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Original article

Effectiveness of upper-limb robotic-assisted therapy in the early rehabilitation phase after stroke: A single-blind, randomised, controlled trial

Stéphanie Dehem [a,b,*], Maxime Gilliaux [a,b,c,d], Gaëtan Stoquart [a,b,e], Christine Detrembleur [a,b], Géraldine Jacquemin [f,g], Sara Palumbo [f], Anne Frederick [h], Thierry Lejeune [a,b,e]

[a] *Université catholique de Louvain, Secteur des Sciences de la Santé, Institut de Recherche Expérimentale et Clinique, Neuro Musculo Skeletal Lab (NMSK), Avenue Mounier 53, B-1200 Brussels, Belgium*
[b] *Université catholique de Louvain, Louvain Bionics, B-1348 Louvain-la-Neuve, Belgium*
[c] *Institut de Formation en Masso-Kinésithérapie La Musse, Allée Louis Martin, CS 20119, 27180 Saint-Sébastien-de-Morsent, France*
[d] *Hôpital La Musse, Allée Louis Martin, CS 20119, 27180 Saint-Sébastien-de-Morsent, France*
[e] *Cliniques universitaires Saint-Luc, Service de médecine physique et réadaptation, Avenue Hippocrate 10, B-1200 Brussels, Belgium*
[f] *Centre Hospitalier Valida, Service de médecine physique et réadaptation, Avenue Josse Goffin 180, B-1082 Brussels, Belgium*
[g] *Université de Montréal, Institut de Réadaptation Gingras-Lindsay de Montreal, Montreal, Canada*
[h] *Centre Hospitalier Neurologique William Lennox, Service de neurologie, Allée de Clerlande 6, B1340 Ottignies, Belgium*

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ABSTRACT

Background: Upper-limb robotic-assisted therapy (RAT) is promising for stroke rehabilitation, particularly in the early phase. When RAT is provided as partial substitution of conventional therapy, it is expected to be at least as effective or might be more effective than conventional therapy. Assessments have usually been restricted to the first 2 domains of the International classification of functioning, disability and health (ICF).
Objective: This was a pragmatic, multicentric, single-blind, randomized controlled trial to evaluate the effectiveness of upper-limb RAT used as partial substitution to conventional therapy in the early phase of stroke rehabilitation, following the 3 ICF domains.
Methods: We randomized 45 patients with acute stroke into 2 groups (conventional therapy, $n = 22$, and RAT, $n = 23$). Both interventions were dose-matched regarding treatment duration and lasted 9 weeks. The conventional therapy group followed a standard rehabilitation. In the RAT group, 4 sessions of conventional therapy (25%) were substituted by RAT each week. RAT consisted of moving the paretic upper limb along a reference trajectory while the robot provided assistance as needed. A blinded assessor evaluated participants before, just after the intervention and 6 months post-stroke, according to the ICF domains UL motor impairments, activity limitations, and social participation restriction.
Results: In total, 28 individuals were assessed after the intervention. The following were more improved in the RAT than conventional therapy group at 6 months post-stroke: gross manual dexterity (Box and Block test +7.7 blocks; $P = 0.02$), upper-limb ability during functional tasks (Wolf Motor Function test +12%; $P = 0.02$) and patient social participation (Stroke Impact Scale +18%; $P = 0.01$). Participants' abilities to perform manual activities and activities of daily living improved similarly in both groups.
Conclusion: For the same duration of daily rehabilitation, RAT combined with conventional therapy during the early rehabilitation phase after stroke is more effective than conventional therapy alone to improve gross manual dexterity, upper-limb ability during functional tasks and patient social participation.

* Corresponding author. Université catholique de Louvain, Institut de Recherche Expérimentale et Clinique, Neuro Musculo Skeletal Lab, Avenue Mounier 53, B-1200 Brussels, Belgium.
E-mail address: stephanie.dehem@uclouvain.be (S. Dehem).

