AAL PROGRAMME

RecoveryFun

An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors

AAL-2021-8-64-CP

Deliverable D2.2 – Methodology for the field trial

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Executive Summary

This document presents the methodology that will be used in the different phase of the system test.

Chapter 1 includes the description of the pilot sites in the three participating countries (Italy, Belgium and Switzerland).

Chapter 2 is dedicated to the rapid test of the interfaces, including the system for the primary users formed by VR headset, exergames and sensor, the App for the informal caregiver and the dashboard for the clinicians.

Chapter 3 presents the approach to the first test of the prototype in clinical environment, a step necessary to highlight eventual problems before delivering the solution at home.

Chapter 4 represent the core of the document and describe the methodology, the protocol and the tools that will be used for the test of the RecoveryFun system in operational environment at the patient's home. This part represents the starting point for the application to the Ethical Committees.

Chapter 5 highlights the ethical and legal issues related to the testing with patients

Chapter 6 presents the bibliography

Chapter 7 includes as Annexes all the detailed methodologies, data collection forms and consensus forms.

1. Introduction

1.1 Purpose of the document

In the RecoveryFun project all end-user involvement activities are concentrated in WP2.
This document describes the tests of the different system components, both the interfaces (virtual reality, wearable sensor, informal caregiver application, clinical platform) and the full integrated system.
For each of the interfaces, specific methodologies will be used to involve end-users and to collect feedback regarding the actual prototype's acceptability and usability.
Furthermore, this document specifies how the prototype will be initially tested in clinical environment, describing the test of first integrated prototype and the pilot in protected environment.
After that, the focus is on the field trial, detailing study background and rationale, study objectives, expected outcomes, study design, recruitment strategy, participants, Case Report Form, limitations and legal and ethical issues.
Results from the tests will be presented in D2.3 field trial evaluation.

1.2 Pilot site description

Italy

INRCA is the leading Italian public Institute in gerontology and geriatrics, devoted to improve quality of life of older persons. It consists of five centres in Italy, comprising four geriatric hospitals, an Alzheimer day care centre, a nursing home and scientific and technology research units.
The objectives of the Institute are focused on successful ageing and the promotion of health of the older person and prevention. Social gerontology is one of the most important research fields, developed in both national and international sphere, cooperating with universities and other research institutes. Currently, there are four lines of research: (1) Biogerontology: cellular determinants, molecular and genetic aging, longevity and age-associated diseases; (2) Prevention and treatment of frailty: management of geriatric diseases and syndromes; (3) Aging and Medicines and (4) Multidimensional assessment and continuity of care. INRCA pursues its goal mainly in an interdisciplinary way, through clinical and translational research, training in the biomedical field as well as in the organization and management of health care services, in particular by means of highly specialized hospitalization and health care.
For the project, the *Centre of Innovative Models for Ageing Care and Technology* of INRCA is involved. It aims at studying the needs of the elderly in the User Centred Design process, as well as the impact and acceptance of the technology to support everyday life, great emphasis is given to technological innovation, promotion and acceptance of technology for the elderly. The centre is indeed involved in various activities aimed at the study of usability and acceptance of smart environments to support the independence and autonomy of the elderly. This commitment is supported through regional, national and international collaborations with universities, research institutes and companies specializing in technology, home automation and artefacts from the house computer, without architectural barriers, with sensors that detect possible hazards, smart appliances and tools with communication interfaces easy for their remote control. For the analysis of Human-Machine and Human-Computer Interactions, and of the acceptability and usability of technology, the Centre benefits from the presence of different labs: the Casamica Lab and the Usability Lab. The Casamica lab is a smart home of about 60 square feet, located close to the Rehabilitation Unit of the INRCA hospital in Ancona. The intelligent environment consists of a kitchen, a bedroom and a bathroom, equipped with assistive devices and home automation technology. The Casamica lab was designed to enable greater independence of older

people and to avoid their admission to care facilities. It represents a unique opportunity to directly test technology with the people in real life, thanks to its strategic location.

Figure 1 INRCA Casamica Lab

The Usability lab is aimed at a) developing prototypes of new technological devices (objects, environments and interfaces) designed for older adults through participatory design, b) designing innovative care models through the integration of clinical experience in the geriatric field and technological innovation, c) assessing human-machine interaction and d) promoting the technological literacy among the older population. The Lab is equipped with the NOLDUS that offers a wide range of software, systems, and services for research on animal and human behaviour such as the FaceReader to gain accurate and reliable data about facial expressions, the eye-tracking system and the BioNomadix® system of wearable wireless devices to gather physiological data.

Figure 2 INRCA Usability Lab

The recruitment strategy at INRCA will be performed in the city of Ancona where a skilled staff will identify possible participants that met the target of the project within the organization and its wide network. The staff will contact primary and secondary end-users as well as stakeholders explaining the study purpose and methods (i.e. co-design sessions) and propose them to take part in it. Individuals who accept to participate are provided with and asked to sign a written informed consent to data treatment in accordance with the GDPR 2018 and the national legislation on privacy and data protection.

Switzerland

ZURZACH Care is the leading group in the Swiss healthcare sector for health prevention, treatment, rehabilitation and reintegration. With 21 locations and around 1’200 employees ZUR offers highest medical, nursing and therapeutic competence. The group includes numerous outpatient centres, rehabilitation clinics, specialist clinics and a company for reintegration as well as subsidiary and partner companies in the field of sleep medicine, cures and rehabilitation at home.

ZURZACH Care has a long tradition of research with a mention of research in the foundation charter from 1957. ZURZACH Care is one of the few providers in rehabilitation to operate its own research department. The research department established since 1992 is focused on clinical research in neurology and neurorehabilitation, musculoskeletal medicine, headache and pain, sleep and technological applications. In doing so, it strengthens the evidence base in rehabilitation and thus makes a professional and social contribution. Furthermore, ZURZACH Care invests in the development of innovative treatment methods and in the seamless medical supply chain.

In addition to traditional physiotherapy and occupational therapy, ZURZACH Care uses robot- and device-assisted therapies to treat patients with neurological and musculoskeletal disorders, among others. In this context, new technologies and modern training therapy approaches are used as part of functional training therapy to improve arm, hand and gait function, among other things.

Figure 3 Examples of robot- and device-assisted therapy for lower limb rehabilitation at ZURZACH Care

The device-assisted therapies also provide opportunities for cognitive/cognitive-motor training. Wheelchair users can also benefit from such therapies. In order to achieve individual therapy goals and improve desired functions, our patients are accompanied by highly trained therapists. The experience gained in the technology-supported forms of training also has a lasting positive effect on the patient’s motivation and self-confidence.


Figure 4 Examples of robot and device-based rehabilitation of the upper extremity at ZURZACH Care

Based on this big and specialized range of services and great expertise along the patient journey (e.g. from health prevention to acute rehabilitation to inpatient and outpatient rehabilitation to domiciliary treatments "reha@home"), ZURZACH Care offers ideal conditions and a patient clientele that corresponds to the project's target group for the RecoveryFun project. For the reasons mentioned above, the headquarter of ZURZACH Care (Rehaklinik Bad Zurzach) is favored for operating the project.

Belgium

TRAINM is a leading outpatient rehabilitation clinic group with locations in Antwerp and Genth-South (Zottegem) specialized in treating patients with neurological disorders. With our multidisciplinary team of medical doctors (neurologists, physical medicine and rehabilitation doctor, psychiatrist), physiotherapists, speech therapists, neuropsychologists and occupational therapists we are focused on improving patients recoveries.

The mission of TRAINM is to continuously improve the recoveries of neurological patients with

1. Personalized multi-disciplinary medical rehabilitation therapies, using scientifically proven therapies and technologies by highly-skilled therapists;
2. All therapies are based on the principle of neuroplasticity;
3. Continuous evaluations, data analysis and information communication.

TRAINM's strategy is to remain the leading outpatient neuro rehabilitation clinic group in Europe maximizing functional recoveries for neurological patients. This strategy implies several elements:

- TRAINM wants to stay ahead with innovation. We believe that remote rehabilitation with VR is key in the future and wants to be part of this development. Our experience, competences and skills will be of added-value to the project.
- The remote rehabilitation will facilitate our expansion outside the boarders of Belgium. Currently, TRAINM has international patients that come to our clinics in Antwerp and Ghent-South (Zottegem) for bootcamps (short and intense therapy plan). Remote rehabilitation is therefore an important factor for the after care of our patients.

TRAINM currently operates 2 clinics in Belgium and is opening a 3rd clinic in Amsterdam in 2023. We treat children and adults with a neurological disorder, e.g. cerebral palsy, acquired brain injury, stroke, multiple sclerosis, Parkinson's disease, spinal cord injury and disorders of consciousness.

At TRAINM-Antwerp we currently treat about 130 patients per month resulting in aproximately 1.700 therapy sessions per month. Many of our patients are long-term recurring patients with weekly sessions.

The project will be conducted at our headquarters in Antwerp, Belgium. TRAINM-Antwerp has a facility of 1.600m² and offers the most innovative and scientifically proven technologies to support the therapies. Thanks to the functional recoveries obtained, the wide range and type of equipment and the highly skilled multidisciplinary team of neurologists, doctors in physical medicine, psychiatrist, neuro physical therapists, neuropsychologists, neuro speech therapists, and occupational therapists, TRAINM was recognized as worldwide Centre of Excellence by DIH, leading distributor of rehabilitation technologies worldwide.

Figure 5 Rehabilitation activities at TRAINM

The recruitment strategy will be performed by our skilled medical and paramedical staff who will identify possible participants that meet the criteria of the project. The staff will contact primary and secondary end-users as well as stakeholders explaining the study purpose and methods. Individuals who accept to participate are provided with and asked to sign a written informed consent to data treatment in accordance with the GDPR 2018 and national legislation on privacy and data protection.

2. Rapid test of the interfaces

Interface tests are based on:

- Rapid tests for the virtual reality and the wearable sensor;
- Qualitative evaluation for the informal caregiver mobile application;
- Workshop with clinicians for the clinical platform.

Each test of the interfaces will be discussed in more detail within the next section.

2.1 Rapid test of the primary users system

The objectives of the rapid testing phase is:

- To receive feedback on the system usability;
- To receive feedback from the users mainly focused on improving the appearance of the product and evaluating the User Experience (UX).

To achieve these goals headset/viewer and the wearable sensor that the participant has to put on the fingers of his/her hand will be tested.

Each rapid test is structured as follows:

- Presentation of RecoveryFun project;
- Collection of socio-demographic data;
- Participant's execution of tasks with the headset and the wearable sensor;
- Collection of user experience information.

The protocol is presented in detail in Annex 7.1, while below is a brief description of the methods used during the testing:

1. **Qualitative methods**

Thinking aloud method

Participants are urged to describe what they did and thought vocally during the accomplishment of tasks. This measure is particularly used with test and analysing methods. The use of thinking aloud allows the researcher to investigate in detail the overall user experience because people express their feelings, thoughts and scepticism directly when using the system. Thinking aloud protocols allow matching each feeling, remark, thought, etc. to an exact point in time and an exact moment of interaction. By only using interviews and questionnaires the data which will be produced spontaneous would be lost for documentation and for the data analysis.

For the aim of the testing phase, it was decided to elaborate precise tasks to be performed by the users, while thinking aloud. At the end of the testing session, a retrospective thinking aloud method will be conducted with the users, in order to 1) be sure to have understood properly the opinion of the users and 2) gain information from the users, after their initial use.

Participant Observation

The entire tests will be audio-recorded in order to collect information for later analysis at the final step. One researcher conducts the test, while another take notes on the observation form, detailing what happened during the test, using the VR test observation sheet (in Annex 7.2). On the same form he or she also note the answers given by the person tested to each question.

In addition, he or she write self-reflective notes to assess the validity of the answers and the cooperation of the user. The notes might contain, for example, whether the person tested seemed to be anxious or uncomfortable in other ways during the VR test or whether he or she seems to enjoy the test, whether the person seems frightened or reluctant to do something, and reflections on the reasons why the person do as he or she did some tasks. Immediately after the interview, the researcher will review the notes to see if any additions and/or corrections are needed, supported also by the recorded audio that he or she could listen again if there is any doubt or need.

During all the activity, the researcher is guided by the following key questions for the observation:

Usability	Did person understand the system aim and functioning?
	Which were the main problems the person had during the task?
	Did person had any problems interacting with the VR?
	How is human-computer interaction? Is the person afraid of using it?
Acceptance	Was the user anxious during the system usage?
	Did the user enjoy using the system?

Table 1 Key questions for the rapid test of the system for the patient

During each testing phase, the researcher collects the observation notes that contain everything which is either not recorded, remains implicit, or otherwise seems to be important. The notes could be written during the interview, but should definitely be done and elaborated as soon as possible after the interview. Besides the assessment of the validity of the answers and the user cooperation, self-reflexive notes are also written. For guiding the field observation, a checklist for the collection of data from thinking aloud and observation of the tasks execution with VR is reported in Annex 7.3 in order to focus the attention on specific behaviour or dimension of interest.

If the person under test did not know how to do a task, the researcher tells him or her how to do it. Although, it is important for the researcher to wait to see if the person being tested is able to do a task on his/her own before helping him/her. If the person exhibits overt or perceived difficulty, the researcher could offer help by documenting it in the appropriate tables (Annex 7.2 and Annex 7.3).

Qualitative questions

During the performance of the test following the execution of the tasks, the participant is asked qualitative questions in order to classify the experience he or she is having and evaluate some essential aspects of it (readability of the text appearing in VR, opinion regarding the music, colour contrasts, perceptions and feelings related to being immersed in VR...)

For example, a qualitative question is “What does it feel like to see your hands in VR?”. All qualitative questions are reported within the protocol.

2. Quantitative methods

Closing questions

In order to collect all the information, an open question and fourteen quantitative questions will be developed, assuring the opportunity of reaching the full understanding of the users’ perspective. The visual analogue scale (VAS) will be used seven times as well as the Likert-type scale in the following formats:

Visual Analogue Scale

Not at all satisfied Highly satisfied

Likert-type Scale

1	2	3	4	5
Not at all satisfied	Not satisfied	Partially satisfied	Satisfied	Highly satisfied

Quest 2.0 - Quebec User Evaluation of Satisfaction with Assistive Technology

For the purpose of assessing patient satisfaction with the headset and the wearable sensor, the QUEST 2.0 will be used. The questionnaire consists of 8 items for each of which the participant should rate his/her satisfaction using a Likert scale from 1 to 5.

1	2	3	4	5
Not at all satisfied	Not satisfied	Partially satisfied	Satisfied	Highly satisfied

Then the participant should select from the 8 satisfaction items, the three that he/she considers most important to him/her.

2.2 Qualitative evaluation of the informal caregiver app

The evaluation of the caregiver application will be based on the analysis of the prototype provided by Canary Technology. This analysis will be guided by the list of requirements previously defined for the application. Starting with the observation of the different prototype screens, each end-user partner will their feedback regarding strengths identified and improvements needed.

Thereafter, the discussion and integration of this feedback will enable the identification of the main aspects to be deepened for the future development and utilization of the mobile application by informal caregivers. These aspects will then be shared with Canary Technology.

2.3 Evaluation of the clinical portal

The evaluation of the clinical platform will be performed through workshops with clinicians aimed at analysing the prototype of the clinical platform.

The workshop will be structured as a group session, lasting about an hour, in which clinicians (doctors and physiotherapists) will be invited to watch and analyse the different prototype screens. In fact, clinical platform prototype allows to simulate the experience of a user by performing the main possible tasks within it.

During the workshop, the discussion will be stimulated by a series of questions raised by the researcher conducting the focus group tailored to obtain the useful and needed information for technical partners.

Indeed, the objective of the workshop with clinicians is to collect feedback especially related to the adequacy of the contents and the best way to display and make them easily accessible and readable.

In Annex 7.5 the methodology for the workshop with clinicians is described in detail.

3. First test of the prototype in clinical environment

The test of the system in clinical environment has a double scope:

- Identify possible critical issues in the use of RecoveryFun integrated solution before the start of the field trial;
- Test the protocol proposed for the field trial in term of identification of the involved patients (inclusion/exclusion criteria) and appropriateness of the tools and questionnaires used for data collection.

For this scope the partner involved will use the most appropriate areas in their facilities.

For both the two round of planned test the procedure will be coherent with the protocol defined for the field trial and will include the following steps:

- Identification of the patients to be involved according to the trial inclusion and exclusion criteria;
- Administration of the tools planned at recruitment;
- Formation of the patient;
- Execution of the rehabilitation session;
- Administration of the T1 planned questionnaires.

The list of tools to be used for the pilot are reported in Table 2

Dimension	Tool	Before	After
Functional ability	Fugl-meyer	X	
Trunk stability	Trunk Impairment scale	X	
Cognitive status	MoCA	X	
Socio-demographic characteristics Subjective health assessment,	Ad hoc questionare	X	
Attitude to technology	MPT SOTU C	X	
Acceptance	Quest- Quebec User Evaluation of Satisfaction with assistive Technology		X
Usability	System Usability Scale (SUS)		X
User experience	User Experience Questionnaire (UEQ)		X
Pilot experience	Semistructured interview		X

Table 2 Dimensions investigated and tools to be used for the pilot

3.1 Test of first integrated prototype

For the pilot in protected environment 5 patient will be recruited.

The objective of the pilot in protected environment is to test the technical validation of the RecoveryFun system functionality with a particular interest to the capability of the system to adapt the range of motion necessary to play the games to the functional ability of the patient.

The process of the test in protected environment will follow the same approaches that will be used for the trial with the only difference that the patient will perform only one rehabilitation session in the hospital promises with the researchers observing him/her, ready to intervene where the patient explicitly requests it.

3.2 Pilot in protected environment

The second round of test will be conducted simulating the condition of the patient using the RecoveryFun system autonomously at home.

This round will include 1 or 2 patients in each pilot site.

A comfortable environment will be created that could be simulate the patient home and after the training the participants will be left alone using the system autonomously. The researchers will observe (without being seen) and video register the behaviour of the participants to identify the difficulties that they have in using the system.

The registration will successively be analysed and compared with the data collected by the sensor to identify the potential critical steps that could create problems in the rehabilitation session.

The presence of the researcher will contribute to make the participant feel comfortable and the researchers will be ready to support the participant in case of blocking problems.

4. Field trial

4.1 Study background and rationale

Aging population is challenging health care systems by ensuring rehabilitation in the long term for patients.

For example, stroke is the third leading cause for long-term disability in most countries and can result in paralysis, speech impairment, loss of memory and reasoning ability, coma or even death.

In additional, a brain injury not only cause health loss and disability for individuals and their families, but also represent a burden to health-care systems and economies through lost productivity and high health-care costs.

Complete or partial loss of movability in an Upper Extremity (UE) is the most commonly reported impairment after suffering a stroke/brain injury which can hinder the performance of activities of daily living (ADL) and significantly undermine the quality of life (QOL) of patients.

Recent neuroplasticity studies indicate that highly repetitive and task-specific training may induce changes in the brain, and this response can be optimized if the task is challenging enough. Therapy with exergames is regarded as an effective and reliable method for the delivery of highly repetitive training that is needed to trigger neuroplasticity. Compared with conventional rehabilitation therapy, use of technology supported tools holds clear advantages such as precisely controlled force-feedback, automated movement control, objective and quantifiable measure of performance.

Growing evidence has revealed that VR has the potential to generate effective rehabilitation environments, which are possibly individualized, safe, and multimodal simulations. Moreover, VR has the potential to provide the key elements of neuroplasticity (i.e., feedback, repetition, intensity, and tasks specific training), which are not usually possible in conventional physical therapies but are helpful to speed up the recovery of UEs .

VR can be an aid to offer home-based rehabilitation with reduced expenditures by the health care system and less effort by the caregiver.

