Addressing Psychosocial and Lifestyle Risk Factors to Promote Primary Cancer Prevention: an integrated platform to promote behavioural change (iBeCHANGE)

Project Number: 101136840

D5.2 – iBC/WS protocol approval and registration

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Disclaimer

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List of Abbreviations

Abbreviation	Explanation
EUT	Fundació Eurecat
GDPR	General Data Protection Regulation
ICO	Institut Català d'Oncologia
IEO	Istituto Europeo di Oncologia
MET	Metabolic Equivalent of Task
POLIMI	Politecnico di Milano
RCT	Randomised Controlled Trial
SD	SporeData
TSQ-WT	Telehealthcare Satisfaction Questionnaire - Wearable Technology
TU/e	Eindhoven University of Technology
UMFCD	Universitatea de Medicină și Farmacie “Carol Davila”
UNIPA	Università degli Studi di Palermo

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Executive Summary

This deliverable (D5.2) presents a sub-study within the iBeChange pilot, focused on integrating wearable devices as part of the intervention. It has been developed under Task 5.5 (T5.5) of Work Package 5 (WP5). Thus, this sub-study builds upon the primary pilot study detailed in Deliverable 5.1 (D5.1) and aims to assess the feasibility, suitability, validity, and preliminary efficacy of incorporating wearable devices into the iBeChange intervention framework.

Indeed, wearable devices offer a powerful, non-intrusive means of collecting health-related data, including behavioural and psychosocial risk factors associated with cancer prevention. By continuously monitoring physiological parameters, these devices can enhance data accuracy and patient engagement, supporting behavioural change and emotional regulation. The selected wearable for this study is the Oura Ring, chosen for its seamless integration with the iBeChange platform, high biometric accuracy, and user-friendly design.

Within the intervention group of the main pilot study (T5.4), the wearable sub-study will be offered to participants. Those who agree to participate will then be randomly assigned to either receive the wearable device or not. Recruitment process, eligibility criteria, endpoints, and statistical analyses are aligned with the overarching study protocol outlined in D5.1 and specifications for the sub-study are presented in this deliverable. The data flow of wearable devices is outlined, along with an analysis of potential risks and benefits. Mitigation strategies are also presented.

This sub-study represents a critical step toward integrating wearable devices into the iBeChange intervention. The findings will inform the feasibility of scaling up wearable integration in future Randomised Controlled Trial (RCT), enhancing the platform’s ability to deliver tailored, data-driven interventions for primary cancer prevention. The insights gained will contribute to optimising user engagement, refining intervention strategies, and improving long-term health outcomes.

1. Introduction

Within Work Package 5 (WP5), a pilot study will be conducted to evaluate the feasibility of recruitment, management, intervention delivery, and assessment procedures using the iBeChange platform. This study, part of Task 5.4 (T5.4), is described in detail in Deliverable 5.1 (D5.1), and serves as a foundational step prior to the full Randomised Controlled Trial (RCT).

As part of this pilot, a wearable sub-study (iBC/WS1) has been designed under Task 5.5 (T5.5), to explore the feasibility and added value of integrating wearable devices within a subgroup of participants. This optional sub-study is offered to participants allocated in the intervention group. Those who consent are randomly assigned to either receive a wearable device or not. The current deliverable D5.2 describes the rationale, procedures, and implementation of this wearable sub-study, which aims to complement self-reported data and smartphone-based monitoring with continuous lifestyle data collected through wearables.

Since the pilot wearable sub-study described in T5.5 involves a subsample of participants from the intervention group of the main pilot study (T5.4), a unified protocol has been developed to streamline the ethical approval process for both. As such, we refer to a single, consolidated pilot study (detailed in D5.1), within which the wearable sub-study (T5.5) is embedded. This integrated approach simplifies procedural steps and helps accelerate ethical approval processes required across all participating clinical centres (IEO, ICO, and UMFCD). Therefore, the information related to the wearable sub-study presented in this deliverable (D5.2) is already included in D5.1, which serves as the comprehensive protocol to be submitted for ethical review.

