TransCare

New care pathways for supporting TRANSitional CARE from hospital to home using AI and personalized digital assistance

D4.1 Ethical pilots' methodology and protocols' definition

Deliverable Id:	D4.1
Deliverable Title:	Ethical pilots' methodology and protocols' definition
Related Work Package:	WP4
Related Task(s):	T4.1
Related Milestone:	MS1
Version:	V1.0
Status:	Final version
Dissemination Level:	PU
Deliverable Type:	R
Due date of deliverable:	M12 (April 2025)
Actual submission date:	29 April 2025
Deliverable lead partner:	IRCCS INRCA
Main author(s):	Federico Barbarossa (INRCA), Arianna Margaritini (INRCA), Roberta Bevilacqua (INRCA)
Contributing authors:	Lars Thomas Boye (TLU), Ionut Anghel (TUC), Camilla Gabrielsen (FAR), Ancuta Nemes (HINS)
Peer-reviewers:	FAR & HINS
Keywords:	Ethical pilot, end users, trial protocol, inclusion criteria, study design

Project partially funded by European Union and Italian Ministry of Health (IT), Unitatea Executiva pentru Finantarea Invatamantului Superior, Dezvoltarii si Inovarii /UEFISCDI) (RO) and The Research Council of Norway (NO)

Version history

Version	Authors	Date	Description
0.1	Federico Barbarossa (INRCA), Arianna Margaritini (INRCA)	26/02/2025	ToC – structure of the deliverable, outline of contents
0.2	Federico Barbarossa (INRCA), Arianna Margaritini (INRCA), Roberta Bevilacqua (INRCA)	05/03/2025	First full draft
0.3	Federico Barbarossa (INRCA), Arianna Margaritini (INRCA)	26/03/2025	Finished draft version of technical adjustments
0.41	Ancuta Nemes (HINS), Ovidiu Anchidin (HINS)	03/04/2025	Refinements and HINS end-user partner input
0.42	Ionut Anghel (TUC)	08/04/2025	Refinements and TUC partner input
0.43	Federico Barbarossa (INRCA), Arianna Margaritini (INRCA)	09/04/2025	Adjustment of partner inputs
0.44	Camilla Gabrielsen (FAR)	14/04/2025	Refinements and FAR end-user partner input
0.45	Lars Thomas Boye (TELLU)	14/04/2025	Refinements and TELLU technical partner input
0.9	Federico Barbarossa (INRCA), Ovidiu Anchidin (HINS), Camilla Gabrielsen (FAR)	15/04/2025	Peer reviews done and addressed
0.99	Federico Barbarossa (INRCA)	28/04/2025	Quality check ready version
1.0	Ionut Anghel (TUC)	29/04/2025	Final version

Summary

List of acronyms

Acronym	Description
ATDPA	Assistive Technology Device Predisposition Assessment
CFS	Clinical Frailty Scale
CHF	Chronic Heart Failure
COPD	Chronic Obstructive Pulmonary Disease
EQ-5D-5L	5-level EuroQol-5D
FAR	FARSUND KOMMUNE
GDPR	General Data Protection Regulation
HINS	HEART INSTITUTE "NICULAE STANCIOIU" CLUJ-NAPOCA
INRCA	ISTITUTO NAZIONALE DI RICOVERO E CURA PER ANZIANI
KRD	KARDE AS
MMSE	Mini-Mental State Examination
RPM	Remote Patient Monitoring
SF-12	Short-form-12-health-survey-questionnaire
SPPB	Short Physical Performance Battery
SUS	System Usability Scale
THCS	Transforming Health and Care Systems
TLU	TELLU AS
TUC	TECHNICAL UNIVERSITY OF CLUJ-NAPOCA
VAS	Visual Analogue Scale
WP	Work Package

Executive summary

The current deliverable is the first document produced by Work Package (WP) 4 covering the project ethical pilot description and trial protocol definition.

The report describes the study design, setting and population of technological intervention planned in TransCare. Specific population description is included, encompassing inclusion and exclusion criteria with a description of each pilot site sample. Moreover, recruitment and testing procedures are thoroughly described along with scales and measurement to be administered during each experimentation phase. The experimentation described in this report is agreed and shared among each end-user partner.

The trial described in this report was also reported on the official document submitted to each partner country's territorial/national ethics committee, which is responsible for approving its feasibility and will initiate the recruitment described later in deliverable D4.2 (Recruited of the selected participants).

The present deliverable related to task 4.1 addresses the following topics: (i) general introduction to re-hospitalization issue (ii) the rationale of the study, (iii) study objective, (iv) study design, setting and population (v) equipment description, (vi) study endpoints, (vii) protocol and procedure, (viii) data analysis and management and (ix) legal and ethical aspects of the trial.

1 Introduction

The transition from hospital to home for an older patient can be a complex and risk-filled process and managing this transition is one of the most critical challenges for health care systems [1]. This transitional period is particularly delicate because patients, still in a clinically vulnerable condition, often face many challenges in adjusting to and coping with the possible repercussions of their illness at home; in fact, they are leaving a highly controlled and organized hospital environment and returning to home life, where health care resources are more limited and managing their own health requires greater personal commitment [2].

Transitional care includes a range of interventions such as discharge planning, medication management and follow-up, psychological support for patients aimed at ensuring continuity of care between hospital and community [3]. Despite these measures, this transfer continues to be a challenge for many patients whose needs are often not fully met. High readmission rates can highlight inefficiencies in discharge processes and post-hospitalization monitoring, as well as being a source of great distress for patients and family members, undermining trust in the health care system. The increase in readmissions also contributes to overburdening medical staff, creating additional management difficulties in health facilities already marked by shortages of health workers [4]. Approximately 20% of patients face complications during this phase, including unexpected re-hospitalizations within a month of discharge, medication management errors and, in some cases, even deaths [5]. In addition, hospital readmissions account for a significant portion of overall inpatient costs and carry a significant clinical and economic burden for both patients and society, especially when they occur shortly after discharge [6].

Re-hospitalization can be influenced by several modifiable factors, both during hospitalization and after discharge. The underlying causes of re-hospitalization are often multifactorial: major problems include inadequate information management between hospital and primary care providers [7], hospital complications, medication errors, and premature discharge [8]. After discharge, lack of timely follow-up, insufficient post-discharge care, poor medication management, and poor patient education [9], are major critical issues. In addition, often the reasons for rehospitalization are not related to the primary event, but to comorbid conditions; consequently, chronic diseases can significantly influence the risk of rehospitalization, regardless of the reason for initial hospitalization [10].

In addition, when talking about re-hospitalization, the condition of the frail older person must be taken into consideration. Hospitalized older adults are particularly vulnerable due to their serious medical conditions, making hospitalization an event that can have significant negative effects, causing further deterioration in functional and cognitive abilities, as well as causing emotional distress [4]. As described above, comorbidities represent significant risk factors for rehospitalization, with heart failure among the most common [11]. Other conditions such as stroke, hip fracture, chronic obstructive pulmonary disease (COPD), and poorly controlled diabetes are also strongly correlated with rehospitalization [12]. Moreover, the presence of geriatric conditions, such as heart failure, frequent falls, polypharmacy, poor general condition, and functional disability, greatly increases the risk of rehospitalization in the older adults [13], demonstrating that there is a close connection between frailty and re-hospitalization.

In this context, hospitalization within 30 days of discharge is considered one of the most representative outcomes of research interest that can describe the overall quality of care provided during and after hospitalization [14]. It is also important to provide supportive health self-management in home situations. As mentioned above, there are various chronic conditions such as Chronic Heart Failure (CHF), COPD, chronic coronary syndromes, hypertension, and diabetes that can increase a patient's chance of being re-hospitalized. These patients are continuously increasing and living longer [15]. Moreover, although in clinical

reality the diseases frequently coexist in the same patient, their combined management has long been neglected and health care has focused on single-disease oriented approaches, often without coordination or integration [16] This fragmentation of care can negatively affect the patient's clinical outcome, increasing the risk of rehospitalization [17]. In this context, technological innovation plays an increasingly important role in improving patient self-monitoring and preventing readmissions.

Several studies have investigated the impact of technology through remote monitoring devices and telehealth programs on reducing re-hospitalizations, particularly for chronic diseases such as heart failure, COPD, and other complex conditions. An early study evaluated a care transition intervention with remote monitoring to reduce hospital readmissions within 180 days in older patients with heart failure. The results showed a positive impact in reducing re-hospitalizations, but the specific efficacy for 30-day re-hospitalizations was not explored as a primary objective [18]. Another study involved a group of patients diagnosed with acute coronary syndrome, heart failure, pneumonia, and COPD, at high-risk post-discharge, with the same outcome of reducing the number of hospital readmissions. Primary outcomes included the number of hospital readmissions and emergency department visits at 3 and 6 months, while secondary outcomes included days of hospital stay and adherence to the home monitoring protocol. The results suggest that the adoption of remote monitoring technologies improves patient self-management rates and reduces the risk of rehospitalization [19]. An additional study involved patients with COPD for 6 months using digital devices for daily monitoring of vital parameters and symptoms. The primary objective was to assess disease self-management through the Partners in Health scale. Secondary outcomes included COPD severity, COPD-related disease literacy, emergency room access, hospitalizations, medication use, and smoking cessation [20]. Finally, a last study evaluated the effectiveness of a remote monitoring system (e-COBAHLT) in older patients with at least two chronic diseases who were discharged from the hospital. The system used biometric sensors to monitor clinical parameters and detect abnormalities, supporting primary care physicians. The primary outcome was the incidence of hospitalization among comorbid patients at 12 months after hospital discharge, and results showed that remote monitoring significantly reduced unplanned hospitalizations compared with traditional care [21].

In conclusion, it can be stated that although several studies have shown positive outcomes in the use of remote monitoring and assistive technologies for chronic disease management and reduction of rehospitalizations, minor focus is given to the 30-day rehospitalization as the primary endpoint. Most research indeed focuses on broader outcomes without specifically assessing the role of early prevention strategies. A more in-depth analysis of this parameter could provide key evidence to optimize care pathways, improve patients' quality of life, and reduce healthcare costs related to avoidable rehospitalizations.

In addition, the use of a personalized remote monitoring system represents a cutting-edge research area that has only gained relevance in recent years and could significantly improve the flow of chronic patient management between home and hospital. Self-monitoring, although already partially investigated [31], remains an area that needs further development to ensure more personalized and autonomous care.

In this context, the goal of TransCare is to assess and evaluate cases of re-hospitalization within 30 days in the older patient, possibly multimorbid, through the adoption of innovative technology and digital solutions aiming for self-management support of monitoring important physiological parameters of the older adult. The integration of these approaches in the care continuum aims to improve home monitoring and active involvement of the patient in his or her own care pathway.

Concurrently, a crucial aspect among main project endpoints is to propose, adapt and expand the application of the developed solution, based on IoT, Machine Learning and digital assistance, to optimize the

management of the transition from hospital to home. This process will consider the peculiarities of the different contexts in which trials will be conducted, ensuring a tailored approach. Implementation will be modulated according to various factors, including language differences, national regulations, and data security policies, to protect patient privacy. A crucial aspect will be improved communication and care planning, fostering effective integration between hospital, primary care physicians and community services. The goal is to make the transition not only safer, but also smoother and more efficient, reducing the risk of re-hospitalization and improving overall patient well-being.

2 Rationale of the study

The principal reason for the study is the constant hospital overload due to re-hospitalization of the same patient over the course of 30 days, that can be reduced by the improvement of the self-management capability of the patients, once at home after hospitalization. It is indeed a very recurrent problem among chronic and multimorbid patients that they are re-hospitalized for the same initial pathological cause. Conditions with the highest readmission rates include CHF, COPD, diabetes, and chronic infectious processes, among others. The recurrence of hospitalizations causes a severe decrease in the quality of life of the patient and his or her family, resulting in physical and psychological stress for both. Likewise, health care workers are overburdened, and health care facilities often do not have enough capacity to handle the influx. Improving patients' self-management skills could significantly reduce the re-hospitalization rate and, consequently, the negative impact on hospitals and healthcare facilities. This issue was addressed in depth within WP3, which focuses on the analysis of the patient's transitional care process, i.e., the pathway from hospital discharge to return to daily life, with the aim of improving continuity of care and reducing re-hospitalizations. The analysis conducted within WP3 reveals common critical issues among partner countries, such as fragmentation of services, poor integration and difficulties in communication between hospitals, primary care physicians and territorial services. For this reason, the development of integrated solutions enables more efficient management of clinical data and more effective coordination among the different actors involved in patient care.

Telemonitoring strategies, home care and personalized support can play a key role in improving patients' quality of life and easing the burden on healthcare facilities. It is for this reason that TransCare aims to create a digital ecosystem for remote monitoring of the multimorbid patient that aims to avoid rehospitalization of the patient by self-monitoring their general health conditions. The TransCare platform will feature a ML-based post discharge analytics component that will analyse data monitored on daily life activity and vital signs to determine insights that can be used by medical professionals to address the problems that require intervention. Concept overview of TransCare project is depicted in Figure 1.

