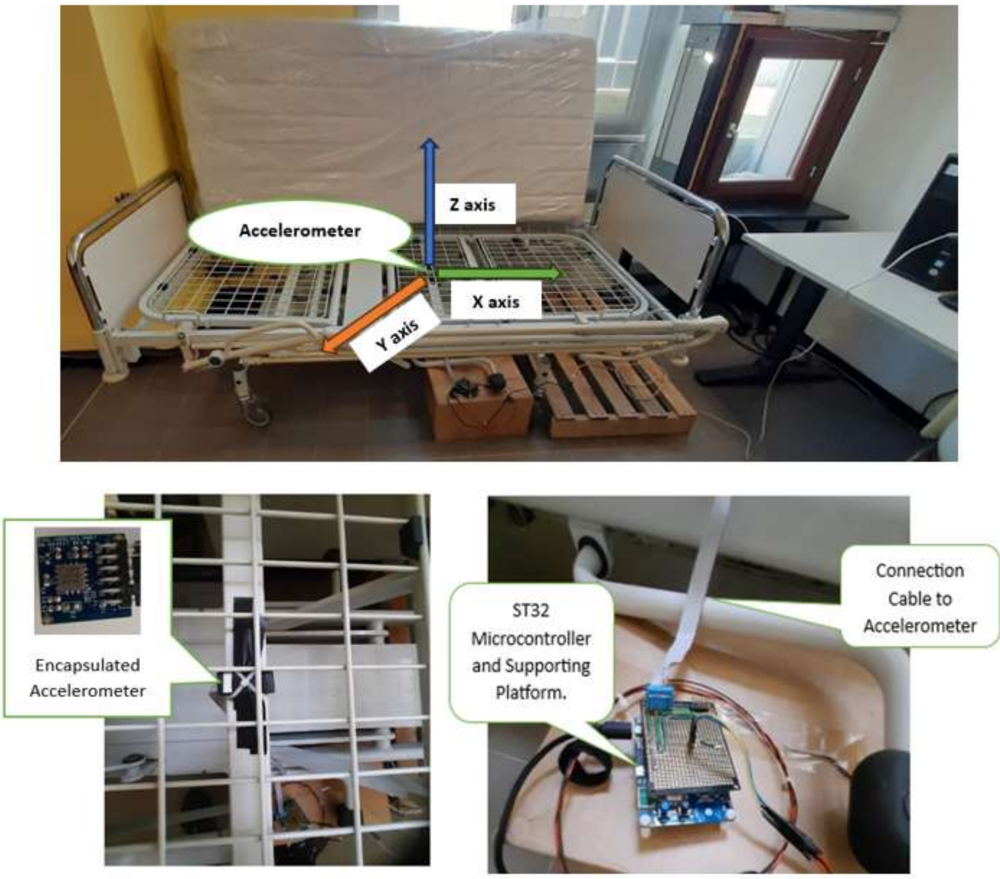

Figure 10. Smart bed and microcontroller platform for accelerometer.

The comparison between the effectiveness of each model is carried out in this specific case. The examined algorithms are Logistic Regression (LR) with one-vs-rest (OvR) and multinomial logistic regression, Linear Discriminant Analysis (LDA), K-Nearest Neighbors Classification (KNN), Classification and Regression Trees (CART), Naive Bayes (NB), Support Vector Machines (SVMs) with one-vs-one (OvO) and one-vs-rest (OvR) strategies, and Random Forest (RF).

The measurements of each individual were obtained in four different laying positions: 1. prone, 2. supine, 3. right side, and 4. left side. Each location serves as the reference or ground truth for the related acceleration data, which is used to train the machine learning model. The research focused on monitoring individuals during sleep under resting settings without any significant physical exertion prior to or during the test. Before the testing, they refrained from engaging in intense walking or running activities. Instead, they either remained at rest or walked regularly for a minimum of 15 minutes. Accelerations were obtained for a duration of 180 seconds for each position. All the values are converted to absolute values for system.

Hence, each participant has produced 4 files (one for position) with 45,000 lines (180 s with 250 Hz) and 4 columns (X-axis, Y-axis, and Z-axis and lying position) for an overall 40 files of raw data. In the next phase, raw data were elaborated before being used to train ML algorithms. A bandpass filter digitally filters raw acceleration along the X-axis, Y-axis, and Z-axis at [0.5–20] Hz to remove unnecessary noise and make the signal smoother.

A window of 125 samples is exploited to extract the relevant features. ML model will predict the lying posture after each window of 125 samples. Therefore, there are 14,400 windows for all signals. K-cross validation is processed with all the concerned models. As shown in Figure 11, the LR-OvR accomplishes the highest accuracy with low standard deviation (std), while LDA and RF algorithms also obtain the high-quality performance among other operated models. KNN and SVM have low fit for this circumstance, especially KNN with poor correctness only about 45% of accuracy. Then, LR-Multinomial and NB have superior results with approximately 84% AND 67% of accuracy respectively. Nevertheless, these results of LR-Multinomial and NB are not sufficient to be trusted for long-term operation. On the other hand, CART reach higher accuracy with more than 90% accuracy, but its efficiency are still inferior to LR-OvR, LDA and RF models. Therefore, the detailed comparison will concentrate on LR-OvR, LDA, and RF as applied models for lying position detection.

