Clinical assessment of the HELLODOC tele-rehabilitation service

Hermie Hermens[a], Barbara Huijgen[a], Claudia Giacomozzi[b], Stephan Ilsbroukx[c], Velio Macellari[b], Elisabet Prats[d], Marco Rogante[b], Maria Francesca Schifini[e], Maria Cristina Spitali[e], Sonia Tasies[d], Mauro Zampolini[e] and Miriam Vollenbroek-Hutten[a]

[a] *Roessingh Research and Development B.V, Enschede, The Netherlands*
[b] *Dipartimento Tecnologie e Salute, Istituto Superiore di Sanità, Rome, Italy*
[c] *National Multiple Sclerosis Centre, Melsbroek, Belgium*
[d] *Fundació Institut Guttmann, Barcelona, Spain*
[e] *ASL n. 3, Umbria, Unità Organica di Riabilitazione Intensiva Neuromotoria, Trevi, Italy*

Summary. Within the EU project HELLODOC, the clinical effectiveness was investigated of the home care activity desk (H-CAD). Eighty-one patients with chronic stroke, traumatic brain injury (TBI) and multiple sclerosis (MS) were recruited; 50 out of 81 received 1 month of H-CAD intervention, with one training session a day lasting 30 minutes for 5 days a week. The overall satisfaction of both patients and therapists was high. The Action Research Arm (ARA) and the Nine Hole Peg Test (NHPT) were used as main outcome measures. They proved the H-CAD system to be at least as effective as usual care. Maybe due to limited length and intensity of treatment, during the training month subjects improved on the individual H-CAD exercises but, as in the usual care group, the arm/hand function remained at the same level.

Key words: tele-rehabilitation, home rehabilitation, arm/hand function, neurologic patients.

Riassunto *(Valutazione clinica del servizio di teleriabilitazione HELLODOC)*. Nell'ambito del Progetto Europeo HELLODOC è stata indagata l'efficacia clinica dell'unità paziente *(home care activity desk,* H-CAD). Sono stati arruolati 81 pazienti affetti da ictus cronico, trauma cranico (*traumatic brain injury,* TBI) e sclerosi multiple (*multiple sclerosis*, MS); 50 sono stati trattati per un mese, utilizzando la piattaforma H-CAD, attraverso sessioni giornaliere di 30 minuti per 5 giorni a settimana. Pazienti e terapisti hanno mostrato un alto livello di soddisfazione. Gli indicatori *action research arm* (ARA) e *nine hole peg test* (NHPT) hanno mostrato che H-CAD è almeno tanto efficace quanto il trattamento tradizionale. Forse a causa della limitata durata ed intensità del trattamento, i pazienti hanno sì mostrato un miglioramento nell'esecuzione dei singoli esercizi durante il mese di trattamento, ma, così come nel gruppo di controllo, il livello di funzionalità dell'arto superiore è rimasto invariato.

Parole chiave: teleriabilitazione, riabilitazione domestica, funzionalità arto superiore, pazienti neurologici.

INTRODUCTION

HELLODOC is the acronym for "Healthcare service linking tele-rehabilitation to disabled people and clinicians". The project started on March 2005 as a 18-months European project co-financed by the European Community Programme eTEN. It was successfully closed on February 2007 after a 6-months extension.

The primary objective of the project was to validate the EU market – more specifically in Italy, Spain, The Netherlands and Belgium – for a home-care service. Main aim of the service is to extend the rehabilitation treatment at patient's home under close supervision of the hospital. The tele-rehabilitation service is mainly addressed to neurological patients affected by traumatic brain injury (TBI), stroke or multiple sclerosis (MS).

Basically, it consists of two main apparatuses: an in-hospital based server and a portable unit to be installed at patients' home. The portable unit, which is usually indicated with the acronym "PU", is an improved version of a prototype of a home activity desk which was developed in the framework of the European project H-CAD (home-care activity desk) (www.iss.it/doc.). For this reason, in the following of the present paper it will be named "H-CAD" system. The instrumented desk allows the execution and monitoring of a configurable set of home exercises the professionals may purposely design to improve the main arm functions.

The clinical study to evaluate the H-CAD home rehabilitation treatment system by demonstrating the clinical effectiveness was a key action of the project. The main research question in this validation trial

Address for correspondence: Hermie J. Hermens, Roessingh Research and Development, Roessinghsbleekweg 33b, 7522 AH Enschede, the Netherlands. E-mail: h.hermens@rrd.nl

was: is the use of the H-CAD system for one month at least as good as usual care for the arm/hand function in stroke, TBI and MS patients?

The hypothesis is that the H-CAD system is at least as effective as the usual care for arm/hand function, measured with outcome measures for arm/hand function, given to the stroke, TBI and MS patients when they are living at home. As most patients are in a chronic phase when they use the H-CAD system the aim is to at least maintain the arm/hand functioning. However by the use of H-CAD, patients are able to train much more intense compared to in hospital settings which could have additional positive effects. For the assessment of arm/hand function disability measures have been used but it has also been investigated whether during the period of training with the H-CAD, execution itself of the H-CAD exercises improved. To this purpose, the parameters of the H-CAD exercises – basically average time per exercise per day – during the month of intervention were used. Besides clinical effectiveness, the user satisfaction of the H-CAD system has been investigated using VAS scales.

