# WeReha research protocol – CoRehab

**20th November 2018, Version 3.0**

# DISCLAIMER

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# Project summary

WeReha is an innovative device for the home rehabilitation of stroke patients developed within the scope of the EU funded project MAGIC-PCP [5]. WeReha is a system that allows patients to perform exercises in a home environment with remote supervision integrated within regular rehabilitation. The principle on which the product is based is that of biofeedback guided rehabilitation, designed to stimulate muscle recovery and contribute to a more effective and more motivating rehabilitation of neuro-motor patterns. WeReha is completely adaptable, allowing only authorized to assign exercises, by planning specific sequences of movements.

WeReha product is composed by the following elements:

- a tablet with a proprietary application on it (the “WeReha app”)
- an inertial sensor with accelerometers, gyroscopes and magnetometers (the “sensor”)
- elastic straps allowing the user to wear it on different parts of the body (the “straps”)
- a series of 3D printed objects where the sensor can be placed that become animated (the “smart objects”)
- a web portal for clinical staff through which they can manage and monitor users (the “web-application”)

The WeReha app presents the patient with a series of rehabilitation exercises in the form of a number of interactive games, driven by body movement, which is captured by the sensor or the hand specific movements using the smart objects. A session with WeReha always starts with a questionnaire on the system, through which the software gains an understanding of the patient’s health conditions and the presence or not of a caregiver for the session. Based on this questionnaire, the software adapts the daily session to minimise risks while maintaining a high level of rehabilitation to help the patient reach their goals. The device works with and without an internet connection, but when the device is connected to the internet, supervisors are able to provide supervision and remote support through a web application.

The web application is hosted on a dedicated server located inside the hospital. Only trained staff will be provided with access to the web application with a unique username and password required for sign on. The exercises assigned for the client to perform at home, are at the discretion of the clinician who is caring for the patient and might require the presence of a caregiver.

The goal of this study is to investigate the applicability and utility of an innovative technology product such as WeReha to the home rehabilitation of stroke patients as an integrative solution to

a conventional exercise program and to assess its acceptance by the patient, caregivers and clinic professionals.

Patients will use WeReha for their home rehabilitation in addition to traditional treatments for up to 12 weeks. The Inclusion criteria for the study have been kept broad in order to assess these factors on a large enough scale, so as not to limit the usage of the device to a specific sub-group of patients. If patients enrolled are in a subacute phase (i.e. within the first 6 months after the stroke onset), they will be enrolled before leaving the hospital or the rehabilitation department and reaching their home. If patients are considered to be in their chronic phase (i.e. over 6 months after stroke onset), they will be enrolled during an outpatient treatment or on a volunteer basis.

Before starting the trial with WeReha, every patient enrolled will receive proper training from a person dedicated to the project (who will be referred to as the “dedicated figure”) appointed by the hospital and financially supported by the sponsor of the study.

## General information

- WeReha - Wearable Rehabilitation for stroke patients
- CoRehab srl, via Klagenfurt 63, 38121, Trento
- David Tacconi, CIO, david@corehab.com, +39 347 8683464
- Belfast HSC Trust and South Eastern HSC Trust are the two sites where recruitment will take place in Northern Ireland

  CoRehab is the study sponsor

## Rationale & background information

Stroke is one of the largest causes of adult disability in the world. Every year it is estimated that approximately 15 million people worldwide suffer a stroke; of these, 5 million die and another 5 million are left permanently disabled, placing a burden on families and communities. Around 20% of stroke survivors are under the age of 65 and hence are still a productive working age [1].

Rehabilitation is one of the most important aspects of care for patients following a stroke and is proven to affect the eventual level of recovery and independence achieved. Community stroke services that provide rehabilitation exist in the study region, and are able to provide support, lifestyle advice and risk factor assessment. Charitable organisation often provides a range of valued support services for stroke patients and their caregivers in the community. When patients leave the hospital quickly after stroke to receive intensive rehabilitation in their home environment it is called ‘Early Supported Discharge’ (ESD). This is usually for people who have milder disabilities after stroke and are able to move about unaided or with minimal help.

There is evidence to suggest the quality of care and outcomes for patients who have sustained a stroke may be improved by an increase in the amount of therapy patients receive. Very often, additional therapy is warranted and needed after 12 weeks and after the standard six month review. It is difficult for patients to access additional therapy services mostly due to cost. Community Stroke services are not widely available nor is it affordable to provide the services needed for many patients. Additionally, the staff needed to provide the services needed, are unavailable and unsustainable [3]. For example, UK service standards indicate that patients referred to community stroke teams should be reviewed between one and three days after hospital discharge. However, the 2015 Post- acute Stroke National Audit found that patients in Northern Ireland may wait up to 5 days after discharge before contact is made by a community stroke team. The rising cost of care, rehabilitation and fiscal constraint create a real risk of a continuing shortfall in therapy provision, thus failing to optimise personal independence for stroke patients. If personal independence is not optimised for stroke patients there is both a detriment to the individual and to society through the economic cost of providing long-term care and support. As a consequence, a project such as WeReha is of critical importance to the healthcare system and the economic implications of the current trend. Testing alternative cost effective methods of optimising recovery and Human Resources are of utmost urgency.

It is widely accepted that timely access to rehabilitation is a key factor in the recovery for people who have survived a stroke. Therapy-based rehabilitation appears to improve independence in personal activities of daily living according to evidence based guidelines [4]. The use of self-management approaches to help patients and caregivers better manage the life-changing impacts of stroke presents an opportunity to improve patient care in a cost effective way [9]. WeReha has been developed to be a cost-effective and accessible system for the greatest possible number of service providers and patients. We recognize that an innovative use of technology may enable providers of stroke services to realistically meet the growing demographic demands on their services and facilitate acceptable or improved care outcomes for stroke patients in Europe.

For these reasons, there is significant benefit in using a solution such as WeReha to enhance the cost-effective provision of rehabilitation for this patient population.

By applying innovative ideas and re-engineering care delivery systems with new solutions such as WeReha, it becomes possible to consider real technological solutions for stroke rehabilitation and the improvement of the well-being of these patients across Europe. WeReha, within the scope of the Magic project [5] seeks to achieve this specifically by optimising the recovery of physical function and personal independence in order to reduce the overall socioeconomic burden of this disease.

