



## Innovations Influencing Physical Medicine and Rehabilitation

# Robotic and Sensor Technology for Upper Limb Rehabilitation

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## Abstract

Robotic and sensor-based neurologic rehabilitation for the upper limb is an established concept for motor learning and is recommended in many national guidelines. The complexity of the human hands and arms and the different activities of daily living are leading to an approach in which robotic and sensor-based devices are used in combination to fulfill the multiple requirements of this intervention. A multidisciplinary team of the Fondazione Don Carlo Gnocchi (FDG), an Italian nonprofit foundation, which spans across the entire Italian territory with 28 rehabilitation centers, developed a strategy for the implementation of robotic rehabilitation within the FDG centers. Using an ad hoc form developed by the team, 4 robotic and sensor-based devices were identified among the robotic therapy devices commercially available to treat the upper limb in a more comprehensive way (from the shoulder to the hand). Encouraging results from a pilot study, which compared this robotic approach with a conventional treatment, led to the deployment of the same set of robotic devices in 8 other FDG centers to start a multicenter randomized controlled trial. Efficiency and economic factors are just as important as clinical outcome. The comparison showed that robotic group therapy costs less than half per session in Germany than standard individual arm therapy with equivalent outcomes. To ensure access to high-quality therapy to the largest possible patient group and lower health care costs, robot-assisted group training is a likely option.

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## Introduction

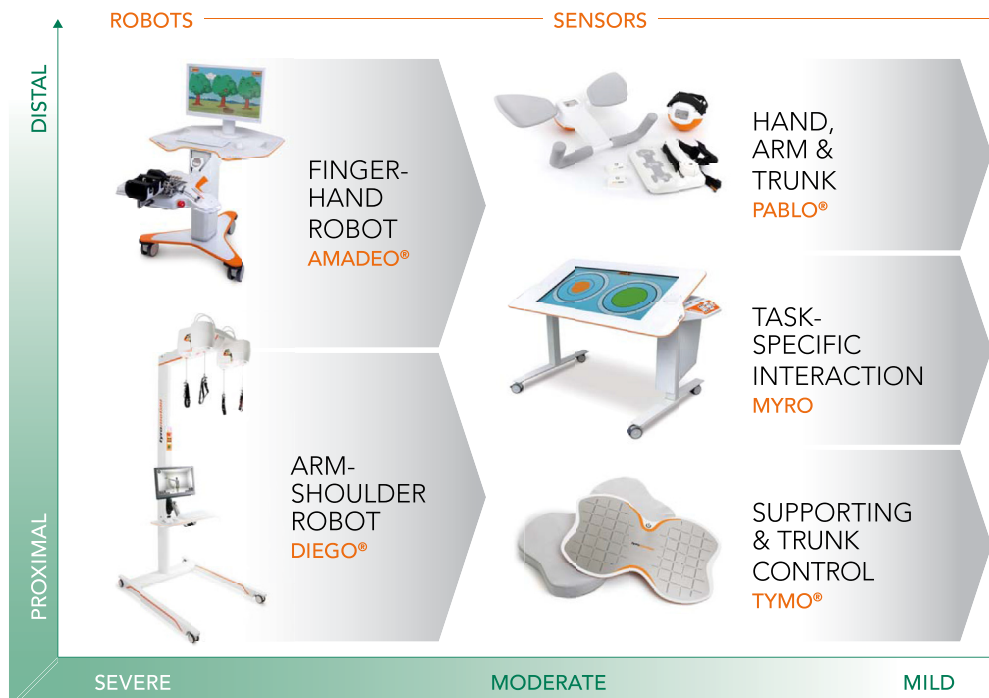
Rapid technologic developments have occurred in recent years, particularly the technology of computer- and robot-assisted devices for upper extremity rehabilitation and virtual reality therapy. This applies to research and broadly to different arm rehabilitation devices. Computer- and robot-assisted forms of therapy have proved to be an important component for optimizing rehabilitation of the upper limb [1]. Hesse et al [2] compared robot-assisted group therapy for the upper limb with individual arm therapy and reported similar outcomes for the 2 groups. In particular, 30-minute robot-assisted group therapy in combination with 30-minute individual arm therapy was as effective as a double session of individual arm therapy for restoration of upper limb motor functions, but the robotic group therapy cost 50% less per patient session compared with standard individual therapy. However, the human upper extremity is a complex physiologic and anatomic

