



Protocol for a Fall Detection Research Study

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1 Introduction

According to the World Health Organization, falls are ranked second as the most common cause of fatal accidents. Annually, approximately 684,000 people die from fall-related injuries worldwide, where the population group over the age of 60 suffers the highest death rate. Nonetheless, non-fatal fall-related accidents tend to have severe consequences. For instance, there are 38 million disability-adjusted life years lost each year due to falls, which considers the impact of disability on an individual’s quality of life and premature death caused by these disabilities. [1]

Given the crucial necessity for providing proper medical attention at an appropriate time following a fall [2], there has been research on fall detection algorithms and their deployment in devices. Fall detection mainly concerns applying certain algorithms and technologies to recognize a fall after it has happened, preferably in a short period [3]. Additionally, an essential aspect of a fall detector is to successfully distinguish various daily regular movements from an actual fall [2]. This fall classification could then assist the victim in calling for medical attention using the detecting device itself or another linked device [4].

There is the idea of applying fall detection using smart watches as the main data collection device. This is motivated by the fact that it is more feasible as it can remain in a natural position on the subject’s body during most daily activities. However, in previous studies, the wrist has proved to be a suboptimal location for a fall detector due to the jerky movements that happen in natural movement, which overlap with data associated with falling. This increases the probability of false alarms occurring, as opposed to if the device was around the hip or head for instance. On the other hand, the wrist remains to be a more accepted location for a fall detector from the user’s perspective [5].

Other studies that have analyzed fall detection in smartwatches have concluded that the detector had a higher chance of noticing the fall if it was on the same side of the wrist. In this case, they used a threshold-based system, which means a fall is classified once predetermined thresholds have been reached. The reason this has been chosen over a pattern-recognition approach was for computational reasons [2].

The primary aim of this research is to assess the fall detection accuracy of a smartwatch-based system and establish a performance benchmark for such systems. If the results are good, a fall detection system can be deployed over smartwatches to provide timely attention to people who have a life-threatening fall.

2 Scenario 1

2.1 Research Question

What is the fall detection accuracy of a smartwatch-based system using data collected from healthy participants?

It is important to conduct this study because it is difficult to get enough data on falls in an observational setting because a person may not fall as many times as required to get accurate training data to train a fall classifier. Thus, it is important to create induced fall experiments to distinguish fall activity from other *activities of daily life* (ADL). This also allows us to annotate all ADLs and perform supervised learning which would be more difficult in an observational study. The results of this study can provide a good starting point for future observational studies.

2.2 Participant Identification

The study will involve individuals aged 18 to 45 years willing to participate in a controlled environment to simulate a fall. Participants will be recruited from the local community and may include both genders and various fitness levels. It is important to emphasize that the study aims to collect data on fall simulations, and participants should be physically capable of engaging in these activities.

2.2.1 Inclusion Criteria

- **Informed Consent:** The participant is willing and able to give informed consent for participation in the study.
- **Gender:** Any

- **Age:** Participants must be between 18 to 45 years of age
- **Physical Health:** Participants should be in generally good physical health, without any medical conditions that would contraindicate physical activity.
- **Physical Ability:** Participants should be able to safely engage in simulated falls without a significant risk of injury.
- **Language:** The participants must be able to communicate and understand instruction in Dutch or English

2.2.2 Exclusion Criteria

- **Age:** Participants below 18 and above 45 years of age
- **Significant Medical Conditions:** Participants with significant medical conditions, such as cardiovascular diseases, severe musculoskeletal issues, or uncontrolled chronic illnesses, may increase the risk of injury during fall simulations.
- **Pregnancy:** Pregnant individuals are excluded from the study due to the potential risks associated with fall simulations during pregnancy.
- **Phobia:** Participants with Basophobia.
- **Physical Limitations:** Participants with any physical limitations or disabilities that could prevent them from safely engaging in fall simulations.

2.3 Measurements

In this study, the aim is to measure the fall detection accuracy of a smartwatch-based system. The primary measurement of interest is the system's ability to accurately detect falls in a controlled environment using data collected from healthy participants. This includes assessing the system's sensitivity, specificity, positive predictive value, and negative predictive value in identifying falls.

We utilize a commercially available smartwatch, Apple Watch 4, with built-in accelerometers, gyroscopes, and other sensors commonly found in consumer-grade wearables to measure fall detection accuracy. This smartwatch is not a medical device but it is designed to monitor various health and activity parameters.