Many stroke survivors suffer postural and balance problems, in addition to hand motor problems as well as other physical challenges. Decreased mobility limits daily life activities and therefore should be a focus for society by increasing movement leading to overall improvement. Virtual reality and biofeedback balance training has already been used in stroke rehabilitation, and previous studies have shown that such technology could improve balance ability ([13, 28]). The

mechanism we want to use even in WeReha is multi-sensory feedback with repeated practices that could facilitate motor learning and brain neuroplasticity.

Compared to conventional rehabilitation, WeReha could also increase subjects' motivation and satisfaction. It is the goal of this study to assess at scale the possible impact of a technology such as WeReha.

A study conducted by the Magic PCP buyers group [5] revealed several important factors for stroke survivors and their caregivers. Stroke patients emphasised that the needs of stroke survivors are not static - they evolve over time - and thus any potential solution should be designed to take this into account. In addition, consultation with a range of stakeholders (clinicians, therapists, patients, families and caregivers) about potential innovative solutions that might improve physical function and personal independence, in the first six months of stroke onset and long term thereafter, highlighted a technology that could provide a range of adjunct solutions to the care process.

Several studies have been conducted where a technology is involved for the care of stroke survivors. Most of them, including control groups, rated the experience as more pleasurable, enjoyable and beneficial ([28], [14]) than the conventional therapy, making the patient more motivated to train.

Türkbey and Kutlay [14] reported a treatment attendance ratio for total training time and training time/session equal to 87% and 90%, respectively; Wittman et al [15] reported that the weekly training did not change over the course of the intervention. Furthermore this positive approach to the technology seems to stimulate a greater daily motor activity (i.e. steps/day) beyond the training sessions [24], [26] with a great gain in quality of life. In addition, the literature reports significant evidence of improvements in functional abilities of stroke patients after a training period with technological devices ([9], [13], [14], [15], [23], [24], [25], [26], [27] [28], [29], [30]). There are also several studies and trials investigating the use of technology in a home environments for stroke survivors to treat upper extremities ([17], [18], [21]) in general for tele-rehabilitation services ([16], [20]) or cognitive treatments [22], but results have been either not presented or shown to be not significant.

Considering the results already obtained in evaluating the clinical efficacy of a technology applied to home-rehabilitation of stroke patients, our clinical trial is primarily designed to analyse the effects of WeReha on a sample of stroke patients, in terms of validity and acceptance by patients, professionals and caregivers.

Though the usage of a technology to improve home rehabilitation is generally assumed to be a factor for improvement in hospitals and community both economically and logistically, no large scale studies have been conducted, so far, to analyse the impact of technology in the process of stroke rehabilitation. Through this study we aim to evaluate the impact of our technology with outcomes dedicated to assess patient’s involvement, acceptance, satisfaction and improvement.

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## Study goals and objectives

The goal of this study is to assess the acceptance and validity of a new technology such as WeReha for home rehabilitation of patients following a stroke episode either in sub-acute or chronic phase. The investigation will be conducted in two different countries: two sites in Northern Ireland and one in Italy.

This study is part of the EU funded Magic PCP project [5], where three different companies will perform similar types of study. Every company will be assigned from September 2018 a trust in Northern Ireland and a site in Italy from among the following: Hospital Le Torrette, Ancona, University D'Annunzio, Chieti, ASL3 Pinerolo, Torino. Once a company has received approval for funds to perform the study (before September 2018), it will also be assigned the site in Italy and then it will apply for the Ethical Committee of that site. Every company is also required by the Magic PCP project [5] to provide 75 devices per country (150 in total). From now on, we will refer to the number of patients relevant to the Northern Irish site..

Let us define the terms and list assumptions we will use throughout the protocol:

- "enrolled patient": a patient is considered enrolled in the study if they are within the inclusion criteria and voluntarily accept to participate and sign the consent form

- "active week": a week in which the patient has performed at least three sessions with WeReha for a minimum of 15 minutes each (as measured by the software)

- "active patient": a patient that has used the device for at least 4 "active weeks"

- "maximum time frame of usage": 20 weeks, according to patients and clinicians feedback collected during our feasibility study (see Safety Consideration section)

- "end of usage": if the participant does not have four active weeks in the first eight weeks of usage or the patient has reached the "maximum time frame of usage" or the patient has voluntarily decided to interrupt the study (drop-off)

The study aims to evaluate as a primary outcome quantifiable measure, the acceptance of technology, through analysis of the following:

- number of enrolled patients at the end of the trial period will be evaluated in order to understand the degree of acceptance of a technology such as WeReha, with the minimum target of 50 patients.

- number of "active weeks" with the device among the patients enrolled

- average minutes of exercise per day conducted with the technology as an objective measure for activity participation

- acceptance of technology, based on the Technology Acceptance Model / TAM as in [11] and [33] provided to patients at the end of the study (see Annex B).

All previous measures will be evaluated in general and for 6 different age-gender groups (male and female below 55, between 55 and 70, above 70).

As secondary outcome measures we will assess objective scales and scores typical for stroke rehabilitation:

- the Barthel index (see [10], [19], [6], [8])
- the Modified Rankin Score (see [19], [30], [7], [8])
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These scores will be compared with standard values and the goal is to show equivalency or improvement from those standard values after the treatment with WeReha.

In addition, we want to demonstrate the logistical and economic benefits of the deployed solution. Dedicated figures (a nurse or physiotherapist hired to run the Clinical Trial research study as explained in the Methodology section) will objectively measure the time taken to training patients and caregivers before leaving the trial site with the device and the number of times patients contact the sponsor for technical assistance.