structure with actuators, sensors, and an end-effector–based kinematic system controlled by a highly sophisticated controller to perform different activities of daily living (ADLs). Reaching, positioning, and grasping are combined, so that most ADLs can be performed in different ways. According to the definition of the U.S. National Bureau of Standards [3], an industrial robot is “A reprogrammable, multi-function manipulator designed to move material, parts, tools, or specialized devices through various programmed motions for the performance of a variety of tasks.” A therapy robot can be defined as a reprogrammable and multifunctional manipulator designed to perform different rehabilitation tasks through various programmed motions. Therefore, it would make sense to set up a robotic system that moves the arm and the hand to fulfill this task, similar to locomotion robots used for gait therapy. Unlike the lower extremity, where a specific walking pattern can be defined, a typical motion pattern for the upper extremity does not exist. Because of the

complexity of the arms and hands and the multitude of motion patterns available, we need to find a different strategy. Similar to the learning of music pieces or the training of movement sequences in sports, therapeutic movements can be broken down into their components: distal repetitive grasping and proximal functional reaching and positioning. From this perspective, it makes sense to use a set of 2 therapy robots, 1 for distal joint and 1 for proximal joint treatment. Another approach to simplify complexity is by decreasing the number of degrees of freedom based on the patient's level of impairment. Robotic devices can be used for motor-driven passive mobilization and active-assisted exercises for severe and moderate impairments, while active exercises can be promoted and guided by feedback from sensor-based devices without motors. Based on the location and severity of impairment of the upper limb and trunk stability, a matrix concept of robotic and sensor-based therapy devices is designed to meet the individual patient's needs. A widely used commercial array of devices is offered by Tyromotion GmbH (Graz, Austria). The array includes 2 robotic devices, AMADEO and DIEGO, and 3 sensor-based systems, PABLO, TYMO, and MYRO (Figure 1). Therapy modalities span from passive mobilization to active-assisted, active, and resisted exercises. To maximize active patient participation during therapy, the use of robots transitions from motor-driven assistance, when it is no longer of benefit to the patient, to sensor-based feedback systems. For the upper limb, 2 robotic and 3 sensor systems cover the entire upper limb and trunk requirements with the right

amount of technology and offer impairment-based and task-specific rehabilitation training.

In addition to the therapeutic approach mentioned earlier, health economics and funding factors are becoming increasingly important. With the introduction of robots to rehabilitation clinics, many therapists feared being replaced by a machine, but this fear is unjustified. Only in combination with therapists can technology help to cope with future challenges. Stroke rates are increasing worldwide: in 2010, 33 million people were living as stroke survivors, and if current trends in stroke continue, then by 2030 there will be 70 million survivors [4]. Further, stroke is a major cause of serious long-term disability, in which 4 of 5 patients are discharged from care with limited arm function [5]. As a result, stroke is one of the most costly neurologic conditions. For the first year after stroke, the mean total direct health care cost per stroke survivor in Germany is €18.500 (U.S.\$21.500), including inpatient and outpatient rehabilitation (37%) and medical care and services (54%). Mean direct lifetime costs are 3.6 times higher than rehabilitation costs within the first year [6]. When considering that indirect cost (eg, lost productivity) is equal to direct cost [7], the overall amount almost doubles. Employment data for physiotherapists in Germany confirm that in clinical practice there are considerably more job vacancies than candidates [8]. In addition to increasing migration to other less physically demanding jobs, the increasing number of patients is promoting the development of new rehabilitation techniques and protocols. Thus, the use of



**Figure 1.** Concept matrix for the application of rehabilitation systems with respect to individual patient needs. Robotic devices with built-in motors and sensors address patients with severe disability and those who need assistance.

robots decreases this imbalance between the supply of therapists and the needs of patients.