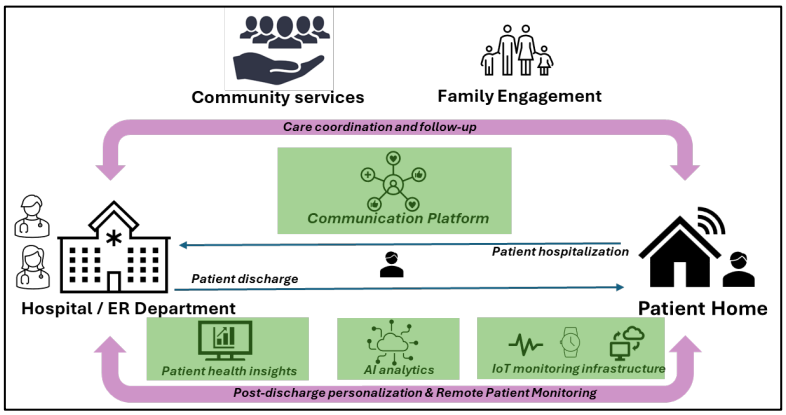


Figure 1TransCare concept overview

3 Study objectives

3.1 Primary objective

Among primary endpoints, we can address two different outcomes: from a clinical perspective, the project aims to measure and evaluate the rehospitalization rate after 30 days after the patient is discharged from the hospital, following a period of applying the new care pathway that features an innovative digital and technological system including medical devices, an activity tracking device and a digital platform. From a technical perspective, the project aims to create an IoT system including medical and non-medical devices accompanied by a digital platform to increase the patient's ability to self-monitor vital parameters based on the control plan proposed by the physician, trying to reduce preventable hospitalization for the patient.

3.2 Secondary objectives

From a clinical perspective, secondary objectives include evaluating re-hospitalization at 60 and 90 days after discharge. Furthermore, the total number of hospitalizations the participant underwent during the whole experimentation duration will be evaluated, to stratify the outcome over a longer period and achieve a more accurate outcome in terms of predictivity and prevention. Moreover, secondary objectives include evaluation of overall health status in terms of physical performance (Short Physical Performance Battery) and quality of life (EQ Visual Analogue Scale, Short Form-12 Health Survey), as well as the evaluation of usability of the platform (System Usability Scale, Psychosocial Impact of Assistive Devices Scale) and reduction of the impact in terms of cost and resources utilizations (Qualitative Interviews). Finally, the project wants to explore the capability of the system in empowering participants in terms of digital/eHealth literacy skills achievement (eHealth Literacy Scale). From a technical perspective, secondary objectives include acquiring a pool of data derived from activity tracking to build ML models that can estimate and predict the physical condition of the patient using the proposed system.

4 Study design, setting and population

The general objective is to measure the 30-day re-hospitalization rate in patients with different conditions characterized by a high risk of re-hospitalization. This will be achieved by using an ecosystem of home devices and a central monitoring platform on 210 older adults recruited from Italy, Romania and Norway. Each country will enrol different number of subjects, as reported in Table 1.

Each end-user partner will recruit population in specific recruiting centre, as reported below:

- Institutul Inimii "Nicolae Stancioiu", Calea Motilor 19-21, 400001, Cluj-Napoca - Romania
- IRCCS INRCA, Via della Montagnola 81, 60129 Ancona – Italy
- Farsund kommune, Postboks 100, 4552, Farsund - Norway

Table 1 Experimental trial participants divided by country

Older adults					
Italy		**Romania**		**Norway**	
Case	*Controls*	*Case*	*Controls*	*Case*	*Controls*
50	50	15	15	40	40
100		30		80	

The pilot study involves three different phases: Recruitment (R), Baseline evaluation (T0), final evaluation 30 days after discharge (T1), first follow-up 60 days after discharge (T2) and second follow-up 90 days after discharge. At 60 and 90 days, patients will continue to use the technology to evaluate the effect of the ecosystem on the other two re-hospitalization outcomes. For this reason, "follow-up evaluations" have been defined. Figure 2 summarizes the pilot study design of Italian trial.

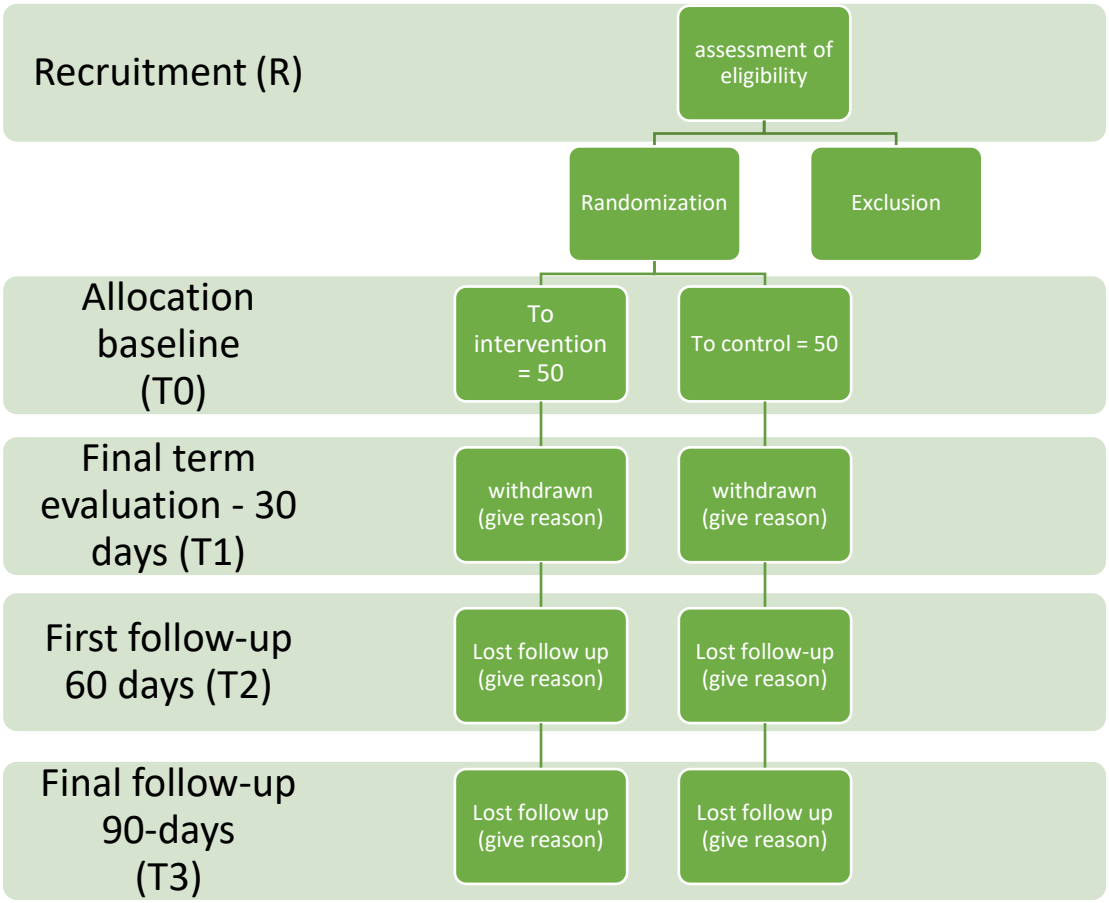


Figure 2 Pilot study design of TransCare Italian trial

4.1 Participants

The inclusion criteria, evaluated at the patient's hospital discharge, are:

- Aged 65 and over;
- Capacity to consent;
- Able to stand and walk even with support;
- MMSE ≥ 18;
- If mild to moderate dementia condition present (18 ≤ MMSE< 26), caregiver presence required, identified as a person close to the participant who comes into contact with the participant at least twice a week;
- CFS score 2-7;
- Own a personal device (smartphone or tablet) with internet connection
- If presence of metastatic cancer, life expectancy > 6 months

The exclusion criteria are:

- Failure to meet the inclusion criteria;
- Allergy to nichel components;
- Concomitant participation in other studies;
- Severe dementia condition
- Terminal chronic renal failure with the need for dialysis
- Inability or unwillingness to sign written informed consent;
- Pacemaker or implantable cardioverter defibrillator;

- Significant visual or hearing impairment;
- Severe systemic diseases with life expectancy 1 year;
- Move to nursing home after discharge;

4.2. Pilot sites description

- **Italy**: In Italy the end-user partner will be recruited from the Geriatrics Operating Unit of IRCCS INRCA. The research team includes multidisciplinary professional personnel that will have the possibility to meet end-users and their families to present the project and the modalities of possible participation. It will be responsibility of the research group to give technical support with the use of the TransCare technological ecosystem and take track of clinical flux of data acquired from each participant to correctly archive it and analyze it afterwards. End-users involved in pilot trial will first be screened by the appropriate physician or nurse for evaluation of clinical and physical/cognitive inclusion criteria and eventual recruitment for the TransCare project. The typical inpatient that is hospitalized in the IRCCS INRCA geriatrics department is an older adult, frail and often multi-morbid, who access the hospital for a series of conditions that fall in the acute infectious processes (urinary, biliary tract infection etc.) or cardiac sphere (chronic heart failure).
- **Norway:** In Norway, patients will be recruited from the municipal care services in collaboration with the local hospital (Sørlandet sykehus avd. Flekkefjord). The municipal services office serves as the single point of contact for all patients and is notified by the hospital of all potential new patients shortly after admission. The project multidisciplinary team will work closely with the municipal services office to identify and recruit patients. When a potential patient is identified, the project multidisciplinary team will meet the patient and their family to present the project. Screening for cognitive and physical inclusion criteria will be a shared responsibility between the hospital and municipal multidisciplinary teams. Home health services will provide technical training on the equipment to the patient and will also be responsible for the daily follow-up. Home health will respond to measurements and forms that trigger alarms. The typical patient receiving care in the FAR municipality is an older, frail patient with chronic illness, infections, or those requiring postoperative rehabilitation.
- **Romania:** In Romania the patients will be recruited from the Cardiology Department of the Niculae Stancioiu Heart Institute. The research team includes cardiologists and technical staff. The cardiologist will screen hospitalized patients to evaluate the clinical, physical and cognitive inclusion criteria and eventual recruitment for the TransCare project. They will meet with the patient and their family to present the project and the modalities of possible participation. The technical specialists will provide support in utilizing the TransCare technological ecosystem, take track of clinical data flow from each participant, and ensure that the data is properly archived for subsequent analysis. The typical inpatient that is hospitalized in the HINS, Cardiology Department presents with heart failure caused by medical conditions such as: chronic coronary syndromes, acute coronary syndromes, or valvular heart disease. Another category of patients is represented by those with arrhythmias, conduction disturbance or peripheral vascular diseases.

5 Equipment

The equipment provided in the trial includes a platform provided by Tellu AS that is responsible for conveying all the information and data captured by the devices on a single hub, a series of medical devices (described in Table 2) communicating with the platform through a mobile application, and an activity tracking wearable smart band (reported in Table 3) that provides insights on physical activity, sleep, and general health. Figure 3 shows an overview of measurement architecture.

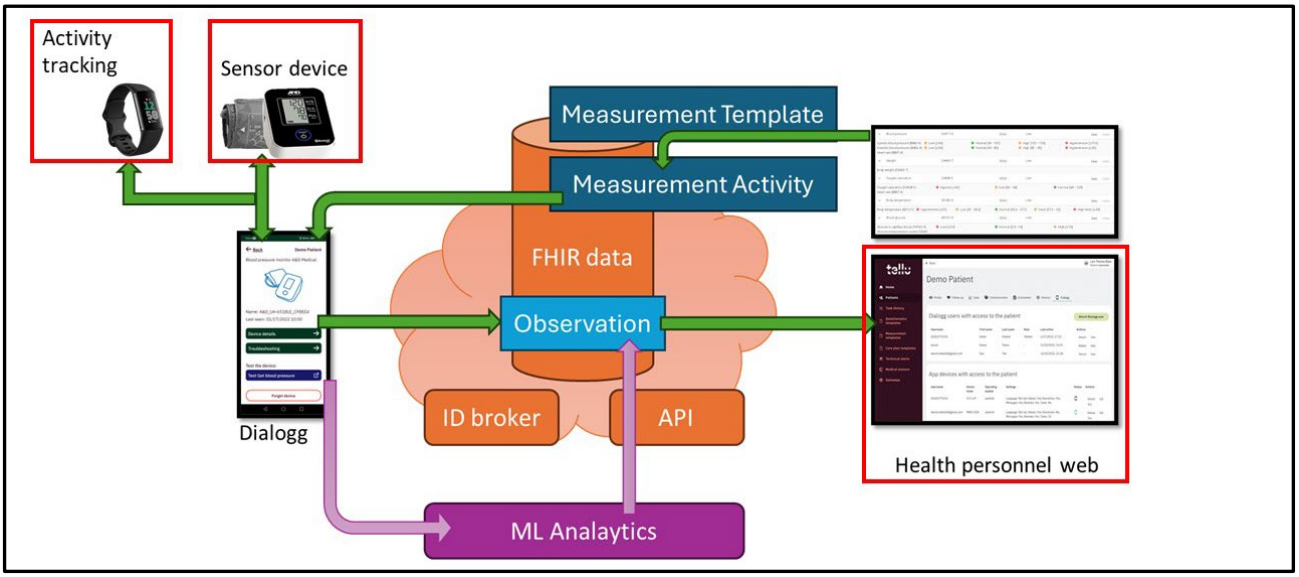


Figure 3 Overview of measurement architecture. Red boxes highlight three major components as stated above (activity sensor, medical sensor devices and platform)

In TransCare, the patient will have an activity tracker and other devices, and report measurements through the patient app, named Dialogg (the platform also supports sending measurements through a separate stationary gateway), as reported in Figure 4.

The right side of Figure 4 shows the various roles involved in providing such a service to the patient. They can all use the Tellucare Remote Patient Monitoring (RPM) web application, which has different user interfaces and functionality for different roles (a user can have access to multiple roles). A service administrator/responsible is involved in onboarding the patient, creating the appropriate care plan, configuring the devices, etc.