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1. Introduction

Upper-limb (UL) rehabilitation of brain-damaged patients remains a challenge [1,2]. Despite intensive interdisciplinary rehabilitation, many have persistent neurological impairments [3] that limit activities and restrict social participation [1,4]. Rehabilitation robots are an innovative technology that is increasingly being studied and used to rehabilitate motor impairments [5]. Robotic-assisted therapy (RAT) allows for applying motor relearning theories because it intensifies the therapy, provides assistance as needed, quantifies the individual's movement performance, and delivers feedback [2,6].

A recent Cochrane review recommended RAT for stroke rehabilitation to reduce UL impairment and improve the execution of activities of daily living (ADL) [5]. However, Zhang et al. [7] highlighted 2 factors that must be taken into account when comparing the effectiveness of RAT and conventional therapy (CT): the post-stroke stage (early or chronic) and the amount of treatment (RAT in substitution or in addition to CT) [7].

The use of RAT is of great interest in the early rehabilitation phase (< 6 months post-stroke), when most of the neuroplasticity takes place. Indeed, neuroplasticity can be increased by active movements of the upper limb. RAT can facilitate movements by supporting UL weight and providing assistance as needed, when motor control is usually insufficient to perform active and functional movements independently [7]. Most studies assessing the effectiveness of RAT evaluated the chronic stage of stroke (> 6 months post-stroke). Mazzoleni et al. suggested that RAT could provide greater functional improvement in the early than chronic phase [8]. The Cochrane review also showed that RAT provided in the acute stage of stroke rehabilitation could improve ADL but not when provided in the chronic stage [5]. However, another meta-analysis found a significant difference between the RAT and CT group (assessed by the Fugl Meyer Assessment [FMA]) with RAT provided in the chronic and not early stage of rehabilitation [7]. Hence, the effectiveness of RAT in early rehabilitation is promising, but more studies are needed.

One meta-analysis found a positive effect of RAT in dose-matched and non-dose-matched randomised control trials (RCTs) [9]. Masiero et al. performed 2 RCTs of the type of treatment provided in the acute stage of stroke rehabilitation. In the first RCT, RAT was provided in addition to CT and in the other, RAT was provided as partial substitution of CT, with the same duration of treatment (40 min of 120 min CT per day were substituted by RAT). The authors found that RAT in addition to CT was more effective than CT alone for improving ADL. They also found that RAT substituting for CT was at least as effective as CT alone [10]. Recent studies demonstrated that RAT significantly decreased UL impairment when provided in addition to CT [9,10], but more studies are required to determine whether RAT is more effective than CT when provided in substitution.

Among previous studies assessing the effectiveness of RAT, none considered all domains of the International Classification of Functioning, Disability and Health (ICF). For instance, the social participation domain is not usually taken into account. Some authors have also advised assessing UL function by using UL kinematics. This is rarely evaluated [9,11].

According to all these considerations, the aim of this multicentric, randomised, controlled, evaluator-blinded trial was to evaluate the effectiveness of UL RAT in the early rehabilitation phase in individuals with stroke, with RAT used as partial substitution to CT. Participants were assessed according to the 3 ICF domains. The hypothesis was that UL RAT provided as substitution for part of CT in the early phase of stroke rehabilitation would ameliorate UL motor impairments, activities and social participation as compared with CT alone.

2. Methods

Patients were all volunteers and provided written informed consent before freely participating in the study. The study was approved by the ethical board of our faculty of medicine of the université catholique de Louvain. The trial was registered at ClinicalTrials.gov (NCT02079779).

2.1. Participants

Patients were recruited from May 2014 to May 2017 in three Belgian inpatient rehabilitation centres: Cliniques universitaires Saint-Luc (Brussels), Centre Hospitalier Valida (Brussels) and Centre Hospitalier Neurologique William Lennox (Ottignies). A physician who did not assess, randomise or rehabilitate patients was in charge of their enrolment. Inclusion criteria were single first ischemic or haemorrhagic stroke; < 1 month delay since stroke; age ≥ 18 years old; Mini-Mental State Examination score ≥ 15 [12] and the ability to understand instructions; FMA-Upper Extremity (FMA-UE) score < 80%, assessed by the computerized adaptive testing system (a higher score indicating less UL motor impairments) [13,14]; and a health status allowing for rehabilitation. Exclusion criteria were stroke located in the brain stem or cerebellum or another orthopaedic or neurological disease altering the paretic UL function.

