

# Design, Development and Deployment of a Hand/Wrist Exoskeleton for Home-Based Rehabilitation After Stroke - SCRIPT Project

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## Abstract

Changes in world-wide population trends have provided new demands for new technologies in areas such as care and rehabilitation. Recent developments in the the field of robotics for neurorehabilitation have shown a range of evidence regarding usefulness of these technologies as a tool to augment traditional physiotherapy. Part of the appeal for these technologies is the possibility to place a rehabilitative tool in one's home, providing a chance for more frequent and accessible technologies for empowering individuals to be in charge of their therapy.

This manuscript provides the background to some of these technologies and introduces the Supervised Care and Rehabilitation Involving Personal Tele-robotics (SCRIPT) project and its unique approach in design and developing technologies for home-based rehabilitation. The project is partially funded by the European Community under framework 7. It uses a user-centred design methodology to develop a hand/wrist rehabilitation device for home-based therapy after stroke. The patient benefits from a dedicated user interface allowing to receive feedback on exercise as well as communicating with the health-care professional. The health-care professional is able to use a dedicated interface to send/receive communications and remote-manage patient's exercise routine. During the first year of the project, 11 prototype passive-actuated devices were developed and 9 of these are currently deployed in a summative evaluation phase in patients' home across Italy, the Netherlands and United Kingdom, while the remaining two devices are used for additional development. The goal of evaluation is to test the feasibility and potential effectiveness of the prototype.

Based on these evaluations, and additional formative feedback on design of this prototype, a second prototype is under development allowing for active and adaptive control of the assisting forces for hand/wrist rehabilitation.

## 1 Introduction

Use of robots for stroke rehabilitation has witnessed 25 years of development [42, 21, 22, 33, 35, 20, 23]. Its context has varied between tools for delivering repetitive training to tools to influence relearning lost motor skills in an engaging and therapeutic context. While a large number of studies have targeted the repetitive training, less work has been dedicated to choice of interactive therapies that can suit different neurological impairments and provide therapeutic gains [27]. In contrast, a physiotherapist is able to sense patients contribution towards a required task and to correct or resist motion as required.

Adaptive and interactive therapeutic exercise is at the heart of the SCRIPT project where new interaction models can lead to detect patient contributions better, thus taking a step closer towards adaptive

and personalised therapy tools. Alongside this, user interface design work focuses on developing engaging and motivating interfaces that can also be personalised towards an individual's choice of training activities, as well as providing adequate encouraging and informative feedback at patient and therapist/clinician levels. Moreover, the use of remote interaction as well as tele-supervision allows for remote monitoring and setup of activities and their goals. With reduced travel to hospitals, clinics or patient homes, this provides more time to the therapist, more space at clinics or hospitals and less inconvenience in travelling with a disability for the patient. It also allows to provide more training time to patients, not limited by therapist availability.

While many projects have targeted training of reaching to targets, due to the inherent complexity of designing grasping tools, a smaller and more recent subset has targeted training of the hand and wrist (e.g. [28, 24, 2]). This is an important feature of the SCRIPT project, targeting recovery of hand and wrist function, which have a more pronounced impact on individual's independence and performance in activities of daily living.

The progress of moving existing rehabilitation robots to smaller clinics or patient homes has been mainly hampered by the current cost of these devices. SCRIPT project intends to target cost by producing two prototype systems, one based on passive actuation and the second with active actuation. Both prototypes aim at producing affordable, yet interactive therapy tools suitable for patient homes and clinics. A second limitation in current technology transfer to homes, clinics or hospitals is the contradictory evidence in support of or against using robot-mediated therapies for neurorehabilitation. A human-robot adaptive therapeutic interaction enables us to further investigations in this area. SCRIPT hypothesises that correct alignment of clinical targets for learning alongside standardised clinical and biomechanical assessments capable of capturing progress are essential in justifying added benefits. Also, it is important to note that while many studies try to match content between conventional physiotherapy and robotic intervention, SCRIPT relies on robotic interventions ability to deliver higher doses of motivational therapy, i.e. more repetitions of engaging interactions. Thus rather than trying to match content and limit the robots main advantage, the SCRIPT vision is to develop the device to be usable for longer period of time at home and clinic.

## 2 Background

### 2.1 Neurorehabilitation

Research into motor relearning and processes of cortical reorganisation after stroke have provided a neurophysiological basis for key aspects that stimulate restoration of arm function [37, 15]. These key aspects include high training intensity, active initiation and execution of movements, and application of functional exercises. With respect to the training intensity, repetition of movements has been shown to strengthen the representation of the trained movements in the brain [9]. Training with a higher frequency or longer duration stimulates functional recovery of the arm [42, 21, 22, 33, 35, 20, 23]. Concerning active initiation and execution of movements, brain studies have shown that cortical activity is larger during active execution of movements than during passive motion, predominantly in secondary motor areas and basal ganglia [43]. Also, motor cortex excitability is higher after active movement training, accompanied by increased agonist activity and decreased antagonist activity, in contrast to passive movement training [13]. Exercise therapy focusing on active initiation and execution of movements is associated with improved arm function [8, 1, 14]. Regarding functional exercises, several studies have shown that functional training, focusing on activities of daily life that are relevant to the patient, results in a normalisation of brain activity [37, 33]. Such normalisation of brain activity is related to improvements in motor control and functional abilities [7]. Therefore, functional exercises are another important feature of exercise therapy to stimulate motor recovery after stroke [9].

## 2.2 Rehabilitation technology

Technological innovations provided an opportunity to design interventions that take many key aspects for stimulation of motor relearning into account, of which rehabilitation robotics is a well-known example. With such a device, the required amount of support to the arm and hand movements can be provided, thereby allowing active practice of movements when this is not possible otherwise. This increases the potential to train intensively, with active contribution by the patient to functional exercises. The application of rehabilitation robotics has been shown to be effective [36, 19, 29]. However, transfer of robotic training effects to activities in daily life is limited, as is observed for most interventions in stroke rehabilitation, including conventional therapy [42]. Contemporary robot-aided therapy focuses mainly on the proximal arm, and results in improvements in the proximal arm only, without generalisation to the wrist and hand [36]. In order to maximise independent use of the upper extremity in daily life, it is important to include functional practice of the wrist and hand. Several technological interventions have been developed for distal arm training, such as the Bi-Manu-Track, which showed promising results [12]. In addition, a distal trainer has been designed to complement the MIT-Manus robotic device for the proximal arm [16]. The first preliminary results of the stand-alone use of this wrist module are optimistic [17]. Moreover, initial research into alternating training of the proximal and distal arm suggests that early involvement of distal arm movements is favourable over proximal training alone in terms of transfer of treatment effects to the untrained arm segments [17]. After stroke, especially wrist, hand and finger extension is problematic, and it is often the last symptom to show some improvement, if any, after recovery of leg function and proximal arm function. Therefore, a training environment in which distal control for grasping and manipulation of objects is optimally supported has a large potential.