**Primary Outcome Measures:**

- Total number of patients enrolled -> KPI: minimum 50 patients enrolled;
- Total number of active patients -> KPI: minimum 40 active patients;
- Total number of patients who drop off, meaning that started the study and had less than 4 active weeks
- Average number of active weeks for each patient: the average number of active weeks is evaluated as the total number of active weeks divided by the number of patients enrolled -> KPI: 8 weeks (excluding drop off before 4 weeks)
- Activity participation, measured in average minutes per day dedicated to exercises with WeReha (measured during active weeks only) -> KPI: min. 45'/week
- Acceptance of the rehabilitation platform WeReha by the patient, evaluated through a questionnaire completed at the end of the study by every participant who consents to the study (see attachment … )
- Previous results will be analysed on different age/gender groups. Age groups are: <55, 55-70, 70-85 both for male and female, for a total of six groups. Target would be to enroll patients within these groups as homogeneously as possible, but since we cannot foresee patients distribution there are no KPIs set for this outcome

**Secondary Outcome Measures:**

- Barthel index and Modified Rankin Score: change from baseline (measured when receiving the device) at the end of the rehabilitation treatment (when returning the device)

- Time dedicated by the specialised personnel to each patient for training to learn the WeReha device before leaving the trial site (measured in minutes/patient)
- Number of calls per week for clinical and technical assistance specific for the WeReha device, registered on a paper or software spreadsheet by the sponsor

## Study Design

This is a pilot study to investigate acceptability of usage of technology to aid rehabilitation of post stroke patients at home. An innovative inertial sensor and interactive games based device, called WeReha, has been designed and developed to best meet the rehabilitation needs of stroke survivors... WeReha is composed of:

- i) an Android tablet running dedicated software
- ii) an inertial blue-tooth sensor with 3D accelerometer, 3D gyroscope and 3D magnetometer
- iii) a kit of elastic straps with a Velcro pocket to wear the sensor on specific body segments (chest, thigh, foot and wrist)
- iv) a kit of 3D printed plastic objects (a hourglass, a plate and a joystick) that become “smart” positioning tools through the use of sensors embedded inside them)

The WeReha software will present the patient with a series of rehabilitation exercises in the form of interactive games, using the worn sensor or the “smart objects”. All the games in WeReha are based on the tracking the three dimensional movements of body segments or the smart objects through the sensor applied to them. The exercises integrated in WeReha have been designed with physiotherapists and clinicians, and are akin to traditional rehabilitation following a stroke that can involve any of the lower limbs (hip, knee and ankle) the upper limb (shoulder, elbow and wrist), the head and the trunk. Some require a sitting position, others a standing position with or without a support, according to the ability of the patient and whether there is supervision or not.

During an exercise which requires the worn sensor, a specific elastic straps among those of the kit has to be used. Dependent on the specific exercise sequence that will be performed; at startup the patient will be guided by the software step by step to:

i) position the elastic strap around a specific body segment;

ii) ii) position the sensor inside the pocket;

iii) iii) Attach the pocket to the elastic strap. Particularly, the body segments involved in wearing the straps are the trunk, the thigh, the foot and the wrist, for balance, lower limb, foot-ankle and upper limbs exercises respectively.

A similar tutorial guides the patient on how to make the objects “smart” and thus trackable in the space and on how to use them correctly during games that simulate aspects of the real life. Specifically, the instructions provided include

i) what object to be used for the specific exercise;

ii) ii) how to position the sensor inside it,

iii) iii) how to move the object in order to reach the game’s target.

Once the sensor is worn or positioned inside an object, before starting the game, the patient is guided through a calibration phase to measure the sensors initial orientation in the space which acts as a reference position for all the movements recorded during the game. This process not only makes the measures more accurate but also nullifies any sensor wrongly positioned when worn (i.e. sensor overturning, rotations, inclinations respect to the body frontal plane).

In this pilot study investigators will recruit as many patients as possible as defined within the inclusion and exclusion criteria. There will be 75 devices available at the site from September 2018 to December 2019. Each patient will be provided with a WeReha device including the tablet and its charger, the inertial sensor and its charging station and cable, a kit of elastic straps together with a Velcro pocket and the 3 plastic objects. Every device can be used twice in order to assess as many patients as possible, providing a new set of straps and smart objects (that are to be considered single user only) and cleaning the other components by following specific and simple instructions provided by CoRehab.

Participants will be consented following a diagnosis of stroke and will keep the device for a maximum of 20 weeks following discharge from the hospital setting. This amount of time has been decided following review by clinicians and therapists during our earlier feasibility work. After that the tablet and the sensor will be collected, cleaned to ensure no cross contamination and meeting infection control guidelines within each Trust and made available for further use... The elastic straps with the pockets and the smart objects are the only personal and single use components, which will be disposed of after use... Secondary outcomes will only be assessed on “active patients”.

There will be a WeReha server available as a cloud solution, compliant with NCSC Cloud Security Principles, on which the web application will run and all the data will be collected whenever a patient’s device is connected to the internet. It is important to highlight that internet connection is not mandatory for the device to work properly as it will propose exercises to the patient as they were prepared initially after patient’s discharge. Then, whenever the device is

connected either through Wi-Fi or cellular network, data will be uploaded to the server through a secure VPN or https protected connection, or at the very latest when the device is returned to the hospital. However, for the sake of the study, we will provide a prepaid internet card to all participants requiring it. Patients data will be always uploaded and maintained in an anonymised formand stored following stringentsecurity and privacy principles.

Data relative to the primary outcome will be collected automatically on the device and uploaded to the server whenever possible. Clinical measurements (such as scales and scores) will be assessed only when starting the study and when returning the device.

WeReha includes a password protected administration area accessible only by the dedicated figure, through which it is possible to manage the reset of data in the local memory once the device is collected and then re-assigned to another patient. In addition, every tablet is provided with a software program installed for a quick and effective remote assistance by the technical staff of the sponsor directly on the patient's WeReha device (Bomgar SW, www.bomgar.com). This is intended as a second level support to patients and will only be required if the dedicated figure cannot solve the issue on which the assistance was sought. WeReha requires an internet connection at patient home in order to allow Corehab's remote intervention.

Following admission to Belfast or South Eastern Trust stroke units, patients will be pre-screened against the inclusion and exclusion criteria. Those who appear to fulfill the criteria will be highlighted by nurses and therapists to the recruiting therapist. Patients will be provided with all the study details and patient information sheet (PIS) to review. A screening log will be used to track the number of patients that are approached to participate. If the patient is ineligible or refuses to participate, the reason will be recorded in the log, if they so choose to provide us with reasons for the same.

