Robot-assisted rehabilitation of the upper limb in persons with Multiple Sclerosis: a pilot study


1REVAL Rehabilitation and Health Care Research Centre, PHL University College, Guffenslaan 39, B-3500 Hasselt, Belgium.
2Expertise Centre for Digital Media, Hasselt University and transnationale University Limburg, Wetenschapspark 2, B-3590 Diepenbeek, Belgium.
3Department of Human Movement Sciences, Maastricht University, Universiteitssingel 50, NL-6229 ER Maastricht, The Netherlands.
4Rehabilitation and Multiple Sclerosis Centre, Boerenganstraat 2, B-3900 Overpelt, Belgium.

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1. INTRODUCTION

Multiple Sclerosis (MS) is a chronic, progressive disease of the central nervous system (CNS). Although the exact aetiology of MS remains unknown, a combination of genetic, infectious, environmental and/or autoimmune factors likely contributes to disease onset. Dependent on the heterogeneous distribution of lesions throughout the CNS, MS may clinically lead to a variation of symptoms such as muscle weakness, spasticity, loss of coordination, sensory disorder and also visual and cognitive deficits, which all may cause severe limitations of functioning in daily life. MS predominantly affects young adults in their most productive years. Its prevalence in Europe varies with latitude of regions with an average being approximately 1/1000.

For a long time, persons with MS have been advised to avoid physical training. Because of the latter and their disability, most individuals with MS are less physically active, with disuse further contributing to muscle weakness and fatigue. At present, however, an increasing number of studies have shown beneficial effects of exercise training in MS regarding lower limb muscle strength, exercise tolerance level, functional mobility (i.e. balance and walking) and quality of life, while no evidence of deleterious effects were described. Unfortunately, the outcomes of exercise therapy on arm function in MS have hardly been investigated. This is surprising because upper extremity dysfunction strongly influences the capacity to perform activities of daily life (ADL) such as self-care, dressing, object manipulations, etc.

Training duration and intensity are considered to be key factors for a successful neurological rehabilitation. As therapy time dedicated to arm function training is limited with MS persons having a multiplicity of symptoms requiring treatment, there is need for additional therapeutic modalities that can be used autonomously by the patients. Within this framework, rehabilitation robotics are a new promising development allowing high-intensity, repetitive, task-specific, interactive treatment of the impaired upper limb. Interactive arm robotic systems provide proprioceptive and visual as well as auditory feedback during the performance of goal-directed movements in a virtual learning environment.

Many robotic devices intended to train the upper limb are now brought on the market, and first randomised-controlled studies of the MIT-MANUS (Massachusetts Institute of Technology-MANUS), the ARM Guide (Assisted Rehabilitation and Measurement Guide), the MIME (Mirror-Image Motion Enabler), the InMotion Shoulder-Elbow Robot, and the BiManu-Track are now published. The MIT-MANUS is a 2 degrees of freedom (DoF) robot that assists reaching movements in the horizontal plane. The ARM Guide, a 4 DoF device, enables reaching in a straight-line trajectory. The MIME consists of a 6 DoF robot arm which is developed for unrestricted bilateral shoulder and elbow movement. The 2 DoF InMotion Shoulder-Elbow Robot, the commercial version (Interactive Motion Technologies Inc., Cambridge, USA) of the MIT-MANUS, allows shoulder and elbow training with supported forearm. Finally, the BiManu-Track is designed to specifically train the distal upper limb by practicing bilateral forearm and wrist movements. The RCT’s regarding the abovementioned robot devices have shown positive effects of robot-assisted arm therapy on motor and functional recovery of the upper extremity in persons with stroke.

The effects of robot-aided therapy on arm motor performance, functional capacity and movement quality in persons with MS are completely unknown. Therefore, the aim of the present pilot study is firstly to design appropriate movement tasks and tests for the upper extremity in a virtual environment using an existing haptic device called PHANTOM, and to assess their clinical applicability in MS patients with upper limb dysfunction and secondly to evaluate the effects of robot-assisted rehabilitation by comparing arm movement control and function before and after a 3-week robot training program.

2. METHODS

2.1 PHANTOM haptic device

The Expertise Centre for Digital Media (EDM, Hasselt University) disposes of a PHANTOM haptic device (SensAble Technologies), which provides 6 DoF input and 3 DoF (translational) force feedback through a stylus-like end-effector. The PHANTOM is coupled to an interactive virtual learning environment (as explained in section 2.2), so that robotic tasks and test can be executed while visual feedback is provided. This set-up is installed at the Rehabilitation and MS Centre Overpelt, where robot-aided training is incorporated in the treatment program.