The present deliverable focuses only on the pilot wearable sub-study under T5.5, providing an in-depth look at the feasibility, suitability, validity and preliminary efficacy of incorporating wearable devices into the pilot study. However, for a more detailed overview of the pilot study as a whole, including regulatory and ethical considerations, please refer to D5.1.

2. Rationale

Wearable devices are advanced technological tools that enable the passive collection of various health-related indicators, including behavioural and psychosocial risk factors linked to cancer development (see D2.1). By continuously measuring physiological parameters, these devices offer a real-time, holistic view of an individual's physical and mental well-being without interfering with daily activities (Piwek et al., 2016). In addition to improving data collection, wearable technology plays a key role in fostering patient engagement and adherence, as many individuals perceive these devices as empowering tools that enhance self-awareness (Patel, Ash & Vopp, 2015). More significantly, wearables contribute to behavioural change and emotional regulation, which are critical aspects in the multidisciplinary approach to primary cancer prevention. The ongoing, real-time data provided by these devices would not only enhance the accuracy and reliability of our research outcomes but would also, when integrated with traditional methodologies, facilitate less intrusive data collection, monitoring, and the personalised delivery of interventions via the iBeChange platform.

Building on these advancements, the main pilot study will include a dedicated optional wearable sub-study involving a subset of participants. The objective is to implement a passive and non-intrusive health monitoring system that leverages wearable sensors to capture information on participants’ health, emotions, and lifestyle. This strategy aims to improve adherence and acceptance by reducing participant burden. Additionally, the sub-study will evaluate the feasibility of incorporating wearable technology to complement existing data collected through questionnaires and smartphone sensors, leading to more precise identification of risk factors and potential interventions. Ultimately, the study will explore whether participants using wearables demonstrate greater behavioural changes and psychosocial adjustments compared to those who do not.

For this sub-study, smart rings will be utilised. In recent years, the **smart ring** market has expanded significantly due to growing demand for discreet and minimally invasive wearable devices. Smart rings represent an innovative class of wearables, offering high accuracy in biometric measurements, an unobtrusive design, and ease of use in everyday life (Fiore et al., 2024; Wang et al., 2024). Compared to smartwatches, smart rings provide a distinct advantage in clinical research: their small size and low visibility make them more compatible with participants’ existing wearable devices while also reducing perceived intrusiveness, thereby potentially lowering the risk of study dropout.

Specifically, the **Oura Ring** has been selected for this sub-study due to its unique combination of continuous health tracking and user-friendly design. It seamlessly integrates with both iOS and Android devices and includes an API that allows remote data access through external applications, such as the one developed within the iBeChange project. Its availability in multiple sizes ensures a comfortable fit for a diverse range of

users, accommodating different anatomical needs. Moreover, the device’s extended battery life (lasting up to eight days) supports uninterrupted data collection, minimising user inconvenience. Importantly, the Oura Ring upholds strong data security and privacy measures by storing collected information on servers located in GDPR-compliant countries. By selecting the Oura Ring, this sub-study aims to strike an optimal balance between data accuracy and participant comfort, ultimately promoting higher adherence rates and enhancing the reliability of the collected data.

3. Study Objectives

The primary objective of this sub-study is to assess the **feasibility** of integrating wearable devices into the iBeChange intervention. In addition to feasibility, the study aims to evaluate the **suitability** of wearables by comparing usability and adherence between participants in the wearable sub-study group and those in the standard iBeChange intervention group (i.e., those who do not receive a wearable device). Specifically, we seek to determine whether the inclusion of wearables enhances participant engagement improves their overall experience with the intervention, and leads to higher adherence rates over time. Understanding participant satisfaction and perceived ease of use will provide insight into whether wearables are a viable tool for complementing the monitoring of psychosocial and behavioural health.