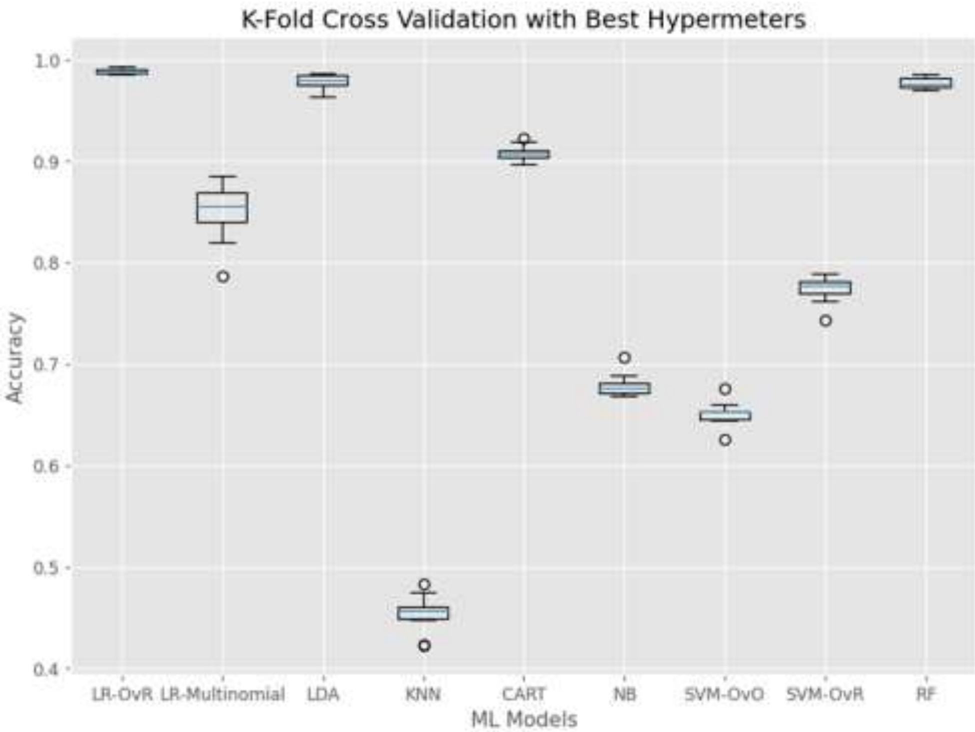

Figure 11. K-fold cross-validation for model evaluations.

TABLE I reports the high-quality functioning of all 3 models with good evaluation metrics. Their total accuracies are all greater than 96 %, especially LR-OvR achieves almost 99 % of accuracy. Together with precision, recall and F1-score, all 3 models have good capability of sleep-position detection.

TABLE I
LG-OvR AND CART TABLE METRIC OF TEST DATA

Sleep Position	Precision			Recall			F1-score			Support Sample Number
	LG-OvR	LDA	RF	LG-OvR	LDA	RF	LG-OvR	LDA	RF	
Right Side	0.98	0.95	0.94	0.96	0.98	0.97	0.97	0.96	0.95	1085
Left Side	0.99	1.00	1.00	1.00	0.97	1.00	0.99	0.99	1.00	1078
Prone	0.99	0.99	0.98	0.99	0.97	0.95	0.99	0.98	0.96	1116
Supine	0.98	0.97	0.97	0.99	0.98	0.96	0.98	0.98	0.97	933
• Total Accuracy of LG-OvR model: 98.55% • Total Accuracy of LDA model: 97.76 % • Total Accuracy of RF model: 96.96 %										4212

The AI models were trained on the workstation, containing an NVIDIA Quadro P620 with a Pascal GPU with 512 CUDA cores (NVIDIA, Santa Clara, CA, USA). The machine includes 2 GB of GDDR5 memory, an Intel Core i7 vPro-10850H Processor running at 2.70 GHz, and 32 GB of RAM.

TABLE II reports each selected model's training time and test time in milliseconds (ms). The RF occupies the longest time for both the training and test process. Instead of training a single model, RF trains multiple decision trees, which increases computational complexity. Each tree in the forest is trained on a different subset of the data, requiring multiple passes through the dataset. On the other hand, the LDA model executes the training data for the quickest period, but LG-OvR performs faster in test data.

TABLE II
TIME COMPARISON BETWEEN 4 SELECTED MODELS

ML model	Training Time (ms)	Test Time (ms)
LG-OvR	1090.031	0.965
LDA	80.003	0.998
RF	8099.036	102.963

This work demonstrates the efficacy of ML algorithms in precisely categorizing sleep positions using data obtained from MEMS accelerometers. After assessing different machine learning algorithms, LR, LDA, KNN, CART, NB, SVM, and RF. Proposed feature selection from accelerometer data are also useful for other researchers to consider in posture recognition based on the accelerometer sensor.

LG-OvR, LDA and RF algorithms were chosen for further analysis with confusion matrix and other ML metrics. The results show that the LG-OvR is the most effective with accuracy rates of over 98%, with fastest execution time after training period. LDA is also competitive model in term of precision and requires least training time. Meanwhile, RF consumes more time of training and test considerably. Taking into account both in terms of time and performance, the LDA is the most suitable algorithm for this specific circumstance. Meanwhile, RF consumes most considerable time in both training and test time. Additionally, RF accuracy is also inferior to the other models.

The implications of these discoveries are substantial in diverse fields, especially in healthcare and well-being. The diverse input features introduced in the work are helpful not only for this research but also for other posture recognition with accelerations. Precise categorization of sleep postures can offer useful information for managing diseases such as OSA, acid reflux, and musculoskeletal discomfort. Furthermore, it can assist athletes in maximizing their recovery and performance, as well as provide insights for creating sleep environments that are ergonomically designed. Last but not least, this research highlights the capacity to combine MEMS accelerometers with ML algorithms to accurately classify sleep positions. Utilizing these technologies can enhance our comprehension of sleep patterns and postures, ultimately leading to enhanced health and well-being for individuals across various groups.

3.3. Physical activity, fitness, and lifestyle monitoring

In the context of health monitoring, regular physical activity plays a crucial role in preventing and reducing risks of chronic diseases, as well as improving the quality of life. Nowadays, wearable technologies, such as smartwatches and wristbands have become popular tools to easily and continuously monitor a number of indicators related to the consumers' health, including motion related information and physiological parameters, as well as sleep metrics and stress levels.