## 2.3 Training at home

Besides this treatment benefit, one of the major advantages of technologically supported interventions is the potential to automate therapy, especially when a rehabilitation device incorporates a motivating training environment, for instance through virtual reality, including (bio)feedback about the patients performance. Regarding a virtual training environment, combining (bio)feedback with progressive exercises is essential to promote independent training with tele-supervision by professionals. Addition of augmented feedback to exercises can stimulate the learning process, by making patients more aware of their performance [44]. Recent studies provide some insight into the optimal application of augmented feedback. A combination of augmented visual and sensory feedback is promising, [30, 31] as well as placing emphasis on movement errors to stimulate motor (re)learning [34, 41].

In combination with a motivating and progressing exercise environment (serious gaming), autonomy and continuity of treatment is enabled in a way that stimulates motor relearning, in the patients home. Such application of rehabilitation devices allows a patient to train independently, in an intensive, active and functional way, in his/her own environment with continuous access to treatment facilities. This provides the patient with a sense of control and autonomy, which might also contribute to a better treatment outcome in itself. It also allows very efficient use of the treatment facilities, and enables practice in more efficient and effective ways. Distributed practice sessions and random variation within practice is more beneficial than blocked practice to improve arm functionality after stroke, due to a more active participation of the patient in the learning process [44]. Moreover, spreading practice sessions across several days also results in enhancement of performance during the remaining practice sessions and on retention of the learned task compared with the same sessions practiced on one day [39]. Thus ideally patients should be able to train variable exercises several (short) times a day, for most days of the week.

In addition, the use of such systems offers the possibility to quantify each patients specific impairments and his/her progress during treatment, using sensitive and objective quantitative indicators of movement performance [18]. Furthermore, a computerised training environment including (bio)feedback enables

remote monitoring of movements and progress (tele-monitoring) and remote supervision by the therapist (tele-supervision). This saves one-to-one treatment time and house visits, allows therapists to attend to multiple patients, increases productivity and alleviates the physical burden on the therapist, which in turn can relieve the pressure on today's healthcare system, where ageing of the population will result in fewer therapists and more patients.

### 3 User-driven system development framework

We employed an interdisciplinary research design to co-design and evaluate the SCRIPT system with people with stroke, carers and stroke professionals in three clinical sites in the United Kingdom (UK), the Netherlands (NL) and Italy (IT). The user-driven system development framework comprises of two main phases. In phase 1, we engaged with potential users of the SCRIPT system to create a clear picture of the target users and the context in which the system intends to operate. The aim of this phase was to provide the technology developers with a detailed knowledge of the diversity of users of the system. A mix of health and social sciences and design methods were used to collect data in this phase including focus groups, in-depth interviews and cultural probes [10].

The findings of the focus groups, which showed participants general attitude and feelings toward technology, were further explored and refined by conducting in-depth interviews and cultural probing during two successive home visits (Figure 1). Cultural probe materials such as diaries and photography activities gave us an opportunity to observe participants behaviours between two home visits whilst the outcome of the probing was used to prompt participants during the interviews. The findings of this phase were summed up to create a collection of persona-based scenarios [4] as representatives of a range of users and their social and personal contexts, their experiences of stroke and technology use, their needs, activities and goals. These user models served to identify user requirements and informed design of the iterative prototyping.

In phase 2, the resulting prototypes were evaluated across three clinical sites using participatory formative evaluation methods such as cognitive walkthrough and cooperative evaluation [32]. Different components of the SCRIPT system including the orthosis, user interface and games were tested out with the members of the steering group committees. In addition, the system was evaluated in participants homes in which people with stroke and their carers were encouraged to think aloud while trying out the system in order to identify main usability problems. The identified problems were summarised and fed back into the process of design to improve the next iteration of the system. The resulting prototypes are tested, redesigned and developed in iterative cycles.

### 4 Passively actuated therapy device, prototype 1

SCRIPT Prototype 1 (SP1) is a wrist, hand and finger orthosis that assists individuals after stroke that suffer from impairments caused by spasticity and abnormal synergies (Figure 2). These impairments are characterised in the wrist and hand by excessive involuntary flexion torques that prevent the hand to be used for many to most activities in daily life. The SP1 can passively offset these undesired torques, but it cannot actively generate or control movements. The user needs to use voluntary muscle activation to perform movements and thus needs to have some residual muscle control to successfully use the device.

The hardware components of the SP1 are:

- Physical interfaces to the user: forearm shell, hand plate, and digit caps with Velcro straps. These physical interfaces are the only components of the SP1 that come in contact with the user.
- Wrist-torque transfer mechanism: double parallelogram between forearm shell and hand plate that allows wrist flexion-extension but blocks all other wrist rotations.



Figure 1: Home visits with cultural probes and in-depth interviews

- Torque-generation mechanisms: digit leaf springs and adjustable tension cords.
- Device controller: micro-controller board that reads the sensors and converts these readings to physiological relevant parameters and transfers them to the main unit. Arm support: commercially acquire arm support (Saebo MAS) that supports the arm against gravity to enable arm movements in individuals after stroke.
- State sensors: integrated measurements units (IMUs) with which the forearm posture can be estimated.

The SP1 physically interfaces with the forearm, hand and fingers of the users using respectively a forearm shell, a hand plate and individual digit caps. To guarantee safe and comfortable interaction, it uses commercially available physical interfaces with a proven track record from Saebo Inc. (Charlotte, NC, USA). The Saebo forearm shells, hand plates and caps are available in multiple sizes and for both left and right hands that are needed to custom fit the SP1 to a wide range of body dimensions.