During robot training, MS subjects are seated comfortably at a table, with their impaired arm placed in a customized adjustable arm support (Ergorest, Eindhoven, The Netherlands), which is attached to the edge of the table. Next, they are instructed to grip and manipulate the PHANTOM stylus in order to control an object on a 19”-computerscreen. Subjects have to perform trajectory, object manipulation and speeded tapping tasks/tests. A 6 DoF upper limb motion is allowed during interaction, which
implies that the PHANTOM enables unrestricted movements of shoulder (flexion and extension, abduction and adduction, inwards and outwards rotation), elbow (flexion and extension, pronation and supination) and wrist (flexion and extension, ulnar and radial deviation, circumduction) joints, requiring whole-limb movement control in the course of training. Data are logged at an average sampling frequency of 1000 Hz. Force, position, orientation, velocity and contact/collision reaction forces are recorded as a vector in coordination frame (x, y, z attributes).

A physical or occupational therapist administers each robotic therapy session, ensuring proper positioning, giving instructions when needed and if necessary to intervene in emergency situations. A push button connected to a safety circuit can be operated by both the therapist and patient to switch off the system’s power in the event of an emergency.

2.2 Virtual environment movement tasks
An adapted virtual learning environment has been designed by EDM in close collaboration with the REVAL Research Group of the PHL University College. Three different robot tasks and tests are applied to train and evaluate MS subjects on arm movement performance (e.g. accuracy and velocity). These tasks/tests are the car trajectory task, the object manipulation task and the speeded tapping task.

During the car trajectory task, subjects have to operate the stylus of the PHANTOM to pilot a car throughout a predefined pathway (see Figure 1). Force feedback is applied to help the subject to keep the car on track. Dependent on the level of disability of the patient, this force can be set on small, medium or large. Large implies that the car can easily be held on course, whereas small allows the patient to make faults, i.e. to go off track, thus making the task more difficult. This way the robot training program can be personalized and progress can be made. Gain can be regulated in a same way, whereby large and small respectively stands for large/small ranges of upper limb motion that have to be executed. Other features to increase the degree of difficulty are the different variations on the trajectory, the car that actually has to turn with the bends in the track (this way eliciting pro- and supination in the forearm) and finally the implementation of viscosity, which exerts an opposite force to the movement direction, whereby the subject has to produce more strength to accomplish the task.

With the object manipulation task (see Figure 2), the subject needs to virtually grab a book by touching it for two seconds. The goal of this task is then to put it in its place in a closet. The available space in the closet to position the book can be small or wide (movement accuracy), can differ in location (high/low, left/right) and can be oblique (again forcing pro- and supination) in order to make the task more difficult. Moreover, both the weight of the book (up to 3 kg), and the gain (small, medium, large) can be adjusted.

The speeded tapping task (see Figure 3) is inspired on the real-life plate tapping task. The aim of this virtual version of plate tapping is to move the PHANTOM rapidly between two targets (=plates), where contact with the plate is called a tap. Two variants are possible: the first one requires the patient to perform 20 correct reciprocal taps as soon as possible across an obstacle between the two plates. Correct means that no collision occurs with the obstacle, and that taps are on the plates. In the second variant, as many correct taps as possible have to be made in a 30 second time interval.

2.3 Participants
Subjects are recruited from the Rehabilitation and MS Centre Overpelt by a neurologist, who will perform a clinical neurological examination, including evaluation of arm strength (Motricity Index), tremor and co-ordination (finger-nose test), and
spasticity (Modified Ashworth Scale) for in- and exclusion of patients. 20 MS patients with clinical definite diagnosis of MS (Expended Disability Status Scale or EDSS 5.0-8.0) and upper limb dysfunction due to muscle weakness will be included. Patients will be excluded in case of relapse of MS or treatment with corticosteroids in the last month prior to the study, upper limb paralysis and severe cognitive or visual dysfunction.

Subjects may participate in the study after they have given their written informed consent. The experimental protocol has been approved by the local Ethical Committee of the Rehabilitation and MS Centre, where robotic therapy will be implemented, as well as the Ethical Committee of Hasselt University.

2.4 Experimental design
A feasibility study and a single-centre RCT are performed, respectively to assess the user friendliness and applicability of the newly designed robotic movement tasks and tests, and to study the effects of a 3-week robot training program on the arm motor performance, functional capacity and movement quality in persons with MS.