2.2. Study design

The study was a single-blind RCT. It was performed in clinical settings and considered a pragmatic trial [15]. Patients were recruited at admission to the rehabilitation centre. They were randomised to the CT or RAT group according to computer-generated randomisation. Randomisation was performed and stored in the coordination centre by a researcher who did not evaluate or rehabilitate patients. Patients were randomised after the first assessment, independently in each hospital and by stratified dynamic allocation based on the FMA-UE (score < 40% or ≥ 40%).

Both groups underwent their rehabilitation sessions during their hospitalisation with their regular physical therapists and occupational therapists. The CT group followed conventional therapy focused on motor rehabilitation, matched with their personal needs and the centre's means. For the RAT group, CT rehabilitation was substituted by RAT for 25% of the total weekly rehabilitation time. Each week, 4 CT sessions (on 4 different days) of 45 min were substituted by RAT. Thus, the RAT group performed 36 RAT sessions in total (4 sessions/week over 9 weeks). As compared with the CT group, the RAT group received the same duration of motor rehabilitation each day including RAT (25%) and CT (75%). To simplify, the acronym RAT was used for the combination of RAT and CT in the intervention group in this manuscript. Depending on impairments, participants additionally received speech language therapy and/or cognitive rehabilitation. These therapies were not modified by the study.

2.3. Robotic-assisted therapy (RAT)

RAT involved using the end-effector REAplan® robot (Axinesis, Wavre, Belgium) illustrated in Appendix A [16]. The session lasted 45 min and was performed under therapist supervision. The exercises on the robot were similar in each centre and consisted of a game, involving moving the paretic hand along a reference trajectory (e.g., golf path) while passing through checkpoints (e.g., golf balls) (Appendix A, part D). During the game, the robot guided participants with assistance as needed [17,18].

2.4. ICF-based functional assessment

Patients were assessed at inclusion (during the first month post-stroke) (T0), after the 9-week intervention (T1) and at 6 months post-stroke (T2). They were assessed by the same blinded evaluator according to the 3 domains of the ICF [19]: UL motor impairments, activity limitations, and social participation restriction.

UL motor impairments were evaluated with the FMA-UE and box and block test (BBT). The rash-validated and computerized adaptive testing system of the FMA-UE was used to assess motor control [13,14]. Gross manual dexterity was assessed with the BBT [20,21].

Activity limitation was evaluated with the Wolf Motor Function Test (S-WMFT) and Abilhand and Activlim questionnaires. The S-WMFT French streamlined version was used to quantify UL motor ability during functional tasks [22,23]. This version included 6 tasks: hand to table, hand to box, reach and retrieve, lift can, lift pencil, and fold towel. The Functional Ability Scale (FAS) for each task was scored from 1, does not attempt with the involved arm, to 5, movement appears to be normal, analysed with the rash model and presented as a percentage (a higher percentage indicating better performance in activities) [22]. Abilhand and Activlim are 2 rash-validated, self-reported questionnaires that evaluate individuals' abilities to perform manual activities and ADL, respectively [24,25]. Results are presented as a percentage, a higher percentage indicating better performance in ADL [24,25].

Social participation was evaluated by using a subscore of the Stroke Impact Scale (SIS_{sb}). Patients only answered the section on how stroke affected their social participation. Each item was rated on a 5-point Likert scale, and the total score is expressed as a percentage, a higher percentage indicating more social participation [26,27].