METHODS

Patients selection

Patients were recruited from Unità Organica di Riabilitazione Intensiva Neuromotoria (UORIN, Italy), Foundation Institute Guttmann (FPING, Spain) and from National Multiple Sclerosis Centre (NMSC, Belgium). UORIN included stroke patients, FPING TBI patients and NMSC MS patients. The subjects were eligible for recruiting if they met the following criteria: (1) age > 18 years; (2) established diagnosis of the specific pathological condition MS, stroke or TBI; (3) nine hole peg test (NHPG) performed in more than 25 seconds; (4) ability to move at least one peg in 180 seconds during the NHPG; (5) sufficient autonomous functioning; (6) internet connection or telephone line and reachable internet provider; (7) clinical status stable; (8) discharged from hospital or rehabilitation setting – person lives at home. Exclusions were: A) disturbed upper limb function not related to MS, TBI or stroke; B) serious cognitive and/or behavioral problems; C) serious emotional problems; D) major visual problems; (E) communication problems; F) medical complications; G) other problems possibly contra-indicating autonomous exercise at home.

Design

The study design was partly a randomized multicenter clinical trial (RCT) to compare the results of the control group which received usual care and general exercises to the intervention group which used the H-CAD system at home for one month.

The study also comprised a patient-control design for the intervention group to investigate if the H-CAD system maintained the same functional ability in the group of patients who underwent the intervention of the H-CAD system compared to usual care they received before and after the intervention.

Protocol

The research flow chart is presented in *Figure 1*. The physicians of the three rehabilitation centres included patients following the inclusion and exclusion criteria. After subjects passed the screening criteria, they signed an informed consent to participate in the study. After baseline assessments, the subjects were randomly assigned to the intervention or control group. A randomization scheme of 2:1 (two intervention group subjects for every one control group subject) was used. The subjects were matched on patient group (stroke, TBI or MS). To get insight in the number of patients needed in the clinical trial to be able to demonstrate the effectiveness of the H-CAD treatment with respect to usual care and to get insight in differences between the three patient groups, a power analysis was performed [1]. It concluded that a total of 90 patients were necessary for the total trial, 60 patients in the intervention group and 30 patients in the control group. The aim was to divide the inclusion over the 3 diagnosis groups (stroke, TBI and MS patients).

All measurements were performed at the centre where the patient had been treated. The included subjects received a baseline measurement (T0). The second measurement (T1) was performed after the month of usual care (for intervention as well as control group). The third measurement (T2) was performed after the month of H-CAD intervention for the intervention group and 2 months after baseline for the control group. A month after T2 a follow up measurement was performed (T3) for the intervention group. The control group received their last measurement (T3) 4 months after baseline.

Treatments

Intervention group

The intervention group underwent one month of usual care, followed by approximately 4 training sessions with the H-CAD system in the hospital. The actual intervention with the H-CAD system at home consisted of one month, whereby the patients had an average of one training session a day lasting 30 minutes for at least 5 days a week. The following exercises are part of the H-CAD system: key, light bulb, book, jar, writing, checkers and keyboard tasks. This set of exercises summarizes the movements for a correct functional activity of the upper limb of the patient for reaching, grasping, lateral pinch, pinch grip, holding, manipulation and finger dexterity. The patient and the therapist had a weekly scheduled videoconference. After the month of exercising with the H-CAD system, the subjects continued their usual care at home.

Control group: usual care

Subjects in the control group received usual care and generic exercises prescribed by their physicians. The therapists completed a diary which contained the exercises performed by the patients and the received treatment.