The SP1 applies the external extension torques on the fingers via passive leaf springs and elastic tension cords. The leaf springs allow the extension force to be applied perpendicular to the fingertip for most of the range of motion, but cannot be directly attached to the finger due to misaligned digit axes of human and device. The leaf spring has cord guides through which the tension cord is routed and is covered in a shrink-wrap to protect the patients against its sharp edges. The tension cord is used to give the finger freedom of movement relative to the leaf springs. The cord is also used to adjust the amount of support by tensioning it more or less using the tension-cord stops on the top of the hand plate.

The force generation and application mechanisms for the thumb are identical to the ones for the fingers. To allow additional freedom of movement in the thumb needed for thumb opposition, the thumb mechanism has an additional rotational degree of freedom that coincides with the wrist axis, with any misalignment being allowed for by the flexibility of the tension cords.

The wrist mechanism uses a double parallelogram between forearm shell and hand plate that allows wrist flexion-extension but blocks all other wrist rotations. The double parallelogram is needed to prevent misalignment between human and device axes and make the device comfortable to use. Through the parallelogram, the rotation of the hand around the wrist flexion-extension axis of the wrist is transferred to the parallelogram clamp at the forearm. There this rotation is actuated using an elastic tension cord. The tension in the cord can be adjusted using the cord stops at the elbow end of the forearm shell.

The external extension force in the digits and the wrist can be adjusted by tensioning the elastic cords. The digits and the wrist have a single tension cord each, and each cord has multiple knots on it.

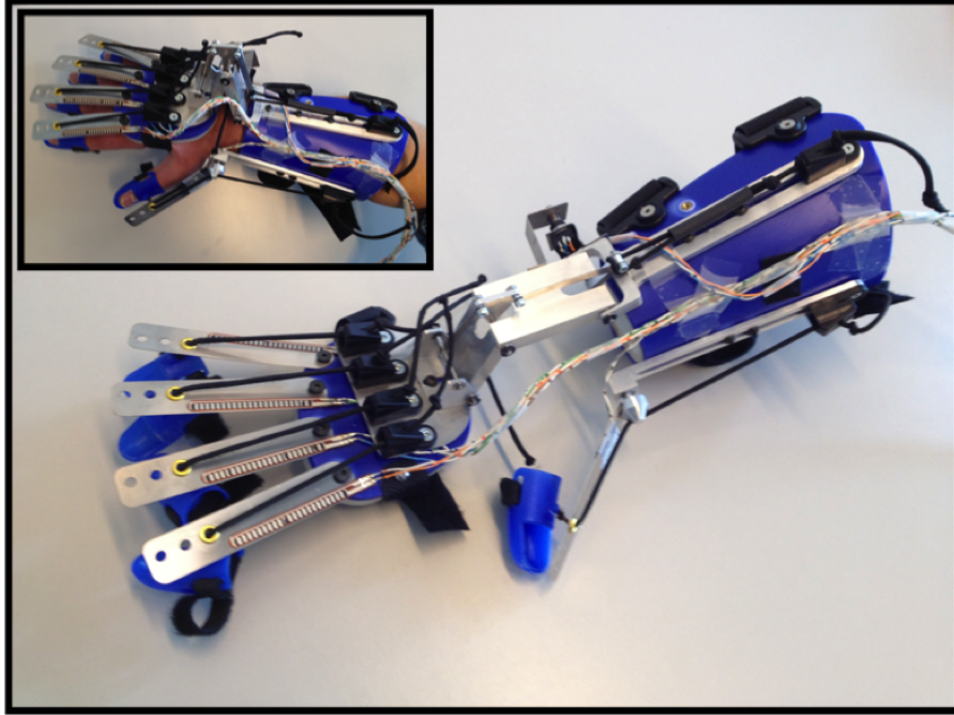


Figure 2: SCRIPT Prototype 1. From left to right: blue digit caps, steel leaf springs, black finger tension cords, red/white/black bending sensor, blue hand plate, black tension-cord stops, metal wrist-torque transmission, black wrist tension cords, blue forearm cuff. The thumb cap, leaf spring, tension cord and additional rotation joint are visible below the wrist joint. All the sensors are connected to the computer interface via electric sensor wires.

These knots can be clamped in the cord stops on the device and tensioning the cord will produce more external extension force. The user is instructed to change the tension based on his impairment and his therapy progress via the physical therapist and the graphical user interface.

The SP1 closely follows the contours of the human body. Most components stay within a volume less than 30mm away from the body. The wrist parallelogram, needed to allow wrist flexion/extension, requires 75mm from the body at maximum wrist extension. The device is not overly disruptive when used as therapy tool, but it is too bulky to be a permanent aid for daily use.

To improve patient comfort, all sharp edges of the devices are either sanded down or covered using protective material such as plastic shrink wrappers. All electrical components (sensors and wirings) are covered using cable sleeves.

The SP1 is equipped with sensors to measure the joint rotations and the applied external extension torques. On the digits this is realised by measuring the deflection of the leaf spring using flexible bending sensors. This deflection can be converted to both an angular deflection of the digit and the applied extension force using the known stiffness properties of the leaf spring. In the wrist, the flexion-extension axis rotation is measured using a potentiometer at the forearm link of the parallelogram.

Finally, the hand position in global space is approximated using the UM6 ultra-miniature orientation sensor (Integrated Measurement Unit) from CH Robotics placed on the forearm that uses rate gyros, accelerometers, magnetic sensors, and an onboard 32-bit ARM Cortex processor to compute sensor

orientation. The orientation and acceleration of the forearm are used for the estimation of slow and fast movements and movement directions.

In order to extract MCP, PIP, and DIP rotations from a single measurement with the help of one bending sensor, a simple angle estimation algorithm is derived. Each flex sensor provides one bending angle reading to each individual finger. In order to extract each digits angular position (MCP, PIP, DIP rotations) from one sensor reading, some assumptions have to be made. It is assumed that there is no dead zone with the flex sensors and rotation of each phalanx is linear and covers the full range of motion except the distal phalanx. Finger caps overlap distal phalanx and middle phalanx at the same time and limit the range of motion of distal phalanx drastically. Abduction and adduction movements are neglected, as well. In addition, a simple initialisation/calibration procedure is required to measure the maximum and minimum sensor values. Similar approach can be easily applied to thumb and wrist.

The bending sensors at the leaf springs and the potentiometer at the wrist mechanisms are sampled using the analog-digital converters in the Arduino Nano microprocessor board. The Arduino passes on the sampled values to the main PC using an Universal Serial Bus (USB) connection. The IMU is connected to a serial-to-usb converter and again connected to the main PC using an USB connection. For both, custom Windows 7 drivers were written to make the signals available to the connected software.