Another important objective is to examine **correlations between wearable device metrics and self-reported measures** related to physical activity levels and psychosocial health. This will help establish whether wearable devices provide reliable, objective data that align with participants’ self-reports, thereby validating their use for measuring behavioural and psychosocial outcomes.

Furthermore, the sub-study aims to explore the **preliminary impact** of using wearables as an adjunct to the iBeChange intervention, investigating whether integrating wearable data can enhance the effectiveness of the personalised recommendations delivered by the recommender system in future iterations of the intervention.

Evaluating these aspects is essential for determining the long-term potential of wearable technology within the iBeChange platform. Indeed, focusing on feasibility is essential to ensure that the integration of wearable devices into the iBeChange intervention is practical, scalable, and well-received by participants before expanding their use in the RCT. Understanding potential logistical challenges, user adherence, and technical limitations will help refine the implementation process and maximize the effectiveness of wearables in supporting behavioural and psychosocial health monitoring. The data collected through wearable devices can aid in the identification of behavioural and psychosocial risk factors and improve the recommender system’s ability to deliver tailored interventions. This study will provide crucial insights into the optimal use of wearable integration in the upcoming RCT.

4. Methods

4.1. Eligibility criteria

The **inclusion** and **exclusion criteria** will be the same as those outlined in the main pilot study, since participants for this sub-sample will be recruited from the iBeChange intervention group. The eligibility criteria will be briefly described below to give an overview of the characteristics of the sample. For more details, please refer to D5.1.

To be involved in the main pilot study and in the wearable sub-study, participants will have to be able to understand and voluntarily provide signed written informed consent, being at a high-risk age for breast, colorectal, or lung cancer, having participated in a test for early detection of one of these types of cancer. Exclusion criteria include history of prior or current personal cancer diagnosis (restricted to the pathology tested for screening for breast and colorectal cancer), current severe disease that may significantly compromise the performance on the study according to the criteria of the investigator, and not owning a smartphone.

In addition to the eligibility criteria applicable to all participants in the main pilot study described in D5.1, additional requirements will be considered for the wearable sub-sample. Specifically, individuals with known **skin conditions**, such as **allergic skin reactions**, active eczema, or contagious dermatological disorders, as well as those with known allergies or previous adverse reactions to **titanium or medical-grade plastic**, will be excluded. No further inclusion or exclusion criteria will be introduced to prevent selection bias. However, it is important to note that the availability of suitable ring sizes may limit the inclusion of some participants in the wearable sub-study. If a participant requires a ring size that is not available, they will not be able to proceed with the study using the wearable device. In such cases, the next eligible participant will be considered to ensure the required sample size is met. Nonetheless, several mitigation strategies have been put in place to minimise this risk, as outlined in the section on potential risks and benefits (Section 5).

4.2. Recruitment and procedure

Participants will be recruited from screening programs for breast, colorectal and lung cancer conducted in three clinical centres: Istituto Europeo di Oncologia (IEO; Milan, Italy), Institut Català d’Oncologia (ICO; Barcelona, Spain), and Universitatea de Medicină și Farmacie “Carol Davila” (UMFCD; Bucharest, Romania). It is to note that this wearable sub-study will also be conducted at the Università degli Studi di Palermo (UNIPA), involving a sample of approximately 25 healthy individuals to assess the acceptability, usability, and user satisfaction with the iBeChange system. Given that the recruitment

strategies, timelines, and procedures for this sub-study differ from those of the main study, a separate protocol will be developed and submitted accordingly. Therefore, no reference to the UNIPA activities is included in the present deliverable.