3.3.1. Analysis and quantification of daily physical activity

Within this framework, the research group from UNIPR (G. Ferrari) conducted a study aimed at analyzing and quantifying the daily physical activity of healthy adult subjects monitored over a 7-month period during their daily life activities, by means of Garmin smartwatches. To this purpose, an Internet of Things (IoT) network was implemented to collect and properly process various health parameters recorded by Garmin smartwatches to derive a novel and concise activity index, denoted as *Physical Activity Index* (PAI). The PAI is calculated on a daily basis as a weighted sum of five specifically selected indicators (i.e., step count, climbed floors, intensity minutes, and Physical Activity Level (PAL)) considering official regulatory guidelines and state-of-the-art references. In detail, a partial percentage of activity is computed for each considered parameter. This percentage is computed by comparing the parameter value with a reference threshold corresponding to the minimum value of the parameter needed to be considered active. All the thresholds are set by taking into account specific recommendations by international organizations, such as World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO), and literature references. Finally, the PAI is derived as the weighed sum of the partial percentages of activity obtained for each considered parameter, as graphically represented in Figure 12.

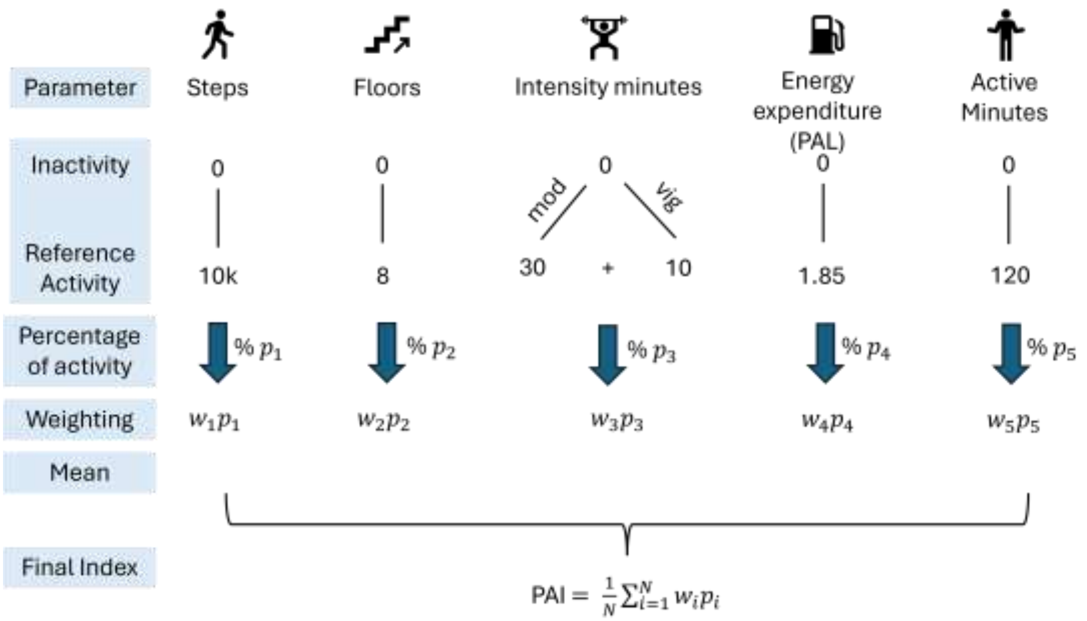

Figure 12. Generic representation of the five components considered in the current version of the PAI.

In order to retrieve the health data of interest of all the involved participants, the HTTPS APIs provided by Garmin through its Garmin Connect Developer Program were exploited to design a dedicated Web platform to access the users' data after the following steps were completed.

1. Each user needs to associate the smartwatch with a smartphone by (i) downloading the Garmin Connect App and (ii) creating a personal account.
2. Each user needs to register to the Web platform and grant access to Garmin data.
3. The Web platform (acting as a client) accesses the protected Garmin data owned by the Garmin Connect Portal (acting as a server) by means of the OAuth 2.0 protocol.

A block diagram representation of the implemented data collection strategy is shown in Figure 13.

The developed Web platform is available at this link https://dare.iotlab.unipr.it/index.php and is aimed at being shared with other partners involved in DARE who are interested in contributing to this study, or in relying on this infrastructure to access data from Garmin smartwatches to carry out other studies. At present, the Web platform has been shared and used by the research group of UNIPD (L. Vedovelli). A screenshot of the platform home page is provided in Figure 14, whereas the screenshots in Figure 15 illustrate the user registration interface, specifically referring to the procedure of providing consent for data access and sharing.

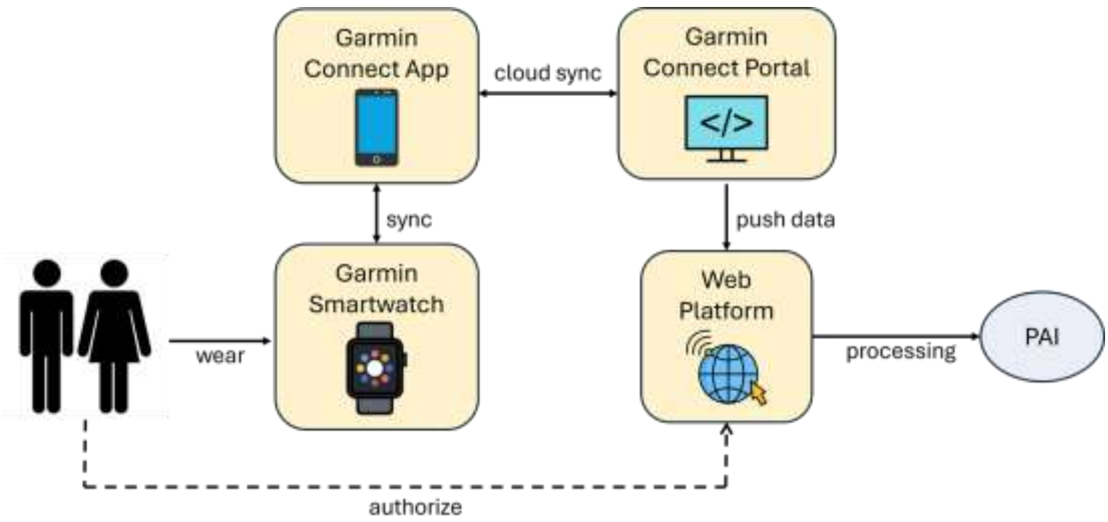

Figure 13. Block diagram of the steps of the data collection strategy.