### How Therapy Robots Can Be Used

Hand function and particularly finger extension are crucial to engage in ADLs such as grasping a glass or buttoning clothes for those patients with severe impairment who often cannot work on the required large number of task repetitions to improve function of the affected hand. These tasks are difficult, exhausting, and produce a high level of frustration often leading to nonuse or use of compensation strategies. A hand robot, such as the AMADEO, helps to train various aspects of the grasping movement and to work on targeted finger extension training. Active participation of the patient's affected hand is promoted with biofeedback and assist-as-needed interactions implemented in a highly motivating therapeutic gaming environment. Patients who are barely able or unable to grasp can perform hundreds of robot-assisted grasping movements, which provides intensive stimulation to the brain. The entire hand and individual finger exercises can be controlled through isometric force, range of motion, or surface electromyography trigger signals, which can be used to train different functional activities. Spasticity can be addressed by the application of vibration and continuous passive movement, which are effective tools to prepare the hand for active and functional use during therapies.

Positioning the arm away from the trunk is a key factor for functional use of the limb. This interaction of simultaneously working on trunk stability and arm movement is challenging for the therapist. An arm robot, such as the DIEGO, helps facilitate therapy by using an intelligent arm weight compensation system. One or both arms are connected with wrist and elbow slings to retractable ropes that are controlled by 4 independent motors equipped with sensors. This enables unilateral or bilateral assistance as needed that adapts to the actual position of the upper limb in 3-dimensional space. The distal wrist and elbow assistance increases proximal trunk and shoulder stability and helps decrease compensatory movements. Functional reaching movements can be trained as a whole and with focus on lifting, reaching, and transferring components of the movement or targeting a specific joint movement at the impairment level. At the same time, the therapist has full access for hands-on (eg, scapula facilitation and trunk control during training). In brief, the robotic arm support enables functional arm movements with large numbers of repetitions in a motivating therapeutic gaming environment.

The transfer of gains to functional situations is challenging; the practice conditions need to match real-life situations as closely as possible to facilitate daily tasks [9]. A multisensory system, such as the MYRO, helps