In some cases, patients who have been discharged from the stroke units to the community may be identified as appropriate for the study. In this case the relevant Trust PI will provide them with the PIS and access for clarification.

Inclusion criteria:

- Ages Eligible for Study: Over the age of 18
- Sexes Eligible for Study: All
- First-time ischemic or haemorrhagic stroke, as documented by a CT or MRI
- Patients able to sit for at least ten minutes and to look after own affairs without assistance i.e. a Modified Rankin Scale (MRS)≤ 2
- Montreal Cognitive Assessment (MoCA) ≥12
- Ability and willingness to participate in the study
- Complete a signed consent form

Exclusion criteria:

- Significant medical conditions that affected function prior to the stroke and would limit normal stroke rehabilitation (e.g. musculoskeletal condition affecting arm function or cardiac condition limiting basic activities of daily living).
- Bilateral weakness of upper extremities
- Unavailability of a caregiver
- Participation in another clinical trial involving rehabilitation (recreational therapy, occupational therapy, physiotherapy) or an investigational drug.

## Methodology

At the trial site, the sponsor of the study will contribute to pay “dedicated figures”, a member of the clinical care team with a specialisation in clinical research (either a nurse or a physiotherapist) selected by the trial site personnel itself, as indicated by the scope of the Magic project [5]. Such figures will be the only people who will have access to all patient clinical records during the whole research study period, including the screening for patients. The dedicated figures will be educated by the sponsor (CoRehab) before starting the study in order to become a WeReha’s expert. They will be instructed on managing technical issues and details regarding the general functioning of the device (how to navigate the device, how to recharge the tablet and the sensor, how to position the sensor inside the objects and how to use them during game, how to wear the sensor) and for additional support they will be provided with a detailed manual for reference. . The sponsor will provide remote support to patients once at home in the first instance using a specific UK telephone number that will be provided to all participants. The WeReha software and manual will also have this phone number. The sponsor will inform the PI of all communication with participants and identify if this was technical (e.g. how to recharge the sensor, what to do if the system seems to be frozen and does not respond, what to do if the sensor does not switch on) or clinical. If it is a clinical difficulty then the PI will make contact with the participant. The dedicated figures will be provide training to patients and caregivers before receiving the device and go home.

Recruitment will start when patients are still in hospital after the onset of their stroke, as early rehabilitation can provide to better results. Whenever a patient is informed about the study or requests information and the inclusion/exclusion criteria are met, the dedicated figure will report that a patient could be enrolled in the study. If a patient accepts to partecipate in the study, he/she have to sign the appropriate documentation within 48 hours.

Only after the dedicated figures have enrolled the patient and the signed consent form is completed will a participant be registered on the WeReha system through the dedicated clinical web application. Patient and the caregiver(s) will then receive appropriate training from the dedicated figures with a device similar to the one they will be using at home. The training will take place in the facility where the patient has been enrolled and it will be carried out by the dedicated figure. This will take the form of an education session aimed to provide the patient and the caregiver with all the technical information required for the correct usage of the device. All participants will also be taught how the biofeedback exercises works in terms of games graphics, goals, bonus, scores as well as how to understand if the movement performed is correct or not. The caregiver is instructed in helping and supporting the patient when required and how to make contact with the supervisor in case assistance for the device is required. Both the patient and the caregiver, before leaving the facility, will be provided with a user manual for WeReha's usage at home.Based on our experience during the feasibility work, this training will last a minimum of 30 minutes up to a maximum of 60 minutes). The dedicated figure will then input the information about the patient into the WeReha web application, together with the results obtained in scores, and scales, resulting in the creation of a rehabilitation protocol, validated with rehabilitation professionals, which will then will be assigned to the patient. In cases where the participant remains in hospital for longer than expected, they will be permitted to use the device in this setting. Use of the device in this setting will not be included in the 20 weeks of usage.

Following discharge, participants will be reviewed in their own environment by the PI to ensure that the device is set up appropriately so that they can perform the exercises assigned. Participant usage of the device will be monitored at eight weeks. If at this stage the participant has not had four active weeks then the PI will review the patient with the expectation of the device being returned. In certain cases patients may have been unwell for a prolonged period and unable to use the device and it will be left to the PI to decide whether to remove the device or to allow the patient to continue using it for the full 20 weeks. All participants recruited to the study will be asked to complete the Technology Assessment Model questionnaire. After 20 weeks, the patient will return the WeReha device and the designated person will complete final assessments (clinical evaluation and questionnaires).

Identifiable data will be retained for the whole research study period. The data retention policy is clearly stated in the Patient Information Sheet. Since the Community Stroke Team provides therapy to patients, the team will highlight any capacity/ safety issues at any time and will then manage the patient to ensure safety.

Once the WeReha is returned to the hospital after being used by a patient, the dedicated person will follow a specific procedure in order to make the device available for any future usage by another patient. This procedure consists of resetting data through the specific button in the administration area of the software and cleaning as per infection control procedures for all the

reusable HW components. Also, new single use components (straps and smart objects) will be prepared for a new patient, so that the device is completely reusable.

Throughout the study, WeReha will suggest exercises in different forms to support rehabilitation of the most important body functions.

1. Video guided and biofeedback assisted exercises are proposed for balance intervention, legs and arms reinforcement and range of motion improvement especially for the foot, ankle, arms and hands. Depending on the exercise, patients are asked to wear one inertial WeReha sensor on the trunk, on a leg, on the foot or on the wrist in order to detect the movements in real time and provide subjects with visual and auditory feedback immediately. The daily sessions is structured in such a way that patients need to change settings and the position of the sensor as little as possible and exercises are grouped in sequences that support this approach. Standing exercises will be proposed only if a caregiver can assist the patient in order to prevent potential falls and minimize patient risk. Clear indications in written form as well as through audio and video tutorials are provided to set up an environment that ensures safety and fall prevention (e.g. the patient is asked to position himself/herself in the corner of a room with a static chair in front of him/her).
2. A WeReha kit also contains three simple objects, an hourglass, a plate and a joystick, through which the patient can practice some functional movements for the hand and the arm. Each object has a spot where the WeReha inertial sensor can be positioned and the object itself becomes “smart”. Through these smart objects, patients will be asked to play some simple, interactive and motivating videogames that require them to perform daily functional tasks (such as pouring the water, spinning an object on the table, move the hand with precision…) through which they will exercise arms and body posture improving their personal abilities. These videogames will also prompt the patient proposing simple tasks to solve the games challenge.