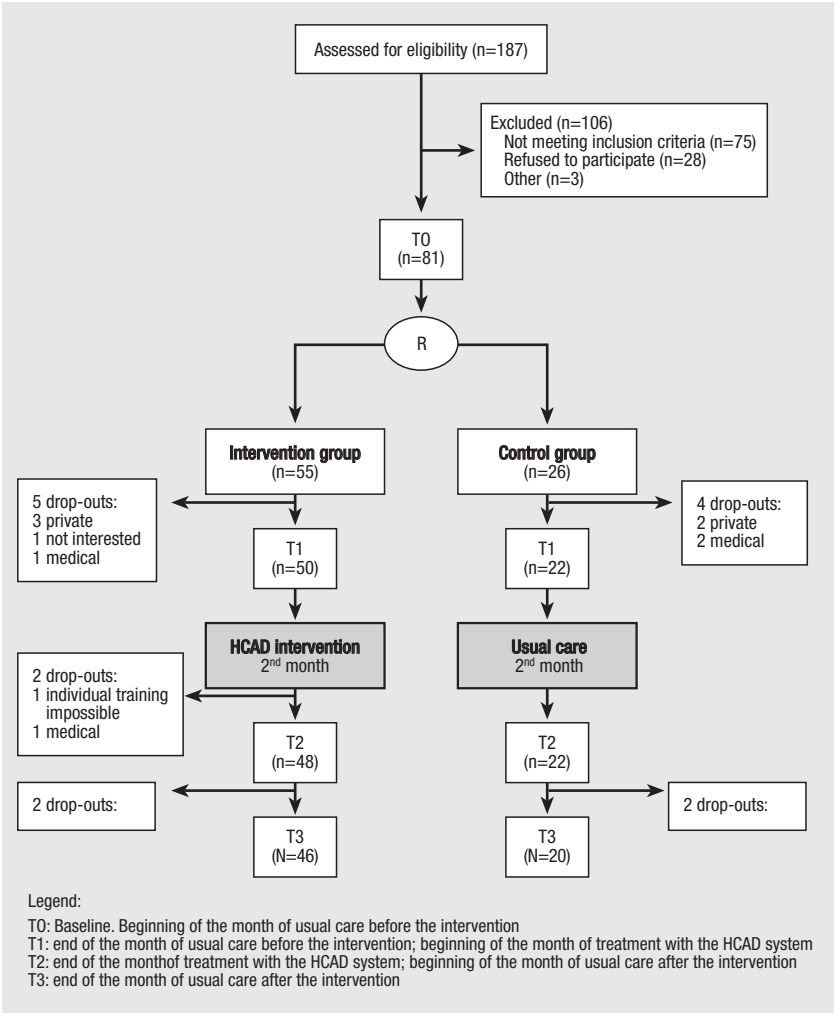

Fig. 1 | *Flow chart for patients recruitment.*

Measurement protocol

Outcome measures

The outcome measures used in the present study are in line with the international classification of functioning, disability, and health (ICF) model. The outcome measures on functioning level were: the Action Research Arm Test (ARA), Wolf Motor Function Test (WMFT), the Barthel Index (BI) and the Abilhand questionnaire. The disability outcome measure was: the Nine Hole Peg Test (NHPT) and the health outcome measure was the MOS 36-item short-form health survey (SF-36).

Main outcome measures

Two outcome parameters representing the performance of the affected arm on functioning as well on disability level were used in the present study as main outcome parameters. In case both arms were affected, the dominant hand was used The main outcome parameters were the ARA test and the NHPT. The ARA test was chosen as the main outcome measure because all the patients were able to perform the total test compared to the WMFT test where the patient has to stand up for some exercises - impossible for wheelchair bound patients. The NHPT was chosen as the second main outcome measure to have a main outcome measure on the disability level as well.

The *ARA* is an observational test consisting of 19 items focusing on grasping objects of different shapes and sizes, and gross movements in the vertical and horizontal planes (score range: 0 to 57) [2, 3]. The total score of all tests together for the affected arm was used in the analysis.

The *NHPT* measures manual dexterity (and reaching and grasping). The total time needed to move the 9 pegs with the affected arm was used as outcome parameter. When the patient was unable to move all nine pegs, the total time of 180 seconds was used.

Secondary outcome measures

The *WMFT* is a lab-based test focusing on arm function that involves 15 timed measures and 2 force-based measures which progress in complexity from engaging individual joints to use of the total arm [4].

For the *H-CAD* related analyses the grip strength of the affected arm was used. The averaged total time over the 15 timed measures of the affected arm

and the averaged functional ability (0-5) over the 15 timed measures for the affected arm were used for data analysis.

The BI is a widely used 100-point assessment of independence in ten daily activities [5]. Total score of the BI was used for data analysis.

The *Abilhand questionnaire* [6] is used to measure manual ability. Abilhand is an inventory of 23 manual activities that the patient was asked to judge on a 4-level scale: 0 (impossible), 1 (difficult), 2 (easy), and 3 (unknown). The test explores both unimanual and bimanual activities done without other human or technical help. The scale was developed with the Rasch measurement model in order to convert a person's ordinal score on a questionnaire into a linear measure of ability located on a unidimensional scale. The logit is a linear unit that expresses the odds of success of the patient on any given item. The manual ability scale is centered on the averaged item difficulty (0 logit). The higher the ability of a patient the more the measure will be located to the right (positive score), the lower the ability of a patient the more the measure will be located to the left (negative score). The logit outcome measure was used in the analyses.

The *Medical outcomes study 36-item short form health survey (SF-36)*, is used to measure physical and social functioning [7, 8]. It allows assessment across 8 health domains: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). Scale scores range from 0 to 100 and all separate scales were used in the analyses.

The *User satisfaction* is assessed by using a visual analog scale (VAS). Six aspects of the participant and therapist's impression (acceptance, aesthetic aspect, ease of use, difficulty of the tasks, appropriateness of the tasks, general opinion) were evaluated. They were asked to score from very bad to excellent on those six aspects of H-CAD system. VAS was turned into a numeric scale from 0 to 100. Scores per aspect were analyzed to interpret if the participants and the therapists are satisfied.

The *H-CAD* parameters received from H-CAD system during the month of intervention were analyzed to detect a possible improvement in the time of executing the exercises. The analyzed exercises were book, pencil, keyboard, jar, checkers, and light bulb. To detect the progress in the various exercises during the month of intervention the averaged time per exercise over the first three days was compared to the averaged time per exercise over the last three days.

Data analysis

Baseline characteristics

Descriptive statistics were used to describe both the intervention and the control group. Descriptive statistics were calculated per diagnosis group for age, length, type of rehabilitation, duration of the diagnosis and all outcome measures at the baseline measurement. An independent t-test or chi-square tests (for nominal values) were used to compare the mean patient characteristics at baseline between the intervention and control group. This was done to investigate whether the intervention and the control group are similar and whether randomization was successful. An ANOVA or chi-square (for nominal values) was performed to compare the patient characteristics at baseline between the three diagnosis groups (stroke, TBI and MS).

The baseline characteristics of the patients that dropped-out and had missing values at the start of the final analyses were described and compared to the patients baseline characteristics that had complete data.

Between-subject comparison

Is the use of the H-CAD system for one month at least as good as usual care for the arm/hand function in stroke, TBI and MS patient?

The frequency and duration of the therapies from the usual care group were described. The frequency and duration of the use of the H-CAD system of the intervention group was also described. It was, in fact, necessary to get insight in the intensity of both therapies to compare them and to enable good interpretation of the results.