2.5. Statistical analysis

Statistical analyses involved using the SigmaStat 3.5 (WPCubed GmbH, Munich, Germany). Data were analysed on an intent-to-treat basis [28]. The normality and equality of variances were checked by the Shapiro-Wilk and Brown-Forsythe statistical tests, respectively. $P < 0.05$ was considered statistically significant. Baseline functional measures were compared by the Student t test or Mann-Whitney test for parametric and non-parametric data, respectively. For outcome variables, a two-way repeated-measures ANOVA ($_{RM}$ANOVA) was used to analyse the interaction between time (T0-T1-T2) and groups (CT-RAT). If this test showed an interaction, it was further analysed with a post-hoc test (Holm–Sidak). However, if data were not normally distributed or variances were not equal, the non-parametric Friedman $_{RM}$ANOVA and the post-hoc Turkey test were used. Effect size was calculated by the Cohen's index (d), rated as small (<0.5); medium (0.5–0.8) or large (>0.8). To analyse the correlation between changes in each ICF domain, Pearson or Spearman correlation was used depending on whether conditions for parametric analysis were fulfilled. Correlation between 0.7 and 0.89 was classified as high. The proportion of participants with greater improvement than the minimal detectable change (MDC) or the clinically important difference (CID) were compared between groups by chi-square test.

3. Results

Between May 2014 and May 2017, 262 stroke patients were screened for eligibility and 45 met the inclusion criteria and agreed to participate. A CONSORT flow diagram [29] of the protocol is provided in Fig. 1. Thirteen patients dropped out during the intervention due to health worsening, personal choice, recurrence of stroke, shoulder pain, death, many missing sessions or discharge without possibility to pursue the protocol. Shoulder pain, reported by one patient in the RAT group, was the only adverse event. However, whether the event was treatment related is unknown. Thus, 32 participants (RAT group = 17; CT group = 15) were assessed after the intervention (T1); 4 from the CT group dropped out before the follow-up assessment. Finally, 28 participants were assessed for the final evaluation (T2) (RAT group = 15; CT group = 13).

Participant characteristics are in Table 1. At baseline, CT and RAT groups were similar in functional assessments.

3.1. Effect of intervention

The RAT group performed a mean (SD) of 520 (437) movements during each 45-min session (Table 2 and Fig. 2).

For the ICF motor impairment domain, assessed by the FMA-UE, $_{RM}$ANOVA showed a significant time effect ($P < 0.001$). The interaction between time and groups was not significant ($P = 0.058$). For gross manual dexterity, assessed by the BBT, $_{RM}$ANOVA showed a significant time effect ($P < 0.001$). The interaction between time and groups showed that gross manual dexterity improved more in the RAT than CT group ($P = 0.02$). The BBT score improved between T0 and T2 from a mean of 3.0 (8.3) to 12.7 (17.3) blocks in the RAT group but from 3.8 (7.5) to 5.1 (9.8) blocks in the CT group. The effect size of the difference in improvement between groups was considered moderate (Cohen's d = 0.63).

For ICF activity domain, $_{RM}$ANOVA showed improvements in UL motor ability during functional tasks, manual ability and ability to perform ADL over time ($P < 0.001$). The interaction between time and groups revealed that UL motor ability was improved more in the RAT than CT group ($P = 0.02$). Indeed, the S-WMFT FAS score improved between T0 and T2 from a mean (SD) of 16% (21.4) to 39% (36.6) in the RAT group but only from 19% (23.6) to 25% (33.1) in the CT group. The effect size of the difference in improvement between groups was considered moderate (Cohen's d = 0.59). We found no significant interaction between time and groups for manual ability and ability to perform ADL ($P = 0.15$–0.16).

Social participation improved over time ($P < 0.001$). The interaction between time and groups revealed greater improvement for the RAT than CT group ($P = 0.01$). Indeed, SIS_{sb} improved between T0 and T2 from a mean (SD) of 36% (21.4) to 59% (24.1) in the RAT group but only from 45% (26.6) to 47% (31.5) in the CT group. The effect size of the difference in improvement between groups was considered large (Cohen's d = 0.88).