Data collected from the Smartwatch on each participant:

- Accelerometer Data - X/Y/Z Channels
- Gyroscope Data - X/Y/Z Channels
- Timestamp
- Heart Rate Data

Data collected about the participant:

- Age
- Height
- Weight

2.4 Procedures

2.4.1 Recruitment

Number of participants to be recruited: **30 participants** (based on previous studies and power analysis of the pilot study)

We recruit the participants through various methods, including

- **Advertisements:** The research team may use digital and print advertisements in relevant locations, such as community centers, gyms, and healthcare facilities. These advertisements will include information about the study’s purpose, eligibility criteria, and contact information for those interested in participating.
- **Online Recruitment:** Online platforms, including social media, research forums, and community websites, may be used to reach a broader audience. Online recruitment methods will direct potential participants to a study-specific website or contact point.
- **Healthcare Providers:** Collaboration with healthcare providers and medical professionals can be beneficial. Their physicians or healthcare providers may refer participants if they meet the eligibility criteria.

2.4.2 Screening and Eligibility

- Participants expressing interest in the study will receive initial information about the study’s purpose and requirements.
- Participants will receive an informed consent form, and their understanding and willingness to participate will be assessed.
- Age and Gender: Participants will be asked about their age and gender to confirm eligibility within the specified range.
- Participants will be asked about their general physical health and known medical conditions that might contraindicate physical activity.
- Participants must provide information about their physical abilities and any known physical limitations.
- Participants will be assessed for their ability to communicate and understand instructions in Dutch or English.
- Participants will be asked if they have Basophobia.
- Female participants will be asked about their pregnancy status.

2.4.3 Data Collection Procedure

Each participant will be asked to perform the activities mentioned in the procedure below. The facility will be set up such that the participants perform the activities safely and are not hurt during the study. The following would be considered to ensure the safety of the participants.

- The floor will have mat padding to absorb the impact of the fall.
- The participants would be provided a full body suit to avoid scuffs and injuries.

A video camera will be used to record the participants as they fall. This video feed will be used to mark the time frames in which the actual falls take place. The videos will be deleted immediately after the study has been finished and all the annotation is completed. The subjects will wear the smartwatch while they perform activities as shown in Table 1. Each of the activities will be performed **three** times.

Once the data is collected, a Research Technician will go through the video footage and annotate the data based on the start and end of each activity like standing, walking, falling, sitting, and jogging.

Each of these activities will be performed for the following amounts of time/distance:

- Jogging: 20 meters
- Stand: 5 seconds
- Sit: 5 seconds
- Stay Lying: 5 seconds
- Walking: 10 meters

Type	Code	Description
Fall Backward	FBST	Subject is standing, falls backwards, and remains on the ground.
	FBSTR	Subject is standing, falls backwards, stays on the ground for a while, and then gets up again.
	FBW	Subject walks, falls backward, and remains on the ground.
	FBWR	Subject walks, falls backward, stays on the ground for a while, and then gets up again.
Fall Forward	FFST	Subject is standing, falls forward, and remains on the ground.
	FFSTR	Subject is standing, falls forward, stays on the ground for a while, and then gets up again.
	FFW	Subject walks, falls forward, and remains on the ground.
	FFWR	Subject walks, falls forward, stays on the ground for a while, and then gets up again.
Left Side Fall	LSFST	Subject is standing, falls on the left side, and remains on the ground.
	LSFSTR	Subject is standing, falls on the left side, stays on the ground for a while, and then gets up again.
	LSFW	Subject walks, falls on the left side, and remains on the ground.
	LSFWR	Subject walks, falls on the left side, stays on the ground for a while, and then gets up again.
Right Side Fall	RSFST	Subject is standing, falls on the right side, and remains on the ground.
	RSFSTR	Subject is standing, falls on the right side, stays on the ground for a while, and then gets up again.
	RSFW	Subject walks, falls on the right side, and remains on the ground.
	RSFWR	Subject walks, falls right side, stays on the ground for a while, and then gets up again.
Pickup object from floor bending	BLOFBST	Subject is standing, bends, picks up an object on the floor, and then stands up again.
	BLOFBWK	Subject walks, bends, picks up an object on the floor, and then stands up again.
Pickup object from floor squatting	BLOFSQST	Subject is standing, squats, picks up an object on the floor, and then stands up again.
	BLOFSQWK	Subject walks, squats, picks up an object on the floor, and then stands up again.
Sit and get up from chair	ASCHST	Subject is standing, sits on a chair, and then stands up again.
	ASCHWK	Subject walks, sits on a chair, and then stands up again.
Sit and get up from sofa	ASSOST	Subject is standing, sits on a sofa, and then stands up again.
	ASSOWK	Subject walks, sits on a sofa, and then stands up again.
Jogging	JOST	Stand is standing, starts jogging
	JOWK	Subject walks, starts jogging