The goal of the clinical trial was to show that the effect of a new treatment (H-CAD) is equal effective as the existing treatment (usual care). To investigate this hypothesis, a so called active control equivalence study [9] was used. To investigate whether the patients in the intervention group (after the month of using the H-CAD system) performed at least as good as the usual care group on arm/hand function the 90% confidence intervals for the changes on the main outcome measures between T2 and T1 were calculated for an effect between the groups (H-CAD and usual care). Ninety percent confidence intervals were used because the tests were two-sided. These analyses were accomplished separately for every diagnosis group (stroke, TBI and MS). To be able to decide whether the changes for the two groups (H-CAD versus usual care) were equal, cut off points needed to be defined beforehand. For the ARA test an improvement or decrease till 3 points was considered as clinical equal [10]. For the NHPT a decrease or increase till 6 seconds was taken as equal [11]. These clinical equality bounds were compared with the calculated confidence bounds in order to conclude whether H-CAD was at least as good as usual care. When the confidence bounds remained between these boundaries, no difference between usual care and H-CAD was found.

Within-subject comparison

Is the H-CAD system for the arm/hand function in stroke, MS and TBI patients at least as good as the usual care within the intervention group proceeding the HCAD?

To investigate changes over time within the intervention group, an active equivalence study was performed. The usual care the intervention group received one month before and one month after H-CAD was compared to the month of using the H-CAD system. For this multiple testing:

1) the month of usual care before the intervention (T0-T1) was compared to the month of using the H-CAD system (T1-T2);
2) the month of usual care after the intervention (T2-T3) was compared to the intervention month (T1-T2).

A significance level of 0.025 and a confidence interval of 95% were used. For the ARA test an improvement or decrease till 3 points was considered as equal [9]. For the NHPT a decrease or increase till 6 seconds was considered as equal [10]. When the confidence bounds remained between these boundaries, the patients function did not change over time, so no differences occurred during usual care or during using the H-CAD system.

User satisfaction

Are the patients and the therapists satisfied with the use of the H-CAD system at home?

The user satisfaction was assessed by using a VAS. Six aspects of the participant and therapist's impression (acceptance, aesthetic aspect, ease of use, difficulty of the tasks, appropriateness of the tasks, general opinion) were evaluated. They were asked to score from very bad to excellent on those six aspects of H-CAD system on a VAS scale. VAS was turned into a numeric scale from 0 to 100. VAS scores of 30 mm or less were categorized as not satisfied; those from 31 mm to 69 mm as average scores (social desirable answers) those with scores of 70 mm or more was categorized as satisfied. The percentage of the patients and therapists dissatisfied and the percentage of the patients and therapists satisfied were reported.

HCAD parameters

Is there an improvement in the execution of the H-CAD exercises during the month of intervention?

The parameters – averaged time per exercise per day – received from H-CAD system during the month of intervention were analyzed to detect a possible improvement in executing the exercises. To detect the progress in the various exercises during the month of intervention the average time per exercise over the first three days was compared to the average time per exercise over the last three days. The differences of these averages per person were calculated and divided by the total number of days the H-CAD system was used (slope). These slopes were analyzed with a one-sample t-test, to test whether or not there is a significant difference from zero. The relative improvement was calculated as a percentage of the seconds of improvement with respect to the mean execution time at the beginning of the intervention month.

The SPSS (version 11.5) statistical computer program was used for statistical analyses. The Shapiro-Wilk statistics was used to test for normality. If not stated, all analyses p-values smaller than 0.05 were considered statistically significant. In case the significance level had to be different – *e.g.*; multiple testing – this was stated explicitly.

RESULTS

Subjects

Forty-seven men and thirthy-four women were included in the study (average age 47.7 years, range 19-79 years). A total of 16 stroke patients were included in the study, 30 TBI patients and 35 MS patients. The average time since the start of the diagnosis was 9.9 years (range 1-35 years). Information about inclusion rate and number of patient data available at each measurement moment is presented in *Figure 1*. Reasons for exclusion of the patients were most often insufficient or none upper limb function, patient could not move one peg of NHPT within 180 seconds or patient arm/hand function was too good (NHPT performed in less than 25 seconds). Some patients had medical complications and some refused to participate in the study.

Baseline characteristics

Patients characteristics and baseline measurements are reported in *Table 1*. Comparison between intervention and control group revealed that there were no significant differences in subject characteristics and baseline measures. Statistically significant differences at baseline were found among the three diagnosis groups on most of the secondary outcome measures. In general, TBI patients had the highest test scores, which means the best arm/hand function at baseline. Bonferroni *post hoc* tests showed that the secondary outcome measures (BI, WMFT and Abilhand) differed significantly between MS and TBI patients. MS group scores were significantly lower than for TBI patients, thus meaning that MS patients arm/hand function was worse at baseline compared to the TBI patients. The average functional ability also differed significantly between MS and stroke patients. Concerning the SF-36 role physical component was significantly different between all diagnosis groups. Vitality and general health perceptions showed significant differences between MS and TBI patients. The role-emotional component showed significant differences between Stroke and MS and between stroke and TBI patients. Physical functioning showed significant differences between stroke and MS patients. TBI patients showed the highest scores on the well-being scales of the SF-36 at baseline. Stroke patients had the worst scores of all three groups on role physical and role emotional, whereas MS patients showed the worst scores on the physical functioning, vitality and general health.