The system allows the operator to only visualize if the technology is functioning and not to give an interpretation of the clinical data or send emergency alert of any kind. The system allows only the monitoring and the data collection of trends to understand the behavior and the disease trajectories over time and not real time/continuously. This is essential for research and patient data collection purposes, improving scientific knowledge on re-hospitalization and facilitating patient self-management. Thus, it is not the role of the operator to continuously monitor the data flowing through the platform, nor is it the role of the operator to promptly alert territorial health continuity services in case of emergency situations. Should the patient or his/her caregiver detect, by direct measurement or visualization on the platform, physiological parameters that may be suspect and indicators of dangerous situation, with or without the presence of symptomatology, then the patient or caregiver will be required to act as he or she would normally do, that is, to alert the appropriate medical authorities or general practitioner.

The administrator role is responsible for managing the account structure, users and devices. This role does not have access to any patient data.

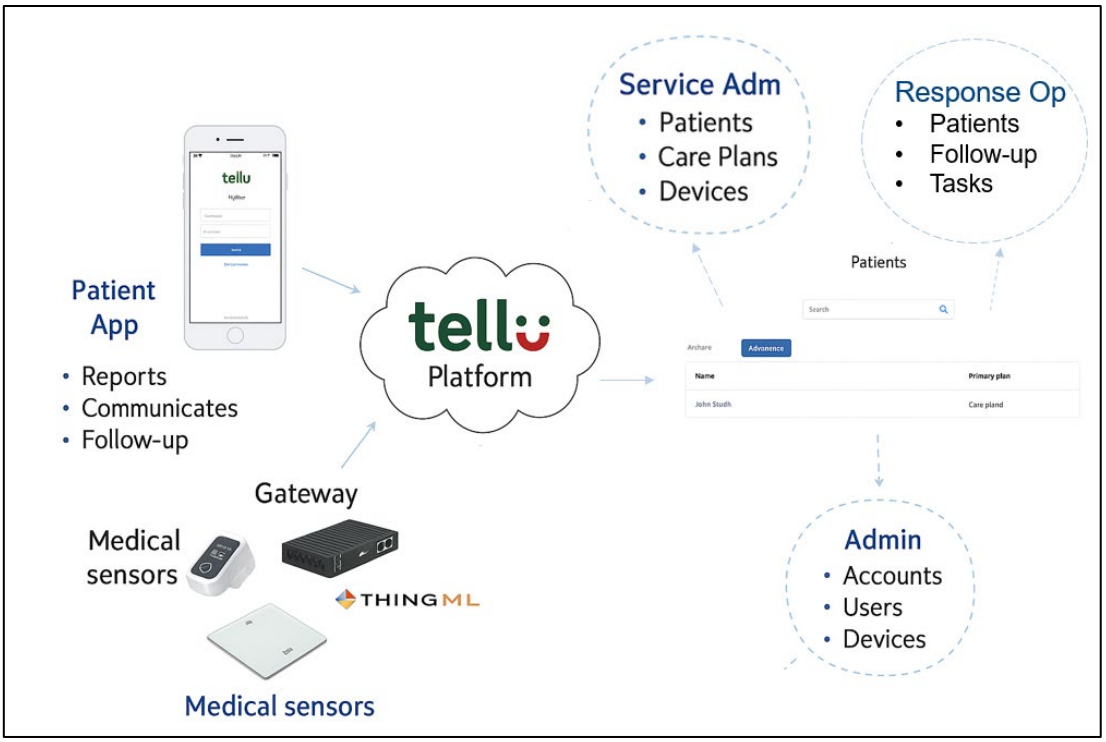


Figure 4 Remote Patient Monitoring overview

5.1. Technical description of medical devices

Medical devices adopted in the experimentation are in charge of acquiring biomedical parameters of the patient relevant to describe clinical condition of discharged patient.

All the patients recruited in this study will be given an established set of devices according to the specific pathology requirement and willingness to use. One exception is the Tanita RD-454 HR Smart Scale device, which will not be directly provided to users, but will be used at every assessment performed by health care personnel in the hospital. Table 2 reports the complete list of medical devices that will be provided to the participants and agreed among end-user partners. It is reported the complete list of all devices included in the international trial, but each end-user partner will adopt one or more devices depending on clinical need and potential use. Detailed information can be retrieved from Sec. 4 of D2.1.

In addition to the devices listed in the Table 2, the Norwegian pilot will use, only for certain patients, a system already integrated into the Tellu Platform that involves camera supervision equipment and personal alarms to enhance safety and support independent living. Camera supervision allows caregivers to remotely monitor individuals, ensuring their well-being while respecting privacy. Personal alarms provide users with a quick way to call for help in emergencies, offering peace of mind through features like GPS tracking and two-way communication. However, these two additional devices will not be adopted by the other partners and remain a feature exclusive to Norway.

Table 2. Medical Devices adopted in the experimentation

Name	Type	Description	Main functionalities
A&D Medical UC-352BLE scale	Medical device (CE)	Smart scale	A weight scale with Bluetooth connectivity. This scale is easy to use – the user stands on the scale until a value is shown on the display, and the measurement (Kg) is automatically transferred to the gateway.

			
Tanita RD-454 HR Smart Scale 	Medical Device (CE)	Smart scale	Device to analyze different body compositions, including body water
A&D Medical UA-651 BLE or UA-656 BLE blood pressure meters 	Medical device (CE)	Blood pressure meter	The cuff is fastened on the arm and the button is pressed on the device to start the measurement. The display shows the status, and the measurement is automatically transferred to the gateway when ready. Parameters acquired: Systolic pressure (mmHg), diastolic pressure (mmHg) and pulse (/min).
Contour Next ONE glucometer 	Medical device (CE)	Glucometer	Device able to acquire blood glucose level (mmol/L)
Nonin Pulse Oximeter 	Medical device (CE)	Pulse oximeter	It starts measuring as soon as a finger is correctly inserted. Spot Check measurement is abled, meaning the device gives one measurement once the value is stable. The device also supports continuous measurement. Parameter acquired: Oxygen saturation (%) and pulse (/min)
A&D Medical UT-201BLE Thermometer 	Medical device (CE)	Thermometer	Device able to measure body temperature (°C). Turned on with the power button and positioned to make the measurement. It beeps when it has a temperature reading, and transfers to the app.
OMRON Complete 	Medical device (CE)	Blood pressure meter + ECG	Device to monitor blood pressure and heart rate. It also has the function of performing a single-lead ECG.

5.2. Technical description of non-medical devices

An activity tracker provides valuable insights into activity, sleep, and general health, offering extensive data from a single device. However, these devices are not medically certified or diagnostic tools, and their measurements, such as heart rate and body temperature, are less accurate than specialized sensors. Despite this, they excel at identifying trends, especially activity levels, which are crucial for target patients in this project. Moreover, they can continuously generate substantial data for scientific analysis. Access can be difficult, as data is typically processed and stored in closed systems, requiring careful consideration when choosing and integrating these devices into TransCare. Table 3 reports a summary of main functionality of the selected device. However, it is not necessary that all end-user partners adopt the same model of the device, but it is important that features (collected parameters) are the same. Further details about activity tracking technology description and integration can be found in Sec.5 of D2.1.

Table 3 Activity tracking smart band description

Name	Type	Description	Main functionalities
Fitbit 	Commercial non-medical device (CE)	Activity tracking smart band	Main tracking functionalities: Heart rate tracking, resting heart rate, steps, distance, calories, sleep tracking stages, blood oxygen tracking, breathing rate, skin temperature variation.

Furthermore, participants and caregivers will be given a tablet where they can use and navigate the platform, as reported in Table 4. Alternatively, participants can download the app to their own device.

Table 4 Tablet description

Name	Type	Description	Main functionalities
Tablet 	Commercial device (CE)	Smart tablet	Main functionalities: Opening and navigating the digital platform for healthcare professionals. Visualizing and using Dialogg app by participants

5.3. Description of platform

The platform developed by Tellu represents an advanced technology infrastructure RPM facilitating the transition of care from the hospital to the home. Designed to provide personalized and secure healthcare, the platform integrates telehealth, alarm management and remote supervision services, offering complete interoperability with medical devices and other healthcare systems through the adoption of open standards. At the core of the platform is a data repository compliant with the HL7 FHIR standard, which enables structured organization and management of patients' clinical information. This repository collects and stores health profiles, treatment plans, measurements acquired through medical devices, and responses to self-assessment questionnaires. This data is accessed through an architecture of modular APIs designed to meet

the specific needs of each type of user. The Dialogg mobile application allows patients to interact with the system, recording measurements and communicating with healthcare professionals. Healthcare providers, on the other hand, use a dedicated web interface to monitor clinical parameters, manage alerts and update care plans. Platform administration is provided by specific tools for user, device and data security management. On the sensitive information protection front, an advanced authentication and security system based on OpenID Connect and OAuth 2.0 is implemented, with strict role management and an encryption system that complies with international ISO 27001 standards and European GDPR regulations. Every transaction is recorded in an audit log to ensure traceability and transparency in data access. A distinctive feature of the platform is its ability to integrate certified medical devices and physical activity tracking systems. With Bluetooth device compatibility, the system captures vital data such as blood pressure, blood glucose, body temperature, and oxygen saturation. In parallel, integration with Fitbit allows monitoring of parameters related to physical activity and sleep quality, providing a complete picture of the patient's health status. The collected data are transmitted and stored in the FHIR database, used for advanced processing based on machine learning, thus enabling timely intervention in case of abnormalities. Further adding value to the platform is its integration with Memas, a digital assistant designed to support patients in the daily management of their health. Through interactive tools, Memas provides educational materials, general suggestions on diet and exercise, as a “disease literacy” information system. No coaching intervention are meant to be performed with the platform.

For Italian participants, the information collected in Memas and provided to the end user are generic guidelines released by Italian National Healthcare Societies (ISS, Ministero della salute) and International healthcare organizations (WHO). Moreover, self-assessment questionnaires will be available in the system, which allow the patient's well-being to be monitored and any critical issues to be reported to health care providers. TelluCare provides the secure and scalable technology infrastructure for managing health data, while Memas enriches the patient's experience, fostering autonomy in managing their own health and improving communication with caregivers. Further detail and specification of digital platform characteristics are reported in Sec 3 of D2.1.

6 Study endpoints

6.1. Primary endpoint

The primary endpoint of the study is constituted by the reduction of the incidence of 30-days re-hospitalization rate, supporting the self-management of the patients through an innovative remote monitoring system. It will be accessed by checking if the older adult is readmitted in the healthcare facility at the end of the 30 days trial period.

6.2. Secondary endpoints

The secondary endpoints are:

- Checking hospital readmission at 60 and 90 days after hospital discharge to evaluate longer term rates.
- Checking how many times the participant possibly got re-hospitalized.
- Improving health status of older person in terms of general quality of life and physical performance. It will be accessed through EQ Visual Analogue Scale [26] and Short Form Health Survey - 12 items [27] for general wellbeing status and Short Physical Performance Battery [23] for physical performance and functional status;
- Accessing the usability of the system, to be evaluated through the System Usability Scale [28] to check specific dashboard usability
- Supporting the empowerment of participants in terms of digital/eHealth literacy skills achievement, skills that will be assessed through eHeals scale [29].
- Evaluate acceptability, usability, effectiveness and willingness to pay of the system through semi-structured interviews;
- Evaluation of clinical resource utilization through interviews.

7 Protocol

For this pilot study, 210 older adults will be enrolled. The participants will be randomized into 2 groups, respectively 105 cases and 105 controls. The randomization technique based on a single sequence of random assignments is used

A summary of all data collected and when these are collected is provided in Table 5. All scales used are validated in all the national languages of each end-user partner (Italian, Norwegian and Romanian) and suitable for administration for the patients recruited in the study. A complete list of scales are attached as Appendix to the present deliverable.

Table 5 Clinical assessments and scales divided by different evaluation times

Scale(s)	**R**	**T0**	**T1**	**T2**	**T3**
Socio-demographic and Anamnesis (**Check-list**)	✓				
MMSE (**cognitive**)	✓				
Short Physical Performance Battery (**physical**)	✓		✓	✓	✓
Clinical Frailty Scale (**Frailty**)	✓				
30-days Rehospitalization rate (**y/n**)			✓		
60-days Rehospitalization rate (**y/n**)				✓	
90-days Rehospitalization rate (y/n)					✓
ATDPA – C (**Technology attitude**)		✓			
EQ-5D-5L (only VAS scale) (**quality of life**)		✓	✓	✓	✓
SF-12 short form (4 weeks recall period) (**impact of health in everyday life)**		✓	✓		✓
Clinical resource utilization			✓	✓	✓
SUS (**Usability of dashboard**)			✓		✓
eHEALS scale (**ehealth literacy**)		✓	✓		✓
Semi-structured interview on self-management improvement, usability and effectiveness of the system			✓		✓

The **Mini Mental State Examination (MMSE)** [22] is a neuropsychological test used to assess cognitive function and detect cognitive impairment; it is particularly useful for monitoring the development of dementia and assessing the cognitive status of patients in clinical settings. Consisting of 30 questions, the test assesses five areas: orientation, registration, attention and computation, recall, language and visuo-constructive skills. The maximum score is 30, with scores below 24 indicating possible cognitive impairment.