Table 1: Protocol of Fall Detection Experiments.

2.4.4 Withdrawal of Participants

During the study a participant may choose to withdraw early from the study at any time. This may happen for several reasons, including but not limited to

- The occurrence of what the participant perceives as an intolerable adverse event.
- Inability to comply with study procedures.
- Participant decision.

If the participant withdraws due to an adverse event, the Investigator will arrange follow-up visits or telephone calls until the adverse event has resolved or stabilized.

2.4.5 Definition of End of Study

The end of study is the point at which all the study data has been entered and fall detection accuracy has been reported.

2.5 Analyses

Analyses Objectives	
Objectives	Outcome Measures
Primary Objective To find the accuracy of the classification model to detect falls	Accuracy score on the test dataset along with a confusion matrix to find out which classes perform poor
Secondary Objective To find the accuracy of the classification model to detect other activities	Accuracy score to detect other activities like sitting, standing etc. This will help in related research

The analysis of the data will involve creating a model that can predict if the subject has fallen in a certain time frame.

Classes : [BASELINE, FALLING, SITTING, STANDING, JOGGING, PICKING, WALKING]

Channels : [Acc-X, Acc-Y, Acc-Z, Gyro-X, Gyro-Y, Gyro-Z, Heartrate]

This would be the pipeline for analysis.

1. Each recording is segmented into 5-second windows with 1 second overlap.
2. Mean, Standard Deviation, Maximum, and Minimum are calculated for each channel of each segment.
3. A new dataset with the windowed characteristics is created along with the labels for each data point. The labels are obtained from the annotation.
4. Dimensionality reduction is performed on the dataset to extract the most important features. This will prevent us from introducing less important features in the model.
5. The data is split into training and test data. It is made sure that there is enough data for each class in training and test set to avoid class imbalance.
6. A classifier model is trained to classify the training data.
7. The model is tested on the test set and the accuracy is noted.
8. Refine the model until maximum accuracy is achieved and report this maximum accuracy.

2.6 Data Management

During the study, the data will be collected and stored in a secure local server using an off-the-shelf time series database solution. All the pre-processing and analysis will be done on this server.

To avoid any privacy risk associated with the video footage of the participant activities, this footage will be destroyed after the study once the annotation is completed.

The data management will follow the FAIR principle.

2.6.1 Findable

- **Unique Identifier:** Each dataset will be tagged with a unique alphanumeric code (e.g., AW4-001), ensuring no direct relation to the participant's identity but allowing traceability throughout the study.
- **Rich Metadata:** Alongside the primary sensor readings, metadata will document the exact activity type, whether it's jogging, standing, or an actual fall. This will also include precise timestamps and potential anomalies like temporary sensor malfunction.
- **Explicit Metadata Relationship:** Metadata will include a session ID, linking back to the specific participant's anonymized identifier and the corresponding recorded video for validation purposes.
- **Data Directory:** A centralized digital directory will be established, cataloging each data session, making the datasets easily searchable for others.

2.6.2 Accessible

- **Standardized Protocol:** Team members will access data through a secure portal, which will have detailed logs of data queries and modifications.
- **Backup and Retrieval:** All data, excluding raw video footage, will be backed up on a weekly basis to an offsite secure server.
- **Access Control:** Multi-factor authentication will be mandatory, ensuring only authorized personnel can access the datasets.

2.6.3 Interoperable

- **Standardized Data Format:** The data will be stored in a common format (e.g., .EDF) to ensure easy integration with data analysis tools and potential external databases.
- **Consistent Vocabulary:** Terms like "fall", "jog", and "stand" will be standardized across all datasets to prevent any ambiguities.
- **Cross-referencing:** Annotators will use a system that links specific timestamps in the sensor data to the corresponding moments in the video recordings, aiding validation.