Figure 14. Screenshot of the home page of the Web platform developed to access and collect data recorded by Garmin smartwatches.

This study, conducted by the research group from UNIPR (G. Ferrari), received the ethical approval by the Research Ethics Board (REB) of the University of Parma in the session of May 25, 2024. At present, this study includes 6 healthy adults (3 female and 3 male volunteers), aged between 25 and 50, who were monitored over a period spanning 7 months. All participants work as researchers and professors at UNIPR, which can be considered as a relatively sedentary work. However, all the subjects perform some physical activity at amateur levels (e.g., yoga, strength training, running, etc.). The Garmin smartwatches considered in this study are the following: Garmin Fēnix 7s, Garmin Forerunner 255, and Garmin Instinct 2 Solar, which were worn by all participants during the entire duration of the study (day and night) and were removed only for charging.

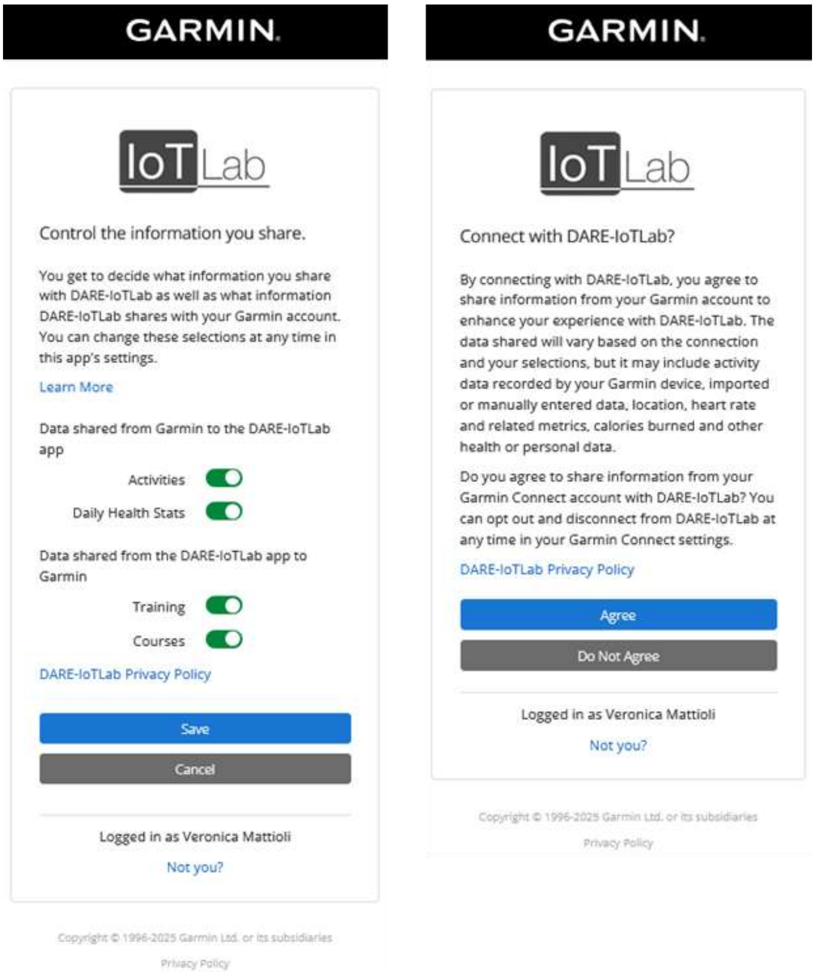

Figure 15. Screenshots of the user registration interface, specifically referring to the procedure of providing consent for data access and sharing.

The PAI was computed daily for each participant and the average value per week was subsequently derived. The results obtained for one subject are shown in the bar plot in Figure 16, where the contribution of the five considered parameters to the computed mean PAI per week are visualized as stacked bars.

A comprehensive discussion of the results of this study was presented at the 19th "International Symposium on Medical Information and Communication Technology" (ISMICT), held in Florence in May 2025 [R3].

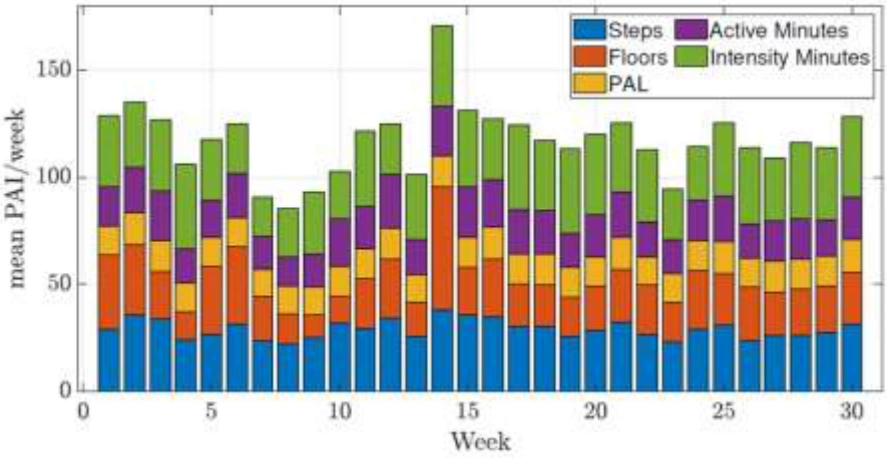

Figure 16. Average value per week of the considered PAI metric computed for the one subject involved in the study.

3.3.2. Analysis of physiological data

The research group from UNIPA (L. Faes) focused on the analysis of physiological data acquired through portable and wearable multi-sensor devices, with the aim of developing robust methodologies for autonomic assessment, stress monitoring, and signal quality evaluation in real-world conditions.