This study is designed as a study to test the usability and acceptability of RecoveryFun system by the patient that needs long term rehabilitation for example after an acute event such as a stroke and to test the following hypotheses during home rehabilitation:

1. Not being constrained to travel periodically to the rehabilitation centre, saving stress for the patient and eventual job leaves for the working family carer accompanying him/her. Such advantage is also linked to the improvement of accessibility of care, thanks to digital solutions;
2. Enjoying the serious exergames of RecoveryFun which will provide stimulation to sustain users' emotional and psychological wellbeing;
3. Performing rehabilitation sessions choosing among different game modes: alone or with the remote monitoring of clinicians;
4. Improving adherence to the rehabilitation plan (users will be able to use the RecoveryFun solution 24/7, at any time during the day, even splitting sessions in different day times).

4.2 Objective of the study

The objective of the study is to investigate regarding the usability and acceptability (primary objective) and treatment effectiveness (secondary objective) of VR used independently at home with non-continuum remote monitoring from the physical therapist.

4.2.1 Research questions

The questions that move researchers to conduct the trail and which will be answered with data collection are:

- After intensive rehabilitation in the hospital, is VR at home suitable to continue rehabilitation by reducing the burden for formal and informal caregiver? Specifically, the questions of the researchers animating the trial is whether the RecoveryFun System can be an easy-to-use and effective rehabilitation tool at the patient's home.
- Will the patient need help to manage the headset?
- If so how much will the caregiver's presence be needed?
- Will the caregiver's load be reduced or will it increase to provide care for the sick care-recipient?
- Will the patient find the same motivation to pursue rehabilitation independently?
- Will being at home without a therapist generate frustration?
- Will the therapist follow the patient remotely by consulting a clinical portal generate a sense of abandonment in the patient?
- The selected population can benefit from (long term) rehabilitation with RecoveryFun system? Will the patient improve his or her motor performance?

4.3 Expected outcome

The primary expected outcomes from the researchers regarding the trial are to test if the RecoveryFun system, used at home, can:

- Be usable and acceptable for the patient at home;
- Create engagement and motivation in order to increase adherence to therapy;
- Provide informal caregiver with a usable tool to support and motivate his/her care-recipient to engage in rehabilitation.
- Reduce the professional's workload by providing continuity of care for the patient;
- Supply the professional with a usable tool to monitor multiple patients simultaneously, utilizing objective and measurable data regarding patient's level of stress and fatigue and the effectiveness and efficiency of the rehabilitation pathway;

Secondary expected outcomes are aimed more specifically to collect preliminary data on the effectiveness of the system in treating the upper extremity in the hemiplegic patient in terms of:

- Increased function and motility of the upper limb
- Increased autonomy in basic activities of daily living.

In addition, as secondary outcomes the system aims to:

- Increase patient's perception of quality of life;
- Reduce caregiver's perceived stress.

4.4 Study design

The acceptability study that we are going to carry out at the three recruitment sites (ZUR, TRAINM, INRCA) aims to test the acceptability and the usability of our proposed system in a group of hemiplegic patients, aged 60 years or older, within one year after the acute event with upper limb hemiplegia (Fugl- Meyer > 33).

4.4.1 Study scheme

The study will last 4 weeks and involve two rehabilitative sessions ranging from a minimum of 10 minutes to a maximum of 30 minutes per week using the VR. Two formation sessions will be performed in the hospital, involving also the caregiver, in which the operation of the system and its proper use will be shown, at which time recruitment and T0 assessments will also be performed. If necessary, formation sessions may increase in order for the patient, supported by the trained caregiver, to be confident enough to use it independently at home. After formation is completed, the patient will take the system home and start rehabilitative sessions. The physical therapist will constantly monitor the progress of the treatment through the clinical platform available to him or her. At the end of each week, the physical therapist will call the patient to ask how he or she is doing and if there are any difficulties and if in-person intervention is needed.

At the end of the 4 weeks, T1 evaluation will be conducted to assess whether the system has been accepted by the patient, detect any critical issues, and the effectiveness of the treatment. Evaluation with the caregiver and professionals will also be carried out at this time. With respect to the informal caregiver, the emphasis will be on the assessment of perceived stress and system usability. Meanwhile, with the clinician, the impact and usability of the system will be mainly explored.

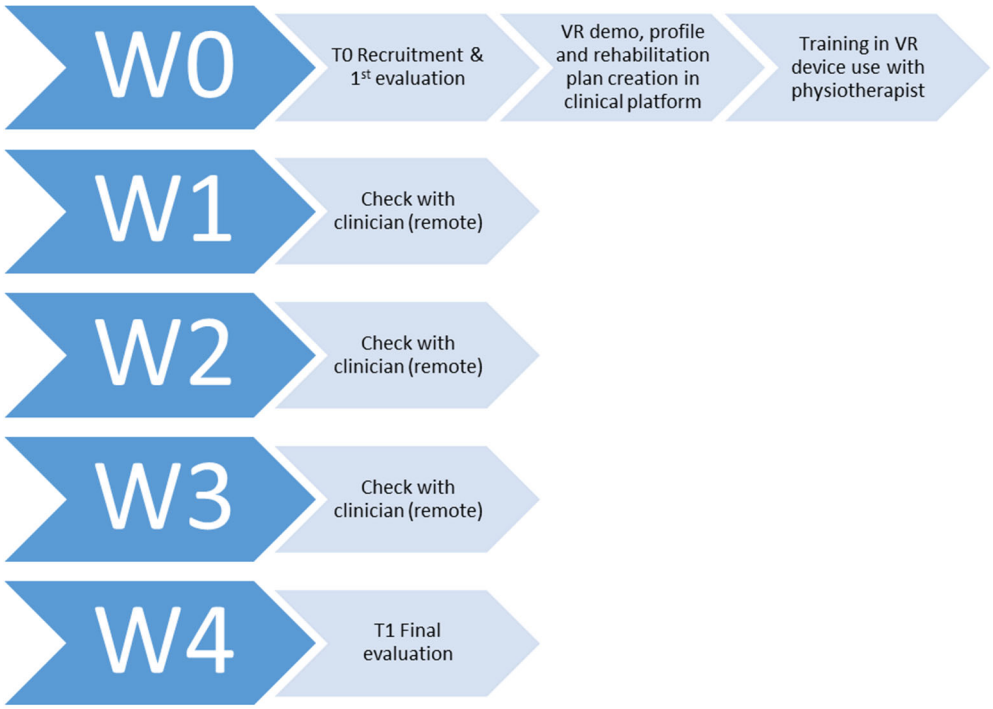

Figure 6 Scheme of the field trial

During the study, patient data will be collected as shown in Table 3.

Dimension	Tool	R	T0	T1
Functional ability	Fugl-meyer	X	X	X
Trunk stability	Trunk Impairment scale	X		

Cognitive status	MoCA	X		
Socio-demographic characteristics Subjective health assessment and Social support	Ad hoc questionnaire		X	
Attitude to technology	MPT SOTU C		X	
Ability to meet expectations	Goal attainment scale (GAS)		X	X
Quality of life	WHOQOL-BREF		X	X
Acceptance	Quest- Quebec User Evaluation of Satisfaction with assistive Technology			X
Usability	System Usability Scale (SUS)			X
	User Experience Questionnaire (UEQ)			X
Intention to pay (demand& cost analysis)	Ad hoc questionnaire			X

Table 3 Dimensions investigated and tools used for the patient during the trial

Table 4 illustrates the tools that will be used to collect informal caregiver data.

Dimension	Tool	T0	T1
Socio-demographic characteristic	Ad hoc questionare	X	
Attitude to technology	MPT SOTU C	X	
Perceived stress related to care	Perceived stress scale	X	X
Usability	System usability scale (SUS)		X
Impact of the system	Ad hoc questionare		X

Table 4 Dimensions investigated and tools used for the informal caregiver

Lastly, tools for collecting data from professionals in each time are presented in Table 5.

Dimension	Tool	T_0	T_1
Attitude to technology	MTP SOTU-P	X	
System impact and ability to meet expectation	Interview		X

Table 5 Dimensions investigated and tools used for the professionals users

4.5 Recruitment strategy in each pilot site

Italy

The participants will be recruited from the lists of the hospitalized and outpatients' of the rehabilitation unit of the INRCA's hospital in Ancona. The rehabilitation unit of INRCA's hospital is managed by Dr. Giovanni Riccardi.

The patient will be contacted to plan a visit with the physiotherapist. Once the informed consent is acquired in duplicate, the physiotherapist and a psychologist will check for compliance with the inclusion and exclusion criteria of the study and proceed to the baseline assessment with questionnaires and clinical trials as stipulated in the study design. Caregiver assessment will also be carried out at this time.

Switzerland

The recruitment strategy is to identify eligible study participants within the ZURZACH Care group: The group includes numerous outpatient centres, rehabilitation clinics, specialist clinics and a company for reintegration as well as subsidiary and partner companies in the field of sleep medicine, cures and rehabilitation at home. Potential participants interested in participating in the field trials who are deemed eligible after screening based on inclusion and exclusion criteria will be recruited and provide written informed consent prior to participation in study-related activities.

Belgium

The recruitment strategy involves selecting eligible individuals within the 2 clinics of TRAINM. A multidisciplinary team, consisting of a Neurologist, Psychiatrist, physical therapist and/or occupational therapist, will be involved in the process.
Patients who will be recruited are those who meet the inclusion criteria.

4.6 Participants

The study figures as a study aimed at verifying the usability and acceptability of the RecoveryFun system by a group of 15 subjects (age>60 years) suffering from an acute event (such as stroke) from no more than 12 months, who reported among the outcomes of the disease a functional impairment to upper limb, while performing the telerehabilitation treatment at their home based in immersive virtual reality.

In order to successfully conclude the trial for reducing the risk of drop out and not generating a sense of frustration in the patient and his/her caregivers, it is important to select patients carefully.

To guarantee that the patient will be able to use the system properly (to date), specific physical/cognitive requirements are needed moreover, the patient should have a caregiver that if necessary can assist him or her during the game session (wearing, initiating and stimulating him/her).

The patient must have good trunk control and be able to maintain a sitting position for at least 30 minutes without feeling fatigue; (s)he must have good upper limb function (gross and fine hand motor skills). The shoulder rom must be wide enough to be able to reach most of the targets of the game. Moreover, the patient has to be able to transfer the load into the pelvis.

The patient should have a good motor function of the upper limb associated with a good degree of autonomy in ADLs.

The conditions necessary for the use of the game force the choice of uncommon patients following an acute event (such as brain injury or stroke).

4.6.1 Inclusion criteria

The criteria defined for including patients are as follows:

Age>= 60 years

No more than 12 months from acute event (for example stroke or injury)

Trunk Impairment Scale (TIS):

- The cut-off for TIS is set at ≥20

Fugl-Meyer Assessment Upper Extremities:

Motor function for upper extremities (section A-D): a minimum Score of ≥33 is requested for the inclusion.

In addition to this general cut-off score, specific items were defined that a participant must fulfil in order to play the games and thus be included in the field trials. These are:

- Section A.II. Volitional movement: value 1 or 2 for items: Shoulder elevation, abduction (90°) and external rotation; Elbow flexion and extension; Forearm pronation
- Section B. Wrist: value 1 or 2 for items stability at 15° dorsiflexion (elbow at 90° and at 0°)
- Section C. Hand: value 1 or 2 for items C. pincer grasp, opposition and D. cylinder grasp
- Section D. Coordination/speed: 1 or 2 for item tremor
- Section H. Sensation, J. Passive joint motion and J. Joint pain will not be considered as these parameters doesn't have an influence on the participants capacity to participate in the intervention.

Presence of an informal caregiver available to participate in the study

4.6.2 Exclusion criteria

Participant is unable to give his/her informed written consent

Technical Requirements based on the safety manual of the "Pico" headset

- Ocular pathologies such as cataracts, glaucoma, and diabetic retinopathy
- Binocular vision abnormalities
- High degree of myopia, astigmatism or far-sightedness
- Presence of corrective glasses not fitting below the VR headset
- Allergy to plastic, PU or fabric
- Pacemakers
- Implanted defibrillators
- Cochlear implants and other hearing aids
- Participants who are not able to put on the VR goggles independently

Presence of pathology that could impact on the ability of using VR system or can be worsened by the use of VR system

- Epilepsy
- Migraine especially with aura and tension headache
- Vertigo or cyber-sickness
- Trigeminal neuralgia
- Pressure sensitivity and hyperalgesia in the face
- Psychotic disorders
- Severe cardiac or pulmonary conditions

- Open wounds, injuries to the head, skin infections and dermatological issues that won't allow the participant to wear the headset
- Tremor o Severe fatigue and exhaustion: the participant is unable to concentrate or stay awake/attentive enough for participating in the intervention for 20min.
- Various phobias (e.g. Claustrophobia)
- Visual neglect

-Presence of cognitive impairment

- Montreal Cognitive Assessment (MoCA) score <23 (Nasreddine et al., 2005)

MoCA, according to literature search, is the most sensitive instrument to detect the presence of mild cognitive impairment (Breton et al., 2019; Chun et al., 2021; Ciesielska et al., 2016). For this reason it was preferred over Mini-Mental State Examination (MMSE). Instead, the score was established to increase the eligibility of more individuals and simultaneously include exclusively people with physiological or initial mild cognitive impairment.

4.6.3 Sample size calculation

A lot of studies have been conducted in the early nineties[1] (Nielsen et al., 1993; Virzi, 1992) to understand which are the right number of users to be involved in usability tests. The rules emerged from these studies can be summarized as follow: (1) Observing four or five participants will allow a practitioner to discover 80% of a product's usability problems, (2) observing additional participants will reveal fewer and fewer new usability problems, and (3) more severe usability problems are easier to detect with the first few participants.

Considering the secondary objective that is to evaluate the impact on patient quality of life and physical health in term of mobility/functionality a number of 15 user in the three countries is a reasonable trade off with the limitation imposed from the project boundaries in term of duration of the intervention and costs.

Conventionally, a 20% drop out rate is considered and regarded as acceptable. So, to guarantee the total planned numeral least 6 subjects will be recruited in each site

4.7 Case Report Form (Data collection forms)

The data that will be collected are by:

- Medical records where available;
- Questionnaires and evaluation tools;
- Interviews;
- The clinical platform for the clinicians;
- The caregiver mobile application;
- VR ReLab application;
- The wearable sensor.

4.8 Limitations

The researchers have noted technical and statistic limitations about the trail.

RecoveryFun System is a prototype that needs to be updated and modified in some parts to be used by a larger patient population. Moreover, the wearability may still be not comfortable for everyone.

Regarding the trial, the number of subject is small and has low statistical validity. Finally, without control group there will be less relevant data regarding the effectiveness of the treatment.

5. Legal and ethical issues

5.1 Informed consensus

All potentially eligible subjects will receive comprehensive information about the study and must provide their consent to participate in the study.

Participants will have to consent to the processing of their personal data in anonymous and aggregate form, in accordance with the EU Regulation 2016/679 (GDPR) on the protection of individuals with regard to the processing of personal data and Legislative Decree No. 101/2018 - Provisions for the adaptation of national legislation to the provisions of the European Regulation 2016/679.

Participants will be informed that their data may be examined by authorised personnel or by members of the relevant ethics committee and officials of the competent regulatory authorities;

All participants and caregivers will be asked to sign an informed consent prior to the start of participation and will be informed that data will be retained for up to 15 years after the end of the study;

Participants may leave the project at any time if they consider participation too burdensome or feel uncomfortable for any reason.

Patient information letter and informed consent forms can be found in Annex 7.6 and 7.7. These forms need to be edited by each partner according to national and institutional information.

5.2 Data handling, archiving, confidentiality and protection

This study will be conducted in full conformance with the laws and regulations of each country involved in the research. Participants information will be collected and processed respecting the appropriate measures to guarantee confidentiality and to ensure compliance with data protection laws, pursuant to Regulation (EU) 2016/679 (GDPR) of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and Legislative Decree 10 August 2018, no. 101 – which aims to standardised the Privacy Code with European regulations.

The data controllers are the end user partners responsible of patient recruitment.

Pursuant to Articles 13, paragraph 2, letters (b) and (d), and Articles 15, 16, 17, 18, and 21 of GDPR 2016/679, participants have the right to request from the Data Controller for access, rectification or deletion of their personal data or to restrict the processing of their personal data or to oppose the processing of their personal data and to lodge a complaint with the Data Protection Authority, following the procedures and directions published on the Authority's official website (in Italy at www.garanteprivacy.it).

Furthermore, all the data controller, pursuant to Article 37 of the GDPR EU 2016/679, identified and nominated a Data Protection Officer (DPO).

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

Participants will be informed of their rights and must provide informed consent for participating in the study.

All personal data will remain separate from questionnaire results and monitoring data records. Materials will be archived for as long as required by current law. The written consent and all paper documentation will be kept closed in a secure locked place in the offices of the recruiting, only accessible to the PIs and the person responsible for data collection.

The database will be saved in electronic format and protected by a password known only to the PIs and the person responsible for data collection.

All data will be preserved for a maximum of 10 years.

Data collected by the clinical web platform, the caregiver mobile app and the wearable sensor will be directly entered into a validated database. The highest standards of information quality management are applied according to ISO 27001 related to the quality management system for ensuring information security. These standards define highly restrictive operating procedures that guarantee the quality, integrity and accuracy of the collected data. The database will be locked after the quality control and quality assurance procedures and coding activities are completed.

All sensor data is hold in a separate **sensor cloud infrastructure**. The data is transmitted secured and stored with no patient information. Only gateway and sensor hashes are associated with the sensor data. The data can be accessed by the Smart Decision Support System and the RecoveryFun application, requesting timespan and sensor hashes.

Sensitive patient data is hold strictly separated from all other data in a **separate secured database on the RecoveryFun application**. A fine graded user management makes patient data available to the authorized medical staff only. This database is encrypted.

Device setup and allocation data is stored separately in the **setup database**. This data does not contain any personal data. Only the patient hash is associated with the corresponding hardware hashes.

The **Smart Decision support System** does not persist any data. Using training plans' data, recorded bio-signals and game logging data, the Smart Decision Support System is able to provide different key data evaluations for a specific exercise, session and therapy plan.

The sensor **interoperability bridge** allows access to specific bio sensor data frames, to be visualized and provided to the clinicians via the Clinical Platform user interface, during their remote and evaluation work. No data is hold or modified in the bridge.

In the separated **evaluation database**, all intermediate evaluation data is stored. The data snippets are totally pseudonymized. They can only be connected to a patient by an authorized clinician for a specific patient. This database holds the data resulting from the evaluations provided from the Smart Decision Support System.

All databases are stored on a **secured cloud infrastructure** by T4C and UNMATCHED in Europe. They fulfil the highest security and privacy requirements – in accordance to all required legislations.

The **data transfer** between all components is **secured and encrypted** at all time.

5.3 Data analysis

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 on the basis of their distribution (assessed using Kolmogorov-Smirnov test). Categorical variables will be expressed as an absolute number and percentage. Comparison between pre- and post- conditions will be evaluated by paired t test (for normal distribution), Mann-Whitney U tests (for non-normal distribution), or Chi-Square tests (for categorical variables). Moreover, a linear regression model on the outcome variation between baseline and follow-up will be estimated in order to evaluate the effect of the treatment adjusted for potential confounders.

5.4 Risk management

We do not expect any negative effects on the health of users related to the use of the system. The hardware technologies used are commercial VR headsets (Pico 4) and wearable devices (Verisense by Shimmer), both CE certified. The researchers will provide clear and detailed information on the terms of use of the technology system and the services offered during the study. The proposed services are intended to improve rehabilitation for people with chronic health conditions and do not replace (in whole or in part) support from professional services. Users taking part in the study will bear minimal direct costs related to the use of the RecoveryFun system (electric power consumption for 30 days with an expected cost lower than 2€).

Technology-integrated rehabilitation treatment and clinical assessments may carry some risks. The use of virtual reality, in fact, can bring initial sense of instability and dizziness.

The risk of this symptoms using VR technology, typically called Cyber Sickness (CS) varies depending on several factors such as individual susceptibility to motion sickness and the intensity and duration of VR experience.

While many individuals experience CS in VR, other appear to be robust to the symptoms. There are not clear evidence in literature of frequency and correlation with individual characteristics.