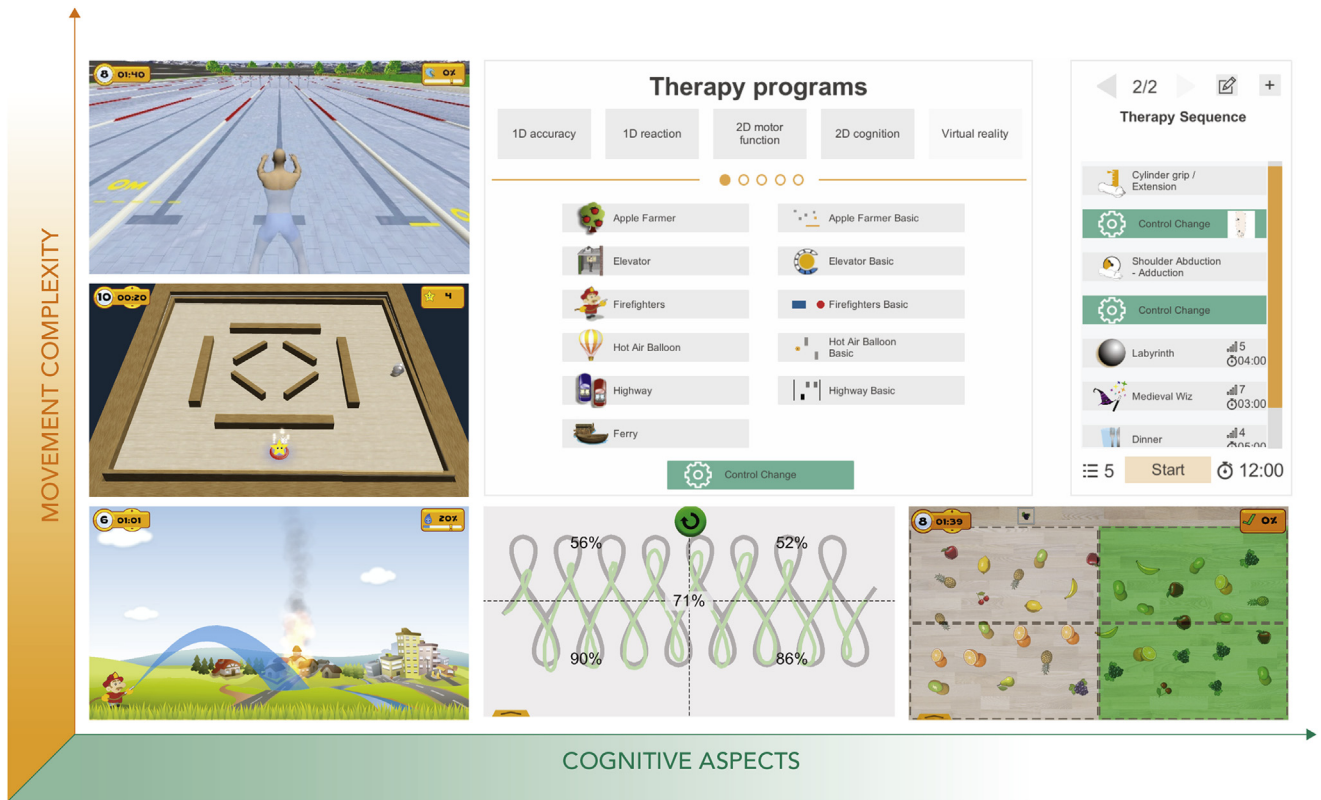
bridge the gap between exercises at the impairment level and ADLs. Interactions with the sensor-based digital surface can be controlled in 3 modes: by real objects (eg, coin, cup, or handle), force (push and pull), and touch. The large surface can change position in space, allowing object pick-and-place exercises to work on gross motor skills and graphomotor exercises (eg, different templates for tracing with a pen or finger) offer tools for fine motor skill training. The limitations and challenges of arm and hand movement can be adjusted with different positions of the system: table top (reaching and transfer), inclined (continuous grading for integrating arm lifting), and vertical board (lifting and transfer). The device has special software settings that enable spatial explorative, cognitive, and visual motor integration skills training, which can help patients with neglect or other cognitive or visual perceptible deficits.

A combination of robotic and sensor-based devices enables the shaping of different training areas, such as movement complexity, cognitive, or rhythmic skills (Figure 2).

### Therapy Robots and Sensors—Clinical Effectiveness and Efficiency

Robot-mediated therapy for recovery of the upper limb is gaining increasing attention from clinicians and researchers, providing promising results [10]. Several robotic and electromechanical systems for the upper limb, such as exoskeleton or end-effector, have been developed. Recent meta-analyses [4,11,12] have highlighted that the studies reviewed are heterogeneous in the devices used for therapeutic treatment and for patients' characteristics and methodologic protocols. Most scientific articles in the literature have focused on the effects of the use of 1 or at most 2 robotic devices (in addition to conventional treatment) compared with a conventional approach. However, there are several commercial devices available and each operates on a limited number of joints and has a limited workspace, mostly in 1 plane. Moreover, these commercial devices are often used for research rather than in clinical practice. It is important for clinicians to choose devices that will ensure the best treatment option to the patients and validate their application in clinical practice.

Robotic devices are expensive, so their use in clinical practice for patients with upper limb impairment can be limited by their cost [13-15]. This limitation could be overcome by optimizing human resources through a new organizational model in which 1 therapist can oversee several patients at the same time. To achieve this, it is crucial to identify a set of robotic and sensor-based systems, with each system acting on a different joint and/or in different planes, to allow a comprehensive upper limb rehabilitation program applying an organizational model that optimizes human resource use.