Table 1 | *Patients characteristics and baseline measurements*

	Diagnosis group	Age (years)	ARA (score 0-57)	NHPT (seconds)	BI (score 0-100)	WMFT test avg. time (seconds)	WMFT test avg. f.a. (score 0-5)	Grip strength (kg)	Abilhand (score - 6.08 – 6.02)
Intervention group	Stroke (n. = 11)	68.6 (8.4)	41.8 (12.6)	98.9 (61.0)	87.8 (14.4)	7.0 (2.3)	3.9 (0.6)	14.0 (10.3)	1.8 (2.6)
	TBI (n. = 20)	32.4 (13.4)	48.0 (14.8)	70.5 (41.2)	85.3 (15.0)	6.1 (3.9)	4.3 (0.7)	25.4 (8.7)	3.1 (1.6)
	MS (n. = 24)	48.1 (11.6)	42.8 (13.8)	65.0 (43.7)	76.3 (27.1)	21.1 (16.4)	4.0 (0.7)	14.9 (12.5)	1.0 (2.8)
	Total (n. = 55)	46.5 (17.7)	44.4 (13.9)	74.9 (48.3)	82.0 (21.0)	13.1 (13.5)	4.1 (0.7)	18.6 (11.8)	1.9 (2.6)
Control group	Stroke (n. = 5)	70.8 (7.1)	45.0 (10.6)	58.5 (46.3)	77.5 (23.9)	7.0 (3.4)	4.0 (1.0)	28.8 (7.3)	1.4 (2.1)
	TBI (n. = 10)	38.3 (17.5)	48.1 (12.1)	67.7 (31.8)	78.1 (20.2)	4.9 (2.4)	4.1 (0.8)	21.6 (11.6)	2.4 (1.6)
	MS (n. = 11)	51.9 (14.5)	45.6 (9.5)	59.0 (22.2)	61.8 (22.1)	23.2 (14.0)	3.5 (0.6)	17.7 (8.6)	0.3 (2.5)
	Total (n. = 26)	50.11 (18.2)	46.4 (10.3)	62.0 (30.3)	70.2 (22.3)	14.5 (13.4)	3.8 (0.8)	20.2 (9.6)	1.3 (2.2)

ANOVA with Bonferroni correction, p<0,05.
ARA: Action Research Arm test
NHPY: Nine Hole Peg test
BI: Barthel Index
WMFT: Wolf Motor Function Test
TBI: Traumatic Brain Injury
MS: Multiple Sclerosis

The baseline characteristics of the patients that dropped-out and had missing values at the beginning of the final analyses did not show significant differences with respect to those patients that had complete data sets. Reasons of drop-outs were mainly personal circumstances, health problems, or loss of interest. Some patients did not obtain complete test scores due to practical problems. A maximum of 7 patients in the intervention group and of 4 patients in the control group had missing data on all tests, thus list wise deletion was applied to all analyses.

Treatments

Usual care in this study was heterogeneous as for approach and intensity. The average frequency was 3 times a week and the average duration of the therapy was 45 minutes per session. Thus, an average treatment time of 9 hours for usual care per month was delivered to each patient of the control group.

The average frequency and duration of the use of the H-CAD system in the intervention group were 5 times a week, 30 minutes practicing with the H-CAD system. This represented an average treatment time of 10 hours a month for each patient of the H-CAD intervention groups.

The treatment time of the H-CAD was thus slightly higher – but not significantly different – compared to usual care.

Intervention groups versus control group

The primary outcome measures at T0 (baseline), T1, T2 and T3 are reported in *Table 2* for all three diagnoses groups and presented separately for the control and intervention group. In general, the ARA test showed constant slight improvement in the usual care as well as in the intervention group. For both groups the NHPT showed an improvement from baseline to T1 and a slight decline from T1 to T2. The control group again showed an improvement from T2 to T3. Only a slight improvement was found for the intervention group. For the separate diagnoses groups the above average trends showed slight variations *(Table 2)*.

Figure 2 represents the 90% confidence intervals for the differences between T2 and T1 between the usual care and the H-CAD group. The horizontal lines in the graphs report the 90% confidence bounds per diagnosis group for the difference between T2 and T1 between the H-CAD and the usual care group and the dots show the average differences. Negative scores show that the difference between T2 and T1 was in favor of the usual care group, positive numbers in favor of the H-CAD group.

All horizontal lines include zero, therefore there was no significant difference between the means of the two groups for all three diagnoses groups. However, for the TBI group, the usual care group showed a greater improvement compared to the H-CAD group on the ARA test. In contrast, The MS H-CAD group showed a greater improvement on the NHPT compared to the usual care group. The widths of the confidence intervals were all outside the equality bounds. This means that the variance of the means were too wide to be able to conclude that the usual care and H-CAD group were exactly equivalent, and the effect of treatment – difference between T2 and T1 – between the usual care group and the H-CAD group partly remained unclear.

Usual care versus HCAD in intervention group

The average scores – over all the time measurements – for the patients in the intervention group showed a slight improvement over time of the main outcome measures. However, statistical analysis revealed that these differences were not significant.

Table 2 | *Main outcome measures at T0(baseline), T1, T2 and T3 for all three diagnoses groups, for both the control and the intervention group. ARA test scores 0-57; NHPT is expressed in seconds (range 0-180)*