2.6.4 Reusable

- **Comprehensive Data Descriptors:** Each data column will have a descriptor, detailing whether it's accelerometer data, gyroscope data, or heart rate. This ensures clarity for future researchers.
- **Licensing:** A clear open-source licensing model will specify the conditions under which the anonymized data can be reused, promoting transparency and fostering collaborative research.
- **Provenance Traceability:** A detailed changelog will track any modifications or annotations to the data, detailing who made the change and when.
- **Alignment with Research Norms:** All data practices will align with prevalent norms in the field of wearable sensor research, ensuring that our data can seamlessly contribute to larger studies or meta-analyses.

By meticulously following this data management strategy, we safeguard participant privacy while preserving data integrity and value for future research endeavors.

2.7 Ethical Considerations

2.7.1 Risk Analysis

Risk Management Sheet				
Risk Description	Probability	Impact	Risk Priority	Mitigation
Injury	4	5	20	<ul style="list-style-type: none">• Mat floor• Padded uniform
Device Malfunction	1	5	5	CE Device certification
Data Leak	3	1	3	Data encryption and security

2.7.2 Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form before any study-specific procedures are performed.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol; the known side effects, and any risks involved in taking part. It will be stated that the participant is free to withdraw from the study at any time without any implications, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed fourteen days consider the information, and the opportunity to question the Investigator, their GP, or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of the participant's dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorized to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

2.8 Privacy

The overall privacy risk associated with this study is very low as no personal data like geo-location, browsing history, or medical history are being tracked. All the data apart from name, age, height, and weight are collected for administrative or eligibility purposes and are not published. The video footage will be deleted immediately after the study is completed.

- **Complete Anonymization:** While the smartwatch records detailed sensor data, any personal identifiers, such as age and gender, will be stored separately. The connection will only be a key ID, ensuring participant anonymity.
- **Encrypted Storage:** All datasets, especially ones containing personal metrics like height and weight, will be encrypted using standard encryption protocols.
- **Retention Policy:** Post-analysis, personal data will be destroyed following a 12-month period, while anonymized sensor data will be retained indefinitely for research continuity.
- **Consent:** Participants will be explicitly informed about the use of their personal data and will provide informed consent. They will have the right to withdraw their consent at any time.

3 Scenario 2

3.1 Research Question

What is the recall of the smartwatch-based system when used on observational data of falls of elderly patients?

3.1.1 Motivation

The research is necessary to understand the accuracy of the fall detection system in elderly people and ensure their safety when the system is deployed. Recall, being the ratio of true positives to all falls, (in this case the ratio of correctly identified falls to falls which both were and were not registered as such) is chosen as the primary metric here. A low recall score would mean that the system struggles with identifying falls. Such a system could lead to absence of assistance, with potentially dire consequences.

3.2 Participant Identification

The study will involve individuals above 65 years of age willing to participate in an observational study. Participants will be residents of assisted living facilities in the Netherlands and may include any gender. As the data will be that of authentic falls, it is important that these individuals are able to and willing to participate, while understanding the aim of the study.

3.2.1 Inclusion Criteria

1. **Informed Consent:** Participants must provide informed consent, indicating that they understand the observational nature of the study and are willing to participate.
2. **Age:** Individuals must be 65 years of age or older.
3. **Gender:** Any.
4. **Residency:** Participants must be residents of an assisted living facility.
5. **Mobility:** Participants should be capable of moving around either independently or with minimal assistance, as the study relates to spontaneous falls.
6. **Cognitive Function:** Participants should have the cognitive ability to understand the study's protocol, including risks and benefits, and to be able to operate the smartwatch.
7. **Language:** The participants must be able to communicate and understand instruction in Dutch or English.

3.2.2 Exclusion Criteria

1. **Lack of Informed Consent:** Participants which did not provide informed consent prior to the start of the study.
2. **Age:** Participants below 65 years of age.
3. **Cognitive & Health Status:** Individuals with severe cognitive impairments such as advanced dementia, serious health complications, or life-threatening illnesses that might put them at significant risk during the observational period or affect their ability to participate.
4. **Mobility:** Individuals who are bedridden or have significant mobility limitations preventing spontaneous movement.
5. **Refusal or Inability to Wear the Smartwatch:** Participants who cannot or will not wear the smartwatch-based system consistently for the duration of the study.