The **Short Physical Performance Battery (SPPB)** [23] assesses physical performance based on three criteria by testing balance, walking speed and chair raising abilities. This scale is a valuable tool for assessing physical function, especially in older adults and individuals with chronic conditions. Because of its simplicity, reliability, and clinical utility, the SPPB is an essential tool for assessing physical function and improving health management in the older person and vulnerable populations.

Clinical Frailty Scale (**CFS**). [24] This descriptive scale divides the older participants into 9 classes based on the information provided by them and their relatives: between 1 and 3 the patient is non-frail, pre- frail if 4, he/she is frail from 5 to 9.

The **Assistive technology device predisposition assessment (ATD PA-C)** [25] module is the user's module that analyzes the user's subjective satisfaction with the results achieved in a variety of functional areas. It is part of the ATD PA (Assistive technology device predisposition assessment) tool and asks the user to prioritize aspects of his or her life where improvements are desired and solicits the user's perspective with respect to the aid.

The **EuroQol Visual Analogue Scale (EQ VAS)** [26] records the respondent's self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. This information can be used as a quantitative measure of health as judged by the individual respondents.

The **Short Form Health Survey - 12 items (SF-12)** [27] is a self-assessment questionnaire designed to measure health-related quality of life quickly and concisely. It is an abbreviated version of the SF-36, with only 12 items that provide a broad assessment of physical and mental health conditions.

The **System Usability Scale (SUS)** [28] is a reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents, from 'Strongly agree' to 'Strongly disagree'. It allows for evaluation of a wide variety of products and services, including hardware, software, mobile devices, websites and applications. It is easy to administer to participants and can be used onsmall sample sizes with reliable results and can effectively differentiate between usable and unusablesystems.

The **eHealth Literacy Scale (eHEALS)** [29] is a 10-item measure of eHealth literacy developed to measure consumers' combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems. Advantages include simplicity and speed, in fact it is a short and easy test to administer, suitable for clinical and research settings; user focus, as it focuses on perceptions and subjective abilities, allowing for identification of specific educational needs; and flexibility, as it can be adapted to different populations and cultural contexts.

A **Semi-structured Interview** is adopted to evaluate the perspective on usability, acceptability, effectiveness and willingness to pay. A complete version of interviews is included in the material to be delivered to Ethical Committee for approval.

A **Clinical Resource Utilization** will be used to investigate consumption of health care resources, use of diagnostic tests and specialized clinical procedures, use of care services, and eventual hospital readmission, throughout the study period.

8 Procedure

8.1. Recruitment (R) and Baseline Evaluation (T0)

Recruitment and experimentation procedures are the same among the three European pilot sites. Patient will be enrolled from the operative unit/facility department, listed below:

- Geriatrics Acute Care Ward of IRCCS INRCA, in the Ancona branch, according defined inclusion criteria.
- Medical and Geriatric Departments at Sørlandet Hospital Health Trust, Flekkefjord, and the allocation of services department of municipality of Farsund according to defined inclusion criteria.
- Cardiology Department of the 'Niculae Stancioiu' Heart Institute, in Cluj-Napoca, according to the defined inclusion criteria.

During the recruitment phase (R), i.e., prior to discharge or within 3 days of discharge, general information will be collected about the subjects, particularly health status and cognitive condition. MMSE will be administered to gain a cognitive level framework, the CFS to evaluate frailty and SPPB to access physical condition.

The investigator will contact (by mail, telephone or physically) the participant to define his availability with a view to setting up the research project at home and will access his/her signed consent. When recruitment is complete, the investigator will randomize the participants into two groups: control group and experimental group. The allocation is done in an alternating randomized manner (ABAB) according to the order of inclusion of the participants. Participants in the experimental group will receive the digital platform already installed in a tablet (Table 4), or alternatively, they will use their own smartphone. In this case, they will be helped with the installation of the application and advised on how to use it. Furthermore, they will receive a set of medical/non-medical devices as reported in Table 2 and Table3. Participants in control group will not be assigned any type of technology but will simply be checked whether they will be re-hospitalized at the end of 30, 60, or 90 days.

At the staring of the experimentation, baseline evaluation (T0) is conducted directly at the hospital or at patient's home according to specific local needs of each end-user partner. The scales included Socio-demographic questionnaires, ATDPA-C, EQ-5D-5L VAS, SF-12 and eHEALS, will be administered.

The participant belonging to experimental group will receive training sessions about the digital platform and the medical/non-medical device utilization.

During the first month of experimentation, the participant belonging to the experimental group will be invited to use the devices in the way he/she wishes. In any case, participants will not be obliged to manipulate the devices.

In addition, during the experimentation phase, participants will be contacted weekly to inquire about the utilization experience and their feelings about the activity and, possibly, offer technical help when needed.

8.2. First Intermediate Evaluation (T1 at 30 days)

Both for the experimental and control group, participants will be checked firstly if they were re-admitted in the hospital after 30 days of system utilization.

Only for the experimental group, after 30 days of system utilization, patients is evaluated or at home or at hospital. Participants will be evaluated on physical condition using the SPPB, quality of life through the VAS,

usability of platform and system using SUS. Clinical resource utilization, self-management improvement and effectiveness of the system will be accessed by administering questionnaires and interviews. Additionally, at T1 endpoint, the participants will be assisted by investigator in case of problem with system.

8.3. Second Intermediate Evaluation (T2 at 60 days)

Both for the experimental and control group, participants will be checked by investigator firstly if they were re-admitted in the hospital after 60 days of system utilization. The investigator will conduct interview for clinical resource utilization and evaluate level of quality of life through VAS and physical condition using the SPPB.

8.4. Final evaluation (T3 at 90 days)

At the end of the trial, both experimental and control group participants are checked if they went into a re-hospitalization after 90 days of system utilization. The investigator will conduct interview for clinical resource utilization, self-management improvement and effectiveness of the system by administering questionnaires and interviews, along with an evaluation of the level of quality of life through VAS and of the physical condition using the SPPB. Moreover, the investigator will evaluate usability of platform and system using SUS, the health-related quality of life using the SF-12 and the eHealth literacy using the eHEALS.

Finally, the devices including tablet, medical and non-medical devices will be withdrawn.

9 Data analysis

- **Sample size:** The study by O'Connor et al. (2023) [30], in which a remote monitoring and tele-health system was tested for the prevention of 30-day re-hospitalization in older patients with heart failure, was taken as a reference to calculate the sample size and statistical power of the study. The research, comparing two groups, one intervention and one control group, as in the case of the TransCare project, showed that the rate of re-admission to the hospital at 30 days (primary endpoint) in the intervention group was 5.2 % while in the control group was 19.3 %. Now, assuming a 14.1 % reduction in 30-day re-hospitalization rates by remote monitoring intervention, and considering a power analysis based on two independent groups (two-tail Fisher's exact test) with an error probability α =0.05 and a statistical power $P = (1 - \beta\ prob.err.) = 0.85$, then a sample of 206 participants, equally allocated with ratio 1/1 in 103 in the intervention group and 103 in the control group, can be sufficient to be considered clinically valid in the pilot trial of TransCare project experimentation.
- **Data collected by the researchers:** The first step of the data analysis will deal with the description of the sample. Continuous variables will be reported as either mean and standard deviation or median and interquartile range based on their distribution (assessed using Kolmogorov-Smirnov test). Categorical variables will be expressed as an absolute number and percentage. Comparison of baseline measurements between groups will be evaluated by unpaired t-test (for normal distribution), Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (for categorical variables). Within each group, independent and dependent variables will be compared between the pre- and post- conditions using the same tests as appropriate. The treatment effect on the outcome variables will be evaluated by using repeated measures ANOVA, to compare the changes over time in the outcome measures between the intervention group and the control group. Moreover, a linear regression model on the outcome variation between baseline and follow-up will be estimated to evaluate the effect of the treatment adjusted for all potential confounders. Descriptive statistical analyses will be performed on the quantitative data with SPSS or Rstudio. All data acquired in the trial will be analysed directly by the research centres involved in the project consortium. Monitored data will be used as input to the ML-based post discharge analytics for training and inference processes allowing for the prediction of different parameters among patients involved in the experimentation. The ML component will determine insights that can be used as support by medical professionals to identify the problems that require proactive intervention. Work will be done on anonymized data and not on personal data, and the AI model will not interact for the testing phase with the end user, be it the patient or the practitioner. The practitioners can only access the results of the ML inference for their remotely monitored patients and to visualize the results in order to support their decisions regarding patients' treatment.
- **Data collected by the technological devices:** One of the uses of the data collected from the medical devices is to infer the rehospitalization rate of the user and to know. The aggregation of activity data from several testing center will serve also to the researcher to pool a data lake to train predictive machine learning model for further implementation in the re-hospitalization field. The analysis of user activity data and their interactions at well-defined milestones in the experiment will make it possible to detect system failures as early as possible, in order to prevent the user from dropping out. All the data will be treated in anonymized during processing and analysis.

10 Risk-benefit analysis

The user may be faced with a technological environment that he/she cannot fully manage or understand. This may generate frustration in the user and drive him/her to abandon it. However, the researchers involved will do training when the devices are installed on their use, functions, and all the risks associated with utilization.

It is also expected that there is a low risk that the user could get hurt with the proposed tools.

Indeed, the hardware devices used are commercial devices and CE certified and/or safety certification, the applications for older people and caregivers will be loaded on the hardware held by the users. Technological dependence represents a major ethical dilemma today and scientific community. To limit the risk, the European Commission's international programmes have introduced guidelines for conducting studies that require the introduction of a new technology, called Responsible Innovation. The core principles of Responsible Innovation are also applied within the TransCare project. A strategy underlying the prevention of technological dependence is the inclusion of different actors around the older people, in the process of acquiring skills and daily use of technology. In this way, technological solutions such as those proposed by TransCare, respond to the definition of socio-technological system that does not expect to replace of the caregiver and the health professionals but stimulates the user to play a leading role in the management of their health. The services proposed are intended to support the post-discharge home monitoring and do not replace (in whole or in part) the support from professional services. During the installation of the technology, moreover, information will be provided to the participants and their caregiver about the limits of the technology. Users who take part in the study will not incur any direct or indirect costs related to the use of the technology platform. The platform will be provided to the subjects by the experimental sites and must be returned to the research team at the end of the trial.

11 Data management

The project committed to the maintenance of participants' anonymity and confidentiality throughout all procedures, including screening, recruitment, testing, evaluation and dissemination procedures. Data collection, usage and storage procedures complied with national laws and the EU's General Data Protection Regulation (GDPR) including the commitment of participants' the right to access, right to be informed, right to withdraw, and right to data erasure. Moreover, the servers are in the European Union and compliant to GDPR. Data collection will be compliant with the principle of data minimization i.e. the collection of personal information from study participants will be limited to what is directly relevant and necessary to accomplish the specific goals of the testing and evaluation work packages. Data entry will be carried out using specific software, providing blocks and data entry checks, to reduce the number of entry errors. All screening data will be discarded upon the project completion. During the testing procedures, all sensory data that the app collects and processes to function as planned will be discarded after the procedures have been completed. Anonymized research data shall be made openly available for secondary analysis from 5 to 10 years after the project completion. A more detailed data management plan is annexed in deliverable D3.3 that deals with ethics and privacy procedures.

12 Legal and technical aspects

The study will be conducted considering regulatory requirements and legal requirements, and the study will be initiated following receipt of an evaluation and approval of the study by an independent Ethics Committee and completion of the administrative requirements of the institution where the study is being conducted.

In addition, all potentially eligible participants will be required to receive complete information about the study and provide their consent to participate in the study. Moreover, participant must provide consent to the processing of personal data in anonymous and aggregate form, in accordance with EU Regulation 2016/679 (GDPR) on the protection of individuals regarding the processing of personal data and Legislative Decree No. 101/2018 - Provisions for the adaptation of national legislation to the provisions of European Regulation 2016/679.

Then, the participant must be informed that his or her data may be examined by authorized personnel or by members of the competent ethics committee and officials of the competent regulatory authorities. Finally, the participant is also informed and asked to provide ad hoc informed consent to participate in the study, including data retention for up to 10 years after completion of the study.

Each signature must be personally dated by each signatory, and the informed consent and any additional patient information must be retained by the investigator. A signed copy of the informed consent and information sheet will be given to each patient, or their informal caregiver or legal tutor, should they be unable to independently give their signed informed consent.

The Participant can indicate his or her agreement to the retention and use of his or her data long after the end of the project under the open access to scientific publications and open research data as requested by the European Commission.

BIBLIOGRAPHY

[1] Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med. 2003 Feb 4;138(3):161-7. doi: 10.7326/0003-4819-138-3-200302040-00007. PMID: 12558354.).

[2] McKeown F. The experiences of older people on discharge from hospital following assessment by the public health nurse. J Clin Nurs. 2007 Mar;16(3):469-76. doi: 10.1111/j.1365-2702.2006.01556.x. PMID: 17335522.

[3] Coleman EA, Mahoney E, Parry C. Assessing the quality of preparation for posthospital care from the patient's perspective: the care transitions measure. Med Care. (2005) 43:246–55. 10.1097/00005650-200503000-00007

[4] Bag Soytas R, Levinoff EJ, Smith L, Doventas A, Morais JA, Veronese N, Soysal P. Predictive Strategies to Reduce the Risk of Rehospitalization with a Focus on Frail Older Adults: A Narrative Review. Epidemiologia (Basel). 2023 Oct 8;4(4):382-407. doi: 10.3390/epidemiologia4040035. PMID: 37873884; PMCID: PMC10594531.