	Control				Intervention				Control				Intervention			
	ARA T0	ARA T1	ARA T2	ARA T3	ARA T0	ARA T1	ARA T2	ARA T3	NHPT T0	NHPT T1	NHPT T2	NHPT T3	NHPT T0	NHPT T1	NHPT T2	NHPT T3
Stroke	45.0 (10.6) n. = 5	39.8 (15.4) n. = 4	47.3 (40.9) n. = 3	55.0 (1.4) n. = 2	41.8 (12.6) n. = 11	39.3 (14.2) n. = 9	40.9 (13.4) n. = 9	42.0 (13.0) n. = 8	58.5 (46.3) n. = 5	55.5 (38.3) n. = 4	61.0 (48.4) n. = 3	33.7 (1.9) n. = 2	98.9 (61.0) n. = 11	85.5 (57.6) n. = 9	88.5 (54.3) n. = 9	96.2 (70.6) n. = 8
TBI	48.1 (12.1) n. = 9	49.3 (10.9) n. = 8	52.6 (7.8) n. = 8	54.4 (4.4) n. = 7	48.0 (14.8) n. = 17	50.3 (13.0) n. = 20	48.7 (15.3) n. = 19	49.6 (13.1) n. = 17	67.7 (31.8) n. = 9	69.9 (30.8) n. = 8	70.8 (38.3) n. = 8	61.6 (25.5) n. = 7	70.5 (41.2) n. = 17	59.1 (23.0) n. = 18	72.7 (40.1) n. = 19	72.7 (41.8) n. = 18
MS	45.6 (9.5) n. = 11	48.4 (9.0) n. = 11	49.3 (7.1) n. = 11	50.4 (7.3) n. = 11	42.8 (13.8) n. = 22	44.8 (12.8) n. = 21	45.9 (13.4) n. = 18	45.2 (12.7) n. = 18	59.0 (22.2) n. = 11	55.6 (22.4) n. = 11	58.6 (21.8) n. = 11	54.3 (16.1) n. = 11	65.0 (43.7) n. = 19	61.9 (40.6) n. = 18	59.6 (42.0) n. = 16	54.7 (43.6) n. = 15
Total	46.4 (10.3) n. = 25	47.2 (10.9) n. = 23	50.2 (8.2) n. = 22	52.3 (6.3) n. = 20	44.4 (13.9) n. = 50	46.0 (13.5) n. = 50	46.1 (14.2) n. = 46	46.3 (12.9) n. = 43	62.0 (30.3) n. = 25	60.5 (27.9) n. = 23	63.4 (31.2) n. = 22	54.8 (20.2) n. = 20	74.9 (48.3) n. = 47	65.5 (39.4) n. = 45	71.2 (44.2) n. = 44	70.7 (50.1) n.= 41

ARA: Action Research Arm test;
NHPT: Nine Hole Peg test;
T0: baseline. Beginning of the month usual care before the intervention;
T1: end of the month of usual care before the intervention; beginning of the month of usual care before the intervention;
T2: end of the month of treatment with the HCAD system; beginning of the month of usual care after the intervention;
T3: end of the month of usual care after the intervention;
TBI: Traumatic Brain Injury;
MS: Multiple Sclerosis.

Figure 3 show the effect of the HCAD month of treatment compared to the usual care month with 95% confidence intervals. The horizontal lines show the confidence bounds for the difference between the HCAD month and the usual care month, the dots show the average differences.

The first horizontal line compares the HCAD month to the month of usual care before the intervention and the second (lower) line compares the HCAD month to the month of usual care after the intervention. The ARA test scores can be considered equivalent, since the horizontal lines remained within the boundaries.

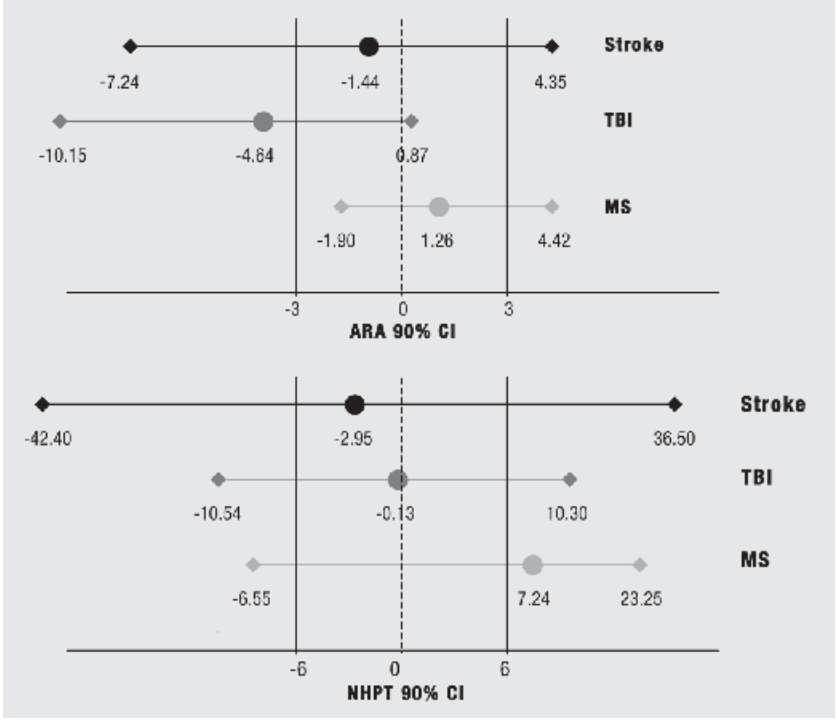

Fig. 2 | *Ninety percent confidence intervals for the ARA and the NHPT test for the differences between T2 and T1 between the usual care and the HCAD group.*