## 5 User interface development and motivational rehabilitation

The interface of the SCRIPT system consists of two separate parts: a user interface (UI) for the patient (Patient UI) and a UI for the therapist (HCP UI). Two separate concepts were developed since the parts are targeted for different user groups, performing different tasks. Also the choice of the platform required a different design, as the Patient UI is based on a touch screen and the HCP UI is controlled with keyboard and mouse using a conventional display.

### 5.1 Analysis of user requirements

In Phase 1 (see section 3), initial engagement with users were carried out to develop an understanding of their experiences of living with stroke as well as their experiences of using technology. A variety of methods from health services research methods (focus groups, one-to-one interviews) and user-centred design methods (technology biography, cultural probes) were used to provide designers and developers with in-depth knowledge about the diversity of the target users and the personal and social context in which the SCRIPT system is expected to operate. The aggregated outcomes were delivered in the form of nine persona-based scenarios as user models to assist developers with the process of design.

For the Patient UI, the following main goals were identified:

- The system must be easy to use for patients.
- Allow quick access to recommended games.
- Direct the users attention to the most important things first.
- Motivate the user, e.g. by using positive feedback.

For the HCP UI, the following main goals were identified:

- Allow the therapist to quickly access an overview of patients and identify patients who need more attention.
- Be consistent with the design of the Patient UI, when adapting to different platforms.

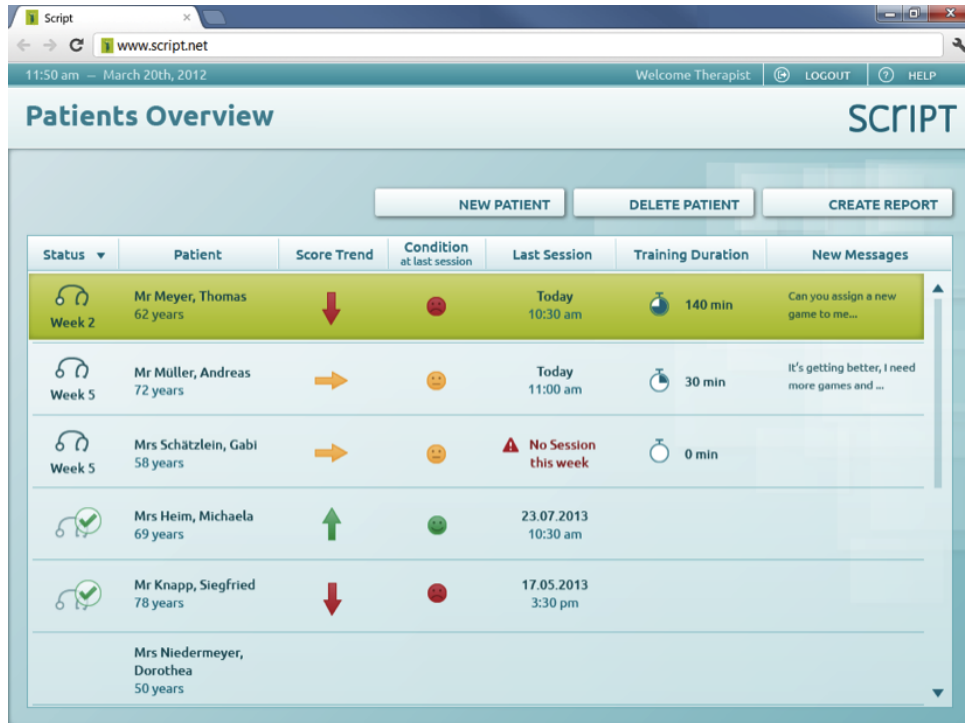


Figure 3: Health care professionals' user interface - patient overview screen

In Phase 2, the first produced SCRIPT system has been evaluated through a usability test, as well as participatory formative evaluation methods such as cognitive walkthrough and cooperative evaluation. The usability test was conducted in Italy, England and the Netherlands with three patients as well as three therapists in each country. Based on the results of the usability test and the formative evaluation, improvements were made to the Patient and HCP UI [38]. SCRIPT 2 will later be tested in a second evaluation, to prove the success of the updates from the first evaluation.

## 5.2 HCP UI

An important screen for the HCP UI is the patient overview (Figure 5.2), which is presented directly after login. The table lists all patients, and presents an overview of the current state of the patients' training:

- Patient's name, age and week of therapy
- The development of the game scores, using simple colour coding (red, yellow, green)
- Patient's own rating of current condition, using a simple colour coding and smileys
- The latest training session
- The total length of this week's training sessions
- New messages received from the patient

In this overview the therapist can immediately recognize patients that need further care, e.g. due to a patient's negative condition rating. A double-click on a cell will lead the HCP directly to the corresponding page, where he has access to detailed information and functionalities. To work with a patient, the HCP UI consists of four main areas:

### 5.2.1 Messages

The message area allows the therapist to exchange text or audio messages with the patients.

### 5.2.2 Progress

The progress area consists of several pages with different charts, e.g. active range of motion (aROM) in-Game (Figure 4), aROM during Calibration, Move Count, Training Duration, Training Session and Game Score. This area provides the therapist with a detailed feedback on the progress of the patient, using visualizations.



Figure 4: Patient progress shown in aROM tab highlighting changes in active range of motion during game play

### 5.2.3 Games

The games area contains of the basic functionality for the therapy with SCRIPT. In this area the therapist assigns games to the patients and adapts the difficulty level of the game (Figure 5). The difficulty set here relates to selection of game levels requiring more difficult to achieve gestures, for example game difficulty increases when lateral movement of the arm are added to the flexion and extension of the hand.

This follows a system similar to Gentile’s taxonomy of motor skills where *Stationary* actions are classified as simplest skills while *In Motion* functions are thought to require more complex skills. [26]



Figure 5: Suggested games are made available to patients using the game assignment functionality

#### 5.2.4 Condition

The content and design of the "condition" area is currently under progress, In this area the therapist will receive feedback on the status of the patient (presented on the left hand side of Figure 5) in terms of affected side and diagnosis as well as other performance metrics allowing to set the therapy plan with these considerations.