It is also important to highlight that patients will gain points and increase their score any time they perform a game/exercise with bonus points being given the more correctly the exercise is performed. By accumulating points patients will receive bonuses and rewards, in order to improve motivation and gain retention.

Every exercise and game has three different levels that correspond to a higher difficulty in performing that task. In the first level, patient will gain 50 points for every correct movement, at the second 100 points and at the third 150 points. Points are accumulated throughout the execution of the exercise and the final score is shown at the end of the exercise itself. In order to move to the level above, patients need to execute the required movement correctly for a specific time or a number of repetitions. The level above will require the performance of a more precise and at the same time more rewarding task. As an example, in stability exercises the patient is required to stay within a specific range shown as a target on the screen while the center of mass, shown on the screen as a moving circle, is measured by the sensor worn at the trunk. For every 0.5 degrees that the patient stays within the required range, they are rewarded 50/100/150 points

(depending on the current level). Initially, at level 1, the target is within a range of +/- 15 degrees both in sagittal and frontal planes and the patient is rewarded 50 points every 0.5 degrees. If the patient stays within the range for a total of 15 degrees then the patient is required to stay within a range of +/- 12 degrees (level 2) in both directions and is rewarded 100 points every 0.5 degrees. If again they stay within the new range for another 15 degrees, the target becomes +/-10 degrees and the points accumulated are 150 every 0.5 degrees.

Also, whenever an exercise is completed, the patient receives a star as a reward for finalising a task, meaning the exercise is executed for the whole time required without skipping it. The combination of scores and stars is then shown at the beginning and at the end of every session. These results and scores have been well received by patients and clinicians during the feasibility work and have been recognised to be a simple but effective motivational aspect of the use of the device. In case the patient needs more details, the staff can always send a more detailed report via email through the web application.

## Safety Considerations

Definitions regarding adverse events are as follows

- Adverse Event: An AE is any untoward medical occurrence in a study participant.

- Unexpected Adverse Reaction: There are no potential adverse reactions to the study activity known so any untoward or unintended response to the study activity will be classified as unexpected.

- Serious Adverse Events: Any adverse event that results in the following:
  - death
  - life threatening events
  - prolongation of existing hospitalisation
  - readmission to hospital
  - persistent or significant disability or incapacity

Causality (the determination of the relationship between an AE and the study activity) will be made by the Chief investigator.

All AEs that occur between the signing of the informed consent form and the last visit will be reported in the CRF using a proforma to classify the nature and severity of the event. AEs will be followed up routinely.

For all AEs, the investigator will obtain information to determine the outcome of the AE and to assess whether it meets the criteria for classification as a SAE, requiring immediate notification.

The start date, duration, intensity, any relationship to the study, actions taken and outcome will be documented using the trial AE reporting proforma.

All serious adverse events or unexpected reactions that occur between the signing of the informed consent form and the last visit will be reported immediately upon knowledge of the event occurring to both the Chief Investigator and sponsors. It will also be reported in the CRF and outcomes will be tracked and followed up.

Causality and expectedness will be assessed by both the Chief investigator and the Sponsor. The sponsor shall keep detailed records of all serious adverse events relating to the trial.

Safety of patients in home environments is one of the main pillars on which WeReha has been built. Considering the patient vulnerability and the uncertainty around supervision while exercising at home, previous feasibility work in a hospital setting to simulate home environment conditions has been undertaken from the 1st February 2018 to the 30th March 2018. The goal was to examine if WeReha can be intended to be used at home setting, if user interface and exercises were appropriate for stroke survivors and if the patient safety is guaranteed.

In total twenty volunteers in a subacute phase who suffered a stroke (13 males and 7 females, mean age of 63+/- 12 y, event occurred on average 1.2 years before this investigation) have been enrolled at Centro di Riabilitazione “Franca Martini” in Trento (Italy), a private health care facilities who treats neurological outpatients. Each volunteer received 1 session a week with WeReha for one month (4 sessions in total). Each session lasted 30’ minute or more, depending on patient’s ability. A dedicated physiotherapist was chosen as a supervisor for educating patients on the usage of the device before the first session and supervising them during each session, also to provide us with important feedback about exercises and games provided. At this aim, he was provided with all the instructions needed on the usage of the device before starting the study. Two days a week were scheduled in order to have all the volunteers performing the session with WeReha (10 of them a day).

Patients were trained on biofeedback exercises for balance, upper and lower limbs mobility and exercises with the three smart objects for the hand and upper limb. The exercises sequences at each session were the same for all patients. Exercises were changed at every session in order to assess as many exercises as possible among those of the WeReha’s library.

Only the first session was actively supervised by the physiotherapist, while during the others the supervisor stayed on the sidelines and intervened only if required. CoRehab staff was observing the study in a completely passive way to record all the interventions required to help volunteers before and during the exercises. After each session all the volunteers were asked to answer to questionnaire about the set-up, the software navigation and the exercises proposed. Each question required an answer with a rating on a scale of value from 1 to 5, where 5 means “Very good” and 1 means “very bad”. The main topics were: the effort on wearing the elastic straps (trunk, thigh, foot and wrist), usability of the software user interface, understanding of video

tutorials and instructions of exercises, software navigation and interaction, understanding of games, ease-of-use to handle the “smart objects”, effectiveness of feedback provided during game, patients attitude with respect to exercises to be performed by themselves or with the aid of a support. Only at the end of the last session patients were asked if they appreciated this innovative and technological home rehabilitation solution and how long they would have used the device willingly.

Furthermore in order to receive as much feedback as possible from the clinical point of view, WeReha was also evaluated by a professionals group (2 physiotherapists, 1 psychiatrist and 1 psychologist) of another private clinic, Fondazione Santa Lucia in Rome, where the staff have a great experience in stroke patients rehabilitation with technology. We asked them to test the device on their own (not on patients) and to answer the same questionnaire underwent to Franca Martini’s patients from a clinical point of view.