The recruitment process at ICO, IEO and UMFCD will follow the same process as described in the main study (see D5.1), and participants will be randomly assigned to either the iBeChange intervention group or to the control group. Participants randomised to the iBeChange intervention group in the pilot study will be offered the opportunity to join the wearable sub-study, until the required sample size is reached in each clinical centre. If participants meet the inclusion and exclusion criteria for the wearable sub-study, and agree to participate, and provide specific informed consent, a second randomisation will be conducted to determine whether they are assigned to the wearable sub-group or not. Participants assigned to the wearable sub-sample will be provided with an Oura Ring, and additional data will be collected from these participants. If the appropriate ring size is not available for a participant, the mitigation actions outlined in the potential risks and benefits section (Section 5) will be implemented.

It is estimated that 33% of the intervention group will receive a wearable device. This corresponds to approximately 30 participants across all centres who will be assigned an Oura ring. Consequently, and based on the cancer type distribution expected in the main pilot study (see D5.1), each clinical centre will have 10 participants with wearable devices, estimated to be distributed as follows (Table 1):

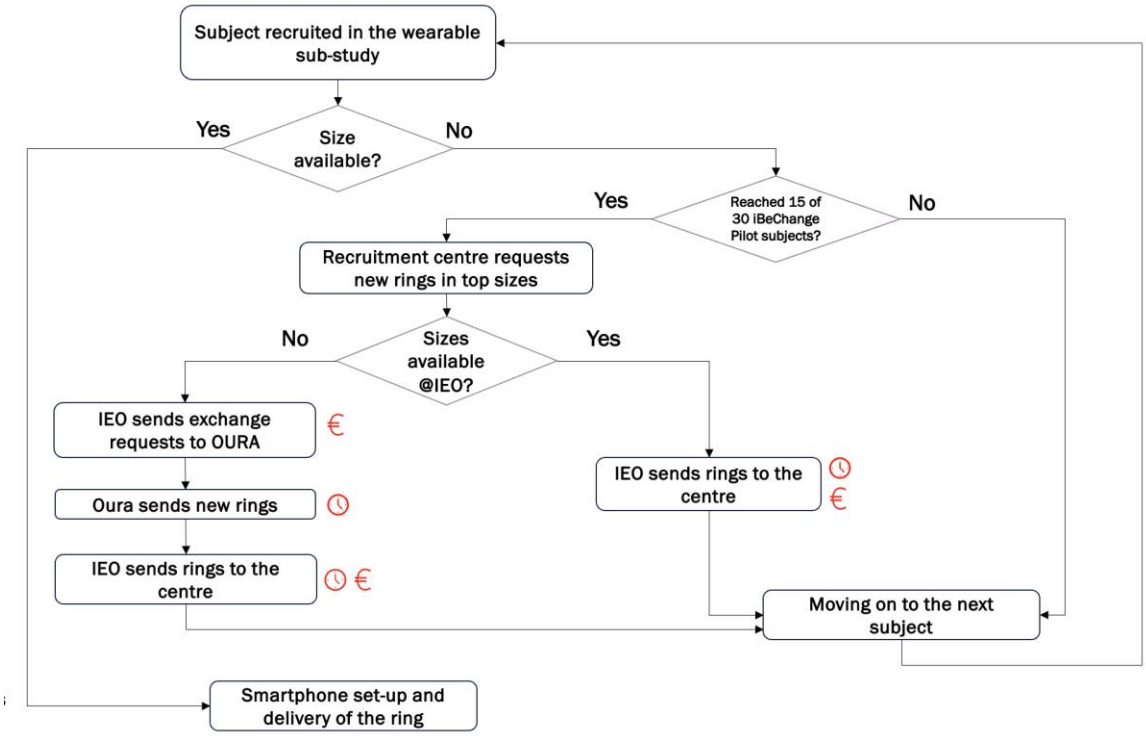
Table 1. Estimated distribution of wearable devices per clinical centre and cancer screening type.