A first line of work [R4] focused on reducing inter-subject physiological variability to improve multilevel stress classification.

The goal of [R5] was to discriminate physiological stress states encompassing rest, orthostatic stress, and cognitive load, using indices derived from Heart Rate Variability (HRV) and Pulse Rate Variability (PRV).

A third line of work [R6] focused on the assessment of autonomic regulation in healthcare operators vulnerable to high occupational stress.

Finally, the study [R7] examined the feasibility of Ultra-Short-Term (UST, i.e., shorter than 5 minutes) analysis of heart rate and arterial pressure time series for assessing cardiovascular coupling, with the aim of differentiate rest, postural stress, and mental stress.
In [R4], a novel normalization procedure was introduced and applied to a driving stress dataset by rescaling ElectroCardioGraphic (ECG) and respiratory recordings to a common temporal domain defined by fixed resting heart and breathing rates, preserving feature correspondences while aligning subjects to comparable baselines.

The datasets of [R5] and [R7] included 127 healthy participants undergoing a structured protocol consisting of rest, head-up tilt, and mental arithmetic test. ECG and continuous arterial pressure were recorded, from which RR-interval, pulse-to-pulse interval and systolic arterial pressure time series were derived. Signal preprocessing included artifact removal, stationarity assessment, parametric spectral modelling, and entropy-based complexity estimation.

In [R6], sixty shift-working nurses were evaluated at two time points (before and after intervention), each involving 5-minute recordings during spontaneous breathing and slow guided breathing. Data were acquired through a multi-sensor device previously developed within other research activities and capable of synchronously acquiring ECG, PhotoPhlethySmographic (PPG), and respiratory signal. Short recordings during spontaneous and paced breathing were used to extract HRV indices and characterize stress-related physiological dynamics before and after a lifestyle intervention.

Overall, the work integrated complementary approaches spanning preprocessing, feature extraction, normalization strategies, cardiovascular variability analysis, and noise-robustness assessment.

In [R4], stress levels were classified using Support Vector Machines (SVM) applied to multidomain features extracted from the normalized physiological signals. Performance was compared against traditional preprocessing techniques such as standard normalization and z-scoring.

In [R5], ten HRV/PRV indices from time, frequency, and information domains were computed, and an automatic feature-selection method based on the Akaike Information Criterion (AIC) was compared with a physiologically motivated feature set defined by domain experts. Four machine-learning algorithms, i.e. LDA, SVM, kNN, and Random Forest, were trained and evaluated. Nested cross-validation was employed to ensure robust performance estimation, and non-parametric statistical tests were used to compare classifiers and feature-selection approaches.

The study [R6] performed a detailed physiological analysis of the acquired signals through different methods for feature extraction. Cardiovascular variability indices were extracted across the time, frequency, and information-theoretic domains, complemented by linear and non-parametric entropy estimators to characterise autonomic complexity. Differences between groups and breathing conditions were then assessed using non-parametric statistical testing.

In [R7], the analysis was based on estimating the coupling measure of Mutual Information Rate (MIR) using multivariate autoregressive models, followed by statistical comparisons of MIR values across time-series lengths and physiological conditions. Correlation analyses were performed to assess how closely UST-derived MIR measures matched the short-term reference values.

Overall, the results establish a coherent framework for the analysis of physiological signals obtained from portable and wearable devices, addressing inter-subject variability, noise robustness, and multimodal feature reliability, and supporting advanced stress monitoring and autonomic assessment in real-world conditions.

The approach proposed in [R4] improved the performance and outperformed standard feature normalization methods. Results demonstrate that aligning recordings to subject-independent baselines enhances the robustness of stress discrimination, supporting the suitability of the approach for wearable-based monitoring in ecological settings.

In [R5], the results indicate a good capability in stress discrimination based on cardiovascular features, with robustness confirmed by the consistent classification performance across several classification models.

In [R6], the findings confirmed the reliability of the multi-sensor device and its suitability for monitoring stress-related physiological responses in real working environments based on short-term beat-to-beat heart period fluctuations analysed with tools guaranteeing low-computational cost.

In [R7], we showed that coupling measures like the MIR can be reliably estimated also in short windows (down to 150 samples) still distinguishing different stress states, thus favouring implementation of these techniques for cardiovascular monitoring from wearable devices.

3.4. Autism in the pediatric population

A cascade funding was developed on the topic of wearable sensors, with the title of "Wearable sensors project: wearable sensors for mobility". The process was coordinated by UNIBO (L. Palmerini). The winner consortium of the cascade funding was made of Politecnico di Milano (PI: Veronica Cimolin), BTS Bioengineering, and IRCCS San Raffaele Pisana. The winner project is entitled: "*SIMBA: Soluzione innovativa con sensori Indossabili per il monitoraggio della Mobilità quotidiana nei bambini con autismo*" (Innovative solution with wearable sensors for daily mobility monitoring in children with autism). The project activity is ongoing. In the first months of the SIMBA project, most of the activities focused on "WP2. Design and Development of the Mobility Monitor". BTS and POLIMI, together with the Spoke, evaluated commercially available inertial sensors by examining accuracy, sampling frequency, storage capacity, connectivity, battery life, and tolerability. After a comparative analysis, the Axivity AX6 (UK) was selected as the most suitable device according to the features present in the call.

Preliminary laboratory tests were carried out at POLIMI and BTS to verify the sensor reliability and to prepare for the experimental phase of "WP3. Use of the Mobility Monitor on Healthy Subjects (Technical Validation)". The Mobility Monitor is currently in phase of definition, including custom belts and straps for wrist, ankle, and trunk, designed for prolonged use and suitable also for participants with autism, including children and adolescents.

BTS is defining the interface between the Mobility Monitor and the DARE data infrastructure, specifying protocols and requirements to ensure seamless interoperability.