Conditions for which use of VR headset is discouraged have been taken into account in the definition of exclusion criteria for the recruitment.

To guarantee patient's safety, rehabilitation sessions will be carried out while the person is seated in a stable chair, possibly with armrests. Moreover, in order to contain potential risks and preserve the benefits for the patient that are considered to be superior to the risks, prior to the start of the trial it will be checked whether there is excellent trunk control by the patient (inclusion criteria) and the execution of a formation will be planned with patient and caregiver. Formation will take place on the premises of the Physiotherapy Department in the presence of a physiotherapist and it will end only when the patient and caregiver have become familiar with the system. This formation will represent even the opportunity to verify the insurgence of cyber sickness for the patient. The physiotherapists will provide clear and detailed information about the terms of use of the technology and the services offered during the study.

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7. Annexes

7.1 Rapid test protocol

PROCEDURES AND SETTING

Setup: Data will collect and analyse in the native language of each site and then the local results will be translated into English language and combined cross-nationally.

Position of test person and researcher: The user should sit in a chair wearing the VR.

Glasses: Ensure that the user wears glasses if this is something he/she use daily.

Informed consent: Prior to any activity, participants should be given written information about the testing and an informed consent obtained. The document(s) should preferably be sent to participants before they meet for testing. The document(s) should be read out loud to participants. The researcher must ask participants whether they have any doubts or questions regarding the information and/or the informed consent and offer to clarify these. The researcher should ensure that the test person gives written consent and writes the date for the consent. If written consent is not given, the testing should not proceed. One copy of the consent will be given to the researcher and one copy kept by the test person.

In Annex 7.4 is reported the Informed Consent Form, that each partner needs to edit with national and institutional information.

Materials: For the correct execution of the test, following materials are required:

- Headset/ viewer;
- Wearable sensor;
- Tablet;
- Chair;
- Informed consent;
- Internet connection;
- Recorder;
- Printed rapid test protocol;
- Observation Sheet for VR;
- Clinical session setup with at least 3 exergames;
- Checklist for the collection of data during tasks execution (optional).

Introduction: During this phase, all the needed information should be given carefully to users, in order to make sure they have understood the aim of the testing as well as the importance of their feedback. The following information should be given:

We are working on a new system RecoveryFun to improve rehabilitation for people with chronic health conditions and to prevent frailty states, through the development of a telerehabilitation solution:

- Suitable for a proactive, integrated, personalized management of home rehabilitation,
- Based on the use of Virtual Reality, IoT connectivity and Artificial intelligence.

The project starts from a system already developed by Tech4Care and tested in clinics. The intent is to develop a version that patient can use at home, with remote control by professionals, for upper limb rehabilitation and cognitive stimulation.

What we would like to learn is how you handle the VR and your opinion about it. We wish to know if things are easy to read, easy to find, how you move around on the ReLabVR. We can still do changes to system. If you have suggestions for improvement, please tell.

We will not test how good you are in using VR, and there are no wrong answers to the questions we ask. If something is hard to do or to understand, please tell us. Then it is probably also difficult for many others and should be done or written in another way.
The experience we get through this session and your feedback are of great importance to us for making the design as good as possible!

INITIAL QUESTIONNAIRE: SOCIO-DEMOGRAPHIC DATA COLLECTION

Before we look at the device, there are few questions I'd like you to answer.

1. How old are you? ____
2. What is your gender?
   - Female
   - Male
3. Where do you live?
   - Switzerland
   - Belgium
   - Italy
4. Who lives in your house with you? (multiple answers are possible)
   - None
   - Spouse/partner
   - Son/daughter
   - Grandchildren
   - Son/sister in law
   - Brothers/sisters
   - Mother/Father
   - Paid caregiver (not relative)
   - Other
   - Refuses to answer

   (Note to interviewer: Please note the exact number of people living with the user)
5. How would you consider your vision capacity? (ability to see in adequate light (with glasses if used)

   ❑ Excellent

   ❑ Good

   ❑ Fair

   ❑ Poor

   ❑ Very poor

   ❑ Don't know

6. What is your level of education?
   - No education
   - Primary education
   - Secondary education
   - Tertiary education (further higher education level or university)
   - Other _____
   - Prefer not to say
7. Can you indicate to what extent you are familiar with each of these technologies? You can choose from the following statements:

   1 = I don't know this technology

   2 = I know this technology but I'm unable to use it myself

3 = I can operate this basically and often need help

4 = I can operate this, I rarely need help

5 = I know the possibilities of it well, I use it and I never need help

		1	2	3	4	5
a.	Computer	❑	❑	❑	❑	❑
b.	Smartphone	❑	❑	❑	❑	❑
c.	Tablet	❑	❑	❑	❑	❑
d.	Digital television	❑	❑	❑	❑	❑
e.	Internet	❑	❑	❑	❑	❑
f.	VR	❑	❑	❑	❑	❑
g.	Wearable sensors	❑	❑	❑	❑	❑

8. Have you ever used VR before?
   - Yes
   - No

TASK EXECUTION (PARTICIPANT OBSERVATION)

Task 1: Wearing and adjusting the visor

We are going to start by wearing the visor. We are not testing your ability, but we want to understand how easy the visor is to use.

[Giving the visor to the user] *Let's start putting on the visor. Can you do it?*

Task 1.1: Fit adjustment

[Referring to the visor he/she is wearing]

Can you please adjust the visor according to your needs?

Configuration (not task object)

[The researcher guides the participant through instructions. The person should use the pointer on the eyes and the buttons located on the right side of the viewer.]

You are now inside a spacecraft. In front of you is a blue dot that moves in relation to the movements you make with your head. Move the dot until it is positioned over the word "library" (icon with 4 dots) in the toolbar. Then press the central button on the right of the viewer while the dot points to the icon. Using the same modality, select "bended ReLab" icon (black icon with white cube in it) and press the button.

Task 2: Login

[The person faces the login screen.]

From now on, you don't have to use the pointer or buttons on the viewer, only your hands.

Can you get into the ReLab app?

The person waits for the log-in screen to disappear (the patient's credentials are already inserted automatically). A horizontal bar with the ReLab app logo appears on the next screen]

Could you please enter the ReLab application?

[The person is in the main room screen]

Q1: *You are now in the main application room. What do you think of this* ***environment****? How do you feel in it?*

Q2: *Now stretch out your arms and look at your* ***hands****. How do you feel seeing your hands inside the VR?*

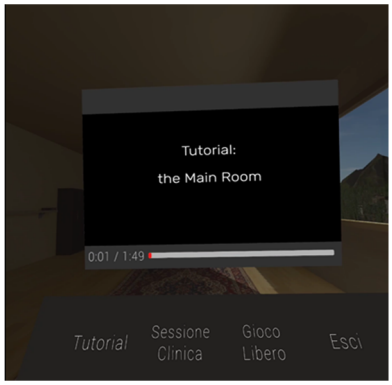
Q3*: Now try to make movements as you like, first with your right hand, then with your left, and finally move both hands. How do you feel about the matching between your hand movements in reality and what you see in VR?*

Q4: *Since you entered the main room you surely have noticed that there is soft* ***music*** *in the background. Do you enjoy it?*

Q5: *There is a* ***bar*** *in front of you. We are not testing your vision. We would like just to know if the colour contrast makes the text on the bar readable or not. Do you find could contrasts appropriate?*

Task 3: Starting the tutorial

Now we ask you to start the tutorial.



[Once the first viewing of the tutorial has finished, it starts again automatically. While the tutorial then starts again, the researcher requests the person's attention.]

Q6: *Do you find the* ***content*** *of the tutorial easy to understand? Do you think this video could help you in using the application?*

Q7: *Does the* ***contrast****between the background colour and the text in the video look appropriate?*

Task 4: Close the main room tutorial

Could you now please close the tutorial?

[The person should press the tutorial button to exit. If he/she presses the "exit" button instead, he exits the ReLab application. If the person performed the task correctly he/she is in the main room screen]

Task 5: Start the clinical session

Now could you please start the clinical session?

[The person should press the “clinical session” button]

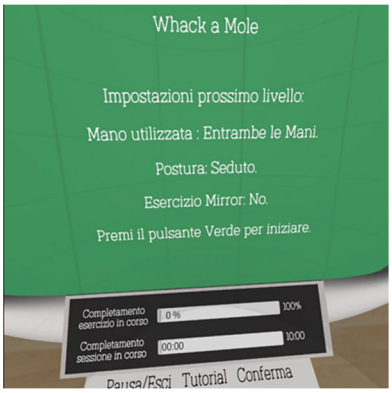
Task 5.1: Text size

Like before, we want to know is if the text is easy to read. Could you try to read the text on the screen in front of you? If you have trouble reading the text you can just tell us.

Task 5.2: Launching the clinical session screen

Please start the session

[The person should press the start button. After pressing it the person is on the following screen (the starting screen of the first exergame)]



Q8: We would like just to know if the **colour contrast** makes the text readable or not. Do you find colour contrast appropriate?

Task 6: Starting the exergame tutorial

[Now the person has to start the exergame tutorial pressing “tutorial” button]

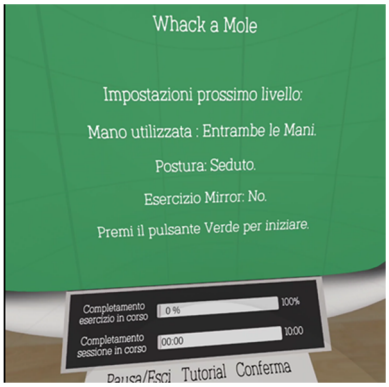
Please start the tutorial and watch the video

Q9: Do you find the **content** of the tutorial easy to understand? Do you think this video could help you in playing the exergame?

Task 6.1: Close the exergame tutorial

Could you now please close the tutorial?

[The person has to press again the "tutorial" button. Then he/she is in the game start-up screen]



Task 7: Starting the exergame

Can you please start the game?

[The person has to press "confirm" bottom]

[The person plays the first exergame and finishes the first exergame]

[The end of game screen appears]

Task 7.1: Ending the exergame

Can you please move on to the next exergame?

[To move on to the next exergame the person has to press the green button]

[The person is in the game start-up screen of the second exergame. The researcher asks the person to start the next game. The start of the second game is not a task]

[The person plays the second exergame. At the end of the second exergame, he/she starts to play the third exergame through the same process. These steps are not the subject of task]

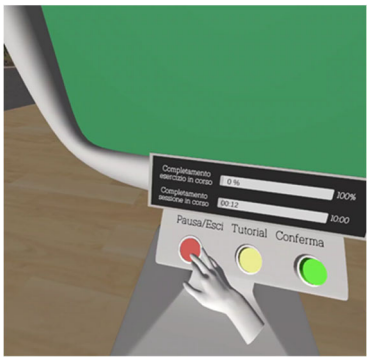
Task 8: Pause the exergame

[In the clinical session setup keep in mind that the game that is paused cannot be the memory as there is a bug in the system.]

[While the person is playing the third exergame, the researcher interrupts him/her and asks to pause the game]

Can you pause the game?

[The person should press “pause/exit” bottom]



Task 8.1: Reading information on the screen

Can you read the information that appear in the screen?

Task 9: Leaving the clinical session

Can you try to exit the clinic session?

[The person has to press again “pause/exit” bottom. Then he/she is in the main room]

Task 10: Remove the visor

You can now remove the visor

***Q10**: Do you think you would be able to remove the visor by yourself?*

To get an overview of the whole system now, we ask you to test also the use of the wearable sensor. This sensor, by detecting fatigue during the exercise session, is able to help the clinician to monitor the progress of the activity and to personalize the rehabilitation of each patient.

[The researcher can find the video of the sensor on the cloud, and we will also send an image with the placement of the sensor, for the correct execution of the test. The researcher guides the participant on the placement of the sensor]

Task 11: Wearing the sensor

[Giving the sensor to the user]

Let's start putting on the sensor. Can you do it?

***Q11:** Does it appear easy for you to wear?*

Task 12: Put on the visor with the sensor

[Giving the visor to the user]

Can you put on the visor?

***Q12:** Now that you are wearing the sensor, is putting on the visor more difficult?*

[The following steps are not task. The researcher guides the person through instructions in starting the clinical session again and performing the first exergame (the person has to press "clinical session" button, to start the session through the green button and then to confirm the start of the game)]

Task 13: Remove the visor

Please take off the visor

Task 14: Switch off the visor

Please switch off the viewer

[The person should press the button on the viewer for some time]

Task 15. Remove the sensor

Please take off the visor

***Q13**: Would you be inclined to put the sensor on while using VR?*

USER EXPERIENCE EVALUATION – CLOSING QUESTIONS

Now I'm going to ask you some very general questions on your experience with the system, if you have liked the system, what are your feelings during the use.

Let's start!

Please, mark on this line what do think about each question.

1. Overall, using the application (ReLabVR) was:

Very difficult — Very easy

2. Visually, the application was:

Unattractive — Appealing

3. The information on the screen was:

Confusing — Very clear

4. The text on the screen was:

Very small — Very large

5. The system is intuitive to use:

Not at all — Very intuitive

6. The toolbar is intuitive to use:

Not at all — Very intuitive

7. The video tutorials were:

Confusing — Very clear

8. I think I could use this application by myself:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

9. I think the system has a good overall comfort in use:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

10. The system appears innovative to me:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

11. I think the system has economic value:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

12. The system has appropriate dimensions (size, height, length, width):

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

13. The weight of the system is adequate:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

14. The system is interactive:

1	2	3	4	5
Completely disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Completely agree

15. Which improvements would you suggest for ReLab VR?

_____
_____
_____
_____

To be submitted to the participant only after performing the tasks with the wearable sensor

Acceptance test - Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)

The purpose of this test is to evaluate how satisfied you are with your assistive device. For each item, rate your satisfaction with your assistive device you experienced by using the following scale of 1 to 5.

1 = not satisfied at all 2 = not very satisfied 3 = more *or* less satisfied 4 = quite satisfied 5 = very satisfied

ASSISTIVE DEVICE: *How satisfied are you with…*	1	2	3	4	5
1. the dimensions (size, height, length, width) of your assistive device? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
2. the weight of your assistive device? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
3. the ease in adjusting (fixing, fastening) the parts of your assistive device? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
4. how safe and secure your assistive device is? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
5. the durability (endurance, resistance to wear) of your assisitive device? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
6. how easy it is to use your assistive device? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
7. how comfortable your assistive device is? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
8. how effective your assistive device is (the degree to which your device meets your needs)? Headset/ viewer Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐

TOTAL

Headset/ viewer _____ / 5

Wearable sensor _____ / 5

Below is the list of the same satisfaction items. Please select the three items that you consider to be the most important to you. Please put an X in the 3 boxes of your choice for headset/viewer and wearable sensor:

Headset/ viewer	1. dimensions	☐	5. durability	☐
	2. weight	☐	6. easy to use	☐
	3. adjustments	☐	7. comfort	☐
	4. safety	☐	8. effectiveness	☐

Wearable sensor	1. dimensions	☐	5. durability	☐
	2. weight	☐	6. easy to use	☐
	3. adjustments	☐	7. comfort	☐
	4. safety	☐	8. effectiveness	☐

7.2 Data collection forms: VR test observation sheet

Legenda: Performed by the user independently: **:);** Executed with help: **:)+H;** Not executed: **:(**

		P 0__ Date: ____/____/_____
Task number	:) +H :(	**Observation, statements from the user, help given, comments**
Task 1 **Wearing the visor**		
Task 1.1 **Adjusting the visor**		
Task 2 **Login**		
Main room screen	/	Q1(environment): Q2(hand): Q3(hand movement): Q4(music): Q5(bar):
Task 3 **Starting the tutorial**		Q6(content): Q7(text contrast):
Task 4 **Close the main room tutorial**		
Task 5 **Start the clinical session**		
Task 5.1 **Text size**		
Task 5.2 **Launching the clinical session screen**		Q8(colour contrast):
Task 6 **Starting the exergame tutorial**		Q9(content):
Task 6.1 **Close the exergame tutorial**		
Task 7 **Starting the exergame**		
Task 7.1 **Ending the exergame**		
Task 8 **Pause the exergame**		
Task 8.1		

Reading information on the screen		
Task 9 **Leaving the clinical session**		
Task 10 **Remove the visor**		Q10(removal in autonomy):
Task 11 **Wearing the sensor**		Q11(easiness to wear):
Task 12 **Put on the visor with the sensor**		Q12(difficulty with sensor):
Task 13 **Remove the visor**		
Task 14 **Switch off the visor**		
Task 15 **Remove the sensor**		Q13(sensor use):

7.3 Data collection forms: Checklist for the collection of data from thinking aloud and observation of the tasks execution with VR

Legenda: Performed by the user independently: **:);** Executed with help: **:) +H;** Not executed: **:(**

Participant	**P01**	**P02**	**P03**	**P04**	**P05**
Task 1					
Task 1.1					
Task 2					
Task 3					
Task 4					
Task 5					
Task 5.1					
Task 5.2					
Task 6					
Task 6.1					
Task 7					
Task 7.1					
Task 8					
Task 8.1					
Task 9					
Task 10					
Task 11					
Task 12					
Task 13					
Task 14					
Task 15					

7.4 Informed consent form for rapid test

INFORMED CONSENT FORM

TITLE OF STUDY: RecoveryFun

NAME OF PROJECT COORDINATOR: Lorena Rossi

NAME OF INTERVIEWER: _____

I, the undersigned (name and surname) _____

Age _____ gender M ☐ F ☐ date of birth ___/___/_____

Address _____n. _____ Post code _____

City _____ tel. _____

RecoveryFun aims to improve rehabilitation for people with chronic health conditions and to prevent frailty states, through the development of a telerehabilitation solution suitable for a proactive, integrated, personalized management of home rehabilitation and based on the use of Virtual Reality, IoT connectivity and Artificial intelligence.

The solution is composed by: a set of exergames based on VR technology; a digital health record management platform to manage patients' profiles, define personalized rehab plans and conduct remote visits; an IoT connected ecosystem for monitoring real-time biosignals of the users; a mobile App for non-professional caregivers, that allows them to monitor the rehabilitation plan of their relatives and provide motivation to the patients; a set of smart and intelligent services for a further personalization of the rehabilitation experience and improve clinicians activity via a Smart Dashboard and a clinical Decision Support System.

I declare

- To participate voluntarily in the rapid test aimed at defining the usability and acceptability of the system developed within the RecoveryFun project. During the session, the person is guided through a series of tasks in the use of the visor to understand the user experience and identify the limitations and potential of the system.
- Have received from the interviewer/researcher mentioned above all clear and comprehensive information about the purpose and procedures of the interview in which I have been asked to take part.
- Having had the opportunity to ask clarifying questions and having had satisfactory answers, as well as having had the opportunity to enquire about the details of the study with a person I trust.
- To be aware
  - that my data may be examined or used for research purposes, but will remain strictly confidential in accordance with current legislation and subsequent amendments and additions;
  - that my data will be used in aggregate form, for the preparation of a final report for the Health Authorities or for a publication, whatever the outcome of the study, always respecting the confidentiality and anonymity of my identity (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, art. 13 of Legislative Decree no. 196/03 in force since 1 January 2004);
  - that I must sign two identical forms of this informed consent: one original will be retained by the interviewer/researcher (and kept for at least 15 years) and the second will be given to me;
  - that in case of any problems or for any further information I should contact:

Name and Surname of person in charge

Address

Telephone number

I therefore freely agree to take part in the interview.

The signature on this form will not affect my legal rights.