Cancer type	**ICO**	**IEO**	**UMFCD**
Breast *(females)*	7	8	7
Lung *(males/females)*	-	2	-
Colorectal *(males/females)*	3	-	3
Total	*10*	*10*	*10*

The Oura Ring will be provided to participants in the wearable sub-group on the same day as their in-person enrolment, if immediately available. On this occasion, participants will

sign the specific informed consent form. The device will then be returned post-intervention (after 12 weeks). If the appropriate ring size is not available at the time of recruitment, the following workflow will outline how the situation will be managed (Figure 1).

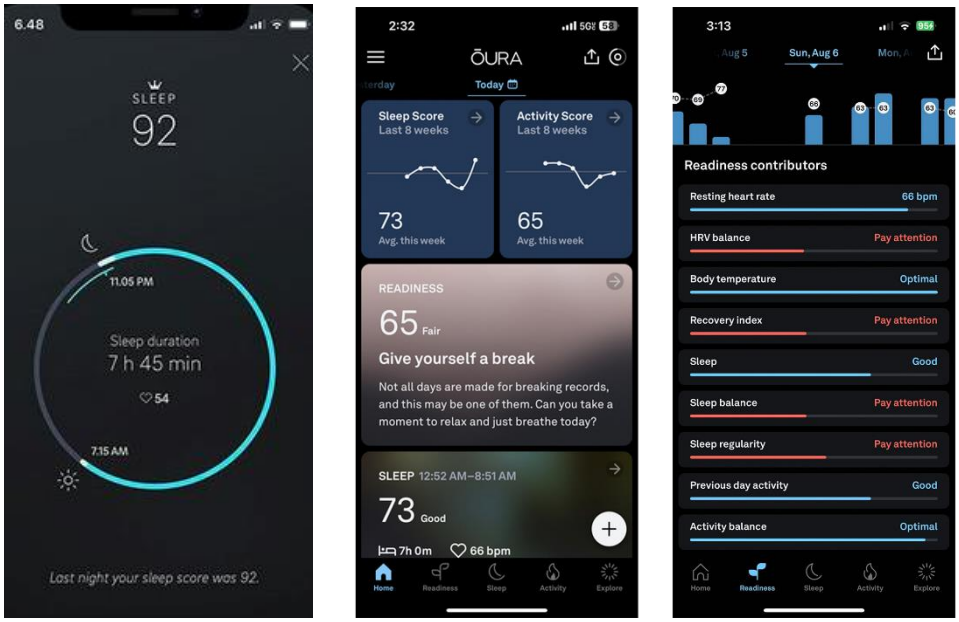
Figure 1. Workflow for managing sizes and unavailability of rings at the time of recruitment.



Note. € = additional costs needed; clock symbol: additional time needed, which results in the participants receiving the ring at a later stage.

The intervention for participants in the wearable sub-sample will be the same as in the main pilot study (see D5.1), consisting of access to the iBeChange platform. Additionally, participants assigned to the wearable group will download the Oura app and create an account. By continuously wearing the Oura Ring and accessing the Oura app at any time, they will gain access to their health metrics. There will also be a button in the iBeChange app that, once pressed, will redirect participants to the Oura app, so that they can see the metrics whenever they want. This real-time data access may and potentially encourage proactive behavioural changes by increasing participants' awareness of their health indicators. Figure 3 provides examples of how health metrics are displayed to participants in the Oura app.

Figure 2. Examples of visualisation of health metrics in the Oura app.



4.3. Endpoints and measures

In this subsection, the endpoints aligned with the study objectives will be outlined, along with the specific data measures to be collected via the wearable devices.

Specifically, **feasibility** will be assessed by completion rate of wearable data collection and the percentage of successful data transmissions without technical issues. The times a ring size is not available at site for a participant will also be registered. Assessing data completion rates and successful transmissions will help demonstrate whether wearables can reliably collect and transfer data to support the intervention. Furthermore, data from wearables logistics will allow to adjust ring size purchases and distribution among clinical sites.

Suitability will be evaluated through a post-intervention questionnaire, namely the System Usability Scale (Brooke, 1996), which is a 10-item tool that is widely used and has demonstrated high reliability and validity. Specifically, changes in usability and adherence rates between participants in the wearable sub-study and those in the standard iBeChange group will be evaluated.