3.3 Measurements

Similarly, as in the previous study protocol, the Apple Watch 4 will be used as the device to collect data. In addition to the data types described earlier, we will also collect data reported by the participants on whether they fell. The details are further explained in the Procedures section (3.4).

Automatically collected data from the Smartwatch on each participant:

- Accelerometer Data - X/Y/Z Channels
- Gyroscope Data - X/Y/Z Channels
- Timestamp
- Heart Rate Data

Manually flagged data by participant from the smartwatch on each participant:

- Fall call timestamp

Data collected about the participant:

- Age
- Height
- Weight

3.4 Procedures

3.4.1 Recruitment

Up to 35% of those aged 65 and above experience a significant fall every year. [6] To minimize the number of participants needed, we have decided to run the study for a period of 180 days. In order to assess the system, we have decided that during this time, we want to record 100 fall events. With this information, we can calculate the number of participants needed, as follows:

Given

$$p_{fall} = 0.35$$

per 365 days, we get the daily probability p_{day} by

$$p_{day} = 1 - (1 - p_{fall})^{\frac{1}{365}}$$

To get the probability for 180 days, p_{180} :

$$p_{180} = 1 - (1 - p_{day})^{180} = 0.191...$$

Which, with

$$n_{events} = 100$$

yields

$$n_{participants} = \frac{n_{events}}{p_{total}} = 522.48..$$

Therefore, the number of participants to be recruited is 523.

Since the participant demographic is different than in the simulated fall study, slightly different recruitment procedures will be followed, namely:

- **Printed Advertisements:** The research team may use print advertisements in assisted living facility common areas, such as the living or dining rooms. These advertisements will include information about the study's purpose, eligibility criteria, and contact information for those interested in participating.
- **Staff and Healthcare Providers:** Collaboration with facility staff, caregivers, and healthcare providers can be beneficial. They may refer participants residing in a facility if they meet the eligibility criteria. They can also distribute the printed advertisements.

3.4.2 Screening and Eligibility

As with recruitment, screening and eligibility assessment has been altered to fit the demographic.

- Participants expressing interest in the study will receive initial information about the study’s purpose and requirements.
- Participants will receive an informed consent form, and their understanding and willingness to participate will be assessed.
- Age: Participants will be asked about their age to confirm eligibility within the specified range.
- Participants will be asked about their general physical health and known medical conditions that might contraindicate physical activity.
- Participants will be assessed for their ability to communicate and understand instructions in either Dutch or English.
- Participants will be examined with regards to their cognitive abilities, assessed by whether they are able to operate the smartwatch after instruction.
- If any exclusion criteria apply to a potential participant, they will be deemed ineligible for the study. Participants meeting all inclusion criteria will be enrolled in the study.

3.4.3 Data Collection Procedure

Each participant will be tasked with wearing the smartwatch for the entire duration of the study. They will be instructed on how and when to charge the device. To get the ground truth data on the falls, the device will be equipped with an application created for tagging real falls. After the participant has been instructed on how to use the app, and their understanding verified, the app can be used to collect the data in two ways. After a participant falls, they will either:

- Tap & hold a button in the app for 5 seconds to indicate that they fell, or
- Will use the app via the voice assistant to indicate their fall

3.4.4 Withdrawal of Participants

During the study a participant may choose to withdraw early from the study at any time. This may happen for several reasons, including but not limited to:

- Inability to comply with study procedures.
- Participant decision.

3.4.5 Definition of end of study

The end of study is the point at which all the study data has been analyzed by the fall detection system and the recall has been reported.

3.5 Analyses

Analyses Objectives	
Objectives	Outcome Measures
Primary Objective To assess the sensitivity (recall) of the model trained on simulated falls in falls observed in the elderly	Recall score on the data set of observed falls
Secondary Objective To improve the recall of the model	Recall score after fine-tuning the model on the observational data

The model from the previous study can classify the 5 second intervals into classes BASELINE, FALLING, SITTING, STANDING, WALKING, JOGGING, and PICKING. Because of this, the analysis of the primary

objective will entail the following:

1. Using the data labels from the fall call timestamps, data preceding the fall call timestamp by 2 minutes will be kept and the rest discarded.
2. Since falls in the elderly are usually slower, the recordings have to be segmented into 10-second windows, which overlap every 2 seconds.
3. The model's output will have to be adjusted to the classes FALLING and NOT-FALLING, where the class NOT-FALLING is a mapping from all the remaining classes.
4. Afterwards, the data is processed similarly as in the previous study.
5. The algorithm is then run on the processed data, and the recall of the system is noted.