[5] Forster AJ, Clark HD, Menard A, Dupuis N, Chernish R, Chandok N, Khan A, van Walraven C. Adverse events among medical patients after discharge from hospital. CMAJ. 2004 Feb 3;170(3):345-9. Erratum in: CMAJ. 2004 Mar 2;170(5):771. PMID: 14757670; PMCID: PMC331384.).

[6] Kansagara D, Englander H, Salanitro A, Kagen D, Theobald C, Freeman M, Kripalani S. Risk prediction models for hospital readmission: a systematic review. JAMA. 2011 Oct 19;306(15):1688-98. doi: 10.1001/jama.2011.1515. PMID: 22009101; PMCID: PMC3603349

[7] Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. JAMA. 2007 Feb 28;297(8):831-41. doi: 10.1001/jama.297.8.831. PMID: 17327525.

[8] Campbell SE, Seymour DG, Primrose WR; ACMEPLUS Project. A systematic literature review of factors affecting outcome in older medical patients admitted to hospital. Age Ageing. 2004 Mar;33(2):110-5. doi: 10.1093/ageing/afh036. PMID: 14960424

[9] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. 2009 Apr 2;360(14):1418-28. doi: 10.1056/NEJMsa0803563. Erratum in: N Engl J Med. 2011 Apr 21;364(16):1582. PMID: 19339721.

[10] Dharmarajan K, Hsieh AF, Lin Z, Bueno H, Ross JS, Horwitz LI, Barreto-Filho JA, Kim N, Suter LG, Bernheim SM, Drye EE, Krumholz HM. Hospital readmission performance and patterns of readmission: retrospective cohort study of Medicare admissions. BMJ. 2013 Nov 20;347:f6571. doi: 10.1136/bmj.f6571. PMID: 24259033; PMCID: PMC3898430

[11] Cheng RK, Cox M, Neely ML, Heidenreich PA, Bhatt DL, Eapen ZJ, Hernandez AF, Butler J, Yancy CW, Fonarow GC. Outcomes in patients with heart failure with preserved, borderline, and reduced ejection fraction in the Medicare population. Am Heart J. 2014 Nov;168(5):721-30. doi: 10.1016/j.ahj.2014.07.008. Epub 2014 Jul 22. PMID: 25440801

[12] Golden AG, Tewary S, Dang S, Roos BA. Care management's challenges and opportunities to reduce the rapid rehospitalization of frail community-dwelling older adults. Gerontologist. 2010 Aug;50(4):451-8. doi: 10.1093/geront/gnq015. Epub 2010 Feb 25. PMID: 20185522

[13] Sganga F, Landi F, Volpato S, Cherubini A, Ruggiero C, Corsonello A, Fabbietti P, Lattanzio F, Gravina EM, Bernabei R, Onder G. Predictors of rehospitalization among older adults: Results of the CRIME Study. Geriatr Gerontol Int. 2017 Oct;17(10):1588-1592. doi: 10.1111/ggi.12938. Epub 2016 Nov 21. PMID: 27868320

[14] Pandey A, Golwala H, Hall HM, Wang TY, Lu D, Xian Y, Chiswell K, Joynt KE, Goyal A, Das SR, Kumbhani D, Julien H, Fonarow GC, de Lemos JA. Association of US Centers for Medicare and Medicaid Services Hospital 30-Day Risk-Standardized Readmission Metric With Care Quality and Outcomes After Acute Myocardial Infarction: Findings From the National Cardiovascular Data Registry/Acute Coronary Treatment and Intervention Outcomes Network Registry-Get With the Guidelines. JAMA Cardiol. 2017 Jul 1;2(7):723-731. doi: 10.1001/jamacardio.2017.1143. PMID: 28445559; PMCID: PMC5815085.

[15]Kobayashi S, Yanai M, Hanagama M, Yamanda S. Burden of chronic obstructive pulmonary disease in the elderly population. Respir Investig. 2014 Sep;52(5):296-301. doi: 10.1016/j.resinv.2014.04.005. Epub 2014 Jun 19. PMID: 25169845.

[16]Bernocchi, Palmira, et al. "A multidisciplinary telehealth program in patients with combined chronic obstructive pulmonary disease and chronic heart failure: study protocol for a randomized controlled trial." Trials 17 (2016): 1-10.

[17]Bilazarian A. High-need high-cost patients: A Concept Analysis. Nurs Forum. 2021 Jan;56(1):127-133. doi: 10.1111/nuf.12500. Epub 2020 Aug 26. PMID: 32851669.

[18]Ong MK et al. Better Effectiveness After Transition–Heart Failure (BEAT-HF) Research Group. Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition -- Heart Failure (BEAT-HF) Randomized Clinical Trial. JAMA Intern Med. 2016 Mar;176(3):310-8. doi: 10.1001/jamainternmed.2015.7712.

[19]Po HW, Chu YC, Tsai HC, Lin CL, Chen CY, Ma MH. Efficacy of Remote Health Monitoring in Reducing Hospital Readmissions Among High-Risk Postdischarge Patients: Prospective Cohort Study. JMIR Form Res. 2024 Sep 13;8:e53455. doi: 10.2196/53455. PMID: 39269747; PMCID: PMC11437225.

[20]Stamenova V, Liang K, Yang R, Engel K, van Lieshout F, Lalingo E, Cheung A, Erwood A, Radina M, Greenwald A, Agarwal P, Sidhu A, Bhatia RS, Shaw J, Shafai R, Bhattacharyya O. Technology-Enabled Self-Management of Chronic Obstructive Pulmonary Disease With or Without Asynchronous Remote Monitoring: Randomized Controlled Trial. J Med Internet Res. 2020 Jul 30;22(7):e18598. doi: 10.2196/18598. PMID: 32729843; PMCID: PMC7426797.

[21]Tchalla A, Marchesseau D, Cardinaud N, Laubarie-Mouret C, Mergans T, Kajeu PJ, Luce S, Friocourt P, Tsala-Effa D, Tovena I, Preux PM, Gayot C. Effectiveness of a home-based telesurveillance program in reducing hospital readmissions in older patients with chronic disease: The eCOBAHLT randomized controlled trial. J Telemed Telecare. 2025 Feb;31(2):231-238. doi: 10.1177/1357633X231174488. Epub 2023 May 23. PMID: 37221865.

[22]Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). Mini-Mental State: A practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research, 12(3), 189-198. https://doi.org/10.1016/0022-3956(75)90026-6

[23]Guralnik JM, Ferrucci L, Pieper CF, Leveille SG, Markides KS, Ostir GV, Studenski S, Berkman LF, Wallace RB (2000) Lower extremity function and subsequent disability consistency across studies, predictive models, and value of gait speed alone compared with the Short Physical Performance Battery. J Gerontol A Biol Sci Med Sci 55: M221–M231

[24]Rockwood, K., Song, X., MacKnight, C., Bergman, H., Hogan, D. B., McDowell, I., & Mitnitski, A. (2005). A global clinical measure of fitness and frailty in elderly people. *Canadian Medical Association Journal*, 173(5), 489–495. https://doi.org/10.1503/cmaj.050051

[25]Andrich, R., Ferrario, M., & Moi, M. (1998). *Matching Person & Technology: Manuale per la valutazione della predisposizione all'uso di ausili*. Portale SIVA.

[26]EuroQol Group. (1990). *EQ Visual Analogue Scale (EQ VAS)*. EuroQol Research Foundation.

[27]Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996 Mar;34(3):220-33. doi: 10.1097/00005650-199603000-00003. PMID: 8628042.

[28]Brooke, John (1996). "SUS: a "quick and dirty" usability scale". In P. W. Jordan; B. Thomas; B. A. Weerdmeester; A. L. McClelland (eds.). Usability Evaluation in Industry. London: Taylor and Francis

[29]Norman CD, Skinner HA. eHEALS: The eHealth Literacy Scale. J Med Internet Res. 2006 Nov 14;8(4):e27. doi: 10.2196/jmir.8.4.e27. PMID: 17213046; PMCID: PMC1794004

[30]O'Connor, Melissa, et al. "Using telehealth to reduce all-cause 30-day hospital readmissions among heart failure patients receiving skilled home health services." Applied clinical informatics 7.02 (2016): 238-247.

[31]Dineen-Griffin S, Garcia-Cardenas V, Williams K, Benrimoj SI. Helping patients help themselves: A systematic review of self-management support strategies in primary health care practice. PLoS One. 2019 Aug 1;14(8):e0220116. doi: 10.1371/journal.pone.0220116. PMID: 31369582; PMCID: PMC6675068

APPENDIX

Socio-Demographic Data

ID patient_____Date

Date of birth (dd /mm /yyyy)	(dd /mm /yyyy)_____/_____/_____
Gender	□ male □ female □ diverse
Residence	□ City □ Suburban □ Rural community
Housing situation	□ Alone □ Shared apartment □ Family □ With (marriage) partner □ Other: ___
Marital status	□ Single □ widowed □ divorced □ married / registered civil partnership □ solid partnership
Do you have children?	□ no □ yes → if yes, how many:
Do you have grandchildren?	□ no □ yes → if yes, how many:
Highest level of education	□ No school degree □ Primary school □ Secondary school □ High school □ University degree
Currently employed	□ no □ yes **→ if yes, please mark where applicable:** □ Part-time □ Minijob □ Full-time

Currently retired	□ no □ yes **→ if yes, since when (year):_____**
Able to stand and walk even with support	□ no □ yes
Use of active implant or not-implant medical devices	□ no □ yes
Pacemaker or implantable cardioverter defibrillator	□ no □ yes
Allergy to nichel components	□ no □ yes
A myocardial infarction or stroke within 1 months	□ no □ yes
Metastatic cancer or immunosuppressive therapy	□ no □ yes
Mini Mental State Examination	SCORE: _____
Clinical Frailty Scale	SCORE: _____

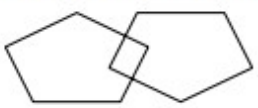
RECRUITMENT

Mini Mental State Examination (MMSE)

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: ***Ask the questions in the order listed. Score one point for each correct response within each question or activity.***

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Clinical Frailty Scale (CFS)

1		**Very Fit** - People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
2		**Well** - People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.
3		**Managing Well** - People whose medical problems are well controlled, but are not regularly active beyond routine walking.
4		**Vulnerable** - While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.
5		**Mildly Frail** - These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and house work.
6		**Moderately Frail** - People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.
7		**Severely Frail** - Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
8		**Very Severely Frail** - Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.
9		**Terminally Ill** - Approaching the end of life. This category applies to people with a life expectancy < 6 months, who are not otherwise evidently frail.

Short Physical Performance Battery

1. Repeated Chair Stands

Instructions: Please **stand up straight as quickly as you can five times, without stopping in between**. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready?

Begin Grading: **Begin stop watch when subject begins to stand up**. Count aloud each time subject arises. **Stop the stopwatch when subject has straightened up completely for the fifth time**. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety. Record the number of seconds and the presence of imbalance.

- Time:__sec (if five stands are completed)
- Number of Stands Completed: 1 2 3 4

5 Chair Stand Ordinal Score:

- 0 = unable
- 1 = > 16.7 sec
- 2 = 16.6-13.7 sec
- 3 = 13.6-11.2 sec
- 4 = < 11.1 sec

2. Balance Testing

Begin with a **semitandem stand** (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

3. Semitandem Stand

Instructions: Now I want you to try to stand with the **side of the heel of one foot touching the big toe of the other foot for about 10 seconds**. You may put either foot in front, whichever is more comfortable for you.

Please watch while I demonstrate. Grading: Stand next to the participant to help him or her into semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and let's go.

- 2 = Held for 10 sec
- 1 = Held for less than 10 sec; (number of seconds held: ___sec)
- 0 = Not attempted

4. Side-by-Side stand

Instructions: I want you to try to **stand with your feet together, side by side, for about 10 sec**. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

5. Tandem Stand

Instructions: Now I want you to try to **stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec**. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

Balance Ordinal Score:

- 0 = side by side 0-9 sec or unable
- 1 = side by side 10, <10 sec semitandem
- 2 = semitandem 10 sec, tandem 0-2 sec
- 3 = semitandem 10 sec, tandem 3-9 sec
- 4 = tandem 10 sec

6. 8' Walk (2.44 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 8'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready? Grading: Press the start button to start the stopwatch as the participant begins walking. **Measure the time** take to walk 8'. Then complete ordinal scoring.

Time: __sec

Gait Ordinal Score:

- 0 = could not do
- 1 = >5.7 sec (<0.43 m/sec)

- 2 = 4.1-6.5 sec (0.44-0.60
- m/sec)
- 3 = 3.2-4.0 (0.61-0.77 m/sec)
- 4 = <3.1 sec (>0.78 m/sec)

Summary Ordinal Score: Range: 0 (worst performance) to 12 (best performance). Shown to have predictive validity showing a gradient of risk for mortality, nursing home admission, and disability.

T0

Initial Person

FORM 4-1 CONSUM

Assistive Technology Device Predisposition Assessment CONSUMER FORM

Name_____ Age_____
Primary Goals (6 months)_____ Today's Date_____
Primary Goals (1 year+)_____ Form completed by_____

A. How would you rate your abilities today in the following 9 areas when using your current AT or other support?

- For item 1-9, mark the best response (1 for *Poor* through 5 for *Excellent*)
- Under *Name of Support* write the name of the support you use where relevant (example: "eyeglasses" for #1, *seeing*)

Write a plus [+] in the spaces where you expect to need more support over the next year (example: "eyeglasses" gets [+] if you'll expect to need stronger lenses during the next year). Write a [-] in the spaces where you expect to need less support, and a [0] where you expect your support should stay the same over the next year.