3.2. Correlation between UL motor improvement scores

Improvements in motor control (FMA-UE) and manual dexterity (BBT) were highly correlated with improvements in manual ability (S-WMFT FAS) (ρ=0.71–0.74; $P < 0.001$), and improvements in ability to perform ADL (Activlim) and social participation (SIS_{sb}) were highly correlated (r = 0.74; $P < 0.001$).

4. Discussion

This study compared UL RAT to CT in the early post-stroke rehabilitation phase. RAT was provided as partial substitution and both groups were dose-matched.

4.1. Effect of RAT

The RAT group showed significantly more improvement in gross manual dexterity (BBT), UL ability during functional tasks

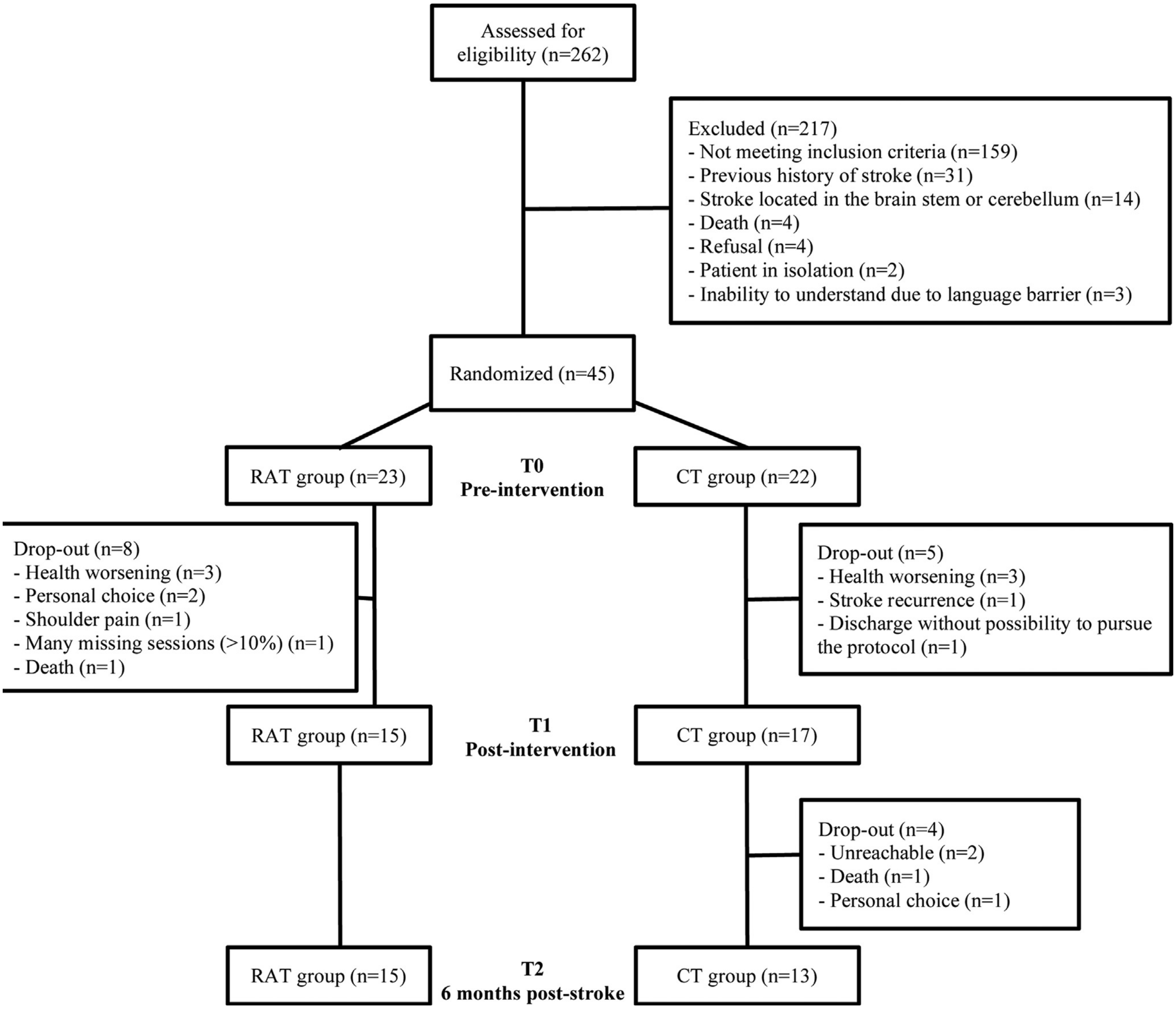

Fig. 1. CONSORT flow diagram of the stroke patients through each stage of the study. RAT: robotic-assisted therapy; CT: conventional therapy.

(S-WMFT FAS) and patient social participation (SIS_{sb}) than the CT group. Differences in improvement between groups were higher than the MDC for the BBT (+8 blocks, MDC = 6 blocks [21]). Concerning the UL motor control (FMA-UE) and the ability to perform manual activities (Abilhand), the RAT group did not improve significantly more than the CT group. However, the differences in improvement between groups were higher than the CID for the FMA-UE (+10%, CID = 7.9% [13]) and higher than the MDC for Abilhand (+10%, MDC = 1.1% [24]).

Previous studies and systematic reviews also found that RAT as partial substitution to CT in the early rehabilitation phase was at least as effective as CT or even better at improving UL function or ability to perform ADL as compared with CT alone [5,8–10]. For example, Sale et al. compared 30 sessions of UL RAT to 30 sessions of CT in the early rehabilitation phase [30]. The authors found a greater improvement in the RAT than CT group for UL motor control (FMA-UE), UL range of motion and Motricity Index [30].

To our knowledge, the present study is the only one to evaluate the effects of RAT on social participation. The SIS_{sb} was improved 18%, on average, more for the RAT than CT group, a significantly better improvement. Between T1 and T2, patients were more likely to develop their social participation (e.g., take a cup of tea with friends, go on holidays). Therefore, evaluating patients a long time after stroke is useful.