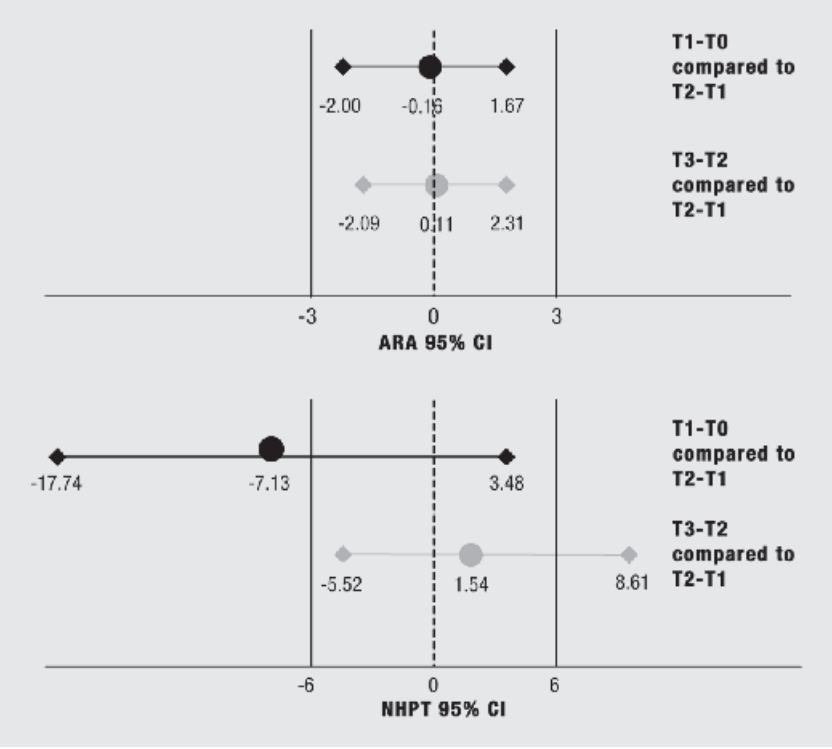

Fig. 3 | *Ninety-five percent confidence intervals for the ARA and the NHPT test for the difference between T2 and T1 compared to the difference between T1 and T0 (and between T2 and T1) between the usual care and the HCAD group.*

The *Figure* shows that the NHPT test scores were not between the boundaries. When the scores were shifted to the left, the month of usual care showed a greater improvement than the month of using the H-CAD system. This means that patients showed a better score at the first usual care month compared to the H-CAD for the nine hole peg test.

User satisfaction

Six aspects of the participant and therapist's satisfaction with the H-CAD system were evaluated with a VAS scale. VAS scores of 30 mm or less were categorized as not satisfied; those from 31 mm to 69 mm as average scores (social desirable answers); those with scores of 70 mm or more were categorized as satisfied *(Table 3)*. The percentage of not satisfied patients and therapists, and the percentage of satisfied patients and therapists are reported in the *Table*. A total of 45 patients and 48 therapists responded to the user satisfaction questionnaire. In general, both patients and therapists were satisfied with the H-CAD system. Both them were less satisfied with the aesthetic aspect of the system and with the difficulty of the tasks.

H-CAD parameters

All 49 patients had a few practice sessions before the actual month of exercising with the H-CAD system at home started. The exercise compliance during treatment varied; the average days exercising with the system was 24 days (SD = 9, range 7-39 days). Also the amount of time and the number of exercises varied from person to person (range number of exercises a day: 2-24 per exercise).

The parameters – basically the average time per exercise per day – received from H-CAD system during the month of intervention were analyzed to detect a possible improvement in executing the exercises. *Table 4* presents the results of these analyses. The first column reports the average execution time at the beginning of the intervention, average over the first 3 days. Column

Table 3 | *User satisfaction*

	Patient Dissatisfaction (%)	Patient Satisfaction (%)	Therapist Dissatisfaction (%)	Therapist Satisfaction (%)
Acceptance	4.4	66.7	2.1	85.4
Aesthetic aspect	11.1	42.2	2.1	58.3
Ease of use	0	84.4	2.1	83.3
Difficulty of the tasks	4.4	57.8	0	62.5
Appropriateness of the tasks	2.2	68.9	0	83.3
General opinion	2.2	77.8	0	68.8

Table 4 | *HCAD parameters.*

	Average time over first 3 days (SD)	Average seconds of improvement (SD)	Relative improvement	Average seconds of improvement per day (SD)	T (p-value)
Jar	31.25 (24.4)	5.17 (13.8)	16.5 %	0.23 (0.7)	2.27 (0.03)*
Keyboard	53.22 (29.4)	6.23 (12.6)	11.7 %	0.53 (1.2)	2.93 (0.01)*
Pencil	72.45 (44.9)	13.67 (18.0)	18.9 %	0.80 (1.5)	3.56 (0.00)*
Book	34.32 (28.2)	7.29 (13.0)	21.4 %	0.46 (0.8)	3.53 (0.00)*
Light bulb	47.84 (27.4)	10.04 (15.0)	21 %	0.81 (1.4)	3.68 (0.00)*
Checkers	47.60 (30.7)	4.29 (15.6)	9.1 %	0.35 (0.86)	2.71 (0.01)*
Key	32.84 (38.4)	7.54 (25.3)	23.0 %	0.48 (1.4)	2.11 (0.04)*

Student's t-test; $p < 0.05$.

two shows the average improvement, expressed in seconds (s), per exercise, and column 3 the relative improvement with respect to the average execution time at the beginning. Column four reports the average ratio between the average improvement – column two – and the days of using the H-CAD system for every person. The above data were analyzed with a one-sample t-test; results showed that for all exercises a significant improvement in execution time was found during the month of H-CAD training.

DISCUSSION

The aim of this study was to investigate the clinical effectiveness of the H-CAD system in a home setting. The hypothesis was that the H-CAD system is at least as effective as the usual care for arm/hand function given to the stroke, TBI and MS patients. The rationale behind such hypothesis is that patients are mainly in a chronic phase when they use the H-CAD system.