Read and approved (handwritten) _____

INFORMATION PURSUANT TO ARTICLES 13-14 EU REG. 2016/679 "GDPR"

Please note that participation in the rapid test involves the processing of personal data by ***institution name***, as Data Controller. Data processing is done in order to define the usability and acceptability of the system developed within the RecoveryFun project and is done with your consent. Participation in the interview is facultative, but the provision of data is compulsory in the case of participation. The data collected are those you provide with this form and during the rapid test. They will be processed by Institute staff, operating on the basis of specific instructions. If necessary, the processing may also involve sensitive (so-called special) data. Identification data will not be disclosed externally, but may be used for research purposes, while aggregated information may be the subject of scientific communication or publication. Personal data will not be disclosed by the ***institution name*** and will not be transferred to non-EU countries. There are no automated decision-making processes. Your data will be kept for as long as is necessary to perform the project correctly and, in any case, for a period of 15 years. The data is processed manually and computerised in accordance with appropriate technical and organisational measures to protect personal data. The interested party may exercise his or her rights under Articles 15 et seq. of the GDPR, as per the form on the institutional website. If he/she believes that he/she has suffered a personal data breach, he/she also has the right to lodge a complaint with the Personal Data Protection Authority. Further information: www.garanteprivacy.it. The Data Protection Officer can be reached at: dpo@morolabs.it. The full information notice is available on the Institute's website, GDPR section, or from the appropriate offices.

7.5 Methodology for the workshop with clinicians

How to read this methodology: The description in square brackets is useful to explain what screen of the clinical portal we are referring to. The introduction in cursive font helps the person conducting the workshop to understand the screen we are referring to (and then to explain it to the participants). In the bold are the questions for the participants.

To access the mock up, click on this link: https://www.figma.com/proto/aw8MUd8tPraoCRzTGapiLz/RecoveryFun---Web-Application-(A1)?page-id=396%3A73699&node-id=397%3A73700&viewport=1084%2C553%2C0.2&scaling=min-zoom&starting-point-node-id=397%3A73700

NOTE 1: You need to be logged in to see the interactive prototype (you can simply log in with Google)

NOTE 2: In the upper Figma bar, click "options" (drop-down) and select "Fit to screen"

NOTE 3: To scroll down the screens to show the participants, just press the right arrow button on your computer keyboard. This will show the mock up screens to be evaluated.

[DASHBOARD screen - Criticals]

This dashboard visually summarises the criticalities present in patients who are using the system in relation to 3 parameters:

1. *Stress and fatigue (called 'Bio Signals', these are the parameters detected by the wearable sensor). The graph with the circles has four quadrants related to the four possible states that can be identified in the patient (stress, concentration, fatigue, relaxation). The greater the colored area in a quadrant, the more advanced the user is in that state.*
2. *Adherence (patient complied with the planned sessions);*

   ✓ *no criticality* ⚠ *to pay attention* ✗ *criticality*
3. *Quality (how well the patient performed the session).*

   ☻ *no criticality* ⚠ *to pay attention* ☹ *criticality*

In addition to symbols, the level of severity is also indicated by the colour used.

White: no criticality Orange: to pay attention Red: criticality

- **Is the information sufficient to have an overview of the critical issues of patients?**
- **Is it useful to have an overview of patients' criticalities?**
- **Are the graphs in the dashboard to monitor stress and fatigue easy to read?**
- **Are the symbols used appropriate?**
- **Are the colours representative of the level of criticality?**

In addition to the overview of existing criticalities, using the horizontal bar at the top right you can filter the type of criticality you want to see: Stress & Fatigue, Adherence and Difficulty (=quality).

Go to the next screen (it is an indication for the person conducting the workshop)

[DASHBOARD ALL screen]

"All" gives an overview of all patients who are using the system

- **Do you find it useful to have an overview of all patients beyond the critical points representation?**

Go to the next screen

[LIVE SESSIONS screen]

This screen lets you know which patients are currently performing the session. We will investigate this aspect later on.

- **Is it useful to have a screen showing which patients are currently performing the session?**

Go to the next screen

[PATIENTS Screen]

The "Patients" item in the left-hand side menu provides a list of all patients registered in the system (including both patients who are currently using the system and patients who have used it in the past).

Go to the next screen

[PATIENT OVERVIEW screen]

We have now accessed the profile of a patient (in this case Paolo Verdi)

Right column

Parameters: in this section an overview of the person's sessions is shown through the choice of the temporal filters (summary, just today, last 2 days, last 7 days, last 30 days)

- **Are these temporal filters adequate?**

Below we can see the same summary as in the dashboard (Stress and Fatigue, Adherence and Quality)

Show: general filter that allows you to filter sessions (always relative to the set time window) in relation to:

- *Live sessions*
- *Successful sessions (green)*
- *Unsuccessful sessions (red) → the system has moved on to the next game (time settings defined by the clinician)*
- *Sessions performed with difficulty (yellow)*
- *Abandoned sessions (grey)*

Temporal filters run in parallel with general filters.

- **Are these general filters adequate?**

Sessions data: summarises (in relation to the set time window) the hours of activity, number of errors and abandoned sessions.

Left column shows (in relation to the set time filter) the sessions performed by the patient.

Each box summarises a session. The first is the live session. The second one summarises a past session by showing the various exergames played and their levels.

- *Green line: level completed*
- *Red line: level not completed → the patient failed the level and then the system switched to the next game (modes are defined by the clinician)*
- *Grey line: person discontinued the session*
- *Red circles with!: errors/difficulties → in the future maybe the possibility to see the screen or video of the error will be implemented*
- *VAS: it is planned that among the exercises to be done using the VR system there can be a moment, set by the clinician, when the patient is asked using the game mode to indicate the level of fatigue*

experienced→ Ratio: compare the objective data (wearable sensor) with the subjective data (patient's perception)

- *Assessment: should be considered as an exergame that the clinician plans into the session to detect the person's range of movement (X, Y and Z axis movement amplitude for both limbs).*

- **Is the VAS and range of motion information useful within the summary of each single session?**

Go to the next screen

[SUMMARY screen]

This screen shows personal data of the patient.

Go to the next screen

[DEVICES screen]

This screen allows you to associate the different devices (VR headset, wearable sensor) with the patient.

Go to the next screen

[OVERVIEW REHAB FIXING screen]

Within the patient overview we have the possibility to initiate a video call, to monitor the session that the patient is performing at home. The tablet is a complement to the home system and the patient can use it (or use the caregiver's smartphone app) to video call the clinician.

The clinician in this screen can simultaneously see in the square on the left the same screen that the patient sees (via VR streaming) and in the square on the right the movements that the patient performs (tablet or smartphone camera).

The clinician can also monitor the level of stress and fatigue through the graph as well as the errors/difficulties performed (red circles on the blue bar).

In addition, the clinician can pause or restart the exergames by pressing the corresponding buttons.

- **Is it useful for the clinician to have the possibility of video-calling the patient in order to monitor the execution of the session?**
- **Is it useful for the clinician to be able to pause or restart the game? For example, when the patient appears stressed/tired or is not very collaborative.**

Go to the next screen

[BIO SIGNALS TRENDS screen]

The graph summarises the trend of the patient's stress and fatigue levels during sessions conducted over the last 30 days. The value appears next to the reference parameter (Stress or Fatigue).

- **Does the graph facilitate monitoring of the patient's level of stress and fatigue?**
- **Are the symbols on the horizontal axis understandable?**
- **Are the colours appropriate?**

Nominal: values in the normal range *Caution: to pay attention* *Critical: critical values*

Dates: session date *Sessions: sessions held on that day* *Exergames: present in the session*

 *VAS filled in by patient*  *range of motion detection*

Go to the next screen

[THERAPY ADHERENCE screen]

The graph summarises the patient's adherence trend during the sessions held in the last 30 days (i.e. whether the patient adhered to the scheduled sessions).

Adherence is divided into:

- *Completion (ability to complete the session), further divided into 4 variables (represented by the lines in the graph)*
- *Schedule (ability to adhere to the frequency), further divided into 7 variables (represented by the lines in the graph).*

Variables are subject to modification and refinement.

Each variable has a bar divided into 3 colours in relation to its criticality (not present, to pay attention, criticality).

- **Is the information comprehensible?**
- **Is it immediate?**
- **Is the number of variables present adequate?**
- **Is the graph used explanatory and clear?**
- **Is the information congruent with the proposed time windows (day, week, last 30 days)?**

Go to the next screen

[QUALITY screen]

The graph summarises the quality of the patient performance during the sessions over the last 30

days (i.e. how well the patient fulfilled the session in relation to the movements and the rehabilitation plan).

Go to the next screen

[DEVICES screen]

The screen shows the device associated with the patient (VR headset).

Go to the next screen

[STRESS screen: RAW DATA]

This screen shows the raw data of stress values measured by the wearable sensor, which is interesting in case you want to export the file with all the data.

Go to the next screen

[COMPLETION screen: RAW DATA COMPLETION]

This screen instead shows the raw data of completion values (ability to complete the session).

Go to the next screen

[OVERVIEW screen: Monday 30th December]

- **Is it useful to detect stress and fatigue within the session (during each exergame)?**
- **Is the graphical way of monitoring the level of stress and fatigue experienced by the patient explanatory?**
- **Is it useful to have information on each difficulty experienced by the patient?**

Here we have an overview of the level of stress (in orange) and fatigue (in red) experienced by the patient on 30 December, during both sessions.

The three light blue/blue columns refer to the severity of the criticality

(Lighter blue: values in the normal range Light blue: to pay attention Blue: critical values)

e.g. Paolo Verdi during the first session had moderate levels of stress during the execution of the first three exergames and critical levels during the last exergames to the point of dropping out of the session (indicated by the grey line).

Go to the next screen

[OVERVIEW screen: COMPLETION TRENDS]

- **Are therapy adherence trends clear?**
- **Is the information adequate or is it excessive?**
- **How do the colours look?**

The graph summarises the variables associated with the patient's Completion (ability to complete the session) over the last 30 days. Completion is one of the two Adherence variables. Each variable has a colour (orange, red, green, blue).

Go to the next screen

[OVERVIEW screen: COMPLETION TRENDS- Training progress]

The graph shows one single variable (Training progress) of the Completion regarding the last 30 days.

- **Is it useful to have such a specific detailed view?**

Go to the next screen

[OVERVIEW screen: MOTION RANGE TRENDS]

- **Are the quality and weekly trend of the range of motion clearly expressed?**
- **Are the proposed graphs clear?**
- **How often would it be useful for the patient to carry out a range of motion assessment?**

The graphs summarise the range of motion assessments made during the sessions, as set up by the clinician.

End of the mock-up

7.6 Informed consent form for the pilot

INFORMED CONSENT FORM

TITLE OF STUDY: RecoveryFun

STUDY CODE:

NAME OF PROJECT COORDINATOR: Lorena Rossi

NAME OF INTERVIEWER: _____

I, the undersigned (name and surname) _____

Age _____ date of birth ___/___/_____

Address _____ n. _____ Post code _____

City _____ tel. _____

Regarding the project, **I declare**

- To have read the information letter explaining the purpose of this study, how it will be conducted and what participation entails.
- To retain a copy of the referral letter and consent.
- To have received adequate answers to all questions.
- To have had enough time to make the decision to participate.
- To understand that participation is free and can be discontinued at any time without consequences.
- To have understood that, after a formation session with a physiotherapist on the system usage, I will start using the Virtual Reality (VR) headset, through which I will play games for rehabilitation purposes, and a wearable sensor to detect physiological parameters. The physiotherapist will define my rehabilitation session through a dedicated clinical platform and monitor the execution of the games through a tablet. At the end of the game session, qualitative and quantitative evaluations will be carried out on the usability and acceptability of the system and on any criticalities that have emerged.
- To have been informed that for the entire duration of the study and for the following 36 months from the end of the study, there is insurance cover for non-pharmacological clinical trials guaranteed by xxx under policy no. xxxx valid until xxxx.
- To have been informed that I have the chance to contact the study manager at any time to ask questions about the study and to request to share with me the results of the study.

Regarding my data handling, **I declare**

- To have understood the terms of the attached RecoveryFun Project privacy policy.
- To agree with the collection and processing of data in the study.

- To have been informed that the project partners will have access to my data without being able to identify me.
- To have understood that the evaluation of this data is done in a pseudo-anonymised manner, using a number and without giving a name.
- To have understood that the coding list linking my name to the code number is only accessible to the trial management and the project management, which means that only these persons can link the data collected to my personal data.
- To have understood that after completion of the research project, on 31.12.2024 at the latest, the code list will be deleted.
- To have understood that at the end of the project, the data will be anonymised so that it will no longer be possible for anyone to associate the collected data with a name.
- To have been informed that I can withdraw my consent to participate in the project without any disadvantages.
- To have been informed that I can request the deletion of all my data at any time, on the understanding that if the coding list has already been deleted, the data record can no longer be identified and therefore cannot be deleted either.
- To have understood that data completely anonymised and no longer traceable to an identity may be used for research purposes, for the preparation of a final report for the Health Authorities or for a scientific publication, whatever the outcome of the study.
- To have understood that the information will be kept for at least 10 years after its evaluation or after the publication of an article on this study. If necessary, anonymised data may be made accessible via an internet database for scientific purposes.

Understood and informed as above and as indicated in the RecoveryFun Privacy Policy, by signing this form, I consent to the processing of my personal data for the project

Place, date and signature of participant: _____	Name of participant in block letters: _____
Name of participant in block letters: _____	Name of the study responsible: _____

Note:

The scientific research policy pursuant to the Data Protection Regulation of each specific country should be attached.

7.7 Information letter for the field trial for the participant

INFORMATION LETTER FOR THE SUBJECT

STUDY TITLE: European Project RecoveryFun

STUDY CODE:

N. OF ENROLMENT:

PARTICIPANT'S INITIALS:

Dear Sir/Madam,

our Institute is conducting a scientific study called 'RecoveryFun', involving also other foreign research institutes. In order to carry out this research, we need the collaboration of people who, like you, possess the necessary characteristics for the study that we are going to describe to you.

Please read this document carefully and, if you wish, discuss it with your family members taking as much time as you need. We invite you to ask us for clarification if the information provided is not comprehensible or if you need further details.

Why is this study being carried out and what does it intend to prove?

RecoveryFun project aims to improve the rehabilitation process of people with chronic diseases or recovering from an acute event, as well as to prevent the onset of frailty conditions. In particular, the objective of the project is to develop an innovative and fun system for upper limb rehabilitation, based on the use of virtual reality, to be used at home, with remote monitoring by professionals, after an initial formation in hospital. Furthermore, the development of a mobile application dedicated to caregivers is included, allowing them to monitor the progress of the rehabilitation and motivate the patient. For this scope the participation to the study of a caregiver is mandatory.

The objective of this study is to verify if RecoveryFun System can be an easy-to-use and effective rehabilitation tool for the patient at home.

Is my participation mandatory?

The decision whether or not to participate in the study is free and up to you. If you decide to participate, you will be provided with an attached informed consent form that you must sign and return to the researcher. If you agree to participate in the study, your rights will be protected in accordance with the ethical principles established by the Declaration of Helsinki and its amendments for the entire duration of the study.

Your participation in this phase of the project is voluntary. You may decide at any time to decline or terminate it. If you wish, the results of the research can be communicated.

What happens if I decide not to participate or withdraw from the study?

If, after agreeing to participate, you decide to withdraw from the study, you may do so freely by notifying the person in charge of the research, without having to provide any justification and without affecting the usual quality of the healthcare services you receive at this centre.

What will my participation in the study imply?

In case you decide to participate in the study, the design of this research involves the collection of personal data such as your psycho-physical health status, your social status, your quality of life, your attitude to

technology and, above all, your perceived level of usability with respect to the technology and your acceptance of it.

The devices that will remain at your disposal for the duration of the trial are: a) the virtual reality headsets, through which you will carry out gaming sessions for rehabilitation purposes; b) a wearable sensor to detect physiological parameters; c) a tablet that will also be used by a caregiver to monitor the rehabilitation sessions; d) a gateway to connect the sensor to internet and e) (optional) a 4G modem to connect the VR headset to internet.

The study will last 4 weeks and will involve two or more rehabilitation sessions using the VR per week., according to the rehabilitation plan defined by the clinician, ranging from a minimum of 10 minutes to a maximum of 30 minutes. Before starting the trial at home, two formation sessions will be performed in the hospital, involving also a caregiver: the operation and the proper use of the system will be shown and assessments about your physical and cognitive status will also be performed. If necessary, number of formation sessions may increase in order for you, with the support of your caregiver, to be confident enough to use it independently at home.

After formation is completed you will take the system already set up home and you will begin your treatment sessions. The physiotherapist will constantly monitor and, if necessary, adjust your treatment remotely through a dedicated clinical platform. One or more caregivers have the chance to follow the progress of your rehabilitation through a caregiver application and motivate you. At the end of each week, the physiotherapist will call you to ask how the sessions are proceeding, if there are any difficulties and if in-person intervention is needed.

At the end of the 4 weeks, clinical and qualitative evaluations will be done to assess whether the system has been accepted from your side, to detect any critical issues and to evaluate the effectiveness of the treatment.

What investigations will I undergo during the study?

If you agree to participate in this study, you will be invited to an initial meeting to verify that your physical and cognitive conditions meet the required criteria.

You will then be asked to answer a questionnaire about your personal and social condition, your psycho-physical health and quality of life, your attitude towards technology in general and towards this system in particular.

This interview will be repeated at the end of the trial.

What risks or inconveniences of the study can be reasonably foreseen?

We do not expect any negative effects on the health of users related to the use of the system. The hardware technologies used are commercial VR headsets and a wearable device, both CE certified and not associated to any severe adverse effects. Statistically, just a small number of people may experience nausea or dizziness while using a VR headset, due to motion sickness. This effects usually quickly resolve once you stop using the system. Anyway, conditions for which use of VR headset is discouraged have been taken into account in the definition of the criteria for the recruitment.

The researchers will provide clear and detailed information on the terms of use of the technology system and the services offered during the study and will be available in case of any problems.

The proposed services are intended to improve rehabilitation for people with chronic health conditions and do not replace (in whole or in part) support from professional services.

Users taking part in the study will incur minimal direct or indirect costs related to the use of the system.

Indeed, all the devices provided to the participants are powered using USB charger and the power consumption of an USB charger is around 5W. Except for the 4G modem that will stay on all the day, the devices used according to the training planned in the trail, should be charged on average for 2 hours every 2-3 days. This means that the expected electric power consumption for the 30 days trial could be estimated in about 4-5 KWh. At the current cost of electricity (mercato tutelato) the expect cost is lower than 2€.

Participants may leave the project at any time if they consider participation too burdensome or feel uncomfortable for any reason.

The study at hand provides for the insurance coverage of the Institute policy xxxxxxx

What are the costs of my participation in the study?

Your possible participation will not entail any costs for you. All the necessary equipment (technological devices, chargers and internet connection) will be provided to you free of charge for the whole duration of the study.

What are the possible advantages of participating in the study?

Your participation in the study will allow you to get in touch with an innovative rehabilitation technology that is not yet on the market and to give your opinion to improve it. This could create an opportunity for you to have fun enjoying the serious games of RecoveryFun and possibly to increase some functional abilities and motility of the upper limbs.

Moreover, with your participation will contribute to the collection of information that may be useful for designing and subsequently validating an innovative and fun telerehabilitation system for the population group to which you belong.

Will the information collected be confidential? (this section should be adapted to each partner)

The collection of your data is necessary for the achievement of the purposes of the study. These purposes involve the operations of collection, registration and storage of personal data by means of manual and computerised instruments with logics strictly related to the purposes themselves and, in any case, in such a way as to guarantee the security and confidentiality of the data. Your data may be processed with the collaboration of third parties expressly appointed by the Data Controller, Data Processors or Persons in Charge of Processing.

If you decide to participate in the study, your information will be collected and processed respecting the appropriate measures to guarantee confidentiality and to ensure compliance with data protection laws, pursuant to Regulation (EU) 2016/679 (GDPR) of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and Legislative Decree 10 August 2018, no. 101 – which aims to standardise the Privacy Code with European regulations.

The data controller is the IRCCS INRCA, based in Via Santa Margherita 5 - 60124 - Ancona.

Pursuant to Articles 13, paragraph 2, letters (b) and (d), and Articles 15, 16, 17, 18, and 21 of GDPR 2016/679, you have the right to request from the Data Controller for access, rectification or deletion of your personal data or to restrict the processing of your personal data or to oppose the processing of your personal data and to lodge a complaint with the Data Protection Authority, following the procedures and directions published on the Authority's official website at www.garanteprivacy.it.