**Figure 2.** Application examples in context with therapy games and software implementation. The software allows the combination of different applications in a therapy sequence.

Since April 2015, a multidisciplinary team of the Fondazione Don Gnocchi (FDG) in Italy has been working under this premise. The FDG is an Italian nonprofit foundation that spans the entire Italian territory with 28 rehabilitation centers.

### Set Identification

The multidisciplinary team consisted of the medical director, 3 physiatrists, 2 neurologists, 3 physical therapists, and 4 bioengineers, was coordinated by the head of the innovation and health technology assessment department, and was created with the intent of developing a strategy for the implementation of robotic rehabilitation within the FDG centers. For this reason, the team evaluated commercially available robotic therapy devices to generate a ranking list of potential solutions required by the FDG. The team also was tasked with the deployment of robotic devices for various FDG centers and promoting the use of such solutions.

The group assessed different devices, including systems for the upper limb and for the hand, using an ad hoc dataset. The features analyzed included general information (commercial name, manufacturer, distributor, name, and confidence level of the assessor), system characteristics (type of system, body segment treated, type of movement, portability, type of assistance provided by the system, main control inputs, configurability,

normative values, and outcome measures), wheelchair access, safety issues, literature data, costs of purchase and maintenance, and motivation and efficiency parameters (autonomous use by the patient, setup time, possibility of using the system in group therapy, and number of clinicians involved during treatment). The team members evaluated 8 different robotic or sensor-based systems for the upper limb and 2 for the hand. The evaluation included robotic devices (exoskeletons and end-effectors) and sensor-based systems.

To rank the therapy devices by purchase priority, the coordination team defined an algorithm based on the weighted sum of item scores in the evaluation form. Data obtained from this algorithm were set against the cost of each device and this process led to the identification of a set of 4 therapy systems (3 robotic devices and 1 sensor device; [Figure 3](#)) that could globally treat the upper limb. The following 4 devices were selected by the multidisciplinary team of the FDG according to this procedure:

1. A robotic device that allows passive, active-assistive, and active finger flexion and extension movements (AMADEO; Tyromotion)
2. A robotic device that allows 3-dimensional unilateral or bilateral movements of the shoulder joint with arm weight compensation against gravity (DIEGO; Tyromotion)



**Figure 3.** The Fondazione Don Carlo Gnocchi identified a set of 4 robotic and sensor-based devices to globally treat the upper limb: (A) a robotic arm-shoulder therapy system (DIEGO; Tyromotion), (B) a robotic finger-hand therapy system (AMADEO; Tyromotion), (C) a sensor-based therapy system for the entire upper limb (PABLO; Tyromotion), and (D) a robotic system for planar movements (Motore; Humanware).

3. A robotic device that allows passive, active-assistive, and active planar movements of the shoulder and elbow joints (Motore; Humanware, Pisa, Italy)
4. A sensor-based system that allows unassisted unilateral or bilateral 3-dimensional movements of the shoulder, elbow, and wrist joint (PABLO; Tyromotion)

The use of the identified set of devices in a new organizational model and their clinical effects (pilot study) were explored in an FDG center in Rome.

### Organizational Model

The use of the identified set of devices in an FDG center in Rome allowed the introduction of a new organizational model in which 1 therapist treats up to 4 patients at the same time, optimizing human resources. A study on a wide sample of patients was performed to evaluate (1) the feasibility of this new organizational model and (2) the impact of the patient's disability and comorbidity on this organizational model. Specifically, in 33 days, 60 patients with upper limb impairment caused by neurologic (91.7%) or orthopedic (8.3%) disorders were studied. A trained researcher was selected

as the observer during each robotic rehabilitation session. Each session, lasting 45 minutes, included 2, 3, or 4 patients treated by 1 physiotherapist at ratios of 1:2 (R2), 1:3 (R3), or 1:4 (R4). The number of patients treated in each rehabilitation session was empirically chosen by the physician depending on the patients' disability, mobility, and comorbidity. For each participant, the physiotherapist selected the device and adapted the exercises to the residual abilities.