In our study, 25% of CT was substituted with RAT in the RAT group. Thus, the treatment duration was similar in both groups, as in the Sale et al. study [30]. Consequently, the greater improvement we observed in the RAT than CT group can be explained by the effect of the robotic device itself, providing assistance as needed, delivering feedback to the individual and providing a large number of repetitions (mean [SD] 520 [437] movements/session in the present study) [2,6]. In the Lo et al. study, FMA-UE and WMFT were significantly more improved with RAT than usual care but not intensive rehabilitation (intensity of movements matched with RAT) [31]. These authors suggested that the key factor in motor recovery was high intensity, repetitive, task-oriented movement training [31]. These recommendations can be followed in clinical practice with a robotic device with the assistance-as-needed control strategy, which helps patients complete their movement and intensifies therapy.

The proportion of all participants with greater improvement than the CID/MDC [21,24] between T0 and T2 was 75% for motor

Table 1
Demographic and clinical characteristics at baseline of participants with acute stroke in the robotic-assisted therapy (RAT) and conventional therapy (CT) groups.

Characteristics	RAT $n = 23$	CT $n = 22$	*P*-value
Characteristics			
Age (years)	67.3 (11.1)	68.6 (19.1)	/
Sex, male/female	11/12	10/12	/
BMI	25.2 (5.7)	24.0 (4.6)	/
Type of stroke, ischemic/haemorrhagic	16/7	19/3	/
Dominant upper limb, left/right	3/20	3/19	/
Affected upper limb, left/right	13/10	10/12	/
Mini Mental State Evaluation (/30)	26.2 (3.1)	24.6 (3.9)	0.23
Assessment time			
Between stroke and T0 (days)	28.1 (4.4)	27.5 (6.6)	0.60
Between stroke and T1 (days)	97.8 (7.5)	98.9 (9.3)	0.71
Between stroke and T2 (days)	194.7 (17.0)	191.3 (12.3)	0.64
Body function and structure			
FMA-UE (%)	32.4 (25.4)	31.6 (27.0)	0.93
BBT (blocks/min)	3.0 (8.3)	3.8 (7.5)	0.67
Activities			
S-WMFT FAS (%)	16.4 (21.4)	18.6 (23.6)	0.77
Abilhand (%)	36.9 (15.6)	41.6 (25.3)	0.31
Activlim (%)	38.9 (19.8)	44.8 (20.7)	0.37
Participation			
Stroke impact scale (%)	36.3 (21.4)	45.2 (26.6)	0.28