In the case of the second objective, the process continues as follows:

5. The model is fine-tuned on the real data, with a test set withheld.
6. The model is tested on the test set and the recall is noted.
7. Refine the model until maximum accuracy is achieved and report this maximum recall.

3.6 Data Management

During the study, the data will be collected and stored in a secure local server using an off-the-shelf time series database solution. All the pre-processing and analysis will be done on this server.

The data management will follow the FAIR principle.

3.6.1 Findable

- **Unique Identifier:** Each dataset will be tagged with a unique alphanumeric code (e.g., AW4-001), ensuring no direct relation to the participant's identity but allowing traceability throughout the study.
- **Rich Metadata:** Alongside the primary sensor readings, metadata will document the two data types, falls and not-falls. This will also include precise timestamps and potential anomalies like temporary sensor malfunction.
- **Explicit Metadata Relationship:** Metadata will include a participant's anonymized identifier, linking back to the corresponding raw sensor data and fall call timestamps for validation purposes.
- **Data Directory:** A centralized digital directory will be established, cataloging each data session, making the datasets easily searchable for others.

3.6.2 Accessible

- **Standardized Protocol:** Team members will access data through a secure portal, which will have detailed logs of data queries and modifications.
- **Backup and Retrieval:** All data, excluding raw video footage, will be backed up on a weekly basis to an offsite secure server.
- **Access Control:** Multi-factor authentication will be mandatory, ensuring only authorized personnel can access the datasets.

3.6.3 Interoperable

- **Standardized Data Format:** The data will be stored in a common format (e.g., .EDF) to ensure easy integration with data analysis tools and potential external databases.
- **Consistent Vocabulary:** The terms "fall", "not-fall" will be standardized across all datasets to prevent any ambiguities.
- **Cross-referencing:** Annotators will use a system that links specific timestamps in the sensor data to the corresponding fall call timestamps, aiding validation.

3.6.4 Reusable

- **Comprehensive Data Descriptors:** Each data column will have a descriptor, detailing whether it's accelerometer data, gyroscope data, heart rate, or fall class.
- **Licensing:** Open-source licensing model will specify the conditions under which the anonymized data can be reused, promoting transparency and fostering collaborative research.
- **Provenance Traceability:** A detailed changelog will track any modifications or annotations to the data, detailing who made the change and when.
- **Alignment with Research Norms:** All data practices will align with prevalent norms in the field of wearable sensor research, ensuring that our data can seamlessly contribute to larger studies or meta-analyses.

4 Ethical Considerations

4.0.1 Caretaker visits

The participant will be regularly visited by their corresponding caretaker, every two days. During this time, the caretaker will ensure that the participant is following the protocol, and ask the participant about any discomfort the participant might have wearing the device, and try to find a solution that will not exclude the participant (such as wearing the device on a different wrist).

4.0.2 Informed Consent

The participant must personally sign and date the latest approved version of the Informed Consent form before any study-specific procedures are performed.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the exact nature of the study, what it will involve for the participant, the implications and constraints of the protocol; the known side effects, and any risks involved in taking part. It will be stated that the participant is free to withdraw from the study at any time without any implications, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed fourteen days consider the information, and the opportunity to question the Investigator, their GP, or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of the participant's dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorized to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

4.1 Privacy

The overall privacy risk associated with this study is very low as no personal data like geo-location, browsing history, or medical history are being tracked. All the data apart from name, age, height, and weight are collected for administrative or eligibility purposes and are not published. The video footage will be deleted immediately after the study is completed.

- **Complete Anonymization:** While the smartwatch records detailed sensor data, any personal identifiers, such as age and gender, will be stored separately. The connection will only be a key ID, ensuring participant anonymity.
- **Encrypted Storage:** All datasets, especially ones containing personal metrics like height and weight, will be encrypted using standard encryption protocols.
- **Consent:** Participants will be explicitly informed about the use of their personal data and will provide informed consent. They will have the right to withdraw their consent at any time.

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