### 5.3 Patient UI

To ensure consistency between the Patient and HCP UI, the same design concept was applied to both interfaces. Also, the areas in the patient UI are mainly the same as in the HCP UI, but with relevant content important to patients.

A requirement for the Patient UI was to offer quick access to the recommended games and to be experienced as easy to use by the patients. Due to these requirements, the UI provides direct access to games on the home screen after login. (Figure 6) Patient UI consists of three main areas:

#### 5.3.1 Progress

In this section (Figure 7) the patient can check the training progress, e.g. game scores and training duration. Scientific statistics like the aROM are not needed for the patient. Design of the charts is

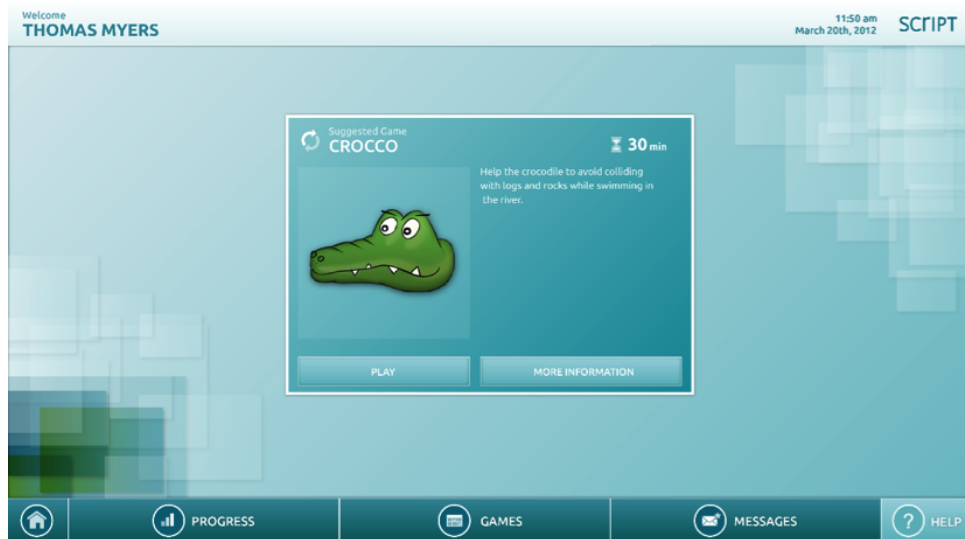


Figure 6: Patient-UI after successful login

adapted to the target users and target system, by reducing the amount of information and increasing the size of the interaction elements. Motivational messages are displayed within and after the games, to motivate the patients to continue with the training.



Figure 7: Progress screen highlighting progress across the 6 weeks of study

### 5.3.2 Games

The patient can choose between different games, assigned by the therapist. For each game, detailed information on how to play the game is available to the patient. (Figure 8)

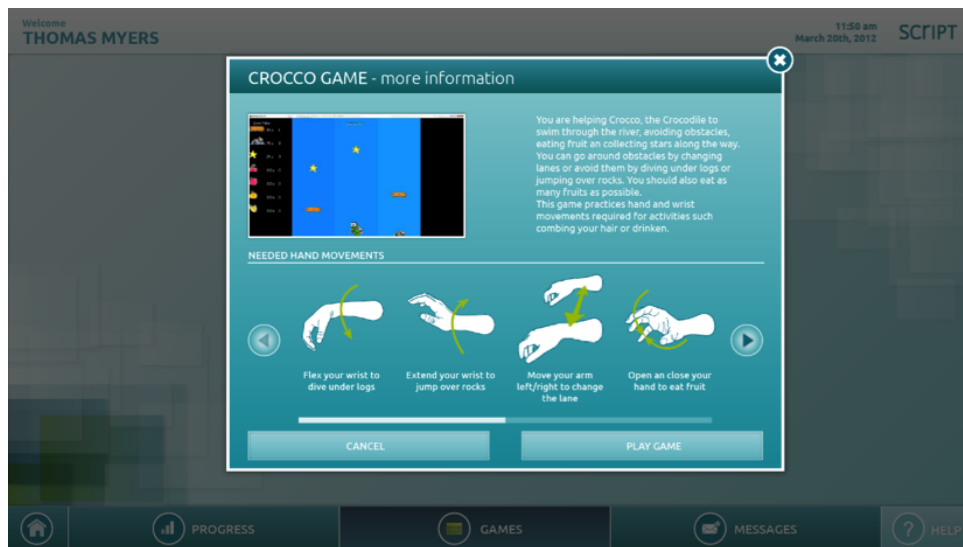


Figure 8: Information regarding playing a game provided via Patient UI

### 5.3.3 Messages

As for the HCP UI, the patient can exchange textual or audio messages with the therapist. The patient enters the message using a touch screen keyboard. (Figure 9)

## 6 Tele-robotic support platform and health-care professional interface

The tele-robotic support platform concerns the implementation of remote access to the patient's system. This enables HCPs to create and change exercise plans during the therapy, to check on the patient data and progress, and communicate with the patient. The platform consists of three components: a replicated database, a HCP webportal, and a decision support system. See Figure 10.

The patient computer communicates with a central server through a replicated database. On the central server there is a webportal and a decision support system. HCPs can access the data through the webportal. Authentication for both patients and HCPs is performed through a regular username-password combination. All network communication is secured through SSL.

### 6.1 Database (Remote Management Interface)

Communication between the patient computer and the central system proceeds entirely through a replicated database, implemented in MySQL. The database is accessed locally through an XML-RPC API. When a new patient system is deployed, as 9 prototype systems are re-used, the replication process wipes

any old data and loads essential data like the patient's information and the initial exercise plans from the central server. From then on, the patient system can function autonomously, but will sync data when an Internet connection is available. It replicates only the data belonging to that patient, so that privacy of other patients is ensured. The local database also has a development mode, which allows functioning without a central server altogether.

## 6.2 HCP Web Portal

The HCP web portal is implemented in PHP and enables access to the patient data through a web browser. As shown in section 5.2, this includes creating patients and exercise plans, sending and receiving text and audio messages, and viewing various patient data, including number of minutes trained, and various training performance statistics, such as aROM and number of movements made. The web portal includes demo accounts with sample data, which are used for instruction, demonstration, and evaluation.

## 6.3 Decision support

The decision support system provides high-level information to the HCP to help monitor patients and select appropriate exercises. To be able to do this, it requires appropriate performance benchmarks. Collected patient data is also used where possible.