To evaluate the feasibility of the organizational model, training time and patient satisfaction (using the visual analog scale) were assessed for each patient in each rehabilitation session. To evaluate the impact of the patient's disability and comorbidity on the organizational model, we recorded the physical burden of illness (using the Comorbidity Index and Severity Index of the Cumulative Illness Rating Scale), disability (Barthel Index and De-ambulation Index), and upper limb impairment (Motoricity Index).

A total of 255 rehabilitation sessions were recorded with a ratio of physiotherapist to patient as follows: 45 sessions (17.7%) with R2, 148 sessions (58.0%) with R3, and 62 sessions (24.3%) with R4. Training time was significantly different among groups ( $P = .007$ ). Post hoc

analysis showed that it was significantly shorter in the R4 group compared with the R2 (mean difference = 3.2 minutes,  $P = .04$ ) and R3 (mean difference = 2.3 minutes,  $P = .01$ ) groups; no differences were found between the R2 and R3 groups ( $P > .99$ ). Moreover, no significant differences were observed in patient satisfaction among the 3 groups. Barthel Index, Deambulation Index, and Cumulative Illness Rating Scale–Severity Index were significantly different between groups R2 and R4 ( $P < .001$ ) and between groups R3 and R4 ( $P < .001$ ) but not between groups R2 and R3 ( $P = .24$ ).

Our results suggested that more than 1 patient (up to 3) could be treated at the same time by 1 therapist without differences in training time using the set of devices described earlier. However, the clinical characteristics of patients need to be considered for successful implementation.

### Pilot Study

A pilot study was designed to evaluate the utility of the identified set of devices in clinical practice and compare the conventional therapeutic approach with robotic treatment of the upper limb in patients after stroke. Thirty consecutive patients (40–85 years old) with subacute status (<6 months) after the first ischemic or hemorrhagic stroke were recruited from 2 FDG centers in Rome: (1) Santa Maria della Provvidenza, where the robotic and sensor-based devices were installed (robotic center), and (2) Santa Maria della Pace (conventional center).

In the 2 centers, patients with a similar case mix were treated. Patients from the robotic center were treated with robotic devices for the upper limb (as described earlier; robotic group), whereas patients from the conventional center were treated using conventional rehabilitation therapy protocols for the upper limb (conventional group). In the robotic group, the distal and proximal segments of the patient's upper limb were treated using robotic and sensor-based devices. The R3 or R4 setting was used depending on the severity of the patients' disability. During each session, the physical therapist was limited to using 1 or 2 systems for each patient to minimize the time required to move patients between systems. Each patient was treated using all 4 devices in alternate fashion. In the conventional group, patients underwent conventional treatment with a ratio of 1 therapist to 1 patient. Rehabilitation treatment, whether robotic or conventional, was performed daily for 45 minutes, 5 days per week, for 30 sessions in total.

After treatment, the 2 groups showed significant improvement in disability (Barthel Index) and upper limb function (Fugl-Meyer score), with greater improvements in the robotic group. This pilot study allowed us to evaluate the effects of rehabilitation using a set of robotic and sensor-based systems and