The **validity** of wearable devices in assessing physical activity levels and psychosocial health will be evaluated through preliminary concurrent validity, measured by the correlation between wearable-derived data and self-reported outcome measures (as detailed in D5.1).

The **preliminary impact** of the use of wearables on the intervention will be evaluated in terms of changes in behavioural and psychosocial outcomes (detailed in D5.1) between participants in the wearable sub-study and the standard iBeChange group.

Data collected through wearable sensors will be related to physical activity and psychosocial health:

Physical activity. We will track the number of steps taken, 1-minute intervals for metabolic equivalent of task (MET); average MET minutes (average MET level sustained throughout the day, factoring in all activities and rest periods); high activity MET minutes and high activity time; low activity MET minutes and low activity time; medium activity MET minutes and medium activity time; sedentary MET minutes and sedentary time; active calories (calories burned during physical activity); total calories (total number of calories burned during the day).

Psychosocial health, we will analyse sleep-related data, including heart rate, heart rate variability (HRV), sleep latency (the time taken to fall asleep), temperature deviations, restless periods, average breathing rate, and overall sleep efficiency, which represents the proportion of time spent asleep relative to total time in bed. We will also examine sleep composition by assessing time spent in light, deep, and REM sleep, as well as sleep and readiness scores, which indicate recovery status and physical preparedness. Additionally, we will monitor stress levels by evaluating physiological arousal through metrics such as heart rate, HRV, movement, and temperature fluctuations over the course of the day.

4.4. Statistical analysis

The wearable data subgroup will be used to assess the feasibility, suitability, and added value of incorporating wearable devices into the study to complement psychosocial and behavioural features already captured through self-reported questionnaires. We will evaluate the quality of the data collected by wearables by assessing missingness and participant adherence to device usage over time. Specifically, we will track the percentage of missing data for each sensor (e.g., heart rate, accelerometer) and assess adherence based on the number of days participants wore the device. To quantify feasibility, we will calculate the frequency of wearable device usage and evaluate any potential barriers to consistent engagement, such as device malfunction or participant non-compliance.

Additionally, we will investigate whether wearable data can provide more granular insights into psychosocial and behavioural risk factors. By correlating specific wearable metrics with corresponding outcome measures, we aim to determine whether these data can supplement or replace outcome assessments through questionnaires. For example, we will assess the relationship between heart rate, steps taken, and physical activity levels by comparing wearable data with the physical activity outcomes measured by the Global Physical Activity Questionnaire (GPAQ) and the International Physical Activity Questionnaire (IPAQ). Pearson correlation coefficients (for continuous, normally distributed variables) or Spearman’s rank correlation (for non-normally distributed

variables) and visual correlation plots will be used to evaluate the strength and direction of these relationships. In addition, we will use Bayesian models to account for potential confounders such as baseline physical activity levels and demographic characteristics. Bayesian approaches offer advantages in small-sample contexts by allowing prior information to be integrated into the estimation process, thereby improving the stability of estimates where data are limited. We will use weakly informative priors, defined a priori based on clinical assumptions and literature, to derive posterior distributions. Importantly, the Bayesian analysis will be conducted only once, after all data have been collected.

Alongside these evaluations, we will test whether participants using wearables demonstrate a higher degree of behavioural change compared to those who did not receive the devices. To assess this, we will compare physical activity and psychosocial outcomes between the wearable and non-wearable groups. For these comparisons, we will use the same statistical methods described above, including Bayesian models and exploratory analysis techniques (e.g., t-tests for between-group comparisons). These analyses will help determine whether the use of wearables leads to more significant improvements in outcomes compared to conventional methods.