The performance benchmarks were developed after some experience with the system, and enable close monitoring of key aspects, like overall gaming performance, aROM, and success and failure rate of in-game moves, as related to game difficulty parameters, like game speed, types of movements required, and required aROM to make a movement. These benchmarks will be used not only for the decision support system, but also for clinical evaluation, in-game adaptation, and patient coaching and motivational messages.

Design and development of this component is progressing in the coming months of the project. Our objectives are to detect both slow and sudden changes, like progress, deterioration and reaching ceiling levels. The information will be presented on the HCP portal in the form of alerts, colour coding, and exercise advice.



Figure 9: Audio or text message between health care professional and the patient is made possible using a messaging interface available on both HCP UI and Patient UI

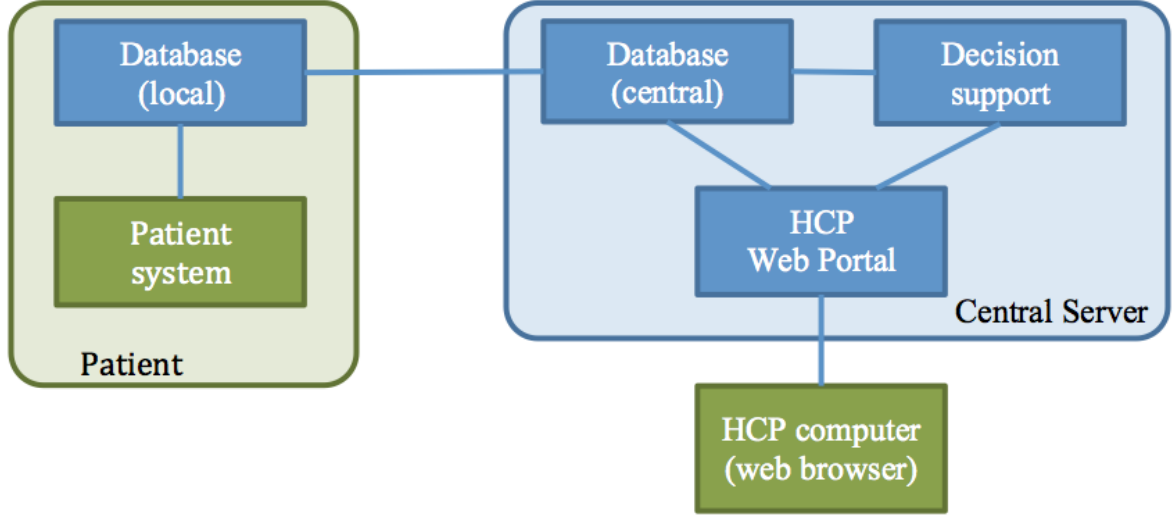


Figure 10: Tele-robotic support platform and its components. The platform comprises of the blue components.

## 7 Adaptive and therapeutic human-robot interaction

An important goal of the project is its focus on adaptive and therapeutic human robot interaction (THRI). The objective here is to cater for inter-individual differences sensed in interaction. To make this possible, a dedicated component is placed in the software architecture (see Figure 12), which constitutes a middleware between the orthosis and the games. Indeed, the THRI processes the signal generated from the device and delivers to the games information about movements performance of the subject. Such information can be of analog type, as angular or positional coordinate of a joint, or discrete, as the message that a specific pattern of movement (gesture) has just been performed. Gestures currently available relate to hand state (open, close or in a grasping position), or the wrist (extended, flexed, prone or supine). Also, we included the recognition of gross arm movements (antero-posterior and lateral displacement of the hand) as those normally performed during activities of daily living by using accelerometers on the forearm part of the arm-cuff.

These movements are matched with actions within the games that are intended for providing therapeutic exercise. Three games were designed and tested within years 1 and 2 of the project: "Sea Shell", "Super Crocco" and "Labyrinth" as shown in Figure 11.

In the Sea Shell game, the patient operates a shell by his/her hand in order to catch fishes. In the Super Crocco game, in addition to grasping, wrist flexion and extension are performed to avoid obstacles, and lateral movements of the hand to move the character on the screen. The Labyrinth game offers, in addition to this, training of forearm prone/supination and antero-posterior movements of the hand.

One of the major challenges in performing gesture recognition with stroke survivors is the inter-individual variability in motor symptoms. For instance, while normative data about range of motion (ROM) for the upper limb joints is available for healthy subjects [25, 40], each patient constitutes a per se case. Considering this, we developed a calibration procedure which measures range of motion (ROM) and duration of movements [6]. This procedure, potentially exploitable for other various movement signals, is run ahead of any practice sessions for the movements which will be required within the game. In this way, the gesture recognition is tailored on the individual patient capabilities. For instance, wrist