	Poor		Average		Excellent	Name of Support	Need more[+], less [-], same [0]
1.Seeing	☐1	☐2	☐3	☐4	☐ 5	_____	_____
2.Hearing	☐1	☐2	☐3	☐4	☐ 5	_____	_____
3.Speech	☐1	☐2	☐3	☐4	☐ 5	_____	_____
4.Understanding, remembering	☐1	☐2	☐3	☐4	☐ 5	_____	_____
5.Physical strength/stamina	☐1	☐2	☐3	☐4	☐ 5	_____	_____
6.Lower body use (hips, legs, feet)	☐1	☐2	☐3	☐4	☐ 5	_____	_____
7.Grasping and use of fingers	☐1	☐2	☐3	☐4	☐ 5	_____	_____
8.Upper body (arms, shoulders, trunk)	☐1	☐2	☐3	☐4	☐ 5	_____	_____
9.Mobility (getting from place to place)	☐1	☐2	☐3	☐4	☐ 5	_____	_____

B. How satisfied are you currently in the following areas?

- For item 10 - 21, mark the best response (1 for *Not satisfied* through 5 for *Very Satisfied*)
- Which 3 items are most important to you? Under 3 Most Importnt, write #1, #2 or #3 for the three areas that concers you most (#1 = most important). Leave the other lines blank.
- For your *3 Most Important* items, write the primary obstacles and barriers you face in the space beside that item

	Not Satisfied		Satisfied		Very Satisfied	3 Most Important
10.Personal care and household activities	☐1	☐2	☐3	☐4	☐5	_____
11.Physical comfort & well-being	☐1	☐2	☐3	☐4	☐5	_____
12.Overall health	☐1	☐2	☐3	☐4	☐5	_____
13.Freedom to go wherever desired	☐1	☐2	☐3	☐4	☐5	_____
14.Participation in desired activities	☐1	☐2	☐3	☐4	☐5	_____
15.Educational attainment	☐1	☐2	☐3	☐4	☐5	_____
16.Employment status/potential	☐1	☐2	☐3	☐4	☐5	_____
17.Family relationships	☐1	☐2	☐3	☐4	☐5	_____
18.Close, intimate relationships	☐1	☐2	☐3	☐4	☐5	_____
19.Autonomy and self-determination (choosing)	☐1	☐2	☐3	☐4	☐5	_____
20.Fitting in, belonging, feeling connected	☐1	☐2	☐3	☐4	☐5	_____
21. Emotional well-being	☐1	☐2	☐3	☐4	☐5	_____

C. Please mark all the statements below that describe you. Mark only those *frequently or often* apply to you and ignore those that very *rarely or never* apply to you.

☐22.I have the support I want from family

☐23.I have the support I want from friends

☐24.I feel encouraged by therapists, caregivers

☐25. I feel the general public accepts me

☐26.I aspire to go to school or work

☐27.I have many things I want to accomplish

☐28.I do what my therapists say without question

☐29.I view my therapist(s) as friends, too

☐30.I am often frustrated or overwhelmed

☐31.I am curious & excited about new things

☐32.I am determined to meet my goals

☐33.I am usually calm and patient

☐34.My life has purpose, meaning

☐35.I am self-disciplined

☐36.I am often angry

☐37.I am often depressed

☐38.I prefer to be left alone

☐39.I am often discouraged

☐40.I am quite resourceful

☐41.I like having a challenge

☐42.I am responsible & reliable

☐43. I am generally satisfied with my life

☐44.I find technology interesting

☐45.I am cooperative

☐46.I prefer a quiet lifestyle

☐47.I often feel isolated & alone

☐48.I accomplish what I set out to do

☐49.I am not sure who I am now

☐50.I want more independence

☐51.I have a good self image

☐52.I often feel insecure

☐53.I feel as if I have little privacy

☐54.My therapist(s) know better than I what I need

Initial 2 of 2	4-1 Device

Assistive Technology Device Predisposition Assessment For Comparing Devices to Meet Desired Outcomes

Name_____ Age_____
Primary Goals (6 months)_____ Today's Date_____
Primary Goals (1 year+)_____

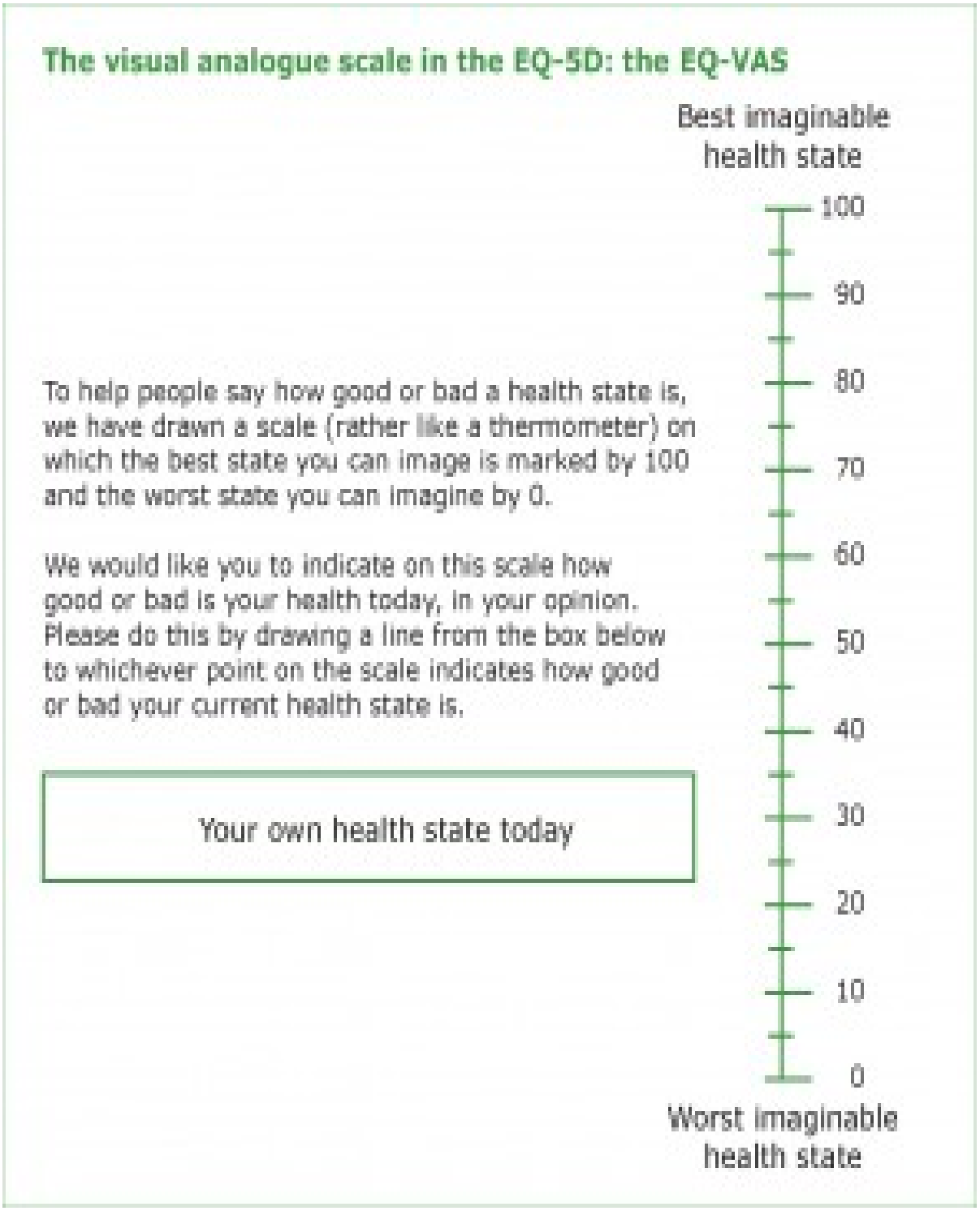
DIRECTIONS: Write the name of each device you are considering in the boxes below under ***Device.*** An example has been provided. For each devide, enter a [x] for the 3 items (A-L) that are most important to you. Then rate each device on the 12 items (A-L) according to the following scale and write your ratings in the appropriate boxes:

5 = All the time (100% of the time)
4 = Often (around 75% of the time)
3 = Half the time, neutral (about 50% of the time)
2 = Sometimes (around 25% of the time)
1 = Not at all (0% of the time)
0 = Not applicable

	Question	Example Quad Cane	Device 1: _____ (device name)	Device 2: _____ (device name)	Device 3: _____ (device name)
A	This device will help me to achieve my goals (including the primary AT goals written above)	5			
B	This device will benefit me and impreve my quality of life	3			
C	I am confident I know how to use this device and its various features	X 4			
D	I will feel more secure (safe, sure of myself) when using this device	X 5			

E	This device will fit well with my accustomed routine	4			
F	I have the capabilities and stamina to use this device without discomfort, stress and fatigue	X 3			
G	The supports, assistance and accommodations exist for successful use of this device	4			
H	This device will physically fit in all desired environments (car, living room, etc.)	3			
I	I will feel comfortable (and *not* self-conscious) using this device around family	4			
J	I will feel comfortable (and *not* self-conscious) using this device around friends	4			
K	I will feel comfortable (and *not* self-conscious) using this device at school or work	4			
L	I will feel comfortable (and *not* self-conscious) using this device around the community	4			
	Total *(add A-L)*	47			

Visual Analogue Scale (VAS)



Health Status - SF-12

«This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer carefully every question. Some questions may look like others, but each one is different».

(FOR THE INTERVIEWER: Pay attention that the subject answer to all questions, otherwise the test is not valid and the total score cannot be calculated.)

1. «In general, would you say your health is»:

Excellent	Very good	Good	Fair	Poor
☐5	☐4	☐3	☐2	☐1

«The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?»

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or shopping	☐1	☐2	☐3
3. Climbing several flights of stairs	☐1	☐2	☐3

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?»

	Yes	No
4. Accomplished less than you would like	☐1	☐0
5. Were limited in the kind of work or other activities	☐1	☐0

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?»

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 0
7. Did work or other activities less carefully than usual	☐ 1	☐ 0

8. «During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?»

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

«These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling»

«How much of the time during the past week...»

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. «During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?»

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

eHealth Literacy Scale

I would like to ask you for your opinion and about your experience using the Internet for health information. For each statement, tell me which response best reflects your opinion and experience *right now*.

1. How **useful** do you feel the Internet is in helping you in making decisions about your health?

o1	o2	o3	o4	o5
Not useful at all	Not useful	Unsure	Useful	Very Useful

2. How **important** is it for you to be able to access health resources on the Internet?

o1	o2	o3	o4	o5
Not important at all	Not important	Unsure	Important	Very important

3. I know **what** health resources are available on the Internet
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

4. I know **where** to find helpful health resources on the Internet
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

5. I know **how** to find helpful health resources on the Internet
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

6) I know **how to use** the Internet to answer my questions about health
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

7) I know how to use **the health information** I find on the Internet to help me
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

8) I have the skills I need to **evaluate** the health resources I find on the Internet
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

9) I can tell **high quality** health resources from **low quality** health resources on the Internet
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

10) I feel **confident** in using information from the Internet to make health decisions
1) o Strongly Disagree
2) o Disagree
3) o Undecided
4) o Agree
5) o Strongly Agree

T1

30-days Rehospitalization rate:

Yes ☐

No ☐

Short Physical Performance Battery

1. **Repeated Chair Stands**

Instructions: Please **stand up straight as quickly as you can five times, without stopping in between**. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready?

Begin Grading: **Begin stop watch when subject begins to stand up**. Count aloud each time subject arises. **Stop the stopwatch when subject has straightened up completely for the fifth time**. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety. Record the number of seconds and the presence of imbalance.

- Time:__sec (if five stands are completed)
- Number of Stands Completed: 1 2 3 4

5 Chair Stand Ordinal Score:

- 0 = unable
- 1 = > 16.7 sec
- 2 = 16.6-13.7 sec
- 3 = 13.6-11.2 sec
- 4 = < 11.1 sec

2. **Balance Testing**

Begin with a **semitandem stand** (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

a. **Semitandem Stand**

Instructions: Now I want you to try to stand with the **side of the heel of one foot touching the big toe of the other foot for about 10 seconds**. You may put either foot in front, whichever is more comfortable for you.

Please watch while I demonstrate. Grading: Stand next to the participant to help him or her into semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and let's go.

- 2 = Held for 10 sec
- 1 = Held for less than 10 sec; (number of seconds held: ____sec)
- 0 = Not attempted

b. Side-by-Side stand

Instructions: I want you to try to **stand with your feet together, side by side, for about 10 sec**. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

3. Tandem Stand

Instructions: Now I want you to try to **stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec**. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

Balance Ordinal Score:

- 0 = side by side 0-9 sec or unable
- 1 = side by side 10, <10 sec semitandem
- 2 = semitandem 10 sec, tandem 0-2 sec
- 3 = semitandem 10 sec, tandem 3-9 sec
- 4 = tandem 10 sec

4. 8' Walk (2.44 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 8'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready? Grading: Press the start button to start the stopwatch as the participant begins walking. **Measure the time** take to walk 8'. Then complete ordinal scoring.