After the two month study period all the answers from the two sites and the comments from Villa Martini’s patients were collected and evaluated. Particularly, WeReha has been evaluated to be a simple and easy-to-use device for stroke patients, even for those who do not have much experience with technological devices (pc, tablet, smartphone…). The first day of training on the usage of the device seemed to be sufficient to guarantee an independent use by patients, especially with regards to the software navigation. It has also been described as motivational and fun by patients, so much so that they would continue the training with WeReha at home on average three months without finding it boring and repetitive. Most importantly, the indication to use the device for 3 months was also provided by clinical staff supervising the feasibility study in both sites, and this is the reason why we have se the maximum time frame to 12 weeks.

However some difficulties has been encountered by volunteers in the set-up and in understanding the exercises tutorial: wearing the Velcro band at the trunk alone seemed to be a difficult task for the majority of them (17 out of 20), the scientific terms (i.e. hip abduction, hand supination/pronation…) used when referring to exercises were not understandable (14 out of 20) and video tutorials seemed to be too long and with too much information to be understood at once (11 out of 20). Furthermore the clinicians agreed on excluding exercises in standing position without supervision of a caregiver.

Considering this feedback, WeReha has been improved as of the first week in April. We consider feasible and reasonable that WeReha can be used for rehabilitation in home environment, as long as the patient safety is ensured while using the device without the caregiver’s supervision. In order to ensure this condition, we added a specific question at startup of the application about the presence or not of a caregiver, so that exercises in standing position are allowed only under supervision as well as exercises requiring the strap on the trunk even if in sitting position.

Furthermore in order to improve the understanding of the exercises, the instructions and the tutorial language have been revised and all the scientific terms have been replaced by easier, more colloquial and explicative ones.

It must be reminded that from the web application every exercise can be labelled if a caregiver is required and it won't be proposed to the patient in case the caregiver is absent.

All activities and results carried out in the trial did not raise security/safety issues and that they comply with national and international regulations on dual-use of goods or dangerous materials and substances. Given the target patients were those that satisfy inclusion and exclusion criteria, it is noted that:

- The WeReha device is a class 1 medical device, in agreement to norm 93/42/EEC
- All the components integrated in WeReha are certified for home usage.
- The WeReha system doesn't take any autonomous decision on the rehabilitation setting: the system has been conceived to leave the clinician the ultimate decision on any action performed by the system (e.g. exercise prescription, advice provided to the patient, notification for the clinician/medical expert,.... ) that may affect directly or indirectly the safety of the patient and the outcomes of the rehabilitation path.
- The system prevents the patient performing exercises if the patient declares during the initial questionnaire that the general healthcare conditions of the day are not satisfactory.
- The system setup is designed in such a way that safety of the patient while performing exercises is ensured, both for the upper and lower body (e.g., preventing falls) as well as ensuring repeatability of exercise conditions in different home environments.
- Usage of webcam or any other video means is not included in WeReha in order to maintain the maximum privacy possible along the home rehabilitation. More specifically, the WeReha application running on the device is configured so the camera of the device is kept locked during the whole time of application execution. The tablet is configured in kiosk mode and only WeReha software and related apps can run on it and patients cannot use it for their own purposes. Also, all tablets will be provided with a safety sticker on the camera to make sure that patients do not feel a threat for their privacy
- Self-assessment questions or the initial questionnaire are only used to ensure an adequate attention level and awareness of progress achieved by the patient and to ensure that the patient can execute the exercise sessions safely and comfortably to the greatest extent. In addition, trained staff with access to the web application have the final decision on everything that is presented to the patient.

## Duration of the study and patient's timeline

The total duration of the study is expected to be approximately 1 year and 4 months, starting at the beginning of September 2018 and ending at the end of December 2019.

Each patient will be required to keep the device for 20 weeks following discharge after which they will return the WeReha device to the hospital. In cases where a participant uses the device for

four of the first eight weeks the device has been assigned, the patient's generated output will be considered as valid.
When a patient starts the evaluation period, some clinical measures will be taken, as well as when (s) he returns the device. Such clinical evaluations are specified in the 'Methodology' section.

## Follow-Up

The product will be provided for a maximum of 20 weeks following discharge to the patient, after which the device will be returned to the PI or the trial site for further usage. Patients are not required to have additional follow up after the study term is completed.

## Data Management and Statistical Analysis

As the primary outcomes of the study are designed to evaluate the impact and acceptance of a new rehabilitative technology for stroke patients, a statistical analysis on the primary outcomes will not be conducted. On the other hand, the study clearly aims to evaluate the number of patients, meeting the inclusion/exclusion criteria that are willing to use this technology and the time they will be using the devices at home. It has also to be noted that this study is part of a research project (Magic-PCP, [5]) where 3 companies will provide their solutions to 1 hospital in Italy and sites in NI, i.e. each company will run a similar trial with identical numbers on different sites. The request and the funding to provide 75 devices on each country and aim at performing a validation on maximum 2 patients per device is a clear requirement of the project. We have then defined the primary and secondary outcomes that we consider crucial for evaluating our proposed technology.

The primary outcome will be evaluated in an anonymised form and considered good if planned KPIs are met or exceeded. Secondary outcomes will be evaluated using an unpaired test to compare pre and post intervention measured values, whereas the Chi-square test will be used to detect the significance of outlier proportions, p values smaller than 0.05 will be considered statistically significant. All calculations will be performed using the Matlab software tool (The Mathworks Inc., Natick, MA, USA). We are also interested in evaluating possible correlations among results for the different groups of patients under examination (male and female <55 years old, 55-70, more than 70) to be better prepared for a future clinical investigation of our device.

All details related to the Data Management are provided in Annex A - Technical Data Management of the present document.

# Anticipated Results of the Study

As stated, this trial is part of the Magic-PCP project [5], and the results of the study aim to demonstrate the impact of the usage of technology for stroke patients and community on a large scale. The project anticipates that devices will be accepted by patients and integrated in their home treatment routine, that they will use it regularly and with the expectation that it improves motivation and as a consequence their quality of life and motor functions.