5. Potential risks and benefits

The wearable sub-study (iBC/WS1) entails both potential advantages and risks that must be carefully evaluated. One of the key benefits is that wearables, such as the Oura Ring, enable continuous and passive health monitoring (Kinnunen et al., 2020; Sharifi-Heris et al., 2024), offering real-time insights into participants' physiological and behavioural patterns. This constant data stream can enhance the precision of health assessments, aid in identifying risk factors, and potentially encourage proactive behavioural changes by increasing participants’ awareness of their health metrics. Furthermore, the Oura Ring’s discreet and non-intrusive design is expected to enhance user adherence, ensuring more reliable data collection.

Nonetheless, the sub-study also presents certain risks. Some participants may experience mild discomfort or skin irritation from wearing the device, although the availability of different ring sizes should help minimise this issue. Additionally, exposure to personal health data could induce stress or anxiety in some individuals, potentially affecting their emotional well-being. Technical challenges, such as connectivity issues, sensing errors due to ring misplacement or battery failures, may also occasionally disrupt data collection.

Another potential challenge is that, despite selecting ring sizes based on the most probable gender- and age-related measurements of the study population, there may still be cases where a suitable size is unavailable for participants assigned to the wearable sub-group.

To mitigate these risks, several strategies will be put in place. Participants will receive clear guidance on device usage, along with access to technical support when needed. They will also be thoroughly informed about data security measures and required to sign a specific informed consent. To reduce the likelihood of non-adherence, structured engagement strategies will be employed to encourage consistent use of the Oura Ring, which is crucial for ensuring data completeness and integration with self-reported measures. These strategies may include visual progress tracking directly through the Oura app and scheduled reminders through notifications to reinforce engagement and improve data reliability. Additionally, psychological support will be available to help participants manage any distress associated with health monitoring.

To address the potential issue of unavailable ring sizes for participants in the wearable sub-group, several measures will be implemented. The rings will be stored at a central clinical centre (i.e., IEO) to facilitate redistribution to other centres if necessary. Additionally, participants may wear the ring on fingers other than the index finger without compromising data collection. If a suitable size is not available, recruitment will proceed with the next eligible participant in the iBeChange intervention group. Finally, if one centre completes its recruitment process before others, any excess rings will be redistributed to centres still enrolling participants.

6. Data flow, management and protection

Participants will be guided through the process of downloading the Oura App, creating a personal Oura account, and accepting the app’s terms and conditions on their smartphone. These steps are essential to enable proper data collection through the Oura Ring and to authenticate each participant within the Oura system. The creation of a personal account ensures that biometric data is securely and reliably linked to the individual participant, while the acceptance of the app’s terms and conditions is a necessary legal and technical requirement for using the device and for enabling data access via the Oura API.