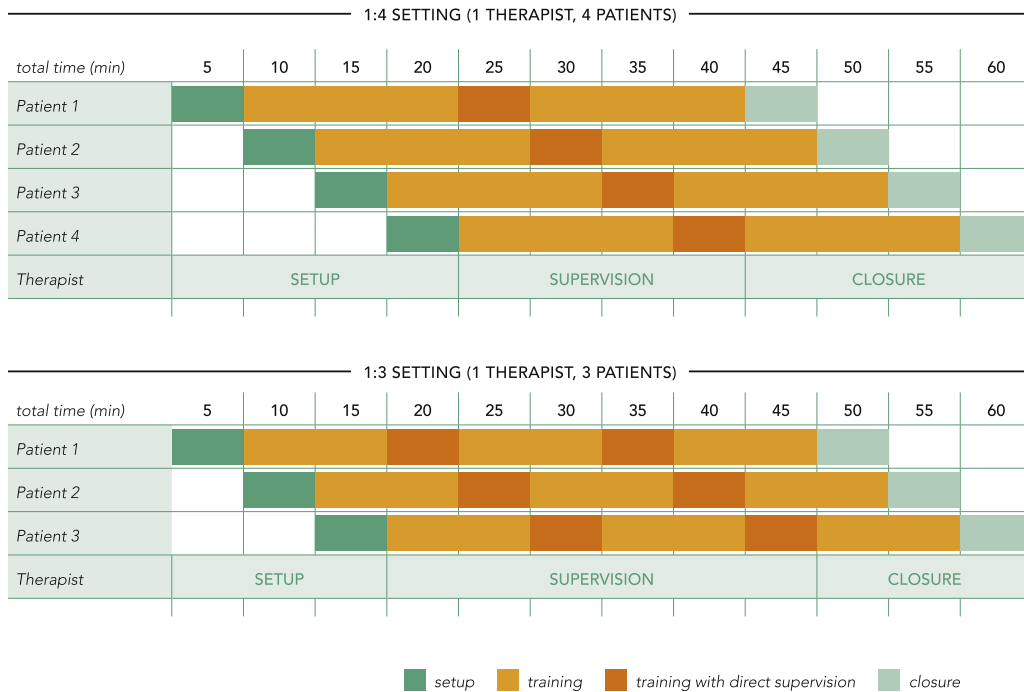
therefore supports the proposed methodology to identify an effective equipment set from a clinical perspective. Note that the comparison between technology-based and conventional treatment in this pilot study was intended to obtain preliminary clinical information before deployment of the devices in other FDG centers. In fact, we wanted to determine whether the clinical effects of the systems were comparable to those achieved by conventional therapy and not the efficacy of the robotic rehabilitation, which requires a randomized controlled trial.

In May 2016 a consensus conference among 9 FDG centers was held on a new protocol for rehabilitation technology, using the selected set of 4 robotic and sensor-based devices and the new therapy care model, for rehabilitation of upper limb in patients with subacute stroke. The aim of this protocol was to determine the efficacy of technology-based treatment on a large sample of patients, within a multicenter randomized controlled trial using the same multiset of devices and the same outcome measures, in an attempt to obtain better-quality scientific evidence than currently available in the literature. The randomized controlled trial is currently ongoing and the results will be available in the near future [16].

### Issues Surrounding Robotic Usability

A comparison of 4 modern well-organized European rehabilitation centers showed that patients with stroke spent on average only 1–3 hours per day in therapy and were inactive the rest of the day [17]. The focus of inpatient therapy is primarily on walking training, whereas upper limb training accounts for only up to half the time dedicated to the lower extremity. Furthermore, the upper limb shows less functional recovery compared with the lower extremity [18]. Because of this situation and the strong evidence that more practice leads to better recovery of motor function of the paretic upper limb [19], it seems advantageous to offer additional treatment time for the upper limb in a robotic group setting as proposed.

The experience of numerous robotic and sensor device installations has shown the feasibility of device-based group therapy. Two different settings are used to illustrate how device-based group therapy can be organized in clinical practice (Figure 4). The 2 settings (R4 and R3) are based on 1-hour overall time for the therapist. Patient arrival and departure times are staggered by 5 minutes, so that the therapist can set up the device individually for each patient and close the session. Short setup and closure times are important to maximize net training time, that is, 35 and 40 minutes per patient for the R4 and R3 settings, respectively. The R4 setting allows on average a 5-minute episode for direct therapist supervision per patient and therefore is less flexible. The R3 setting offers on average twice the



**Figure 4.** Two possibilities for organizing device-based group therapy for the upper limb in clinical practice.

time for direct supervision per patient and therefore is more flexible and suitable if patients have medium to severe disability and might need more guidance by the therapist. For device-based group therapy, the severity mix and clinical characteristics of the patient group should be considered.