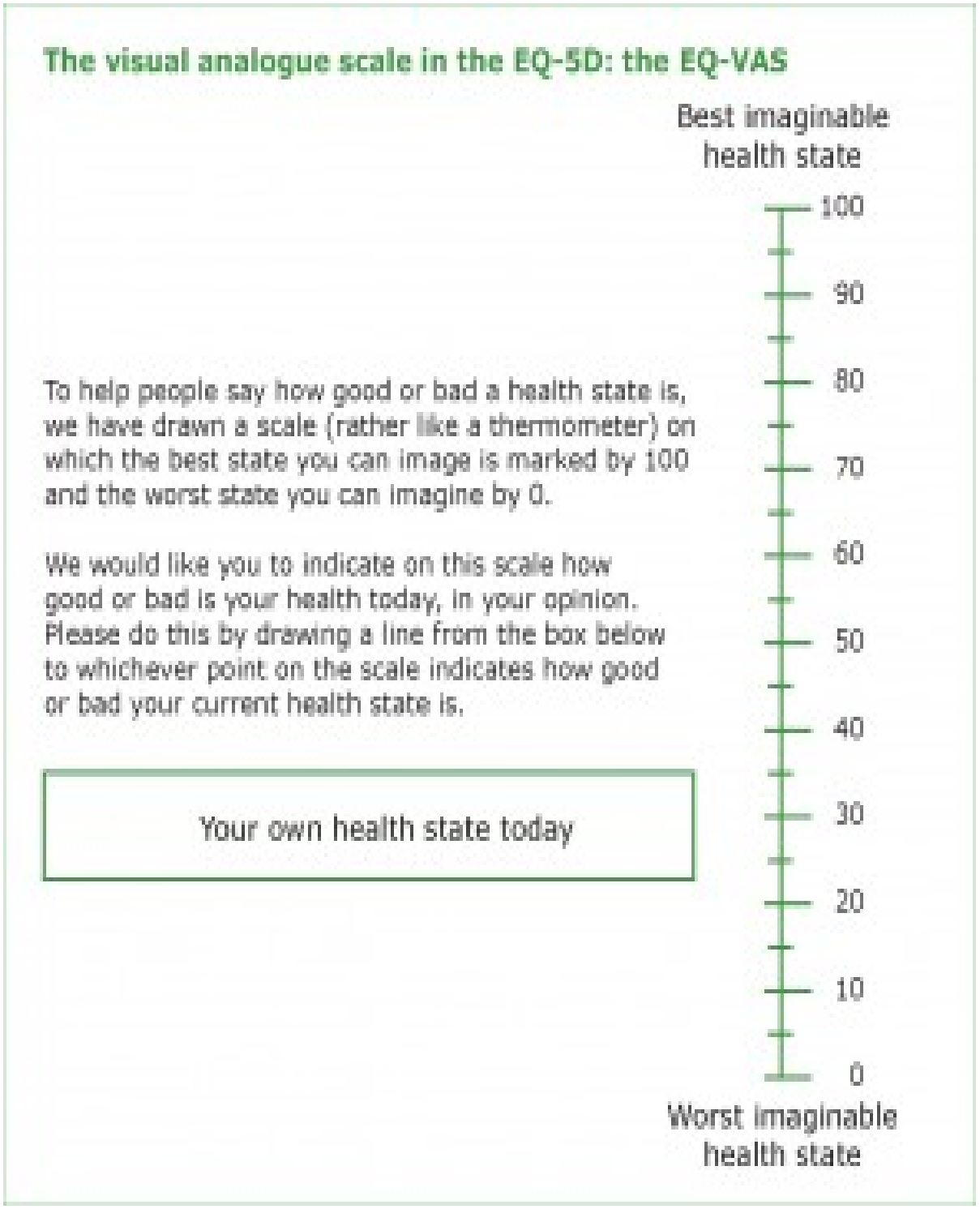
Time: __sec

Gait Ordinal Score:

- 0 = could not do
- 1 = >5.7 sec (<0.43 m/sec)
- 2 = 4.1-6.5 sec (0.44-0.60
- m/sec)
- 3 = 3.2-4.0 (0.61-0.77 m/sec)
- 4 = <3.1 sec (>0.78 m/sec)

Summary Ordinal Score: Range: 0 (worst performance) to 12 (best performance). Shown to have predictive validity showing a gradient of risk for mortality, nursing home admission, and disability.

Visual Analogue Scale (VAS)



Health Status - SF-12

«This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer carefully every question. Some questions may look like others, but each one is different».

(FOR THE INTERVIEWER: Pay attention that the subject answer to all questions, otherwise the test is not valid and the total score cannot be calculated.)

1. «In general, would you say your health is»:

Excellent	Very good	Good	Fair	Poor
☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

«The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?»

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or shopping	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?»

	Yes	No
4. Accomplished less than you would like	☐ 1	☐ 0
5. Were limited in the kind of work or other activities	☐ 1	☐ 0

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?»

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 0
7. Did work or other activities less carefully than usual	☐ 1	☐ 0

8. «During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?»

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

«These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling»

«How much of the time during the past week...»

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. «During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?»

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

eHealth Literacy Scale

I would like to ask you for your opinion and about your experience using the Internet for health information. For each statement, tell me which response best reflects your opinion and experience *right now*.

1. How **useful** do you feel the Internet is in helping you in making decisions about your health?

o1	o2	o3	o4	o5
Not useful at all	Not useful	Unsure	Useful	Very Useful

2. How **important** is it for you to be able to access health resources on the Internet?

o1	o2	o3	o4	o5
Not important at all	Not important	Unsure	Important	Very important

3. I know **what** health resources are available on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

4. I know **where** to find helpful health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

5. I know **how** to find helpful health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

6) I know **how to use** the Internet to answer my questions about health

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

7) I know how to use **the health information** I find on the Internet to help me

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

8) I have the skills I need to **evaluate** the health resources I find on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

9) I can tell **high quality** health resources from **low quality** health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

10) I feel **confident** in using information from the Internet to make health decisions

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

System Usability Scale

*The following section relates to your **feelings and thoughts** that may rise while using the **application/device**. Please circle one in each of the following statements, the number that reflects your impressions. There is only one answer possible.*

Statement	strongly disagree ⟷ strongly agree				
1. I think that I would like to use the system more often.	1	2	3	4	5
2. I found the system unnecessarily complex.	1	2	3	4	5
3. I found the system was easily to handle.	1	2	3	4	5
4. I think I would need the help of a technical person to be able to use the system.	1	2	3	4	5
5. I found the different functions in the system were well integrated.	1	2	3	4	5
6. I think the system were too instable.	1	2	3	4	5
7. I can imagine that most of the people can easily learn to handle the system very quickly.	1	2	3	4	5
8. I found the system very uncomfortable to use.	1	2	3	4	5
9. I felt very safe while using the system.	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system.	1	2	3	4	5

Semi-structured interview

ACCEPTANCE	
How often did you use the system during the day?	
Did you feel nervous using the system? Why?	
Did you feel embarrassed using the system in your family? Why?	
What features did you find most useful? And those that you did not like? Do you miss anything?	
Which benefit did it bring to your everyday life?	
Do you think that constant and continued use will benefit you?	
Do you think your anxiety is reduced with the use of the system?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	
Did you enjoy using the system or did you perceive it as an obligation?	
Does the product exactly match your needs? If not, what would you like to see added?	
Do you have concerns about privacy and the use of your data and personal information?	

USABILITY	
What is your impression of the system after using it for this period?	
Did you find the system easy to use? If not, what could make it easier?	
How long did it take you to fully understand the system?	
What actions did you have difficulty with? What took a lot of time to do?	
Do you feel confident while using the system?	
Do you think it is necessary to have technological skills to be able to use the system to its fullest?	

WILLINGNESS TO PAY	
If you imagine the system is on the market, what would help you decide whether or not to purchase it?	
If the system will be launched, how should it be financed?	
How much would you pay the service per month?	
Do you think that such kind of service should be provided/payed by healthcare insurance or national healthcare system?	

Clinical Resource Utilization

Healthcare resource consumption					
Previous physician visits - During the past 4 weeks					
Type of visit	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a) General practitioner	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b) Specialist	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c) Emergency Room (without hospitalization)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
Use of diagnostic tests and specialist clinic procedures - During the past 4 weeks					
Type	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
d)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
e)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
f)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
g)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3

Use of care services - During the past 4 weeks

Type	Total number	Recruitment pathology-related?	Reimbursement		
			NHS / public insurance	Private insurance	Out-of-pocket
a) Nurse home visit	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
b) Physiotherapy	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
c) Home help	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
d) Social transport	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
e) Day care center	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
f) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
g) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3

Hospital admissions - During the retention in the study

Admission → Discharge (DD-MM-YY)	Diagnosis at discharge	Recruitment pathology-related?	Reimbursement		
			NHS / public insurance	Private insurance	Out-of-pocket
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3

T2

60-days Rehospitalization rate:

Yes ☐

No ☐

Short Physical Performance Battery

1. Repeated Chair Stands

Instructions: Please **stand up straight as quickly as you can five times, without stopping in between**. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready?

Begin Grading: **Begin stop watch when subject begins to stand up**. Count aloud each time subject arises. **Stop the stopwatch when subject has straightened up completely for the fifth time**. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety. Record the number of seconds and the presence of imbalance.

- Time:__sec (if five stands are completed)
- Number of Stands Completed: 1 2 3 4

5 Chair Stand Ordinal Score:

- 0 = unable
- 1 = > 16.7 sec
- 2 = 16.6-13.7 sec
- 3 = 13.6-11.2 sec
- 4 = < 11.1 sec

2. Balance Testing

Begin with a **semitandem stand** (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

a. Semitandem Stand

Instructions: Now I want you to try to stand with the **side of the heel of one foot touching the big toe of the other foot for about 10 seconds**. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate. Grading: Stand next to the participant to help him or her into

semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and let's go.

- 2 = Held for 10 sec
- 1 = Held for less than 10 sec; (number of seconds held: ___sec)
- 0 = Not attempted

b. Side-by-Side stand

Instructions: I want you to try to **stand with your feet together, side by side, for about 10 sec**. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

3. Tandem Stand

Instructions: Now I want you to try to **stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec**. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

Balance Ordinal Score:

- 0 = side by side 0-9 sec or unable

- 1 = side by side 10, <10 sec semitandem
- 2 = semitandem 10 sec, tandem 0-2 sec
- 3 = semitandem 10 sec, tandem 3-9 sec
- 4 = tandem 10 sec

4. 8' Walk (2.44 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 8'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready? Grading: Press the start button to start the stopwatch as the participant begins walking. **Measure the time** take to walk 8'. Then complete ordinal scoring.

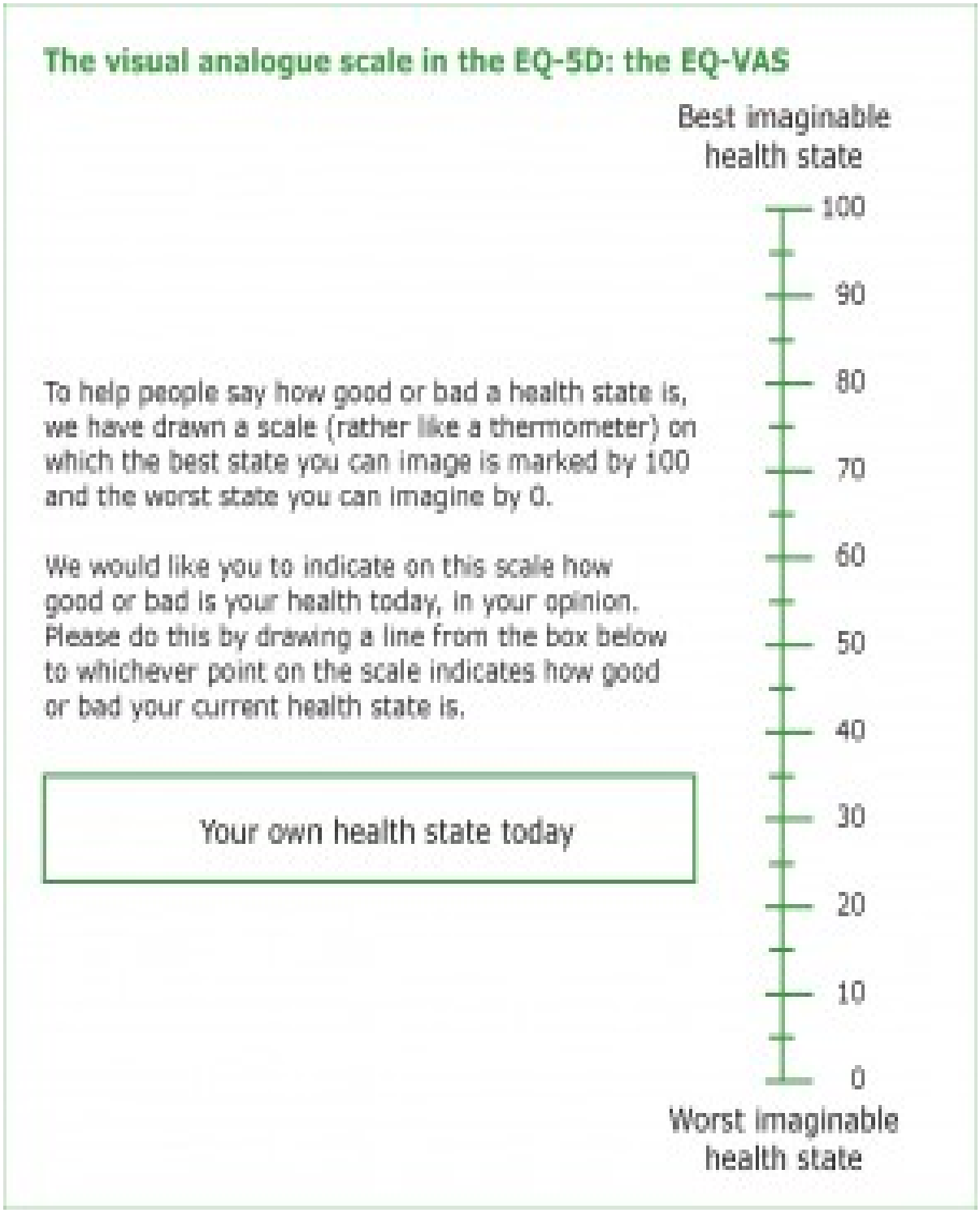
Time: __sec

Gait Ordinal Score:

- 0 = could not do
- 1 = >5.7 sec (<0.43 m/sec)
- 2 = 4.1-6.5 sec (0.44-0.60
- m/sec)
- 3 = 3.2-4.0 (0.61-0.77 m/sec)
- 4 = <3.1 sec (>0.78 m/sec)

Summary Ordinal Score: Range: 0 (worst performance) to 12 (best performance). Shown to have predictive validity showing a gradient of risk for mortality, nursing home admission, and disability.