User comments and feedback are collected by means of a questionnaire, i.e. the System Usability Scale (SUS), and Visual Analogue Scales (VAS) to investigate the applicability of the PHANTOM-based movement tasks in a virtual environment. Preliminary test subject’s comments were already reported to further improve the concerned robotic tasks. Descriptive data about the usability of these tasks will be obtained at the start of the RCT, when robot-assisted training begins.

For the clinical trial, MS patients will be randomly assigned to a robot group (n=10) or a control group (n=10) and compared to a control group of healthy subjects (n=10). The robot group receives robot-aided therapy of the upper limb during 30 minutes on week days for 3 weeks, added to the conventional treatment program, while the MS control group receives no additional arm training. Healthy controls were included to document normal motor performance on the robotic tests, and to investigate short term learning effects.

2.5 Outcome measures
Concerning the feasibility of the robot tasks/tests, the SUS and VAS are administered. The SUS is a simple, ten-item scale yielding a single (subjective) number which represents the overall usability of the system being evaluated. It is generally administered after the respondent has had the opportunity to use the system, but before any debriefing or discussion takes place. SUS scores have a range of 0 (poor usability) to 100 (high usability). Additional user feedback is gathered through VAS, consisting of a 100 mm line with a statement or question (e.g. are you tired after completing this robot training?) representing the extremes (0, not tired at all; 100, very tired) of the dimension being assessed.

Arm motor performance, functional capacity and movement quality are evaluated twice, before and after the 3-week robot training program. Calibrated digital MicroFET2 and Jamar hand-held dynamometers are used to quantify muscle strength changes. The MicroFET2 is applied to validly and objectively measure muscle force during manual muscle testing in all planes, while the Jamar specifically can be used to determine hand force (in Newton).

Functional capacity of the upper extremity is assessed by means of pegboard testing (Nine Hole Peg Test, Grooved Pegboard Test, Purdue Pegboard Test), the Action Research Arm test as well as the tests of the PHANTOM robotic device itself. Reliability and validity of the three pegboard tests have been demonstrated and normative data are available. The Nine Hole Peg Test is a simple, timed test of fine motor coordination. The test involves the placement of 9 pegs in 9 holes. Subjects are scored on the amount of time it takes to place and remove all 9 pegs one by one. The Grooved Pegboard is a manipulative dexterity test consisting of 25 holes with randomly positioned slots. Pegs with a key along one side must be rotated to match the hole before they can be inserted. The necessary time to accomplish the task is scored. The Purdue Pegboard consists of two vertical rows of each 25 holes. Testing involves (the combining and) sequential insertion of pegs, collars, and washers. The amount of combinations that is placed within a time frame of 60 seconds is scored. Finally, the Action Research Arm test is a reliable and valid clinical scale to evaluate arm functional skills. This test composes four subtests, i.e. grasp, grip, pinch and gross movement, whereby a total of 19 items is tested and scored on a 4-point ordinal rating scale (0-3). Scores for the test ranges as such from 0 to 57. Tests with the PHANTOM are similar to the robotic tasks as described in section 2.2. Spatial (e.g. the traversed trajectory versus the ideal trajectory) and temporal (e.g. time necessary to finish the trajectory) parameters are calculated.

Accelerometry data from the PASAQ data logger (Maastricht Instruments, Maastricht, The Netherlands) will be analysed to assess intersegmental co-ordination of the upper limb as a measure of movement quality. Subjects are equipped with three 3D Minimod accelerometers (McRoberts BV, The Hague, The Netherlands), while performing three standard movement tasks that mimic activities of daily living, i.e. pouring water from a jar in a cup, inserting a coin in a groove and combing hair. One is placed on the lower arm at the wrist joint, one at the upper arm close to the elbow joint and another one on the clavicle. The accelerometers are synchronized and data is logged at a sampling rate of 100 Hz. These data are validated with a VICON motion analysis system, available at Maastricht University.

3. RESULTS
The study design and practicalities are now carefully prepared, while first patients’ comments on the feasibility of the robotic tasks/tests have been recorded. Initial test subjects (n=4) were MS patients with no or only mild upper limb dysfunction, who evaluated the virtual learning environment after interaction during a single practice session. They all commented positively, giving high scores (range 85-90) on the SUS. One MS patient with decreased motor co-ordination had difficulties in stabilising her arm during the object manipulation task in order to grasp the book, demonstrating that these tasks/tests are likely challenging enough for the intended target group.

The intervention trial will start at the end of February 2008. Descriptive data about usability and results of the first patients completing the trial will be presented at the HRIO8 Conference.

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5. REFERENCES