Furthermore, IRCCS INRCA, pursuant to Article 37 of the GDPR EU 2016/679, identified and nominated a Data Protection Officer (DPO) who can be contacted at dpo@morolabs.it .

You could also be informed of the updated list of Data Processors by sending a communication to the Data Controller through the Ethics Committee Secretariat.

All your personal data will remain separate from questionnaire results and monitoring data records. Materials will be archived for as long as required by current law. The written consent and all paper documentation will

be kept closed in a secure locked place in the offices of Centro Modelli Assistenziali e Nuove Tecnologie, only accessible to the PI and the person responsible for data collection.

The database will be saved in electronic format and protected by a password known only to the PI and the person responsible for data collection.

All data will be preserved for a maximum of 10 years.

Data collected during the trial will be directly entered into a validated database. The highest standards of information quality management are applied according to ISO 27001 related to the quality management system for ensuring information security. These standards define highly restrictive operating procedures that guarantee the quality, integrity and accuracy of the collected data. The database will be locked after the quality control and quality assurance procedures and coding activities are completed.

The cloud servers used for storing and processing the data needed to operate the system will be managed in Europe, in accordance with current regulation.

Furthermore, at any time and without giving any reason, you may withdraw your consent and interrupt your participation in the study, in which case no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research.

All clinical data may be inspected by the Regulatory Authorities, monitoring and auditing personnel, without any possibility of tracing your identity. The results of the study will be used for scientific research purposes and may be published, but your identity will always remain confidential. You will also have the right to request the correction of any errors. This information may be used by the Study Promoter and related companies, affiliates and licensees.

Will I be able to know the results of the study?

If you wish, at the end of the study, you may be informed of the results of the trial and, in particular, those concerning you.

Who should I contact if I need further information or help?

Further information on the study can be obtained at any time by contacting the Studi PI Dr. Giovanni Riccardi, the project manager Dr Lorena Rossi (tel. T.: +39 071/8004893) and the research staff responsible for the study, Dr …, at this facility. The protocol of the trial illustrated was drafted in accordance with the current revision of the Declaration of Helsinki, and was approved by the Bioethics Committee of this Institute whose contact details are: President, Dr Marco Giulioni and Secretary, Dr Anna Rita Bonfigli, e-mail: comitatoetico@inrca.it, tel. 0718003500 - 3719.

7.8 Informed consent for the field trial for the participant

INFORMED CONSENT FORM

TITLE OF STUDY: RecoveryFun

STUDY CODE:

NAME OF PROJECT COORDINATOR: Lorena Rossi

NAME OF INTERVIEWER: _____

I, the undersigned (name and surname) _____

Age _____ date of birth ___/___/_____

Address _____ n. _____ Post code _____

City _____ tel. _____

Regarding the project, **I declare**

- To have read the information letter explaining the purpose of this study, how it will be conducted and what participation entails.
- To retain a copy of the referral letter and consent.
- To have received adequate answers to all questions.
- To have had enough time to make the decision to participate.
- To understand that participation is free and can be discontinued at any time without consequences.
- To have understood that I will be given: a) the virtual reality headsets, through which I will carry out gaming sessions for rehabilitation purposes; b) a tablet to be used by the caregiver to monitor the execution of the game; c) a wearable sensor to detect physiological parameters; d) a gateway to connect the sensor to internet and e) (optional) a 4G modem to connect the VR headset to internet. The study will last 4 weeks and will involve two initial formation sessions performed in the hospital, involving a caregiver. After formation is completed, the system will be delivered at my home and I will begin my treatment sessions. The physical therapist will constantly monitor and adjust, if necessary, my treatment remotely through a dedicated clinical platform. My caregiver will follow the progress of the rehabilitation through a caregiver application. At the end of each week, the physiotherapist will call me to ask how the sessions are proceeding, if there are any difficulties and if in-person intervention is needed. At the end of the 4 weeks, clinical and qualitative evaluations will be done to assess whether the system has been accepted from my side, to detect any critical issues, and to evaluate the effectiveness of the treatment.
- To have been informed that for the entire duration of the study and for the following 36 months from the end of the study, there is insurance cover for non-pharmacological clinical trials guaranteed by xxx under policy xxxx.
- To have been informed that I have the chance to contact the study manager at any time to ask questions about the study and to request to share with me the results of the study.

Regarding my data handling, **I declare**

- To have understood the terms of the attached RecoveryFun Project privacy policy;
- To agree with the collection and processing of data in the study
- To have been informed that the project partners will have access to my data without being able to identify me;
- To have understood that the evaluation of this data is done in a pseudo-anonymised manner, using a number and without giving a name.
- To have understood that the coding list linking my name to the code number is only accessible to the trial management and the project management, which means that only these persons can link the data collected to my personal data
- To have understood that after completion of the research project, on 31.12.2024 at the latest, the code list will be deleted.
- To have understood that at the end of the project, the data will be anonymised so that it will no longer be possible for anyone to associate the collected data with a name.
- To have been informed that I can withdraw my consent to participate in the project without any disadvantages.
- To have been informed that I can request the deletion of all my data at any time, on the understanding that if the coding list has already been deleted, the data record can no longer be identified and therefore cannot be deleted either.
- To have understood that data completely anonymised and no longer traceable to an identity may be used for research purposes, for the preparation of a final report for the Health Authorities or for a scientific publication, whatever the outcome of the study.
- To have understood that the information will be kept for at least 10 years after its evaluation or after the publication of an article on this study. If necessary, anonymised data may be made accessible via an internet database for scientific purposes.

Understood and informed as above and as indicated in the RecoveryFun Privacy Policy, by signing this form, I consent to the processing of my personal data for the project

Place, date and signature of participant:	Name of participant in block letters:
_____	_____
Place, date and signature of the study responsible:	Name of the study responsible:
_____	_____

Note:

The scientific research policy pursuant to the Data Protection Regulation of each specific country should be attached.

7.9 Information letter for the field trial for the informal caregiver

INFORMATION LETTER FOR THE CAREGIVER

STUDY TITLE: European Project RecoveryFun

STUDY CODE:

N. OF ENROLMENT:

PARTICIPANT'S INITIALS:

Dear Sir/Madam,

our Institute is conducting a scientific study called "RecoveryFun", involving also other foreign research institutes. In order to carry out this research, we need the collaboration of people who, like you, are caregivers of people who possess the necessary characteristics for the study that we are going to describe to you.

Please read this document carefully, taking as much time as you need. We invite you to ask us for clarification if the information provided is not comprehensible or if you need further details.

Why is this study being carried out and what does it intend to prove?

RecoveryFun project aims to improve the rehabilitation process of people with chronic diseases or recovering from an acute event, as well as to prevent the onset of frailty conditions. In particular, the objective of the project is to develop an innovative and fun system for upper limb rehabilitation, based on the use of virtual reality, to be used at home, with remote monitoring by professionals, after an initial formation in hospital. Furthermore, the development of a mobile application dedicated to caregivers is included, allowing to monitor the progress of the rehabilitation and motivate the patient. For this scope, your participation in the study, as a caregiver of a patient, is mandatory. At any time, however, you may decide to decline or terminate your participation.

The aim of this study is to test whether the RecoveryFun system can be an easy-to-use and effective rehabilitation tool for a patient at home.

Is my participation mandatory?

The decision whether or not to participate in the study is free and up to you. If you decide to participate, you will be provided with an attached informed consent form that you must sign and return to the researcher. If you agree to participate in the study, your rights will be protected in accordance with the ethical principles established by the Declaration of Helsinki and its amendments for the entire duration of the study.

Your participation in this phase of the project is voluntary. You may decide at any time to decline or terminate it. If you wish, the results of the research can be communicated.

What happens if I decide not to participate or withdraw from the study?

If, after agreeing to participate, you decide to withdraw from the study, you may do so freely by notifying the person in charge of the research, without having to provide any justification and without affecting the usual quality of the healthcare services that the person you care for receives at this centre.

What will my participation in the study imply?

In case you decide to participate in the study, the design of this research involves the collection of personal data such as your social status, your care burden, your attitude to technology and, above all, your perception of the usability and acceptability of technology.

For the duration of the study you will have the possibility to use the tablet, given to the person you care for, to monitor the progress of the games he/she will play for rehabilitation purposes. In addition, you will be given credentials to access the mobile application for caregivers so that you can follow the progress of the rehabilitation and motivate the person you care for.

The study will last 4 weeks and will include two formation sessions in the hospital, also involving the person you care for: you will be shown how the system works and how to use it correctly, and assessments will be made of your social status, your care burden and your attitude towards the technology. If necessary, the number of training sessions can be increased so that you are confident enough to support the person in your care in using the system at home independently.

At the end of the formation, you will start using the mobile application and the tablet.

At the end of the 4 weeks, quantitative and qualitative evaluations will be carried out to assess the usability of the system, identify any critical issues and evaluate the effectiveness of the treatment.

What investigations will I undergo during the study?

If you agree to participate in this study, You will be asked to answer a number of questionnaires concerning your personal and social data, your care burden, and your attitude towards technology in general and with this system in particular.

This evaluation will be repeated at the end of the trial.

What risks or inconveniences of the study can be reasonably foreseen?

We do not expect any negative effects on the health of users related to the use of the system.

The researchers will provide clear and detailed information on the terms of use of the technology system and the services offered during the study and will be available in case of any problems.

The proposed services are intended to improve rehabilitation for people with chronic health conditions and do not replace (in whole or in part) support from professional services.

Users taking part in the study will incur minimal direct or indirect costs related to the use of the system.

Indeed, all the devices provided to the participants are powered using USB charger and the power consumption of an USB charger is around 5W. Except for the 4G modem that will stay on all the day, the devices used according to the training planned in the trail, should be charged on average for 2 hours every 2-3 days. This means that the expected electric power consumption for the 30 days trial could be estimated in about 4-5 KWh. At the current cost of electricity (mercato tutelato) the expect cost is lower than 2€.

Participants may leave the project at any time if they consider participation too burdensome or feel uncomfortable for any reason.

The study at hand provides for the insurance coverage of the Institute policy No. xxxxxxx.

What are the costs of my participation in the study?

Your possible participation will not entail any costs for you. All the necessary equipment (technological devices, chargers and internet connection) will be provided to the person in your care free of charge for the whole duration of the study.

What are the possible advantages of participating in the study?

Your participation in the study will allow you to get in touch with an innovative rehabilitation technology that is not yet on the market and to give your opinion to improve it. This could create an opportunity for You to

follow the rehabilitation process of the person in your care and to motivate him/her to perform the game sessions.

Moreover, with your participation will contribute to the collection of information that may be useful for designing and subsequently validating an innovative and fun telerehabilitation system for the population group to which you belong.

Will the information collected be confidential? (section to be adapted to each partner)

The collection of your data is necessary for the achievement of the purposes of the study. These purposes involve the operations of collection, registration and storage of personal data by means of manual and computerised instruments with logics strictly related to the purposes themselves and, in any case, in such a way as to guarantee the security and confidentiality of the data. Your data may be processed with the collaboration of third parties expressly appointed by the Data Controller, Data Processors or Persons in Charge of Processing.

If you decide to participate in the study, your information will be collected and processed respecting the appropriate measures to guarantee confidentiality and to ensure compliance with data protection laws, pursuant to Regulation (EU) 2016/679 (GDPR) of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and Legislative Decree 10 August 2018, no. 101 – which aims to standardise the Privacy Code with European regulations.

The data controller is the IRCCS INRCA, based in Via Santa Margherita 5 - 60124 - Ancona.

Pursuant to Articles 13, paragraph 2, letters (b) and (d), and Articles 15, 16, 17, 18, and 21 of GDPR 2016/679, you have the right to request from the Data Controller for access, rectification or deletion of your personal data or to restrict the processing of your personal data or to oppose the processing of your personal data and to lodge a complaint with the Data Protection Authority, following the procedures and directions published on the Authority's official website at www.garanteprivacy.it.

Furthermore, IRCCS INRCA, pursuant to Article 37 of the GDPR EU 2016/679, identified and nominated a Data Protection Officer (DPO) who can be contacted at dpo@morolabs.it .

You could also be informed of the updated list of Data Processors by sending a communication to the Data Controller through the Ethics Committee Secretariat.

All your personal data will remain separate from questionnaire results and monitoring data records. Materials will be archived for as long as required by current law. The written consent and all paper documentation will be kept closed in a secure locked place in the offices of Centro Modelli Assistenziali e Nuove Tecnologie, only accessible to the PI and the person responsible for data collection.

The database will be saved in electronic format and protected by a password known only to the PI and the person responsible for data collection.

All data will be preserved for a maximum of 10 years.

Data collected during the trial will be directly entered into a validated database. The highest standards of information quality management are applied according to ISO 27001 related to the quality management system for ensuring information security. These standards define highly restrictive operating procedures that guarantee the quality, integrity and accuracy of the collected data. The database will be locked after the quality control and quality assurance procedures and coding activities are completed.

The cloud servers used for storing and processing the data needed to operate the system will be managed in Europe, in accordance with current regulation.

Furthermore, at any time and without giving any reason, you may withdraw your consent and interrupt your participation in the study, in which case no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research.

All clinical data may be inspected by the Regulatory Authorities, monitoring and auditing personnel, without any possibility of tracing your identity. The results of the study will be used for scientific research purposes

and may be published, but your identity will always remain confidential. You will also have the right to request the correction of any errors. This information may be used by the Study Promoter and related companies, affiliates and licensees.

Potrò conoscere i risultati dello studio?

Se Lei lo desidera, alla fine dello studio, potranno esserLe comunicati i risultati della sperimentazione e, in particolare, quelli che La riguardano.

Chi devo contattare nel caso in cui avessi bisogno di ulteriori informazioni o di aiuto?

In ogni momento potrà chiedere maggiori informazioni riguardanti lo studio, rivolgendosi, presso questa Struttura, al PI dello studio Dott. Giovanni Riccardi, alla responsabile del progetto Dott.ssa Lorena Rossi (tel. +39 071/8004893) e al personale di ricerca che si occupa dello studio, Dott.ssa Valentina Tombolesi (tel. +39 071 8004634) . Il protocollo della sperimentazione illustrata è stato redatto in conformità alla revisione corrente della Dichiarazione di Helsinki, ed è stato approvato dal Comitato di Bioetica di questo Istituto i cui recapiti sono: Presidente, Dott. Marco Giulioni e Segretaria, Dott.ssa Anna Rita Bonfigli, e-mail: comitatoetico@inrca.it, tel. 0718003500 – 3719.

7.10 Informed consent for the field trial for the informal caregiver

INFORMED CONSENT FORM FOR THE CAREGIVER

TITLE OF STUDY: RecoveryFun

STUDY CODE:

NAME OF PROJECT COORDINATOR: Lorena Rossi

NAME OF INTERVIEWER: _____

I, the undersigned (name and surname) _____

Age _____ date of birth ___/___/_____

Address _____ n. _____ Post code _____

City _____ tel. _____

Regarding the project, **I declare**

- To have read the information letter explaining the purpose of this study, how it will be conducted and what participation entails.
- To retain a copy of the referral letter and consent.
- To have received adequate answers to all questions.
- To have had enough time to make the decision to participate.
- To understand that participation is free and can be discontinued at any time without consequences.
- To have understood that I will have the chance to use the tablet, given to the person I care for, in order to monitor the progress of the exergames sessions he/she will play for rehabilitation purposes. Also, I will be given credentials to access the mobile application for caregivers so that I can follow the progress of the rehabilitation and motivate the person I care for. The study will last four weeks and will include two initial formation sessions in the hospital, in which I will participate together with the person I care for. After completing this formation, I will start using the mobile application and the tablet. At the end of the 4 weeks, quantitative and qualitative evaluations will be carried out to assess the usability of the system, identify any critical issues and evaluate the effectiveness of the treatment.
- To have been informed that for the entire duration of the study and for the following 36 months from the end of the study, there is insurance cover for non-pharmacological clinical trials guaranteed by xxxx under policy no. xxxxx.
- To have been informed that I have the chance to contact the study manager at any time to ask questions about the study and to request to share with me the results of the study.

Regarding my data handling, **I declare**

- To have understood the terms of the attached RecoveryFun Project privacy policy.
- To agree with the collection and processing of data in the study.
- To have been informed that the project partners will have access to my data without being able to identify me.
- To have understood that the evaluation of this data is done in a pseudo-anonymised manner, using a number and without giving a name.
- To have understood that the coding list linking my name to the code number is only accessible to the trial management and the project management, which means that only these persons can link the data collected to my personal data.
- To have understood that after completion of the research project, on 31.12.2024 at the latest, the code list will be deleted.
- To have understood that at the end of the project, the data will be anonymised so that it will no longer be possible for anyone to associate the collected data with a name.
- To have been informed that I can withdraw my consent to participate in the project without any disadvantages.
- To have been informed that I can request the deletion of all my data at any time, on the understanding that if the coding list has already been deleted, the data record can no longer be identified and therefore cannot be deleted either.
- To have understood that data completely anonymised and no longer traceable to an identity may be used for research purposes, for the preparation of a final report for the Health Authorities or for a scientific publication, whatever the outcome of the study.
- To have understood that the information will be kept for at least 10 years after its evaluation or after the publication of an article on this study. If necessary, anonymised data may be made accessible via an internet database for scientific purposes.

Understood and informed as above and as indicated in the RecoveryFun Privacy Policy, by signing this form, I consent to the processing of my personal data for the project

Place, date and signature of participant: _____	Name of participant in block letters: _____
Name of participant in block letters: _____	Name of the study responsible: _____

Note:

The scientific research policy pursuant to the Data Protection Regulation of each specific country should be attached.

7.11 Information letter for the family doctor (where applicable)

LETTER TO THE FAMILY DOCTOR

RecoveryFun: An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors

To the family doctor

of Mr/Mrs .....

Dear Colleague,

With this letter we invite You to collaborate with us regarding the successful outcome of the study related to the project entitled **RecoveryFun: An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors**, for the evaluation of the acceptability of the RecoveryFun system by the elderly person needing upper limb rehabilitation and living at home.

The promoter of the study is the IRCCS-INRCA of Ancona.

The study is coordinated by Dr. Giovanni Riccardi of the Rehabilitation Medicine Unit of the IRCCS INRCA, Ancona site.

The project is addressed to elderly people needing rehabilitation following an acute event occurred in the last 12 months that caused a functional impairment to upper limb (e.g. ICTUS/cerebrovascular injuries). The objective of the study is to understand whether the RecoveryFun system is manageable and acceptable by the person who needs to continue rehabilitation activity after undergoing the standard rehabilitation procedure at health centres or clinics. The RecoveryFun kit will be provided to the patient who will use it at home and will offer the opportunity to follow a personalised telerehabilitation pathway constantly monitored by the remote healthcare professional.

The RecoveryFun system includes a VR headset, a wearable sensor for measuring certain physiological parameters, a clinical portal dedicated to the clinician and a mobile application for the caregiver.

The system, using a VR headset, will allow the patient to enter an immersive virtual reality in which he/she will have to play games proposed by the platform that will stimulate him/her cognitively and physically.

Through the caregiver app, the caregiver will be able to monitor adherence to therapy and receive information that will enable him/her to support the patient by motivating and stimulating him/her to follow the rehabilitation plan.

Through the clinical portal, the health professional will be able to define the most appropriate rehabilitation plan for the patient and keep track of his/her activity determining, based on the data collected during the rehabilitation sessions, which games and time settings are the most suitable.

The study will last 4 weeks and the patient will have to use the VR headset following the plan defined by the clinician, which will include at least two sessions per week for a minimum time of 10 minutes. The period of use at home is preceded by a formation phase that will take place under the supervision of the physiotherapist in the physiotherapy clinics of INRCA hospital in Via Della Montagnola, in which the patient and caregiver will be instructed about the use of the system. The physiotherapist will call the patient weekly to find out the progress of the rehabilitation sessions, intervening in person where necessary.

People participating in the study will receive the following evaluations: anamnestic collection (physiological, pathological and pharmacological), health status assessment, upper limb motility, cognitive status, trunk control.