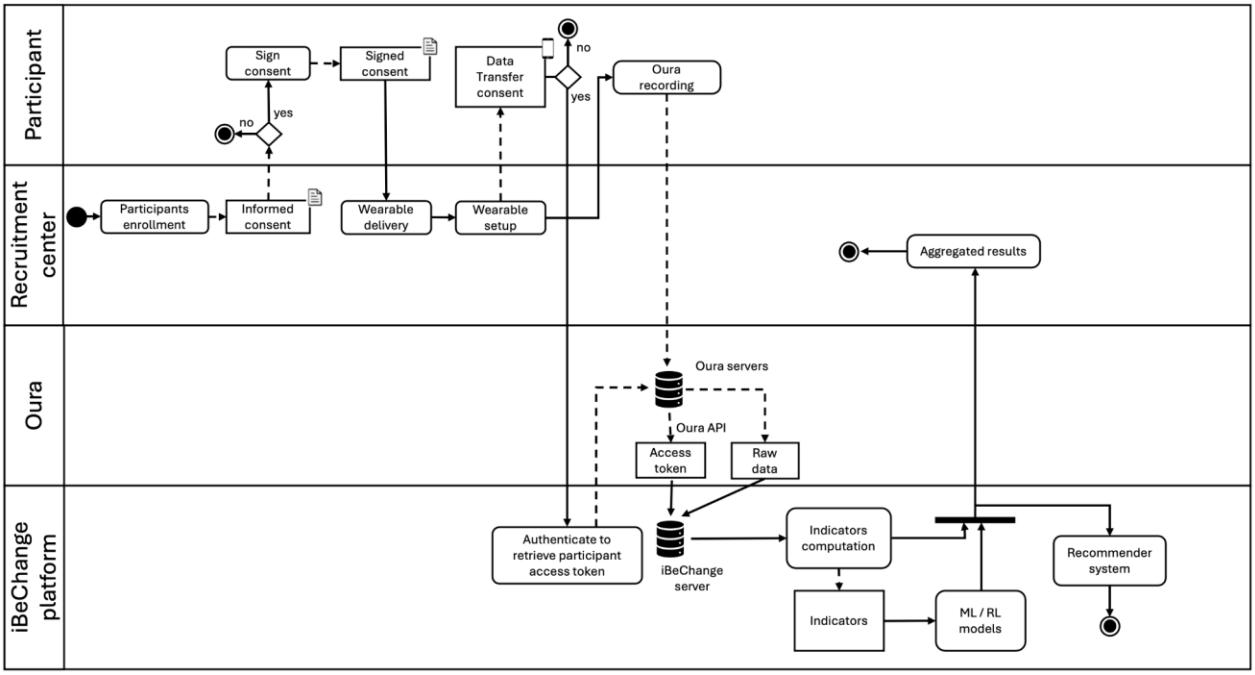
The data collected via the Oura Ring will be stored on Oura’s servers, which are located in Finland (EU) and managed in full compliance with GDPR regulations to ensure data security. Participants will explicitly consent to data transfer both through the informed consent process and within the app.

Data from the Oura Ring will be retrieved from Oura’s servers using the Oura API and subsequently transmitted to the iBeChange server, which is managed by Fundació Eurecat (EUT). Once the raw wearable data have been securely stored on the iBeChange server, technical partners will have access to them for specific purposes: (1) POLIMI will process the time series data to derive meaningful indicators, which will then be stored in the iBeChange database; (2) POLIMI and TU/e will integrate these indicators into the recommender system to optimise the timing of personalised recommendations.

Finally, aggregated analysis results will be made available to the recruitment centres and SD for conducting statistical analyses.

The data flow for wearable data processing is illustrated in Figure 3.

Figure 3. Data flow of wearable data.



Data will be stored for 5 years after the end of the study. GDPR rules will be followed (please refer to the Joint Controller Agreement).

7. Conclusions

This deliverable (D5.2) has presented the rationale, objectives, endpoints, and procedures for the wearable sub-study (iBC/WS1), designed to complement the pilot study detailed in D5.1. Specifically, this sub-study will evaluate the feasibility, suitability, validity, and preliminary efficacy of integrating the Oura Ring into the iBeChange intervention, particularly in relation to physical activity and psychosocial health.

As previously mentioned, the iBeChange Consortium has chosen to adopt a unified protocol, which has been compiled and will be submitted for ethics approval as outlined in D5.1. This deliverable serves as a supplementary document to that protocol. The protocol registration process will be initiated shortly, and an adapted version of this deliverable with the ethical approval letter and study ID registration will be uploaded following approval from the ethics committee, incorporating any necessary updates.

Furthermore, an additional wearable sub-study will be conducted at the Università degli Studi di Palermo (UNIPA), involving approximately 25 healthy participants. This study aims to assess the acceptability, usability, and user satisfaction of the iBeChange system in combination with wearable technology. Due to variations in the recruitment process and timeline, along with the incorporation of eye-tracking measures, a distinct ethical protocol will be submitted specifically for this study.

8. References

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Version history

Version	Description	Date completed
v1.0	First version drafted	01/04/2025
V1.1	Consortium revision	07/04/2025
v2.0	Final version uploaded	14/04/2025