For WP3, the ethical documentation was approved by the Ethics Committee of Politecnico di Milano in the session of June 23rd, 2025. Twenty-seven healthy volunteers (aged 20–65 yrs, BMI 18.5–24.9 Kg/m2) were recruited. Experimental procedures involved placement of IMUs on the lower back, wrist, ankle, and foot and passive markers for the optoelectronic system (i.e., gold standard reference). Participants performed standardized tasks, including the 10-meter walking test, 2-minute walking test, Timed Up and Go test, upper limb reaching and other movements involving upper limbs or lower limbs, and a lab-based task simulating daily-life movements. Data from the optoelectronic system and from the IMUs are being exported and processed using dedicated algorithms and some parameters were identified and computed. The ENMO (Euclidean Norm Minus One) metric was identified to assess movement presence/absence and intensity, and some additional kinematic parameters are being compared with the gold standard to define a ranking of sensor locations.

For "WP4. Validation of the Mobility Monitor on Patients (Clinical Validation)", ethical approval was obtained from the San Raffaele Pisana Ethics Committee in the session of November 5th, 2025; IRCCS San Raffaele Pisana has begun patient selection.

All activities are carried out in close coordination with the Spoke through regular meetings ("WP1 Coordination with the Spoke").

3.5. Aging

3.5.1. Fall risk assessment through wearable inertial sensors: a systematic review and individual participant data meta-analysis

Falls are a leading cause of years lived with disability all around the world. Current approaches for fall prevention are based on fall risk assessment. The Falls and Technology Working Group of the World Guidelines for Fall Prevention and Management for Older Adults has identified as a research priority the need to form "a consensus on identifying objective biomarkers of fall risk via gait and balance assessment." The current study aims to assess the prognostic ability of biomarkers based on wearable inertial sensors data to predict falls.

As a first study, literature reviews about sensor-based fall prediction were systematically searched for. Starting from these reviews, articles describing datasets of ≥ 20 community-dwelling individuals with prospective data from wearable inertial sensors and on falls were retrieved. The search was extended to five data portals, looked manually for additional references, and advertised during meetings and conference presentations. The authors of the included articles were invited to contribute their datasets for an Individual-Participant Data (IPD) meta-analysis on fall prediction based on wearable inertial sensors.

Then, 59 articles were identified describing 48 datasets from 23 countries involving between 21 to 32,619 participants (median 144.5, total 56,150). Most datasets (37) had inclusion criteria reflecting the general older adult population, while others targeted specific populations, including subjects with PD (5), multiple sclerosis (2), stroke (2), and others (4).

Between 1 and 10 (median 1) wearable inertial sensors were used for motion evaluation during functional tests in the laboratory/clinic (19 datasets), during real-world daily activities (12 datasets), or both (17 datasets). Each article proposed 0-592 (median 7) sensor-based biomarkers (i.e., features extracted). The participants were followed up for fall ascertainment for 6-60 months (median 12 months). Mean prevalence of fallers was 33%. Of all sensor-based biomarkers, 27% were deemed associated with falls according to either a statistical hypothesis test or a feature selection procedure.

Thus far, 20 authors have accepted the invitation to join the IPD meta-analysis with their datasets. The available datasets are currently being mapped to signal processing pipelines to replicate and test the list of biomarkers proposed in the literature as associated with falls.

The corpus of available datasets is expected to represent a valuable resource for testing the performance of existing wearable sensor-based biomarkers for fall risk estimation and for developing fall risk models beyond the state of the art.

Preliminary findings were disseminated as conference contributions [R8], [R9], [R10], [R11].

3.5.2. InChianti Study

Recent advancements in digital health have focused on establishing robust benchmarks for real-world mobility, widely recognized as a "sixth vital sign" of functional status in aging and relevant to fall risk assessments. A pivotal study from the UNIBO research group entitled “Walking into aging: real-world mobility patterns and digital benchmarks from the InCHIANTI Study” [R12] addresses this need by providing comprehensive reference values for digital mobility outcomes (DMOs) in community-dwelling older adults. Utilizing the Mobilise-D computational pipeline on data from the InCHIANTI cohort (Tuscany, Italy), the study analyzed metrics such as walking activity, pace, rhythm, and bout-to-bout variability. This study identified significant non-linear trends in these parameters, pinpointing specific age ranges where mobility reduction accelerates and highlighting distinct trajectories based on sex and anthropometric data.

Establishing these normative reference values is essential for distinguishing between physiological aging and pathological decline in clinical research. The availability of such high-resolution benchmarks allows future studies to contextualize sensor-derived data against a validated population standard. By integrating these precise digital markers with longitudinal monitoring, researchers can better detect subtle deviations in gait and activity that precede adverse events. This methodological foundation is particularly relevant for initiatives aiming at developing predictive models for falls, as it validates the use of wearable technology to capture the complexity of real-world motor behavior outside the artificial constraints of a laboratory setting.

3.5.3. DARE-FallsPredict Study

Falls are a major cause of injury, disability, and loss of independence among older adults. Several predictors (either based on questionnaires or measurable variables) are proposed in the literature, although their accuracy and clinical applicability remain limited. Wearable sensors enable continuous monitoring of activity, sleep, and heart rate, which combined with clinical assessments, as the validated questionnaires-based fall risk index FRAT-up, may enhance personalized fall-risk identification. This integrated approach could support targeted fall prevention strategies, reduce healthcare costs, and promote healthy ageing.

In the context of falls prediction, the DARE-FALLSPREDICT study (A. Silvani, M. Domenicali) was developed through a collaboration between UNIBO and AUSL Romagna. FALLSPREDICT aims at recruiting adults aged 65 years and older, that are discharged patients from the Ravenna Hospital. The participants undergo one week of monitoring at baseline and again at 6 months, using a lower back IMU (i.e., Dynaport7, Mc Roberts, Den Haag, The Netherlands) and a wrist accelerometer (GENEActiv, ActivInsights Ltd, UK). They also complete questionnaires (i.e., short-FESi, CES-D, PSQI, MMSE) and functional assessments (walk test, Romberg test, and Timed Up and Go). The Romberg test is performed using a stabilometric platform (Vertigo V, PhysioSensing, Portugal). For each participant, the FRAT-UP score is also calculated. This validated fall-risk index integrates information on previous falls, mobility and balance impairments, medication use, and comorbidities to provide an estimate of one-year fall risk. Follow-up phone calls over 12 months collect information on falls, including their context, consequences, and associated healthcare costs.