The importance of the study lies above all in the collection of information that may be useful to improve the system allowing the patient to continue the rehabilitation process through telerehabilitation with personalised treatments remotely monitored by the clinician in order to maintain or improve the objectives achieved during the conventional rehabilitation process.

Since we consider the involvement of the family doctor in a such kind of study to be important, we decided to directly inform You about Your patient's decision to participate in the study and, at the same time, ask You to confirm to Your patient the importance of participating in this initiative. In case of any adverse events, You will be promptly informed in order to take appropriate action.
The data collected will be kept strictly confidential and treated in accordance with Article 3 of the General Data Protection Regulation 2016/679 of the European Union and will be handled anonymously.
We will be grateful for Your cooperation in this regard, confident that you won’t miss to support us.
Kind Regards

7.12 Case Report Form for the Pilot

RecoveryFun

An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors

RECRUITMENT PILOT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Fugl-Meyer

A. UPPER EXTREMITY, sitting position					
I. Reflex activity			**none**	**can be elicited**	
Flexors: biceps and finger flexors (at least one) **Extensors**: triceps			0 0	2 2	
Subtotal I (max 4)					
II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). **Extensor synergy:** Hand from ipsilateral ear to the contralateral knee	Shoulder Elbow Forearm	retraction elevation abduction (90°) external rotation flexion supination	0 0 0 0 0 0	1 1 1 1 1 1	2 2 2 2 2 2
	Shoulder Elbow Forearm	adduction/internal rotation extension pronation	0 0 0	1 1 1	2 2 2
Subtotal II (max 18)					
III. Volitional movement mixing synergies, without compensation			**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)		0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion		0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position		0	1	2
Subtotal III (max 6)					
IV. Volitional movement with little or no synergy			**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm neutral	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation		0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion		0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position		0	1	2
Subtotal IV (max 6)					
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side			**hyper**	**lively**	**normal**
Biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total A (max 36)					

B. WRIST support may be provided at the elbow to take or hold the starting position, no support at wrist, check the passive range of motion prior testing		none	partial	full
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction elbow at 90°, forearm pronated shoulder at 0°	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
Total B (max 10)				

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. Hook grasp flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. Thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. Pincer grasp, opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. Cylinder grasp cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. Spherical grasp fingers in abduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
Total C (max 14)				

D. COORDINATION/SPEED, sitting, after one trial with both arms, eyes closed, tip of the index finger from knee to nose, 5 times as fast as possible		marked	slight	none
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	**2 - 5s**	**< 2s**
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
Total D (max 6)				

Total A-D (max 66)	

H. SENSATION, upper extremity eyes closed, compared with the unaffected side		**anesthesia**	**hypoesthesia or dysesthesia**	**normal**
Light touch	upper arm, forearm palmary surface of the hand	0 0	1 1	2 2
		less than 3/4 correct or absence	**3/4 correct or considerable difference**	**correct 100%, little or no difference**
Position small alterations in the position	shoulder elbow wrist thumb (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

I. PASSIVE JOINT MOTION, upper extremity, sitting position, compare with the unaffected side				**J. JOINT PAIN** during passive motion, upper extremity		
	only few degrees (less than 10° in shoulder)	decreased	normal	pronounced pain during movement or very marked pain at the end of the movement	some pain	no pain
Shoulder						
Flexion (0° - 180°)	0	1	2	0	1	2
Abduction (0°-90°)	0	1	2	0	1	2
External rotation	0	1	2	0	1	2
Internal rotation	0	1	2	0	1	2
Elbow						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Forearm						
Pronation	0	1	2	0	1	2
Supination	0	1	2	0	1	2
Wrist						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Fingers						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Total (max 24)				**Total** (max 24)		

A. UPPER EXTREMITY	/36
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/ 6
TOTAL A-D (motor function)	/66

H. SENSATION	/12
I. PASSIVE JOINT MOTION	/24
J. JOINT PAIN	/24

Trunk Impairment Scale (TIS)

Item				
	Static sitting balance			
1	Starting position	Patient falls or cannot maintain starting position for 10 seconds without arm support	☐	0
		Patient can maintain starting position for 10 seconds		
		If score= 0, then TIS total score =0	☐	2
2	Starting position Therapist crosses the unaffected leg over the hemiplegic leg	Patient falls or cannot maintain sitting position for 10 seconds without arm support	☐	0
		Patient can maintain sitting position for 10 seconds	☐	2
3	Starting position Patient crosses the unaffected leg over the hemiplegic leg	Patient falls	☐	0
		Patient cannot cross the legs without arm support on bed or table	☐	1
		Patient crosses the legs but displaces the trunk more than 10 cm backwards or assists crossing with the hand	☐	2
		Patient crosses the legs without trunk displacement or assistance	☐	3
		Total static sitting balance		/ 7
	Dynamic sitting balance			
1	Starting position Patient is instructed to touch the bed or table with the hemiplegic elbow (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐	0
		Patient moves actively without help, elbow touches bed or table	☐	1
		If score =0, then items 2 and 3 score 0		
2	Repeat item 1	Patient demonstrates no or opposite shortening/ lengthening	☐	0
		Patient demonstrates appropriate shortening/lengthening	☐	1
		If score =0, then item 3 scores 0		
3	Repeat item 1	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet	☐	0
		Patient moves without compensation	☐	1
4	Starting position Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐	0
		Patient moves actively without help, elbow touches bed or table	☐	1
		If score =0, then items 5 and 6 score 0		

	hemiplegic side) and return to the starting position			
5	Repeat item 4	Patient demonstrates no or opposite shortening/ lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 6 scores 0	☐ ☐	0 1
6	Repeat item 4	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet Patient moves without compensation	☐ ☐	0 1
7	Starting position Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient demonstrates no or opposite shortening /lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 8 scores 0	☐ ☐	0 1
8	Repeat item 7	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) Patient moves without compensation	☐ ☐	0 1
9	Starting position Patient is instructed to lift pelvis from bed or table at the unaffected side (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient demonstrates no or opposite shortening/ lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 10 scores 0	☐ ☐	0 1
10	Repeat item 9	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) Patient moves without compensation	☐ ☐	0 1
		Total dynamic sitting balance		/10
	Co-ordination			
1	Starting position Patient is instructed to rotate upper trunk 6 times (every shoulder should be moved	Hemiplegic side is not moved three times Rotation is asymmetrical Rotation is symmetrical If score =0, then item 2 scores 0	☐ ☐ ☐	0 1 2

	forward 3 times), first side that moves must be hemiplegic side, head should be fixated in starting position			
2	Repeat item 1 within 6 seconds	Rotation is asymmetrical	☐	0
		Rotation is symmetrical	☐	1
3	Starting position Patient is instructed to rotate lower trunk 6 times (every knee should be moved forward 3 times), first side that moves must be hemiplegic side, upper trunk should be fixated in starting position	Hemiplegic side is not moved three times	☐	0
		Rotation is asymmetrical	☐	1
		Rotation is symmetrical	☐	2
		If score =0, then item 4 scores 0		
4	Repeat item 3 within 6 seconds	Rotation is asymmetrical	☐	0
		Rotation is symmetrical	☐	1
		Total co-ordination		/6
		Total Trunk Impairment Scale		/23

MoCA – Montreal Cognitive Assessment

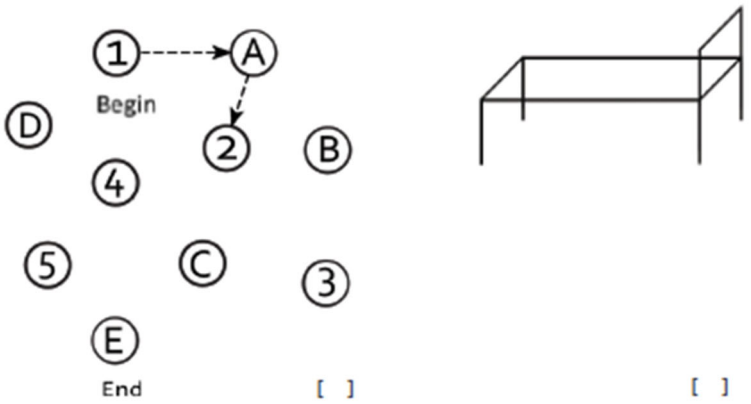
MONTREAL COGNITIVE ASSESSMENT (MoCA®)

Version 8.3 English

Name:
Education: Date of birth :
Sex: DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy bed



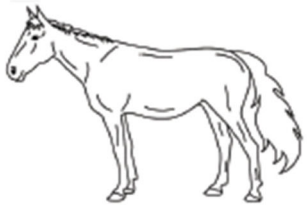
[ ] [ ]

Draw CLOCK (Five past ten)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING



[ ]

[ ]

[ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	LEG	COTTON	SCHOOL	TOMATO	WHITE
1st TRIAL					
2nd TRIAL					

NO POINTS

ATTENTION Read list of digits (1 digit/sec.).

Subject has to repeat them in the forward order. [ ] 2 4 8 1 5

Subject has to repeat them in the backward order. [ ] 4 2 7

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors.

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 60. [ ] 53 [ ] 46 [ ] 39 [ ] 32 [ ] 25

4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt

__/3

LANGUAGE Repeat: The child walked his dog in the park after midnight. [ ]

The artist finished his painting at the right moment for the exhibition. [ ]

__/2

Language Fluency. Name maximum number of words in one minute that begin with the letter B. [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] hammer - screwdriver [ ] matches - lamp

__/2

DELAYED RECALL — Memory Index Score (MIS)

(MIS)	Has to recall words	LEG	COTTON	SCHOOL	TOMATO	WHITE	Points for UNCUED recall only
X3	WITH NO CUE	[ ]	[ ]	[ ]	[ ]	[ ]	
X2	Category cue						MIS = ____/15
X1	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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MIS: /15
(Normal ≥ 26/30)

TOTAL __/30

Administered by: _____

Training and Certification are required to ensure accuracy.

Add 1 point if ≤ 12 yr education

PRE-PILOT EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Socio-demographic characteristics

1. Date of birth _____/_____/_____
   (dd /mm /yyyy)

2. Sex M ☐ 1 F ☐ 2 I prefer not to answer ☐ 3

3. Please specify what is your marital status at present:

Married (living with the spouse/wife)	☐ 1
Full time relationship	☐ 2
Separated (married, but living separately)	☐ 3
Divorced	☐ 4
Single	☐ 5
Widowed	☐ 6
Don't know	☐ 98
Refused	☐ 99

4. Can you indicate which of the following education level have you reached?

No education	☐ 0
Primary education	☐ 1
Secondary education	☐ 2
Tertiary education (university or further education level)	☐ 3
Don't know	☐ 98
Refused	☐ 99

5. Total years of education _____

6. Please indicate your present working situation (multiple answers possible):

6.1 Retired	☐ 1
6.2 Still working full time	☐ 1
6.3 Still working part time	☐ 1
6.4 Unemployed	☐ 1
6.5 Work inside the home	☐ 1
6.6 Don't know	☐ 98

6.7 Refused	☐99

7. What are your personal income sources? (multiple answers possible)

7.1 Work	☐ 1
7.2 Pension	☐ 1
7.3 Unearned income	☐ 1
7.4 Help from relatives	☐ 1
7.5 Welfare state provision	☐ 1
7.6 Other	☐ 1
7.7 Don't know	☐98
7.8 Refused	☐99

8. If "other", please specify _____

9. Who lives in your home with you? (multiple answers possible)

Category	**Code**	**Number of…**
9.1 No one	☐ 1	N.A.
9.2 Spouse/partner	☐ 1	N.A.
9.3 Sons and daughters	☐ 1	
9.4 Grandchildren	☐ 1	
9.5 Children's spouses	☐ 1	
9.6 Brothers/Sisters	☐ 1	
9.7 Mother/Father	☐ 1	
9.8 Paid caregiver (not relative)	☐ 1	
9.9 Others	☐ 1	
9.10 Refused	☐99	N.A.

(Note for the interviewer: Sign the exact number of people that live with the elder _____)

10. If "other", please specify _____

Subjective health assessment

1. Are you taking any medicine? 1 ☐ Yes 0 ☐ No

2. If yes, can you indicate the name, reason and frequency with which you take them?

Name of the medicine	Reason	Frequency

3. Do you use any walking aid? 1 ☐ Yes 0 ☐ No

4. If yes, which one? _____

5. Can you read a book, watch TV? 1 ☐ Yes 0 ☐ No

6. Can you follow a conversation, use the telephone (also with hearing aids)?
   1 ☐ Yes 0 ☐ No

7. How do you rate your health at the moment?

Excellent □ 5	Good □ 4	Sufficient □ 3	Poor □ 2	Very poor □ 1

8. How do you rate your physical mobility at the moment?

Excellent□ 5	Good □ 4	Sufficient □ 3	Poor □ 2	Very poor □ 1

9. How do you rate your visual ability (ability to see in adequate light and with glasses, if used)?

Appropriate	*See details, including regular newspaper/book prints*	☐ 5
Compromised	*Sees large print, but not regular newspaper/book prints*	☐ 4
Moderately compromised	*Limited vision; cannot see headlines, but can identify objects*	☐ 3
Highly compromised	*Object identification in doubt, but the eyes seem to follow the objects*	☐ 2
Severely compromised	*Absence of vision or sees only light, colours or shapes; eyes do not seem to follow objects*	☐ 1
He/she does not know		☐ **98**
He/she refuses		☐ **99**

10. How do you rate your ability to hear (ability to hear with hearing aid, if used)?

He/she hears adequately	*Normal speech, the television, the telephone, the doorbell*	☐ 4

With little difficulty	*When he/she is not in a silent environment*	☐ 3
He/she only hears on special occasions	*The interlocutor has to adjust the volume of his voice and speak distinctly*	☐ 2
Highly compromised	*Lack of useful hearing*	☐ 1
He/she does not know		☐ **98**
He/she refuses		☐ **99**

SURVEY OF TECHNOLOGY USE (MTP SOTU-C)

1. TECHNOLOGIES YOU FREQUENTLY USE:

List the technologies that you use most frequently (for example, personal computer, VCR, bank ATM, CD player, ...)

1. _____ 6. _____
2. _____ 7. _____
3. _____ 8. _____
4. _____ 9. _____
5. _____ 10. _____

Answer all the questions below by checking the option that most accurately applies to you. If you are uncertain about a response, check the neutral category.

2. OVERALL EXPERIENCES WITH CURRENT TECHNOLOGIES USED

Generally feel	***Neutral***	***Generally feel***
They are satisfying O	O	they are frustrating O
They help my creativity O	O	they interfere with my creativity O
They are encouraging O	O	they are discouraging O
They bring me together with people O	O	they separate me from people O
Thay raise my opinion of myself O	O	they lower my opinion of myself O

3. PERSPECTIVES ON TECHNOLOGIES

	Feel positive about	***Neutral***	***Feel negative about***
My childhood technology experiences	O	O	O
My technology experiences in school	O	O	O
My technology experiences at home	O	O	O
My most recent technology experiences	O	O	O

Generally feel	***Neutral***	***Generally feel***
I am comfortable with technology O	O	I am intimidated by technology O
I approach technology in a thinking way O	O	I approach technologies in a feeling way O
I feel good around technology O	O	I feel anxious around technology O
Other people encourage my technology use O	O	Other people discourage my technology use O

4. YOUR TYPICAL ACTIVITIES

Generally feel	*Neutral*	*Generally feel*
I prefer to be active O	O	I prefer passive activities O
I prefer group activities O	O	I prefer solitary activities O
My activities are satisfying O	O	My activities are frustrating O
I regularly seek fresh, new activities O	O	My activities have not changed in a long time O

5. SOME OF YOUR PERSONAL/SOCIAL CHARTERISTIC

Generally feel	*Neutral*	*Generally feel*
Composed/ calm O	O	Anxious O
Happy O	O	Depressed O
Tolerant O	O	Angry or frustrated O
Positive in outgoing O	O	Negative in outlook O
Expressive/outgoing O	O	Quiet/withdrawn O
Patient O	O	Impatient O
Motivated O	O	Unmotivated O
Persevering O	O	Easily discouraged O

Generally feel	*Neutral*	*Generally feel*
I am THINKING person O	O	I am FEELING person O
I frequently interact with family/spouse O	O	I seldom interact with family/spouse O
I frequently interact with non-family/friends O	O	I seldom interact with non- family/friends O
I have a good sense of well-being O	O	I have a poor sense of well-being O
I am physically independent O	O	I am physically dependent O
I am emotionally independent O	O	I am emotionally dependent O

POST PILOT EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

QUEST

(Quebec User Evaluation of Satisfaction with Assistive Technology)

For each of the 12 items, rate your satisfaction with the assistive devices you experienced by using the following scale of 1 to 5.

1 = not satisfied at all 2 = not very satisfied 3 = more *or* less satisfied 4 = quite satisfied 5 = very satisfied

ASSISTIVE DEVICE: *How satisfied are you with…*	1	2	3	4	5
1. the dimensions (size, height, length, width) of your assistive device? 1.1 Headset 1.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
2. the weight of your assistive device? 2.1 Headset 2.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
3. the ease in adjusting (fixing, fastening) the parts of your assistive device? 3.1 Headset 3.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
4. how safe and secure your assistive device is? 4.1 Headset 4.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
5. the durability (endurance, resistance to wear) of your assisitive device? 5.1 Headset 5.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
6. how easy it is to use your assistive device? 6.1 Headset 6.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
7. how comfortable your assistive device is? 7.1 Headset 7.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
8. how effective your assistive device is (the degree to which your device meets your needs)? 8.1 Headset 8.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐

TOTAL

Headset _____ / 40

Wearable sensor _____ / 40

Below is the list of the same satisfaction items. Please select the **three items** that you consider to be the most important to you. Please put an X in the 3 boxes of your choice for headset/viewer and wearable sensor:

Headset	9.1 dimensions	☐ 1	9.5 durability	☐ 1
	9.2 weight	☐ 1	9.6 easy to use	☐ 1
	9.3 adjustments	☐ 1	9.7 comfort	☐ 1
	9.4 safety	☐ 1	9.8 effectiveness	☐ 1

Wearable sensor	10.1 dimensions	☐ 1	10.5 durability	☐ 1
	10.2 weight	☐ 1	10.6 easy to use	☐ 1
	10.3 adjustments	☐ 1	10.7 comfort	☐ 1
	10.4 safety	☐ 1	10.8 effectiveness	☐ 1

SUS – System Usability Scale

	1 Strongly disagree → 5 Strongly agree				
1. I think that I would like to use this system frequently	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. I found the system unnecessarily complex	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. I thought the system was easy to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.I think that I would need the support of a technical person to be able to use this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. I found the various functions in the system were well integrated	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. I thought there was too much inconsistency in this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. I would imagine that most people would learn to use the system very quickly	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. I found the system very cumbersome to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. I felt very confident 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

User Experience Questionnaire (UEQ)

Please assess the product now by ticking one circle per line.

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26

Pilot experience

1. Did you have difficulty wearing and adjusting the headset?

   YES ☐ 1 NO ☐ 0

2. If you answered yes, can you please explain it: _____

3. Did you feel the weight of the headset was suitable?

   YES ☐ 1 NO ☐ 0

4. Did you have difficulty wearing and adjusting the sensor?

   YES ☐ 1 NO ☐ 0

5. If you answered yes, can you please explain it: _____

6. Does having the sensor on impact during the execution of exergames?

   _____

   _____

7. Did you find the screens visible at a proper distance or are they too close or too distant?

   _____

   _____

8. Was the range of motion within the exergames adequate for you? Could you catch/drag/hit the elements as provided by the exergames?