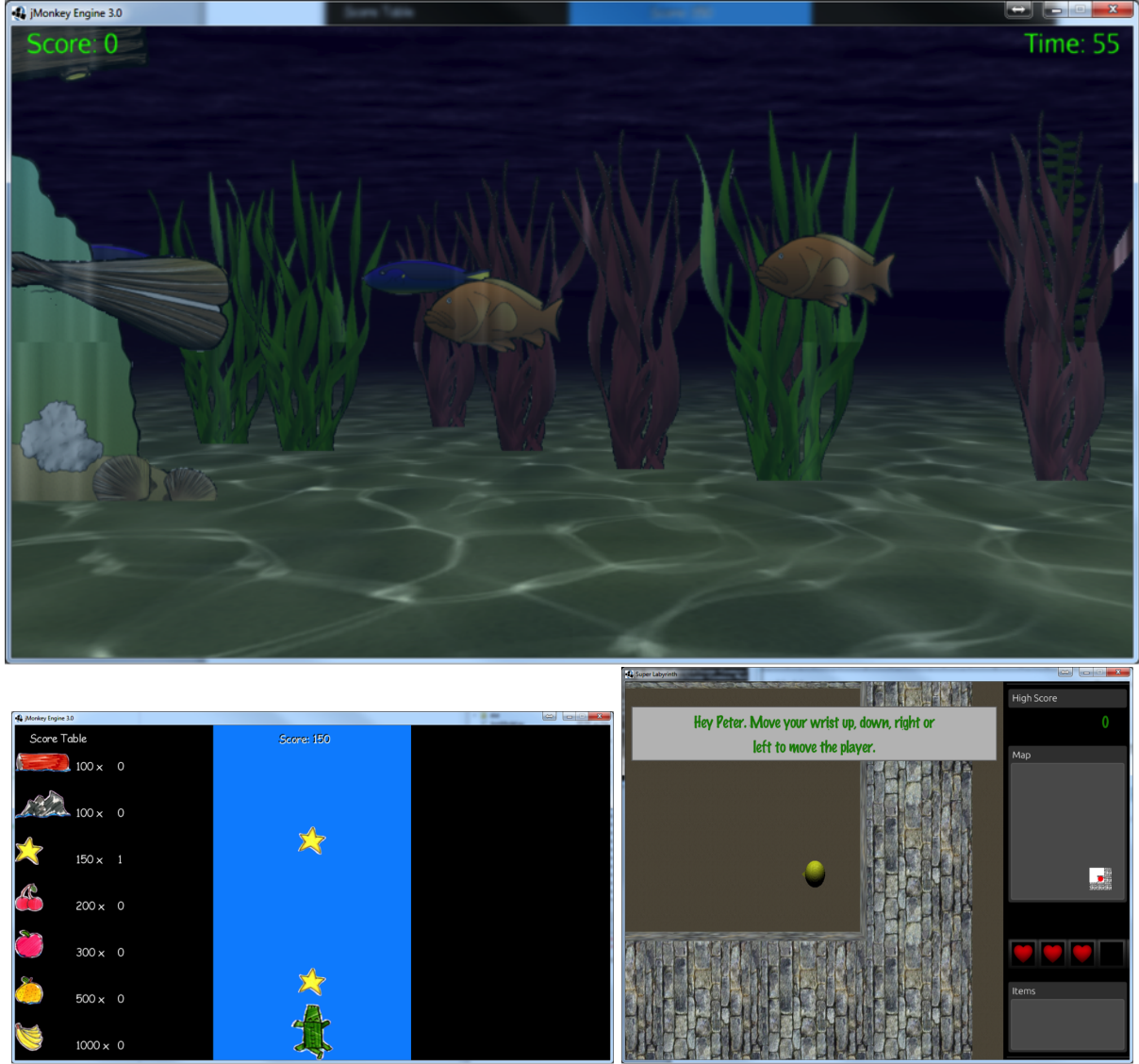


Figure 11: Three prototype exercise games, top: Sea Shell; bottom left: Super Crocco; bottom right: Labyrinth

extension is marked by reaching the 90% of the ROM measured during the calibration.

Another requirement for the therapeutic human robot interaction is to be adaptive. In the domain of rehabilitation robotics, a fundamental principle is that the robot should assist-as-needed [5]. However, the passive device does not allow any automatic regulation of the physical support provided, which is set by the therapist. Hence, the THRI further modulates the task difficulty using the speed of the game to prolong interaction time.

At the beginning, movements are required at a speed matching the time measured during the calibration. At the end of each movement, patients performance is assessed by considering whether he/she

is lagging or leading with respect to a model-generated movement profile [3] which matches their own movements in terms of amplitude and duration. The lag/lead score is the fraction of trajectory in which the subject was anticipating the reference trajectory. The speed of the game is then rescaled based on the last 10 lag/lead scores, in order to make the exercise nor too challenging nor too easy, according to the challenge point framework [11]. Future development will include the support for the active-actuated device to allow for changing assistance/resistance, recognition of functional type of gestures and an alternative method to estimate the subjects contribution to movement, based on the energy flow between the patient and the device.

## 8 Integration of hardware and software components

The SCRIPT project provides a framework for periodic, rapid and seamless integration of software and hardware components - therapy devices, therapeutic human-robot interface, games, patient user interface for game selection and performance assessment, therapist interface and data security components.

The integration framework defines the hardware and software architecture of the system and the choice of operating systems, a communication subsystem, data storage mechanism, logging system, a software repository, issue tracking system and quality assurance procedures.

The objective is to ensure a working hardware and software with adequate training prior to the start of each summative evaluation phase of the project. Moreover, integration activities frequently seeks news benchmarks and outcome parameters for device operation and interaction quality.

### 8.1 Architecture

The system has a wide range of software which needs to meet very different requirements, such as distributed fault-tolerant communication, real-time control and monitoring of the devices and an intuitive, responsive, and graphically rich therapeutic user-interface. The system adopts a modular component-based architecture, as shown in Figure 12, which supports software that is scalable, reusable, lightweight, dynamically reconfigurable and portable between platforms. The architecture allows flexibility in terms of choice of operating system, programming languages, tools and libraries. The architecture is open and flexible, but at the same time clearly defines the interfaces, which facilitate distributed system development with periodic integration cycles.

### 8.2 Operating system, programming Languages, tools and libraries

The patients system runs on Microsoft Windows 7 Professional, as this meets the needs of being responsive to user actions, while at the same time providing a rich graphical interface and simplifying the design and development of software. Windows 7 also provides a rich set of communications and data storage mechanisms. It does not offer deterministic timings, but experimental results have shown that, coupled with a multi-core PC and sufficient memory, it is adequate for the performance requirements of SCRIPT. The therapists system can run on Windows and Linux systems.

Software components are implemented as independent co-operating processes, using a variety of programming languages and tools, such as MySQL, Apache, C++, Python, PHP, Java, Javascript and JMonkey.

### 8.3 Communication sub-system

The SCRIPT project uses Google Protocol Buffers to define and manipulate message data sent using stream and datagram sockets between software components on the patient PC. Protocol Buffers provide a flexible, efficient and automated mechanism for serialising structured data in C++, Java and Python.