A parallel study, DARE-FALLSPREDICT-GP is conducted in Bologna, by UNIBO (A. Silvani), involving older adults recruited from the general population. Participants follow a similar protocol, undergoing one week of monitoring at baseline and at 6 months. In addition to the devices used in Ravenna, the Bologna cohort wrist sensor also contains a photoplethysmography sensor. The same set of questionnaires is administered, along with the walk test. The Romberg test and Timed Up and Go test are not included in the Bologna protocol. The FRAT-UP score is also calculated. Follow-up phone calls over 12 months collect detailed information on falls and related healthcare costs.

The protocol scheme and the experimental setup are reported in Figure 17 and Figure 18, respectively.

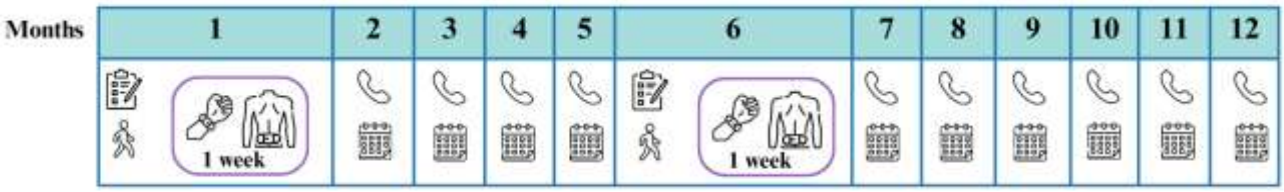

Figure 17. FALLSPREDICT and FALLSPREDICT-GP study protocol.

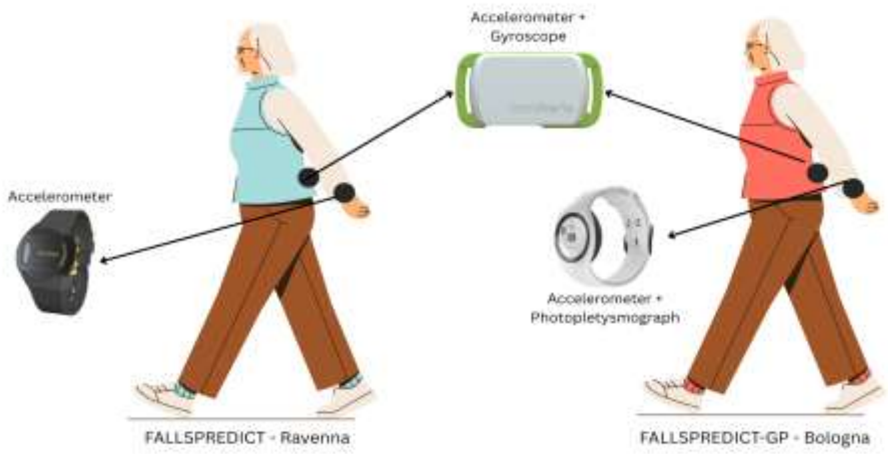

Figure 18. Experimental setup of FALLSPREDICT (on the left), and FALLSPREDICT-GP (on the right).

The wrist accelerometer is worn on the non-dominant hand in order to estimate:

- sleep variables: Sleep Period Time (SPT), Total Sleep Time (TST), Wake After Sleep Onset (WASO), Sleep Onset, Sleep Offset, Sleep Fragmentation, Sleep Efficiency;
- circadian variables: Inter-daily Stability (IS), Intra-daily Variability (IV), acrotime, acrophase;
- physical activity level: time spent in inactivity, and light, moderate, vigorous activities.

The wrist PhotoPletismoGraph (PPG) is used to estimate:

- heart rate variables: Heart Rate (HR) during day and night, heart rate dip, Percentage of Inflection Points (PIP, indicating HR fragmentation) during the night;
- Heart Rate Varibility (HRV) variables: Standard Deviation of all Normal-to-Normal intervals (SDNN), Root Mean Square of Successive Differences between normal-to-normal intervals (RMSSD),

The lower back IMU is used to estimate:

- gait variables: gait speed, gait duration, stride time, stride length, cadence, step count, walking bout count;
- sit to stand variables: vertical displacement, sit to stand duration, sit to stand count, acceleration range, gyroscope range, smoothness;
- turns variables: turns count, number of steps, turn angle, turn duration, mean velocity, peak velocity.

The primary objective of the DARE-FALLSPREDICT and DARE-FALLSPREDICT-GP projects is to develop a model to estimate one-year fall risk in older adults, aiming for a C-statistic of at least 0.75 after correction for optimism. A two-step approach will be used to develop the model. First, variables, collected from wearable sensors and grouped into domains (sleep and movement), will undergo dimensionality reduction and variable selection to identify the most informative predictors. Second, these selected variables, together with the FRAT-UP score, will be included in a multiple regression model to estimate one-year fall risk. In addition, a dynamic model will be tested to estimate fall risk over six-month windows.

In order to process the raw signal data, UNIBO developed and adapted various pipelines. In particular, the GGIR R pipeline [R13] is being used for the sleep and activity-level domains, while the Python Mobilise-D pipeline [R14] is used for gait, and the Python *beliefppg* pipeline [R15] for HR. These pipelines are being deployed to the Alma Health DB (https://www.almahealthdb.it/), the data infrastructure from University of Bologna. An example of the 24-hour profile averaged among the 7 days in a subject from FALLSPREDICT-GP is showed in Figure 19.