Visual Analogic Scale (VAS)



Clinical Resource Utilization

Healthcare resource consumption					
Previous physician visits - During the past 4 weeks					
Type of visit	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a) General practitioner	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b) Specialist	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c) Emergency Room (without hospitalization)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
Use of diagnostic tests and specialist clinic procedures - During the past 4 weeks					
Type	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
d)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
e)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
f)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
g)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3

Use of care services - During the past 4 weeks

Type	Total number	Recruitment pathology-related?	Reimbursement		
			NHS / public insurance	Private insurance	Out-of-pocket
a) Nurse home visit	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
b) Physiotherapy	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
c) Home help	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
d) Social transport	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
e) Day care center	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
f) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
g) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3

Hospital admissions - During the retention in the study

Admission → Discharge (DD-MM-YY)	Diagnosis at discharge	Recruitment pathology-related?	Reimbursement		
			NHS / public insurance	Private insurance	Out-of-pocket
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3

T3

90-days Rehospitalization rate:

Yes ☐

No ☐

Short Physical Performance Battery

1. Repeated Chair Stands

Instructions: Please **stand up straight as quickly as you can five times, without stopping in between**. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready?

Begin Grading: **Begin stop watch when subject begins to stand up**. Count aloud each time subject arises. **Stop the stopwatch when subject has straightened up completely for the fifth time**. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety. Record the number of seconds and the presence of imbalance.

- Time:__sec (if five stands are completed)
- Number of Stands Completed: 1 2 3 4

5 Chair Stand Ordinal Score:

- 0 = unable
- 1 = > 16.7 sec
- 2 = 16.6-13.7 sec
- 3 = 13.6-11.2 sec
- 4 = < 11.1 sec

2. Balance Testing

Begin with a **semitandem stand** (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

a. Semitandem Stand

Instructions: Now I want you to try to stand with the **side of the heel of one foot touching the big toe of the other foot for about 10 seconds**. You may put either foot in front, whichever is more comfortable for

you. Please watch while I demonstrate. Grading: Stand next to the participant to help him or her into semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and let's go.

- 2 = Held for 10 sec
- 1 = Held for less than 10 sec; (number of seconds held: ___sec)
- 0 = Not attempted

b. Side-by-Side stand

Instructions: I want you to try to **stand with your feet together, side by side, for about 10 sec**. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

3. Tandem Stand

Instructions: Now I want you to try to **stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec**. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and let's go.

- 2 = Held of 10 sec
- 1 = Held for less than 10 sec; (number of seconds held:___ sec)
- 0 = Not attempted

Balance Ordinal Score:

- 0 = side by side 0-9 sec or unable
- 1 = side by side 10, <10 sec semitandem
- 2 = semitandem 10 sec, tandem 0-2 sec
- 3 = semitandem 10 sec, tandem 3-9 sec
- 4 = tandem 10 sec

4. 8' Walk (2.44 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 8'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready? Grading: Press the start button to start the stopwatch as the participant begins walking. **Measure the time** take to walk 8'. Then complete ordinal scoring.

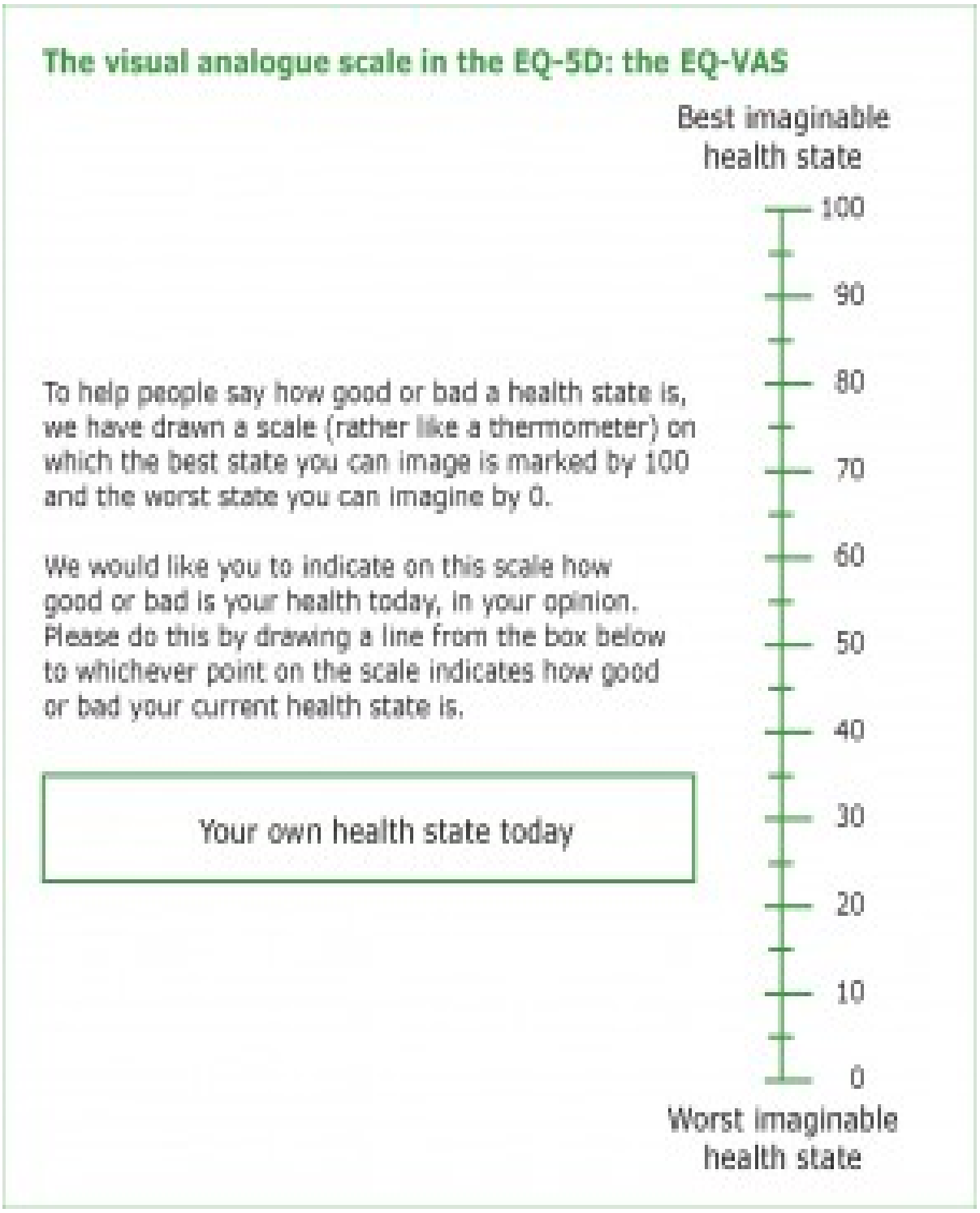
Time: __sec

Gait Ordinal Score:

- 0 = could not do
- 1 = >5.7 sec (<0.43 m/sec)
- 2 = 4.1-6.5 sec (0.44-0.60
- m/sec)
- 3 = 3.2-4.0 (0.61-0.77 m/sec)
- 4 = <3.1 sec (>0.78 m/sec)

Summary Ordinal Score: Range: 0 (worst performance) to 12 (best performance). Shown to have predictive validity showing a gradient of risk for mortality, nursing home admission, and disability.

Visual Analogic Scale (VAS)



eHealth Literacy Scale

I would like to ask you for your opinion and about your experience using the Internet for health information. For each statement, tell me which response best reflects your opinion and experience *right now*.

1. How **useful** do you feel the Internet is in helping you in making decisions about your health?

o1	o2	o3	o4	o5
Not useful at all	Not useful	Unsure	Useful	Very Useful

2. How **important** is it for you to be able to access health resources on the Internet?

o1	o2	o3	o4	o5
Not important at all	Not important	Unsure	Important	Very important

3. I know **what** health resources are available on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

4. I know **where** to find helpful health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

5. I know **how** to find helpful health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

6) I know **how to use** the Internet to answer my questions about health

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

7) I know how to use **the health information** I find on the Internet to help me

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

8) I have the skills I need to **evaluate** the health resources I find on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

9) I can tell **high quality** health resources from **low quality** health resources on the Internet

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

10) I feel **confident** in using information from the Internet to make health decisions

1) o Strongly Disagree

2) o Disagree

3) o Undecided

4) o Agree

5) o Strongly Agree

System Usability Scale

*The following section relates to your **feelings and thoughts** that may rise while using the **application/device**. Please circle one in each of the following statements, the number that reflects your impressions. There is only one answer possible.*

Statement	strongly disagree ⟷ strongly agree				
1. I think that I would like to use the system more often.	1	2	3	4	5
2. I found the system unnecessarily complex.	1	2	3	4	5
3. I found the system was easily to handle.	1	2	3	4	5
4. I think I would need the help of a technical person to be able to use the system.	1	2	3	4	5
5. I found the different functions in the system were well integrated.	1	2	3	4	5
6. I think the system were too instable.	1	2	3	4	5
7. I can imagine that most of the people can easily learn to handle the system very quickly.	1	2	3	4	5
8. I found the system very uncomfortable to use.	1	2	3	4	5
9. I felt very safe while using the system.	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system.	1	2	3	4	5

Health Status - SF-12

«This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer carefully every question. Some questions may look like others, but each one is different».

(FOR THE INTERVIEWER: Pay attention that the subject answer to all questions, otherwise the test is not valid and the total score cannot be calculated.)

1. «In general, would you say your health is»:

Excellent	Very good	Good	Fair	Poor
☐5	☐4	☐3	☐2	☐1

«The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?»

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or shopping	☐1	☐2	☐3
3. Climbing several flights of stairs	☐1	☐2	☐3

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?»

	Yes	No
4. Accomplished less than you would like	☐1	☐0
5. Were limited in the kind of work or other activities	☐1	☐0

«During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?»

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 0
7. Did work or other activities less carefully than usual	☐ 1	☐ 0

8. «During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?»

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

«These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling»

«How much of the time during the past week...»

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. «During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?»

All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Clinical Resource Utilization

Healthcare resource consumption					
Previous physician visits - During the past 4 weeks					
Type of visit	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a) General practitioner	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b) Specialist	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c) Emergency Room (without hospitalization)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
Use of diagnostic tests and specialist clinic procedures - During the past 4 weeks					
Type	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
b)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
c)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
d)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
e)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
f)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3
g)	——	Yes ☐1 No ☐0	☐1	☐ 2	☐ 3

Use of care services - During the past 4 weeks					
Type	**Total number**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
a) Nurse home visit	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
b) Physiotherapy	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
c) Home help	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
d) Social transport	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
e) Day care center	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
f) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3
g) Other (specify_____)	____	Yes ☐ No ☐	☐ 1	☐ 2	☐ 3

Hospital admissions - During the retention in the study					
Admission → Discharge (DD-MM-YY)	**Diagnosis at discharge**	**Recruitment pathology-related?**	**Reimbursement**		
			NHS / public insurance	**Private insurance**	**Out-of-pocket**
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3
___/___/___→___/___/___	_____	Yes ☐ 1 No ☐ 0	☐ 1	☐ 2	☐ 3

Semi-structured interview

ACCEPTANCE	
How often did you use the system during the day?	
Did you feel nervous using the system? Why?	
Did you feel embarrassed using the system in your family? Why?	
What features did you find most useful? And those that you did not like? Do you miss anything?	
Which benefit did it bring to your everyday life?	
Do you think that constant and continued use will benefit you?	
Do you think your anxiety is reduced with the use of the system?	
Do you think there are any risks or negative effects of using the system that we have not discussed?	
Did you enjoy using the system or did you perceive it as an obligation?	
Does the product exactly match your needs? If not, what would you like to see added?	
Do you have concerns about privacy and the use of your data and personal information?	

USABILITY	
What is your impression of the system after using it for this period?	
Did you find the system easy to use? If not, what could make it easier?	
How long did it take you to fully understand the system?	
What actions did you have difficulty with? What took a lot of time to do?	
Do you feel confident while using the system?	
Do you think it is necessary to have technological skills to be able to use the system to its fullest?	
WILLINGNESS TO PAY	
If you imagine the system is on the market, what would help you decide whether or not to purchase it?	
If the system will be launched, how should it be financed?	
How much would you pay the service per month?	
Do you think that such kind of service should be provided/paid by healthcare insurance or national healthcare system?	