   _____

   _____

9. Was the written text in your opinion clearly visible or did it seem blurry in parts?

   _____

   _____

10. Was the bar placed at the correct distance and height to select buttons with hands?

    _____

    _____

11. Could you please rank your just completed experience with the headset using at most three adjectives?

    _____

7.13 Case Report Form for the trial participant

RecoveryFun

An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors

RECRUITMENT PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Fugl-Meyer

A. UPPER EXTREMITY, sitting position					
I. Reflex activity			**none**	**can be elicited**	
Flexors: biceps and finger flexors (at least one) **Extensors**: triceps			0 0	2 2	
Subtotal I (max 4)					
II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). **Extensor synergy:** Hand from ipsilateral ear to the contralateral knee	Shoulder Elbow Forearm	retraction elevation abduction (90°) external rotation flexion supination	0 0 0 0 0 0	1 1 1 1 1 1	2 2 2 2 2 2
	Shoulder Elbow Forearm	adduction/internal rotation extension pronation	0 0 0	1 1 1	2 2 2
Subtotal II (max 18)					
III. Volitional movement mixing synergies, without compensation			**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)		0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion		0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position		0	1	2
Subtotal III (max 6)					
IV. Volitional movement with little or no synergy			**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm neutral	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation		0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion		0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position		0	1	2
Subtotal IV (max 6)					
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side			**hyper**	**lively**	**normal**
Biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total A (max 36)					

B. WRIST support may be provided at the elbow to take or hold the starting position, no support at wrist, check the passive range of motion prior testing		none	partial	full
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction elbow at 90°, forearm pronated shoulder at 0°	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
Total B (max 10)				

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. Hook grasp flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. Thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. Pincer grasp, opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. Cylinder grasp cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. Spherical grasp fingers in abduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
Total C (max 14)				

D. COORDINATION/SPEED, sitting, after one trial with both arms, eyes closed, tip of the index finger from knee to nose, 5 times as fast as possible		marked	slight	none
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	**2 - 5s**	**< 2s**
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
Total D (max 6)				

Total A-D (max 66)	

H. SENSATION, upper extremity eyes closed, compared with the unaffected side		**anesthesia**	**hypoesthesia or dysesthesia**	**normal**
Light touch	upper arm, forearm palmary surface of the hand	0 0	1 1	2 2
		less than 3/4 correct or absence	**3/4 correct or considerable difference**	**correct 100%, little or no difference**
Position small alterations in the position	shoulder elbow wrist thumb (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

I. PASSIVE JOINT MOTION, upper extremity, sitting position, compare with the unaffected side				**J. JOINT PAIN** during passive motion, upper extremity		
	only few degrees (less than 10° in shoulder)	decreased	normal	pronounced pain during movement or very marked pain at the end of the movement	some pain	no pain
Shoulder						
Flexion (0° - 180°)	0	1	2	0	1	2
Abduction (0°-90°)	0	1	2	0	1	2
External rotation	0	1	2	0	1	2
Internal rotation	0	1	2	0	1	2
Elbow						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Forearm						
Pronation	0	1	2	0	1	2
Supination	0	1	2	0	1	2
Wrist						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Fingers						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Total (max 24)				**Total** (max 24)		

A. UPPER EXTREMITY	/36
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/ 6
TOTAL A-D (motor function)	/66

H. SENSATION	/12
I. PASSIVE JOINT MOTION	/24
J. JOINT PAIN	/24

Trunk Impairment Scale (TIS)

Item				
	Static sitting balance			
1	Starting position	Patient falls or cannot maintain starting position for 10 seconds without arm support	☐	0
		Patient can maintain starting position for 10 seconds		
		If score= 0, then TIS total score =0	☐	2
2	Starting position Therapist crosses the unaffected leg over the hemiplegic leg	Patient falls or cannot maintain sitting position for 10 seconds without arm support	☐	0
		Patient can maintain sitting position for 10 seconds	☐	2
3	Starting position Patient crosses the unaffected leg over the hemiplegic leg	Patient falls	☐	0
		Patient cannot cross the legs without arm support on bed or table	☐	1
		Patient crosses the legs but displaces the trunk more than 10 cm backwards or assists crossing with the hand	☐	2
		Patient crosses the legs without trunk displacement or assistance	☐	3
		Total static sitting balance		/ 7
	Dynamic sitting balance			
1	Starting position Patient is instructed to touch the bed or table with the hemiplegic elbow (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐	0
		Patient moves actively without help, elbow touches bed or table	☐	1
		If score =0, then items 2 and 3 score 0		
2	Repeat item 1	Patient demonstrates no or opposite shortening/ lengthening	☐	0
		Patient demonstrates appropriate shortening/lengthening	☐	1
		If score =0, then item 3 scores 0		
3	Repeat item 1	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet	☐	0
		Patient moves without compensation	☐	1
4	Starting position Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the	Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table	☐	0
		Patient moves actively without help, elbow touches bed or table	☐	1
		If score =0, then items 5 and 6 score 0		

	hemiplegic side) and return to the starting position			
5	Repeat item 4	Patient demonstrates no or opposite shortening/ lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 6 scores 0	☐ ☐	0 1
6	Repeat item 4	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet Patient moves without compensation	☐ ☐	0 1
7	Starting position Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient demonstrates no or opposite shortening /lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 8 scores 0	☐ ☐	0 1
8	Repeat item 7	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) Patient moves without compensation	☐ ☐	0 1
9	Starting position Patient is instructed to lift pelvis from bed or table at the unaffected side (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position	Patient demonstrates no or opposite shortening/ lengthening Patient demonstrates appropriate shortening/lengthening If score =0, then item 10 scores 0	☐ ☐	0 1
10	Repeat item 9	Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) Patient moves without compensation	☐ ☐	0 1
		Total dynamic sitting balance		/10
	Co-ordination			
1	Starting position Patient is instructed to rotate upper trunk 6 times (every shoulder should be moved	Hemiplegic side is not moved three times Rotation is asymmetrical Rotation is symmetrical If score =0, then item 2 scores 0	☐ ☐ ☐	0 1 2

	forward 3 times), first side that moves must be hemiplegic side, head should be fixated in starting position			
2	Repeat item 1 within 6 seconds	Rotation is asymmetrical	☐	0
		Rotation is symmetrical	☐	1
3	Starting position Patient is instructed to rotate lower trunk 6 times (every knee should be moved forward 3 times), first side that moves must be hemiplegic side, upper trunk should be fixated in starting position	Hemiplegic side is not moved three times	☐	0
		Rotation is asymmetrical	☐	1
		Rotation is symmetrical	☐	2
		If score =0, then item 4 scores 0		
4	Repeat item 3 within 6 seconds	Rotation is asymmetrical	☐	0
		Rotation is symmetrical	☐	1
		Total co-ordination		/6
		Total Trunk Impairment Scale		/23

MoCA – Montreal Cognitive Assessment

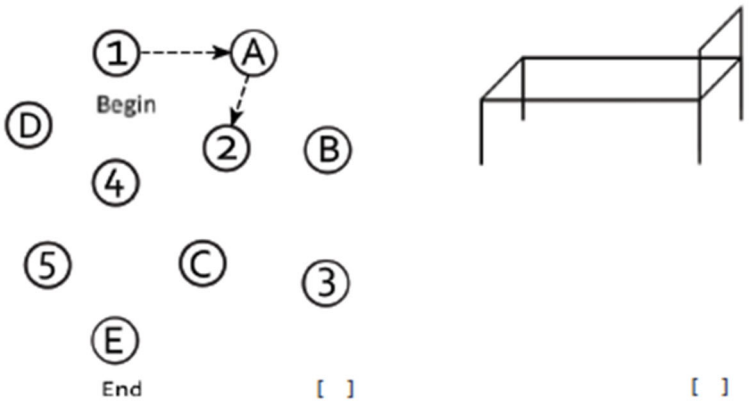
MONTREAL COGNITIVE ASSESSMENT (MoCA®)

Version 8.3 English

Name:
Education: Date of birth :
Sex: DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy bed



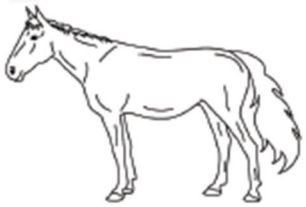
[ ] [ ]

Draw CLOCK (Five past ten)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING



[ ]

[ ]

[ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	LEG	COTTON	SCHOOL	TOMATO	WHITE
1st TRIAL					
2nd TRIAL					

NO POINTS

ATTENTION Read list of digits (1 digit/sec.).

Subject has to repeat them in the forward order. [ ] 2 4 8 1 5

Subject has to repeat them in the backward order. [ ] 4 2 7

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors.

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 60. [ ] 53 [ ] 46 [ ] 39 [ ] 32 [ ] 25

4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt

__/3

LANGUAGE Repeat: The child walked his dog in the park after midnight. [ ]

The artist finished his painting at the right moment for the exhibition. [ ]

__/2

Language Fluency. Name maximum number of words in one minute that begin with the letter B. [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] hammer - screwdriver [ ] matches - lamp

__/2

DELAYED RECALL — Memory Index Score (MIS)

(MIS)	Has to recall words	LEG	COTTON	SCHOOL	TOMATO	WHITE	Points for UNCUED recall only
X3	WITH NO CUE	[ ]	[ ]	[ ]	[ ]	[ ]	
X2	Category cue						MIS = ____/15
X1	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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MIS: /15
(Normal ≥ 26/30)

TOTAL __/30

Administered by: _____

Training and Certification are required to ensure accuracy.

Add 1 point if ≤ 12 yr education

BASELINE EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Socio-demographic characteristics

2. Date of birth _____/_____/_____
(dd /mm /yyyy)

4. Sex M ☐ 1 F ☐ 2 I prefer not to answer ☐ 3

5. Please specify what is your marital status at present:

Married (living with the spouse/wife)	☐ 1
Full time relationship	☐ 2
Separated (married, but living separately)	☐ 3
Divorced	☐ 4
Single	☐ 5
Widowed	☐ 6
Don't know	☐ 98
Refused	☐ 99

5. Can you indicate which of the following education level have you reached?

No education	☐ 0
Primary education	☐ 1
Secondary education	☐ 2
Tertiary education (university or further education level)	☐ 3
Don't know	☐ 98
Refused	☐ 99

7. Total years of education _____

8. Please indicate your present working situation (multiple answers possible):

6.1 Retired	☐ 1
6.2 Still working full time	☐ 1
6.3 Still working part time	☐ 1
6.4 Unemployed	☐ 1
6.5 Work inside the home	☐ 1
6.6 Don't know	☐ 98

6.7 Refused	☐99

8. What are your personal income sources? (multiple answers possible)

7.1 Work	☐ 1
7.2 Pension	☐ 1
7.3 Unearned income	☐ 1
7.4 Help from relatives	☐ 1
7.5 Welfare state provision	☐ 1
7.6 Other	☐ 1
7.7 Don't know	☐98
7.8 Refused	☐99

10. If "other", please specify _____

11. Who lives in your home with you? (multiple answers possible)

Category		**Code**	**Number of…**
9.11	No one	☐ 1	N.A.
9.12	Spouse/partner	☐ 1	N.A.
9.13	Sons and daughters	☐ 1	
9.14	Grandchildren	☐ 1	
9.15	Children's spouses	☐ 1	
9.16	Brothers/Sisters	☐ 1	
9.17	Mother/Father	☐ 1	
9.18	Paid caregiver (not relative)	☐ 1	
9.19	Others	☐ 1	
9.20	Refused	☐99	N.A.

(Note for the interviewer: Sign the exact number of people that live with the elder _____)

10. If "other", please specify _____

Subjective health assessment

1. Are you taking any medicine? 1 ☐ Yes 0 ☐ No

3. If yes,can you indicate the name, reason and frequency with which you take them?

Name of the medicine	Reason	Frequency

7. Do you use any walking aid? 1 ☐ Yes 0 ☐ No

8. If yes, which one? _____

9. Can you read a book, watch TV? 1 ☐ Yes 0 ☐ No

10. Can you follow a conversation, use the telephone (also with hearing aids)?

1 ☐ Yes 0 ☐ No

8. How do you rate your health at the moment?

Excellent □ 5	Good □ 4	Sufficient □ 3	Poor □ 2	Very poor □ 1

9. How do you rate your physical mobility at the moment?

Excellent□ 5	Good □ 4	Sufficient □ 3	Poor □ 2	Very poor □ 1

10. How do you rate your visual ability (ability to see in adequate light and with glasses, if used)?

Appropriate	*See details, including regular newspaper/book prints*	☐ 5
Compromised	*Sees large print, but not regular newspaper/book prints*	☐ 4
Moderately compromised	*Limited vision; cannot see headlines, but can identify objects*	☐ 3
Highly compromised	*Object identification in doubt, but the eyes seem to follow the objects*	☐ 2
Severely compromised	*Absence of vision or sees only light, colours or shapes; eyes do not seem to follow objects*	☐ 1
He/she does not know		☐ **98**
He/she refuses		☐ **99**

11. How do you rate your ability to hear (ability to hear with hearing aid, if used)?

He/she hears adequately	*Normal speech, the television, the telephone, the doorbell*	☐ 4

With little difficulty	*When he/she is not in a silent environment*	☐ 3
He/she only hears on special occasions	*The interlocutor has to adjust the volume of his voice and speak distinctly*	☐ 2
Highly compromised	*Lack of useful hearing*	☐ 1
He/she does not know		☐ **98**
He/she refuses		☐ **99**

Social support

1 Have you ever felt that you need help? Yes ☐ 1 No ☐ 0

2 Who do you usually ask for help when you need it?

No one	☐ 0
Spouse/partner	☐ 1
Son	☐ 2
Daughter	☐ 3
Grandchildren	☐ 4
Son in law	☐ 5
Daughter in law	☐ 6
Brother/Sister	☐ 7
Mother/Father	☐ 8
Paid caregiver (relative)	☐ 9
Paid caregiver (not relative)	☐ 10
Friend	☐ 11
Neighbour	☐ 12
Others	☐ 13
Don't know	☐ **98**
Refused	☐ **99**

3 If "other", please specify _____

4 Have you any relatives to ask for help with activities of daily life? Yes ☐ 1 No ☐ 0 (Go to quest 6)

5 How many? _____

6 Are you satisfied with the help you receive from your relative(s)?

Very satisfied	☐ 5
Satisfied	☐ 4
Neither satisfied nor dissatisfied	☐ 3
Dissatisfied	☐ 2
Very dissatisfied	☐ 1
Don't know	☐ **98**

Refused	☐ **99**

7 Have you any friends to ask for help with activities of daily life? Yes ☐ 1 No ☐ 0 (Go to quest 9)

8 How many? _____

9 Are you satisfied with the help you receive from your friend(s)?

Very satisfied	☐ 5
Satisfied	☐ 4
Neither satisfied nor dissatisfied	☐ 3
Dissatisfied	☐ 2
Very dissatisfied	☐ 1
Don't know	☐ **98**
Refused	☐ **99**

10 Have you any neighbours to ask for help with activities of daily life? Yes ☐ 1 No ☐ 0 (Go to quest 12)

11 How many? _____

12 Are you satisfied with the help you receive from your neighbour(s)?

Very satisfied	☐ 5
Satisfied	☐ 4
Neither satisfied nor dissatisfied	☐ 3
Dissatisfied	☐ 2
Very dissatisfied	☐ 1
Don't know	☐ **98**
Refused	☐ **99**

SURVEY OF TECHNOLOGY USE (MTP SOTU-C)

1. TECHNOLOGIES YOU FREQUENTLY USE:

List the technologies that you use most frequently (for example, personal computer, VCR, bank ATM, CD player, ...)

1. _____ 6. _____
2. _____ 7. _____
3. _____ 8. _____
4. _____ 9. _____
5. _____ 10. _____

Answer all the questions below by checking the option that most accurately applies to you. If you are uncertain about a response, check the neutral category.

2. OVERALL EXPERIENCES WITH CURRENT TECHNOLOGIES USED

Generally feel	***Neutral***	***Generally feel***
They are satisfying O	O	they are frustrating O
They help my creativity O	O	they interfere with my creativity O
They are encouraging O	O	they are discouraging O
They bring me together with people O	O	they separate me from people O
Thay raise my opinion of myself O	O	they lower my opinion of myself O

3. PERSPECTIVES ON TECHNOLOGIES

	Feel positive about	***Neutral***	***Feel negative about***
My childhood technology experiences	O	O	O
My technology experiences in school	O	O	O
My technology experiences at home	O	O	O
My most recent technology experiences	O	O	O

Generally feel	***Neutral***	***Generally feel***
I am comfortable with technology O	O	I am intimidated by technology O
I approach technology in a thinking way O	O	I approach technologies in a feeling way O
I feel good around technology O	O	I feel anxious around technology O
Other people encourage my technology use O	O	Other people discourage my technology use O

4. YOUR TYPICAL ACTIVITIES

Generally feel	*Neutral*	*Generally feel*
I prefer to be active O	O	I prefer passive activities O
I prefer group activities O	O	I prefer solitary activities O
My activities are satisfying O	O	My activities are frustrating O
I regularly seek fresh, new activities O	O	My activities have not changed in a long time O

5. SOME OF YOUR PERSONAL/SOCIAL CHARTERISTIC

Generally feel	*Neutral*	*Generally feel*
Composed/ calm O	O	Anxious O
Happy O	O	Depressed O
Tolerant O	O	Angry or frustrated O
Positive in outgoing O	O	Negative in outlook O
Expressive/outgoing O	O	Quiet/withdrawn O
Patient O	O	Impatient O
Motivated O	O	Unmotivated O
Persevering O	O	Easily discouraged O

Generally feel	*Neutral*	*Generally feel*
I am THINKING person O	O	I am FEELING person O
I frequently interact with family/spouse O	O	I seldom interact with family/spouse O
I frequently interact with non-family/friends O	O	I seldom interact with non- family/friends O
I have a good sense of well-being O	O	I have a poor sense of well-being O
I am physically independent O	O	I am physically dependent O
I am emotionally independent O	O	I am emotionally dependent O

WHOQOL- BREF
(World Health Organization Quality Of Life)

Please read the question, assess your feelings, for the last two weeks, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Fairly Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the **last two weeks**.

		Not at all	A Small amount	A Moderate amount	A great deal	An Extreme amount
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5	How much do you enjoy life?	1	2	3	4	5
6	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
7	How well are you able to concentrate?	1	2	3	4	5
8	How safe do you feel in your daily life?	1	2	3	4	5
9	How healthy is your physical environment?	1	2	3	4	5

		Not at all	Slightly	Somewhat	To a great extent	Completely
10	Do you have enough energy for everyday life?	1	2	3	4	5
11	Are you able to accept your bodily appearance?	1	2	3	4	5
12	Have you enough money to meet your needs?	1	2	3	4	5
13	How available to you is the information you need in your daily life?	1	2	3	4	5
14	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
15	How well are you able to get around physically?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the over the **last two weeks**.

		Very Dissatisfied	Fairly Dissatisfied	Neither Satified nor Dissatisfied	Satisfied	Very satisfied
16	How satisfied are you with your sleep?	1	2	3	4	5
17	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18	How satisfied are you with your capacity for work	1	2	3	4	5
19	How satisfied are you with yourself?	1	2	3	4	5
20	How satisfied are you with your personal relationships?	1	2	3	4	5

21	How satisfied are you with your sex life?	1	2	3	4	5
22	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24	How satisfied are you with your access to health services?	1	2	3	4	5
25	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the **last two weeks.**

		Never	Infrequently	Sometimes	Frequently	Always
26	How often do you have negative feelings such as blue mood, despair, anxiety or depression?	1	2	3	4	5

Goal Attainment Scale (GAS)

Identify the goals

Patient goals for treatment are:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

Goal	At baseline	Expected outcome
1.		
2.		
3.		
4.		
5.		
6.		