Results of the ARA test showed a slight improvement in both the usual care as well as in the intervention group. Also the secondary outcome measures showed a slight improvement or remained at the same level over the testing period for both groups. Most of these differences were however not significant. In general, we can conclude that the arm/hand function remained at the same level in both groups. Within the H-CAD group, results showed that the month of using the H-CAD system was not statistically different from the period of usual care before or after the H-CAD intervention. The patients in the intervention group maintained the same function on grasping objects and on gross movements during the complete testing period (ARA test).

A key advantage of the H-CAD system is that patients are able to train more intensively than they can do during regular therapy - usual care -. However, in the current study the intensity of training was only slightly in favor of the H-CAD group whereas the direct time investment for therapists is much lower when the patients use the H-CAD system compared to usual care. The time investment for the H-CAD system for therapists consists of: installing the H-CAD system, a weekly videoconference, and collecting the system at the end of the month. For usual care, the therapists have, on average, three sessions a week (treatments) with the patient. Thus, usual care asks the therapists for at least 2 sessions more per week per patient. The amount and type of usual care and generic exercises varied per centre and per patient, since usual care was not given by following a prescribed protocol.

On the basis of the above observations, we can conclude that the H-CAD system is much more efficient than usual care for the stroke, TBI and MS patients to maintain their arm/hand function.

Those patients of the intervention group who did show an improvement on the ARA test score after using the H-CAD system, used the system more frequently than those patients who did not show an improvement. Besides that, all patients who showed an improvement on the main outcome measures had a significant lower baseline ARA test score. Based on this, it can be suggested that patients with low baseline ARA scores and patients with high training intensity have a better chance on improvement of arm/hand function using the H-CAD system.

During the month of treatment with the H-CAD system, patients showed significant improvement on the individual task execution time. These results might be partly due to a learning effect; however, to minimize such effect, all patients practiced with the system for a few days before starting the period of testing with the system. During these first days, the learning effect should mostly have been filtered out.

The different exercises on the H-CAD system mainly train the digital grip (thumb and forefinger), the hand grasp, hand strength and precision, arm function, shoulder flexion/abduction, forearm pronation/supination and elbow extension.

It might be possible that if the H-CAD system is used for longer than a month, the improvements on the execution time reveal changes on arm hand function. Further research is deserved to answer this hypothesis. Finally, it could also be possible that the learned tasks on the H-CAD system are difficult to translate to functional daily tasks, and that more consults or information for the patient are needed to translate the learned tasks to everyday life.

The overall satisfaction of both patients and ther-

apists concerning the H-CAD system was high. However, some modifications should be made with respect to the aesthetic aspects and to overcome the difficulty of the tasks, and more options of different levels should be available.

In conclusion, based on the high satisfaction of both patients and therapists, and together with the clinical finding that the H-CAD system is at least as effective as usual care, the use of the H-CAD system might be a good and efficient alternative for usual care in Stroke, TBI and MS patients living at home, to train and maintain their arm/hand function. The use of a H-CAD system can increase the therapy time for the patient, while decreasing the effort and time occupation for therapists.

Acknowledgements

The Authors wish to thank all the HELLODOC partners who contributed to the clinical trial.

Submitted on invitation.
Accepted on 15 December 2007.

References

1. Vollenbroek-Hutten MMR, Huijgen BCH. Power analysis for clinical trial. Healthcare service linking tele-rehabilitation to disabile people and clinicians. Deriverable n. 510 of the e-TEN project HELLODOC, 2006.
2. Lyle RC. A performance test for assessment of upper limb function in physical rehabilitation treatment and research. *Int J Rehabilitation Res* 1981;4:483-92.
3. Wagenaar RC, Meijer OG, van Wieringen PC, Kuik DJ, Hazenberg GJ, Lindeboom J, Wichers F, Rijswijk H. The functional recovery of stroke: a comparison between neurodevelopment treatment and the Brunnstrom method. *Scand J Rehabil Med* 1990;22(1):1-8.
4. Wolf SL, Catlin PA, Ellis M, Archer AL, Morgan B, Piacentino A. Assessing wolf motor function test as outcome measure for research in patients after stroke. *Stroke* 2001;32:1635-9.
5. Mahony FI, Barthel DW. Functional evaluation: the Barthel index. *Md State Med J* 1965;14:61-5.
6. Penta M, Tesio L, Arnould C, Zancan A, Thonnard JL. The Abilhand questionnaire as a measure of manual ability in chronic stroke patients: rasch based validation and relationship to upper limb impairment. *Stroke* 2001;32:1627-34.
7. Ware JE, Sherbourne CD, The MOS 36-item short-form health survey. *Med Care* 1992;30:473-83.
8. Aaronson NK, Muller M, Cohen PDA, Essink-Bot ML, Fekkes M, Sanderman R, Spranger MAG, Velde A te, Verrips E. Translation, validation, and norming of the dutch language version of the SF-36 health survey in communication and chronic disease populations. *J Clin Epidemiol* 1998;51(11):1055-68.
9. Senn S. *Statistical issues in drug development*. Chichester: Wiley; 1997.
10. Lee van der JH, Wagenaar RC, Lankhorst GJ, Vogelaar TW, Devillé WL, Bouter LM. Forced use of the upper extremity in chronic stroke patients; results from a single-blind randomized trial. *Stroke* 1999;30:2369-75.
11. Vaney C, Heinzel_gutenbrunner M, Jobin P, Tschopp F, Gattlen B, Hagen U, Schnelle M, Reif M. Efficacy, safety and tolerability of an orally administered cannabis extract in the treatment of spasticity in patients with multiple sclerosis: a randomized, double-blind, placebo-controlled, crossover study. *Multiple Sclerosis* 2004;10:417-42.