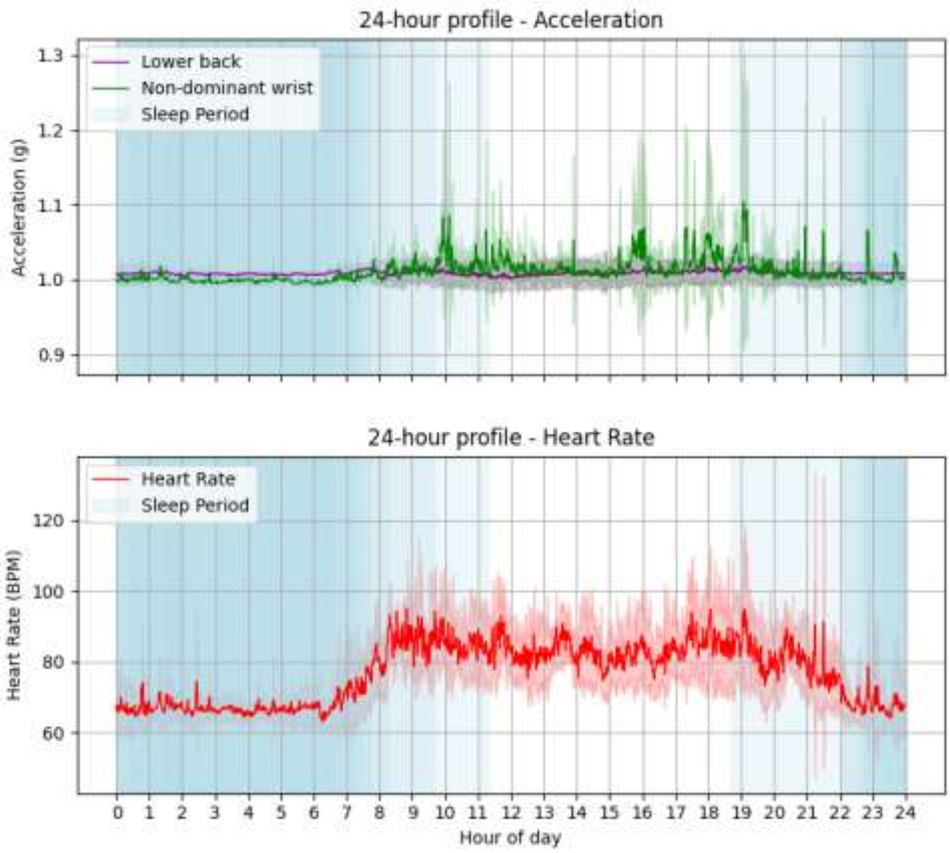

Figure 19. 24-hour profile of the magnitude of the acceleration from the sensor at the lower back and the sensor at the non-dominant wrist, and of the heart rate. The sleep period is also reported as shaded areas.

Preliminary findings were disseminating as abstracts at conferences [R16], [R17], [R18].

3.6. Prevention in the general population

A cascade funding was developed by UNIBO on the topic of clinical apps, with the title of "Development of the DARE's app platform for data acquisition". The cascade funding was proposed for the development of a platform that could allow the creation of digital clinical trials (where every citizen could access simply using an app on the smartphone). As examples of the features included in this smartphone app there are: authentication, creation and initialization of clinical trials, privacy-preserving personal data management, and connection to external sources such as wearables. Cascade Funding was awarded to UNIDAV (beneficiary) and its technical delegate for development (Ud'Anet). The development of the DARE's App was continuously followed and first prototypal versions of the app were released and tested.

The beneficiary UNIDAV and its technical delegate for development Ud'Anet are applying the release plan of the DARE's App, as defined in the cascade project, starting on a previously available platform for clinical trials (TrialsAlive). The cascade project is jointly managed with the Extreme Programming (XP) methodology, with frequent releases and iterations with the technical counterpart of the DARE consortium. The six planned releases of prototypal versions are related to the main functionalities of the App, summarised as follows:

- v1: mock-up generation for preliminary test of requirements and functionalities
- v2: user authentication with registration, login, and password management
- v3: collecting informed consent from participants in a clinical study
- v4: activation and management of a new clinical study
- v5: creating and submitting a questionnaire and/or a physical test within a clinical study
- v6: data collection from a wearable device.

The v4 has been released and it is currently under test. To facilitate the scheduling of the following releases, wearable specifications have been anticipated and discussed.

4.Conclusions and Next Steps

Up to Month 36, different partners of Spoke 1 within DARE have actively employed wearable and portable devices to achieve health-related goals, in line with the DARE mission. The activities presented in this Deliverable demonstrate the feasibility of wearable-based solutions in different contexts, providing valuable insights into device performance, data collection strategies, analysis methodologies, and practical implications for future studies. While the current work has primarily focused on individual study goals, it has provided a solid foundation for understanding the capabilities and limitations of different wearable systems in real-world and clinical contexts.

Overall, the studies reported in this Deliverable reflect different levels of technological and methodological maturity. Feasibility sudies have demonstrated the potential of wearable and portable solutions to reliably acquire and process data of interest across different application contexts, such as motion analysis, physiological monitoring, and sleep assessment. On the other hand, other studies reflect a more advanced status and have already been tested on representative participant cohorts, such as children with autism and elederly frail people, approaching real-world deployment in the contexts of neurodevelopmental disorders assessment and falls prediction. Furthermore, aspects related to regulatory requirements and certification have been considered. The overview of wearable sensors employed across DARE, presented in this Deliverable, reports if the medical certification is present for each identified device. Devices which are not classified as medical devices are nonetheless compliant with safety standards, ensuring their safe use in research and pilot studies.

Future steps will be mainly aimed at enhancing cross-pollination and collaboration between different partners. Efforts will be devoted to build standardized solutions to unify data processing and analysis based on the communalities between the various studies. The adoption of shared applications or platforms for data acquisition, including the DARE's App, will be promoted to facilitate the integration across studies. The adoption of different devices will also be considered, on the basis of the results obtained so far, in order to address existing limitations and improve the study outcomes. These measures aim at maximizing the impact of the wearable technologies employed in DARE supporting the development of robust, interoperable methodologies for enhancing health and quality of life.

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