Results will be collated by the buyers group also with other ongoing studies within the umbrella of the Magic PCP project and compared eventually with existing studies that we referred to.

# Ethics

The trial sponsor is committed to make use of the principle of “GOOD FAITH”. The user-centered approach that guided the WeReha system realisation is essential not only to assure it’s functioning according to the target group’s needs and requirements, but it is also aimed at achieving the user’s ethical acceptance of the system.

The trial sponsor confirms that all results and activities carried out in this research study will not raise security/safety issues nor EU-classified information as background and that they will comply with national and international regulations on dual-use goods or dangerous materials and substances.

Furthermore, the trial sponsor declares that:

- Every individual that participates as research subjects will be handled as individuals worthy of honour and respect.
- The research subjects will be free to choose about participating or withdrawing when they feel it is necessary and the informed consent to participant in the clinical trial and any product demonstration session must given freely. Both the Patient Information Sheet and the template for the informed consent are attached to this document.
- Reasonable steps will be taken to ensure the integrity of data, which means that data will be reliable for its intended use, accurate and complete.
- All research participants will be treated as equal participants contributing valuable information. In addition, the WeReha system has been designed to function without any legal, civil, economic, gender and social rights discrimination

**Data protection & research participant’s confidentiality**

The trial sponsor declares that the principles of the European Regulation concerning the processing of personal data by the Community institutions and bodies as well as the Regulation on Privacy and Electronic Communications and the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 will be followed in the whole research study. This commitment

implies that only the necessary amount of personal information will be collected for the purpose of this Research Study, that retention and disposal periods will be clearly defined and enforced, that personal information gathered for a specific purpose will not be used for purposes other than directed without the consent of the individual and that in the default setting of the system, the participant is already protected against privacy risks.

Annex A - Technical Data Management Plan provides the following information about all personal and health data involved in the research study: nature of data, purpose of data collection, tools and procedure for data collection, where data is stored and how it is protected at rest, who can access data, data retention period. The WeReha system implements proper security techniques that are acknowledged to be proactive measures to address personal and health data confidentiality. They include: authentication, authorization, data encryption in transit and at rest, pseudonymization for data processed within the system and anonymization of data that is exported for the validation by the solution technology provider to assess the system performance, adoption, and behaviour.

## Budget and support for the Project

This trial will be supported by the MAGIC-PCP [5] EU funded project in which CoRehab result currently as one of the 4 company that has entered phase 2 of the project. Three companies out of four will have access to phase 3, and in this case only the proposed study will be run.

# ANNEX A - DATA MANAGEMENT PLAN

This section provides details about how personal and health data involved in the research study are managed in the research study.

**PATIENT INDIVIDUAL DATA SETS**

- Patient's personal info
- Patient's clinical data
- Patient's rehabilitation programme
- Patient's safety questionnaire – live data
- Patient's exercise (individual) reports – live data
- Patient's informed consent (Clinical Trial)
- Patient's anonymized record

| **ID** | **Patient_Personal_Info** |
|---|---|
| **Description** | This data set includes: Name, Address, Postcode, Date of birth, Age, Sex, Gender, Tel n., NHS no., Mobile/home no., email address |
| **Purpose of data collection** | Recruitment and Enrolment of patient. For the Clinical trial purpose, it can be assumed that only a nickname, Age, Sex and, if requested, the NHS no. will be inserted into WeReha system. In particular, NHS no. could be used to export individual patient reports in order to be easily integrated in the NHS systems. |
| **How Data is collected** | The WeReha clinical application provides a dedicated UI for registering a patient into the WeReha system and inserting patient personal info. Patient's data can be considered anonymised in the WeReha database, as name and surname won't be stored together with other personal information.<br>Only users registered in the WeReha clinical application and assigned with proper access rights (e.g. hospital staff involved in the clinical trial like the dedicated figure specifically hired by the research study sponsor) can execute such operation. |
| **Where Data is stored and how it is protected at rest** | Patient personal Info are stored in a dedicated database of the WeReha system, located in the hospital hosting the research study, separated from the database storing all other patient data. Database records are ciphered with symmetrical encryption. |

| | |
|---|---|
| **Who can access data** | Only users registered in the WeReha clinical application and assigned with proper access rights (e.g. hospital staff involved in the clinical trial like the nurse specifically hired by the project consortium) can access patient personal info. |
| **Data retention period** | N/A |

| | |
|---|---|
| **ID** | **Patient_Clinical_Data** |
| **Description** | This data set includes the following diagnosis and diagnostic data (available at the time of Patient enrollment into the WeReha system), .e.g. Berger scale score, Rankin score |
| **Purpose of data collection** | This information is used to support: (a) the initial screening of the patients for recruitment; (b) the pre-assessment of the patient clinical condition; (c) the setting of the Rehabilitation Program based on that; (d) the assessment of the rehabilitation outcomes with respect to the condition of the patient at the beginning of the rehabilitation period. |
| **How Data is collected** | Patient Clinical Data are initially inserted by the dedicated figurein making the enrollment of the patient and at the end of the treatment with WeReha.<br>The WeReha clinical application provides a dedicated UI for inserting such data in the WeReha system.<br>Only authorized users (e.g. clinical trial nurse) that are successfully authenticated to WeReha clinical application can execute such operation.<br>The WeReha staff will never have direct access to Individual Patient Clinical data, but only to those necessary to assess the system performance, adoption, behavior. This means that WeReha staff will only collect aggregated Patient Clinical Data along with other reports produced by the WeReha system (see also WeReha_Exp_Rep). |
| **Where Data is stored and how it is protected at rest** | Patient Clinical Data are stored in a dedicated database of the WeReha system, located in the clinical trial site, separated from database storing Patient Personal Info. The database is encrypted with symmetric algorithm. The symmetric key is generated by and embedded in the WeReha system during set-up, it is not known to the WeReha staff. |
| **Who can access data** | Only users (e.g. the dedicated figure) that are successfully authenticated to WeReha clinical application and with proper access rights can access Patient Clinical Data). |
| **Data retention period** | Data Retention period will finish at the end of Magic trial timeframe. |