As discussed earlier, robotic group training is effective and economically efficient. This technology is not only the subject of research but also has been established worldwide in everyday clinical practice. Nevertheless, there are some device requirements that need to be considered for effective and efficient training:

- **Accessibility:** wheelchair access and device adjustment options for a patient's physiologic position
- **Setup time:** typically 2-5 minutes to ensure and maximize effective net therapy time
- **Assessment:** technology allows a quick and unbiased objective assessment of patient status
- **Motivation:** therapeutically meaningful software applications that meet the goals set while the patient has fun and remains engaged
- **Automated reporting and documentation:** detailed therapy data and individual parameter settings across all devices
- **Staff training time:** learn a common software that is shared across various devices

## Summary

Robotic and sensor-based upper limb training after the development of neurologic disorders has been

established as a method to treat motor dysfunction and cognition deficits, for research, and use in numerous clinics worldwide. Although robots for the lower extremity are mainly focused on promoting a prescribed gait pattern to improve walking, the strategy for upper extremity robotics is much more complex, not only because of the 27 degrees of freedom of the upper limb but also because of the variety and complexity of ADLs and the way they are performed. To offer a practical solution and to meet the requirements for upper limb training on a broad basis, a matrix approach can be used. This means that robotic and sensor-based devices are integrated to address distal and proximal training and are stratified for patients with mild to severe disability.

This approach was studied in a pilot study, based on the use of 4 devices (AMADEO, DIEGO, PABLO, and Motore), that compared the outcome of robotic group therapy with conventional individual therapy performed daily for 45 minutes, 5 days per week, for a total of 30 sessions. The 2 groups received the same amount of therapy. Between-group analysis showed that higher changes (greater improvement) were detected in the Barthel Index, De-ambulation Index, and Fugl-Meyer score for the robotic group.

Therapy dose and intensity are major predictors of an effective upper limb rehabilitation program. Robot-assisted group training meets the principles of motor learning and is intended to increase the amount of upper limb therapy within the framework of existing clinic models. This can be achieved by implementing an innovative organization model using a staggered therapy for patients in an R3 or R4 setting.

Limitations of current robotic and sensor systems for the upper limb and future directions can be divided in 2 areas: hardware and software (clinical application). For hardware, do we need to develop the “perfect upper limb rehabilitation robot”? Owing to technical limitations, it is not expected that an upper extremity robot will be engineered in the near future that can reproduce human upper limb movements considerably better. Moreover, even if this “perfect therapy robot” could be built, the material cost (considering 27 motors to move 27 degrees of freedom), space needed, and its resultant usability would likely be limited. Also, the mechanical structure of most current systems can be considered adequate for the ratio of development effort to clinical benefit, taking into account that typically even small technical improvements require great development effort. For current software, is the therapeutic intelligence of upper limb rehabilitation systems sufficient? Most clinical trials that study robotic and sensor technology for upper limb rehabilitation do not describe the number of repetitions, exact intensity, time, dose, overall number, and frequency of applied therapy sessions in detail and the aspects of combinations with conventional therapies [5]. Hence, the general knowledge about the exact therapy content is limited and the evidence for generalized and across-device recommendations for therapy protocols is lacking. Therefore, advancements of therapy robots should be mainly directed toward improving the therapeutic software and functionality rather than the mechanical structure of the machines. Software applications hold great potential to increase the motivation to train, incorporate and simplify expert knowledge, and make both available to a large number of users. Furthermore, a cross-system software platform with a shared terminology seems helpful in guiding future directions to address questions on therapy dose and intensity, device selection, and how often or when they should be used.

In addition to the clinical aspects, economic factors are important, not only for health care plans but also because of the pressure to lower overall health care costs to more sustainable levels. Studies indicate that robot-assisted therapy costs less than standard intensive arm training with equivalent outcomes. Robots are an essential part of a modern therapy concept and are important to improve the overall quality of neurologic rehabilitation.

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## Disclosure

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