Weight the goals

Goal	Importance	Difficulty	Weight (I x D)	Baseline score
1.				
2.				
3.				
4.				
5.				
6.				
			Sum=	

FINAL EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Fugl-Meyer

A. UPPER EXTREMITY, sitting position					
I. Reflex activity			**none**	**can be elicited**	
Flexors: biceps and finger flexors (at least one) **Extensors**: triceps			0 0	2 2	
Subtotal I (max 4)					
II. Volitional movement within synergies, without gravitational help			**none**	**partial**	**full**
Flexor synergy: Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). **Extensor synergy:** Hand from ipsilateral ear to the contralateral knee	Shoulder Elbow Forearm	retraction elevation abduction (90°) external rotation flexion supination	0 0 0 0 0 0	1 1 1 1 1 1	2 2 2 2 2 2
	Shoulder Elbow Forearm	adduction/internal rotation extension pronation	0 0 0	1 1 1	2 2 2
Subtotal II (max 18)					
III. Volitional movement mixing synergies, without compensation			**none**	**partial**	**full**
Hand to lumbar spine hand on lap	cannot perform or hand in front of ant-sup iliac spine hand behind ant-sup iliac spine (without compensation) hand to lumbar spine (without compensation)		0	1	2
Shoulder flexion 0°- 90° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion		0	1	2
Pronation-supination elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position		0	1	2
Subtotal III (max 6)					
IV. Volitional movement with little or no synergy			**none**	**partial**	**full**
Shoulder abduction 0 - 90° elbow at 0° forearm neutral	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation		0	1	2
Shoulder flexion 90° - 180° elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion		0	1	2
Pronation/supination elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position		0	1	2
Subtotal IV (max 6)					
V. Normal reflex activity assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side			**hyper**	**lively**	**normal**
Biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive		0	1	2
Subtotal V (max 2)					
Total A (max 36)					

B. WRIST support may be provided at the elbow to take or hold the starting position, no support at wrist, check the passive range of motion prior testing		none	partial	full
Stability at 15° dorsiflexion elbow at 90°, forearm pronated shoulder at 0°	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 90°, forearm pronated shoulder at 0°, slight finger flexion	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Stability at 15° dorsiflexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	less than 15° active dorsiflexion dorsiflexion 15°, no resistance tolerated maintains dorsiflexion against resistance	0	1	2
Repeated dorsifexion / volar flexion elbow at 0°, forearm pronated slight shoulder flexion/abduction	cannot perform volitionally limited active range of motion full active range of motion, smoothly	0	1	2
Circumduction elbow at 90°, forearm pronated shoulder at 0°	cannot perform volitionally jerky movement or incomplete complete and smooth circumduction	0	1	2
Total B (max 10)				

C. HAND support may be provided at the elbow to keep 90° flexion, no support at the wrist, compare with unaffected hand, the objects are interposed, active grasp		none	partial	full
Mass flexion from full active or passive extension		0	1	2
Mass extension from full active or passive flexion		0	1	2
GRASP				
a. Hook grasp flexion in PIP and DIP (digits II-V), extension in MCP II-V	cannot be performed can hold position but weak maintains position against resistance	0	1	2
b. Thumb adduction 1-st CMC, MCP, IP at 0°, scrap of paper between thumb and 2-nd MCP joint	cannot be performed can hold paper but not against tug can hold paper against a tug	0	1	2
c. Pincer grasp, opposition pulpa of the thumb against the pulpa of 2-nd finger, pencil, tug upward	cannot be performed can hold pencil but not against tug can hold pencil against a tug	0	1	2
d. Cylinder grasp cylinder shaped object (small can) tug upward, opposition of thumb and fingers	cannot be performed can hold cylinder but not against tug can hold cylinder against a tug	0	1	2
e. Spherical grasp fingers in abduction/flexion, thumb opposed, tennis ball, tug away	cannot be performed can hold ball but not against tug can hold ball against a tug	0	1	2
Total C (max 14)				

D. COORDINATION/SPEED, sitting, after one trial with both arms, eyes closed, tip of the index finger from knee to nose, 5 times as fast as possible		marked	slight	none
Tremor		0	1	2
Dysmetria	pronounced or unsystematic slight and systematic no dysmetria	0	1	2
		≥ 6s	**2 - 5s**	**< 2s**
Time start and end with the hand on the knee	6 or more seconds slower than unaffected side 2-5 seconds slower than unaffected side less than 2 seconds difference	0	1	2
Total D (max 6)				

Total A-D (max 66)	

H. SENSATION, upper extremity eyes closed, compared with the unaffected side		**anesthesia**	**hypoesthesia or dysesthesia**	**normal**
Light touch	upper arm, forearm palmary surface of the hand	0 0	1 1	2 2
		less than 3/4 correct or absence	**3/4 correct or considerable difference**	**correct 100%, little or no difference**
Position small alterations in the position	shoulder elbow wrist thumb (IP-joint)	0 0 0 0	1 1 1 1	2 2 2 2
			Total H (max12)	

I. PASSIVE JOINT MOTION, upper extremity, sitting position, compare with the unaffected side				**J. JOINT PAIN** during passive motion, upper extremity		
	only few degrees (less than 10° in shoulder)	decreased	normal	pronounced pain during movement or very marked pain at the end of the movement	some pain	no pain
Shoulder						
Flexion (0° - 180°)	0	1	2	0	1	2
Abduction (0°-90°)	0	1	2	0	1	2
External rotation	0	1	2	0	1	2
Internal rotation	0	1	2	0	1	2
Elbow						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Forearm						
Pronation	0	1	2	0	1	2
Supination	0	1	2	0	1	2
Wrist						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Fingers						
Flexion	0	1	2	0	1	2
Extension	0	1	2	0	1	2
Total (max 24)				**Total** (max 24)		

A. UPPER EXTREMITY	/36
B. WRIST	/10
C. HAND	/14
D. COORDINATION / SPEED	/ 6
TOTAL A-D (motor function)	/66

H. SENSATION	/12
I. PASSIVE JOINT MOTION	/24
J. JOINT PAIN	/24

WHOQOL- BREF
(World Health Organization Quality Of Life)

Please read the question, assess your feelings, for the last two weeks, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Fairly Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the **last two weeks**.

		Not at all	A Small amount	A Moderate amount	A great deal	An Extreme amount
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5	How much do you enjoy life?	1	2	3	4	5
6	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
7	How well are you able to concentrate?	1	2	3	4	5
8	How safe do you feel in your daily life?	1	2	3	4	5
9	How healthy is your physical environment?	1	2	3	4	5

		Not at all	Slightly	Somewhat	To a great extent	Completely
10	Do you have enough energy for everyday life?	1	2	3	4	5
11	Are you able to accept your bodily appearance?	1	2	3	4	5
12	Have you enough money to meet your needs?	1	2	3	4	5
13	How available to you is the information you need in your daily life?	1	2	3	4	5
14	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
15	How well are you able to get around physically?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the over the **last two weeks.**

		Very Dissatisfied	Fairly Dissatisfied	Neither Satified nor Dissatisfied	Satisfied	Very satisfied
16	How satisfied are you with your sleep?	1	2	3	4	5
17	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18	How satisfied are you with your capacity for work	1	2	3	4	5
19	How satisfied are you with yourself?	1	2	3	4	5
20	How satisfied are you with your personal relationships?	1	2	3	4	5

21	How satisfied are you with your sex life?	1	2	3	4	5
22	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24	How satisfied are you with your access to health services?	1	2	3	4	5
25	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the **last two weeks**.

		Never	Infrequently	Sometimes	Frequently	Always
26	How often do you have negative feelings such as blue mood, despair, anxiety or depression?	1	2	3	4	5

QUEST

(Quebec User Evaluation of Satisfaction with Assistive Technology)

For each of the 12 items, rate your satisfaction with the assistive devices you experienced by using the following scale of 1 to 5.

1 = not satisfied at all 2 = not very satisfied 3 = more *or* less satisfied 4 = quite satisfied 5 = very satisfied

ASSISTIVE DEVICE: *How satisfied are you with…*	1	2	3	4	5
3. the dimensions (size, height, length, width) of your assistive device? 1.1 Headset 1.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
4. the weight of your assistive device? 2.1 Headset 2.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
4. the ease in adjusting (fixing, fastening) the parts of your assistive device? 3.1 Headset 3.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
5. how safe and secure your assistive device is? 4.1 Headset 4.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
6. the durability (endurance, resistance to wear) of your assisitive device? 5.1 Headset 5.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
7. how easy it is to use your assistive device? 6.1 Headset 6.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
8. how comfortable your assistive device is? 7.1 Headset 7.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐
9. how effective your assistive device is (the degree to which your device meets your needs)? 8.1 Headset 8.2 Wearable sensor	☐ ☐	☐ ☐	☐ ☐	☐ ☐	☐ ☐

TOTAL

Headset _____ / 40

Wearable sensor _____ / 40

Below is the list of the same satisfaction items. Please select the **three items** that you consider to be the most important to you. Please put an X in the 3 boxes of your choice for headset/viewer and wearable sensor:

Headset	9.1 dimensions	☐ 1	9.5 durability	☐ 1
	9.2 weight	☐ 1	9.6 easy to use	☐ 1
	9.3 adjustments	☐ 1	9.7 comfort	☐ 1
	9.4 safety	☐ 1	9.8 effectiveness	☐ 1

Wearable sensor	10.1 dimensions	☐ 1	10.5 durability	☐ 1
	10.2 weight	☐ 1	10.6 easy to use	☐ 1
	10.3 adjustments	☐ 1	10.7 comfort	☐ 1
	10.4 safety	☐ 1	10.8 effectiveness	☐ 1

Goal Attainment Scale (GAS)

Goal	Importance	Difficulty	Weight (I x D)	Baseline score	Outcome score
1.					
2.					
3.					
4.					
5.					
6.					
			Sum=		

	Achieved outcome
1.	
2.	
3.	
4.	
5.	
6.	

SUS – System Usability Scale

	1 Strongly disagree → 5 Strongly agree				
1. I think that I would like to use this system frequently	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. I found the system unnecessarily complex	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. I thought the system was easy to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.I think that I would need the support of a technical person to be able to use this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. I found the various functions in the system were well integrated	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. I thought there was too much inconsistency in this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. I would imagine that most people would learn to use the system very quickly	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. I found the system very cumbersome to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. I felt very confident 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

User Experience Questionnaire (UEQ)

Please assess the product now by ticking one circle per line.

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26

DEMAND AND COST INFORMATION

1. Would you say that the system has been:

Extremely useful/helpful	☐ 4
Fairly useful/helpful	☐ 3
Only slightly useful/helpful	☐ 2
Not all at useful	☐ 1
Not applicable	☐ 97
Don't know	☐ 98
Refused	☐ 99

2. What would help you most to decide whether to use or not a home rehabilitation system?

Trying out the device myself	☐ 1
Having a recommendation from a friend or family member	☐ 2
Seeing someone demonstrate the use of the device	☐ 3
Having a recommendation from my physician or other trusted health care worker	☐ 4
Other	☐ 5
Don't know	☐ 98
Refused	☐ 99

3. If "other", please specify _____

4. Rate the following factors in terms of their importance when you think about whether or not to use a home rehabilitation system.

   Rate your opinion using a scale from **1 = Not important at all** to **5 = Very important**.

Factor	1	2	3	4	5	DK 98	Ref. 99
4.1 State of my health	☐	☐	☐	☐	☐	☐	☐
4.2 Ease of use	☐	☐	☐	☐	☐	☐	☐
4.3 Cost	☐	☐	☐	☐	☐	☐	☐
4.4 Level of comfort with technology	☐	☐	☐	☐	☐	☐	☐
4.5 Perceived value	☐	☐	☐	☐	☐	☐	☐
4.6 Whether insurance scheme will pay for part or all of the cost	☐	☐	☐	☐	☐	☐	☐
4.7 Aesthetic appearance of the device	☐	☐	☐	☐	☐	☐	☐
4.8 Easy to buy/availability	☐	☐	☐	☐	☐	☐	☐
4.9 Recommendation from my physician	☐	☐	☐	☐	☐	☐	☐
4.10 How much support I receive from caregivers	☐	☐	☐	☐	☐	☐	☐
4.11 Other	☐	☐	☐	☐	☐	☐	☐

5. If “other”, please specify _____

7.14 Case Report Form for the informal Caregiver

RecoveryFun

An integrated VR-based tele-rehabilitation platform to support RECOVERY and maintenance of FUNctional abilities among seniors

CAREGIVER BASELINE EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

Socio-demographic characteristics

3. Date of birth _____/_____/_____
(dd /mm /yyyy)

6. Sex M ☐ 1 F ☐ 2 I prefer not to answer ☐ 3

7. Please specify what is your marital status at present:

Married (living with the spouse/wife)	☐ 1
Full time relationship	☐ 2
Separated (married, but living separately)	☐ 3
Divorced	☐ 4
Single	☐ 5
Widowed	☐ 6
Don't know	☐ 98
Refused	☐ 99

6. Can you indicate which of the following education level have you reached?

No education	☐ 0
Primary education	☐ 1
Secondary education	☐ 2
Tertiary education (university or further education level)	☐ 3
Don't know	☐ 98
Refused	☐ 99

9. Total years of education _____

10. Please indicate your present working situation (multiple answers possible):

6.1 Retired	☐ 1
6.2 Still working full time	☐ 1
6.3 Still working part time	☐ 1
6.4 Unemployed	☐ 1
6.5 Work inside the home	☐ 1
6.6 Don't know	☐ 98

6.7 Refused	☐99

9. What relationship do you have with the person you are assisting/supporting in the rehabilitation process?

7.1 Friend	☐ 1
7.2 Spouse/partner	☐ 1
7.3 Brothers/sisters	☐ 1
7.4 Mother/Father	☐ 1
7.5 Others	☐ 1
7.6 Refused	☐ 99

12. If “other”, please specify _____

SURVEY OF TECHNOLOGY USE (MTP SOTU-C)

1. TECHNOLOGIES YOU FREQUENTLY USE:

List the technologies that you use most frequently (for example, personal computer, VCR, bank ATM, CD player, ...)

1. _____ 6. _____
2. _____ 7. _____
3. _____ 8. _____
4. _____ 9. _____
5. _____ 10. _____

Answer all the questions below by checking the option that most accurately applies to you. If you are uncertain about a response, check the neutral category.

2. OVERALL EXPERIENCES WITH CURRENT TECHNOLOGIES USED

Generally feel	***Neutral***	***Generally feel***
They are satisfying O	O	they are frustrating O
They help my creativity O	O	they interfere with my creativity O
They are encouraging O	O	they are discouraging O
They bring me together with people O	O	they separate me from people O
Thay raise my opinion of myself O	O	they lower my opinion of myself O

3. PERSPECTIVES ON TECHNOLOGIES

	Feel positive about	***Neutral***	***Feel negative about***
My childhood technology experiences	O	O	O
My technology experiences in school	O	O	O
My technology experiences at home	O	O	O
My most recent technology experiences	O	O	O

Generally feel	***Neutral***	***Generally feel***
I am comfortable with technology O	O	I am intimidated by technology O
I approach technology in a thinking way O	O	I approach technologies in a feeling way O
I feel good around technology O	O	I feel anxious around technology O
Other people encourage my technology use O	O	Other people discourage my technology use O

4. YOUR TYPICAL ACTIVITIES

Generally feel	*Neutral*	*Generally feel*
I prefer to be active O	O	I prefer passive activities O
I prefer group activities O	O	I prefer solitary activities O
My activities are satisfying O	O	My activities are frustrating O
I regularly seek fresh, new activities O	O	My activities have not changed in a long time O

5. SOME OF YOUR PERSONAL/SOCIAL CHARTERISTIC

Generally feel	*Neutral*	*Generally feel*
Composed/ calm O	O	Anxious O
Happy O	O	Depressed O
Tolerant O	O	Angry or frustrated O
Positive in outgoing O	O	Negative in outlook O
Expressive/outgoing O	O	Quiet/withdrawn O
Patient O	O	Impatient O
Motivated O	O	Unmotivated O
Persevering O	O	Easily discouraged O

Generally feel	*Neutral*	*Generally feel*
I am THINKING person O	O	I am FEELING person O
I frequently interact with family/spouse O	O	I seldom interact with family/spouse O
I frequently interact with non-family/friends O	O	I seldom interact with non- family/friends O
I have a good sense of well-being O	O	I have a poor sense of well-being O
I am physically independent O	O	I am physically dependent O
I am emotionally independent O	O	I am emotionally dependent O

PERCEIVED STRESS SCALE

The questions in this scale ask you about your feelings and thoughts during the last month.
In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?.....	**0 1 2 3 4**
2. In the last month, how often have you felt that you were unable to control the important things in your life?.....	**0 1 2 3 4**
3. In the last month, how often have you felt nervous and “stressed”?.....	**0 1 2 3 4**
4. In the last month, how often have you felt confident about your ability to handle your personal problems?.....	**0 1 2 3 4**
5. In the last month, how often have you felt that things were going your way?.....	**0 1 2 3 4**
6. In the last month, how often have you found that you could not cope with all the things that you had to do?.....	**0 1 2 3 4**
7. In the last month, how often have you been able to control irritations in your life?.....	**0 1 2 3 4**
8. In the last month, how often have you felt that you were on top of things?.....	**0 1 2 3 4**
9. In the last month, how often have you been angered because of things that were outside of your control?.....	**0 1 2 3 4**
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?.....	**0 1 2 3 4**

CAREGIVER FINAL EVALUATION PROTOCOL

Subject Identification code: ___/___/___

Date of compilation: _____/_____/_____

Country of compilation: _____

Name of the interviewer: _____

SUS – System Usability Scale

	1 Strongly disagree → 5 Strongly agree				
1. I think that I would like to use this system frequently	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. I found the system unnecessarily complex	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. I thought the system was easy to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.I think that I would need the support of a technical person to be able to use this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. I found the various functions in the system were well integrated	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. I thought there was too much inconsistency in this system	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. I would imagine that most people would learn to use the system very quickly	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. I found the system very cumbersome to use	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. I felt very confident 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

PERCEIVED STRESS SCALE

The questions in this scale ask you about your feelings and thoughts during the last month.
In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?.....	**0 1 2 3 4**
2. In the last month, how often have you felt that you were unable to control the important things in your life?.....	**0 1 2 3 4**
3. In the last month, how often have you felt nervous and “stressed”?.....	**0 1 2 3 4**
4. In the last month, how often have you felt confident about your ability to handle your personal problems?.....	**0 1 2 3 4**
5. In the last month, how often have you felt that things were going your way?.....	**0 1 2 3 4**
6. In the last month, how often have you found that you could not cope with all the things that you had to do?.....	**0 1 2 3 4**
7. In the last month, how often have you been able to control irritations in your life?.....	**0 1 2 3 4**
8. In the last month, how often have you felt that you were on top of things?.....	**0 1 2 3 4**
9. In the last month, how often have you been angered because of things that were outside of your control?.....	**0 1 2 3 4**
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?.....	**0 1 2 3 4**

Impact of the system

1. How often did you use the caregiver app?

☐ 1 Never
☐ 2 Rarely
☐ 3 Sometimes
☐ 4 Quite Frequently
☐ 5 Nearly Always

2. In your opinion, how helpful was the caregiver application in your relative's home rehabilitation process?

☐ 1 Not important
☐ 2 Somewhat unimportant
☐ 3 Neutral
☐ 4 Somewhat important
☐ 5 Very important

3. In your opinion the system for the person you are assisting was:

Extremely useful/helpful	☐ 4
Fairly useful/helpful	☐ 3
Only slightly useful/helpful	☐ 2
Not useful at all	☐ 1
Don't know	☐ 98
Refused	☐ 99

4. In your perspective and considering the supporting role you played during the rehabilitation process, did the use of the system relieve you from burdens you had during classical rehabilitation (without the use of the system), or on the contrary was it an additional extra burden? Why?

_____
_____
_____
_____

5. Do you prefer classical rehabilitation, or do you agree in integrating classical rehabilitation with home telerehabilitation systems such as RecoveryFun? Why?

_____

_____

_____

_____

6. In the current situation where telerehabilitation is only partially reimbursed do you think it could be valuable to pay for the use of this system?

Yes ☐ 1 No ☐ 0

7. If you agreed to pay for the use of the system, what additional amount would be reasonable to pay monthly (in euros) to use this service, in your opinion?

I would not be willing to pay additional amounts for such system	☐ 0
50-100	☐ 1
100-150	☐ 2
150-200	☐ 3
200-250 250-300	☐ 4
300 or more	☐ 5
Don't know	☐98
Refused	☐99

8. Please indicate three positive aspects of the RecoveryFun system

_____

9. Please indicate three negative aspects of the RecoveryFun system

_____