| ID | Patient_Rehab_Progr |
|---|---|
| **Description** | The Rehabilitation program specifically tailored for the patient, set by the rehabilitation specialist for the treatment period. |
| **Purpose of data collection** | This information is used by the WeReha to propose exercises session to patient on a daily basis. |
| **How Data is collected** | The clinical application provides UI for setting the rehabilitation program. This operation is only permitted to authorized users of the clinical application (e.g. the dedicated figure). |
| **Where Data is stored and how it is protected at rest** | This information is stored along with Patient Clinical Data in the WeReha system (Refer to Patient_Clinical_Data).<br>This information is sent via an encrypted channel and stored locally in the WeReha Patient application (in a dedicated database in patient's device). |
| **Who can access data** | Only user that are successfully authenticated to WeReha clinical application and with proper access rights can create, visualize and modify Patient Clinical Data (i.e. the nurse, refer to Patient_Clinical_Data).<br>This information can be also visualized by accessing the patient application in the patient's device. |
| **Data retention period** | Refer to Patient_Clinical_Data |

| ID | Patient_Safety_Quest |
|---|---|
| **Description** | Patient answers to questionnaires presented by the WeReha Patient Application, through which the software understands the environment in which the patient is immersed, his/her daily health conditions, the presence or not of a caregiver throughout the session. |

| | |
|---|---|
| **Purpose of data collection** | WeReha Clinical Application uses the answers by the patient to filter the exercises that can be or cannot be done for environmental conditions or because they require the presence of a caregiver (as for instance standing exercises), or, if the patient declares not to be in good general conditions, the session will be shorten up or postponed. WeReha is never responsible to raise alarms for patient's conditions. |
| **How Data is collected** | Questionnaire forms are presented to the patient through the WeReha Patient Application UI. |
| **Where Data is stored and how it is protected at rest** | This information is stored locally to the patient device. It is also sent via an encrypted channel to the WeReha Clinical Application along with other exercise session information (Patient_Exer_Report) and stored along with the Patient_Clinical_Data records. |
| **Who can access data** | Refer to Patient_Clinical_Data |
| **Data retention period** | Refer to Patient_Clinical_Data |

| **ID** | **Patient_Exer_Report** |
|---|---|
| **Description** | Record containing data and results of the daily exercise session performed by the patient |
| **Purpose of data collection** | To enable data analysis at individual level (e.g. to evaluate patient performance in a certain period). |
| **How Data is collected** | The WeReha Patient Application collects data from the application sensors/devices to produce the Patient_Exer_Report. |
| **Where Data is stored and how it is protected at rest** | This information is stored locally to the patient device. It is also sent via an encrypted channel to the WeReha Clinical Application along with patient's answers to questionnaires (Patient_Safety_Quest) and stored along with the Patient_Clinical_Data records. |
| **Who can access data** | Refer to Patient_Clinical_Data |

| | |
|---|---|
| **Data retention period** | Refer to Patient_Clinical_Data |

| | |
|---|---|
| **ID** | **Anonym_Patient_Record** |
| **Description** | For each patient, a record containing (5 years) age range, gender, the results of the daily exercise sessions performed by the patient, diagnosis and diagnostic data (e.g. Berger scale score, Rankin score) available at the beginning of the treatment period and evaluated at the end of it. |
| **Purpose of data collection** | To enable the evaluation of WeReha system performance/adaptation/behavior a well as the measurement of the research study primary and secondary outcomes. |
| **How Data is collected** | WeReha provides a tool to export anonymized patient records from the system. |
| **Where Data is stored and how it is protected at rest** | N/A |
| **Who can access data** | Anonym_Patient_Report are accessed by CoRehab for statistical data analysis and outcomes measurements. |
| **Data retention period** | N/A |

| | |
|---|---|
| **ID** | **Patient_Informed_Consent** |
| **Description** | Patient Informed consent (paper document) |
| **Purpose of data collection** | The signed informed consent is mandatory for participating in the WeReha - Magic clinical trial. |

| | |
|---|---|
| **How Data is collected** | A hard copy of the informed consent form is provided by the dedicate figurein person to those patients who manifested interest to participate to the WeReha - Magic clinical trial. Only informed consent signed by hand by the patient in person (or by his/her caregiver when applicable) will be accepted for participating. |
| **Where Data is stored and how it is protected at rest** | Patient_Informed_Consent will be kept in hospital repositories in rooms the access of which in permitted to authorized medical staff only and according to existing policies. |
| **Who can access data** | The dedicated figure(and possibly other authorized members of hospital staff involved in the clinical trial). |
| **Data retention period** | The retention period of the informed consent is determined by HSC policies. |

# ANNEX B - Technology Acceptance Model questionnaire for patients

The TAM questionnaire has been tailored to the WeReha intervention by taking into account the patient's involvement in the program, knowledge on disability and satisfaction. It comprises 22 items each rated in a seven-point Likert-scale, whereby a score of one refers to "I do not agree at all" and a score of seven refers to "I agree entirely". Patients will evaluate acceptance answering this questionnaire when returning the device.

*Perceived Ease of Use*

1. I found the device easy to use.
2. Learning to use the device would be easy for me.
3. My interaction with the device was clear and understandable.
4. I think the messages displayed by the WeReha system would be clear.
5. I think it would be easy to acquire the skills required to use the device
6. I found technologies such as WeReha easy to use.
7. In general, I think the WeReha system is easy to use.

*Perceived Usefulness*

8. Using the device can enhance my effectiveness in training.
9. Using the device can improve my training performance.
10. Using the device can increase my productivity in training.
11. I found the device useful.
12. Using technologies such as WeReha would improve the follow up of my rehabilitation.
13. In general, the WeReha system may help to improve the rehabilitation

*Attitude Toward Using*

14. I dislike the idea of using technology for home rehabilitation
15. I have a generally favorable attitude toward using technology for home rehabilitation.
16. I believe it is (would be) a good idea to use these device for my training.

17. Using technology for home rehabilitation is a foolish idea.

18. In general, I think that my family/friends would support the use of the WeReha system.

*Behavioral Intention to Use*

19. I intend to use the device in my further training.

20. I will use the device often when available.

21. I intend to use the device frequently for my training.

22. I intend to use technology when it is necessary for my rehabilitation.