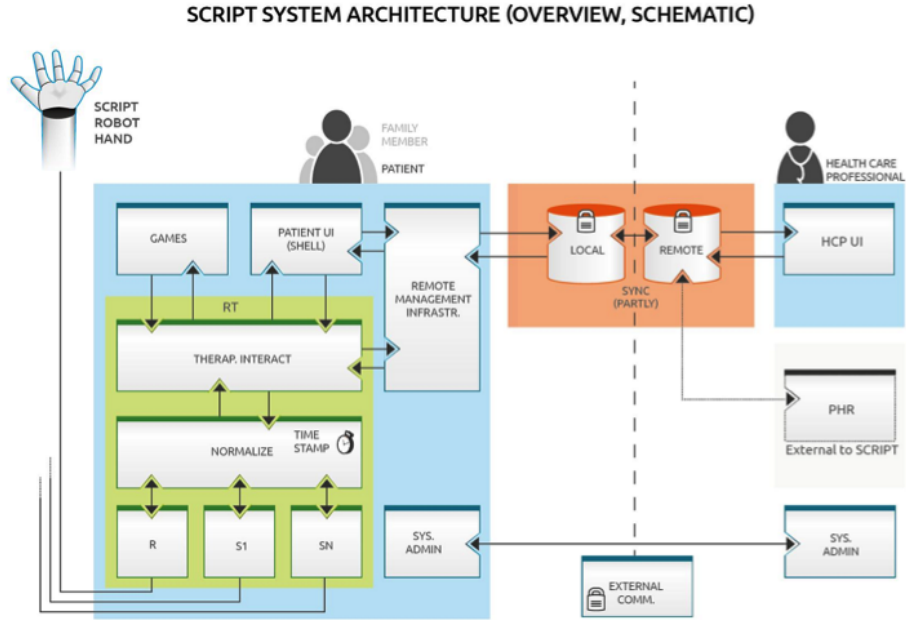


Figure 12: SCRIPT System Architecture

Using protocol buffer is lighter weight than manipulating XML data structures and allows changes to message data structures without breaking existing code. Communication between the patient PC and the remote server is via XML-RPC.

#### 8.4 SVN source control, issue tracking system and quality assurance

The integration framework provides a project SVN server and establishes a common understanding for record keeping and versioning different hardware and software design iterations. A part of this includes a common prototype assignment where each integration phase results in a system prototype that does not change throughout any of the summative phases of the project.

The TRAC system is used to track issues that arise during usability, formative and summative evaluations of the project. This assists project management by tracking and prioritising software bugs fixes and functional change requests.

The integration framework has defined quality assurance procedures which ensure that a therapy device is thoroughly tested and calibrated before being added to a patient system, after which the fully integrated system is tested before being installed in a patients home.

## 9 Evaluation, impact assessment and benchmarking

The integrated SCRIPT system enables home-based, active training of wrist and hand exercises in a game environment providing adequate challenge and feedback on performance with a schedule and dose of choice for each patient, while still enabling remote supervision by a HCP, offline. Such a system that can prolong neurorehabilitation out of the clinic, i.e. at patients homes and with low-cost treatments,

addresses a major issue in current healthcare. The current status after many years of development of rehabilitation technology for post-stroke arm training, especially concerning robot-aided rehabilitation, has indicated that arm function improves as much after robotic treatment as after conventional therapy, if provided with the same intensity of treatment [36, 19, 23, 29]. Currently, rehabilitation technology presents merely a tool to enable more independent practice, as a way to enhance the amount of treatment patients can receive, without being limited by therapist availability. Although it is assumed that patients will practice independently when provided with the opportunity, this is a highly relevant question when deploying a technology-supported system for training of the arm and hand in the home setting. Therefore, this is one of the main issues addressed during evaluation and impact assessment of the SCRIPT system.

Besides Formative Evaluation (FE) focussing on user-engagement in design and system development to enhance the acceptability of the system, the clinical study design applied in this project (Summative Evaluation (SE)) involves evaluation of the SCRIPT system in a situation where treatment protocols haven't been fixed or personally supervised. On the contrary, except for the recommendation to practice 30 minutes per day for 6 days a week, participating chronic stroke patients are left entirely free in their choice on when and for how long they want to practice with the SCRIPT system during the 6 weeks deployment at their home. During these 6 weeks, patients are remotely supervised on their progress by a healthcare professional (HCP) through the HCP portal. The progress in terms of game scores serves as the basis for the HCP to select appropriate exercises targeting e.g., wrist flexion/extension movements combined with grasping/hand opening gestures. This decision is refined, if needed, during short weekly home visits by the HCP to check on the patient.

The summative evaluation assesses feasibility of self-administered tele-robotic devices on several levels across three European-wide user-evaluation centres (University of Sheffield in the United Kingdom, San Raffaele S.p.A. in Italy, Roessingh Research and Development in the Netherlands), which allows validation of usefulness of the SCRIPT system. In terms of user acceptance, actual amount of use, usability and motivation are examined during and after the use period. In addition, patients are assessed clinically prior to, after and at two-month post-intervention using established and validated clinical outcomes for arm and hand function (amongst others the Fugl-Meyer assessment and Action Research Arm Test).

At the moment, 23 of the intended 30 chronic stroke patients with marked limitations in arm and hand function have been included. Of these, 12 patients have completed the training and evaluation sessions so far, and have been able to use the SCRIPT system successfully at their home. These highly preliminary findings of the ongoing study suggest that deployment of self-administered training is feasible. Future analysis of the clinical outcomes, as well as amount of use, intensity of training, usability and user acceptance of the complete sample allows for a comprehensive analysis of relations between user acceptance, actual amount of use and the influence of self-administered home-based training on arm and hand function.

## 10 Conclusions and future work

The design, development and deployment of a home-based rehabilitation device for mediating repetitive exercise via a passive-actuated hand/wrist exoskeleton device was presented here. Aspects highlighted included the importance of user-centred design and inclusion of potential users as co-developers and co-designers. This was made possible by employing multiple phases of interaction during the design cycles. A critical step here was to start with understanding the potential users and their diversity using in-depth interviews and cultural probes. These culminated in system requirements that were used for developing the prototype system. The prototype was then assessed against those user requirements using formative evaluation cycles often consisting of focus groups and steering group meetings.

This manuscript highlights different aspects of development, ranging from the hardware including

the prosthetic device, to software components such as patient and health care professional user interfaces. Resulting system was replicated into 11 prototypes, from which 9 are being used for summative evaluation. The objective of this evaluation was to assess the feasibility of a home-based rehabilitation device. Although early, preliminary results obtained from 12 patients that completed this evaluation phase indicate supportive evidence for feasibility of such devices for home use.

Future work focuses on active-tuning of the amount of assistance provided to the hand and wrist, while providing more exercise games with an additional set of gestures within these games. This is to enhance the functional and goal-oriented nature of the exercises. Also, the decision support system under development will provide a chance to assist in monitoring patients' remotely using performance benchmarks and by detecting sudden and slow changes in progress. A second summative evaluation phase is planned to test the resulting system.

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