Data are mean (SD). BMI: body mass index; T0: inclusion (before treatment); T1: after the 9-week intervention; T2: 6 months post-stroke; FMA-UE: Fugl Meyer Assessment Upper Extremity; BBT: box and block test; S-WMFT FAS: Functional Ability Scale of the streamlined version of the Wolf Motor Function Test.

control and 75% for manual ability. Overall, 32% of patients showed > 20% improvement in social participation (this threshold was arbitrarily chosen on the basis of the MDC from the other SIS subscores) (Fig. 3). All participants with > 20% improvement in social participation also showed improvement more than the CID/MDC for motor control and manual ability. The proportion of patients with improvement in manual ability more than the MDC between T0 and T2 was significantly higher in the RAT than CT group (93% vs. 53%; $P = 0.03$), and the proportion with > 20% improvement in social participation between T0 and T2 was also significantly higher in the RAT than CT group (47% vs. 8%; $P = 0.04$).

Moreover, at 6 months post-stroke, the RAT group seemed to recover better than the CT group. Results were consistent with Masiero et al. [32], who evaluated the effectiveness of RAT provided in addition to CT in acute stroke patients [32]. The RAT group showed significantly improved motor function (at 1.5 and 3 months post-stroke), and improvements were sustained at 8 months follow-up [32]. Indeed, intensive repetition of movements has been shown to provide a long-term retention effect. Park et al. showed that short-duration, intensive reach training can have a retention effect on motor impairments in chronic stroke patients [33]. The long-term effectiveness in the RAT group was not related to the post-rehabilitation lifestyle. Indeed, a similar number of patients in both groups returned home (73% RAT group and 71% CT group) or to a nursing home (27% RAT group and 29% CT group) between T1 and T2.

During RAT with an end-effector robot, individuals trained for reaching movements but not grasping movements. Patients or therapists could fear that proximal UL rehabilitation would be carried out at the expense of distal UL recovery [34]. However, we showed that gross manual dexterity was significantly more improved in the RAT than CT group. This improvement was in accordance with Gilliaux et al., who evaluated the effectiveness of RAT using the REAplan® robot in children with cerebral palsy [16]. The authors also found a significant improvement in gross manual dexterity (BBT) in the RAT group [16]. In acute stroke patients, Masiero et al. compared CT and RAT as partial substitution [35] and found that both groups improved similarly, without any difference between groups in gross manual dexterity (BBT) [35]. Therefore, because it does not seem to deteriorate distal UL recovery, RAT can be used safely in the early rehabilitation phase after stroke.

Uncertainty remains as to whether RAT should be used in addition to or instead of CT in routine clinical practice. Currently, Masiero et al. recommended using it in addition in the early rehabilitation phase, when improvements are likely to be greater and instead of in the chronic phase [10]. One key factor is the patient's tolerance to the high intensity of RAT [7]. In the present study, RAT was well tolerated when used to substitute for part of CT. Systematic reviews showed that it was safe when used as substitution and in addition to CT [5,9].

4.2. Correlation between UL motor improvement scores

Our participants' improvements in motor control and gross manual dexterity were highly correlated with improvement in manual ability. The correlation between improvements in activi-

Table 2
Functional results at each evaluation time and two-way repeated measures ANOVA results comparing the treatment effects between the RAT and CT groups.

ICF domain	RAT group			CT group			Time effect *P*-value	Group effect *P*-value	Interaction: group x time *P*-value	Effect size of the difference of improvement (from T0 to T2) between groups, Cohen's *d*
	T0 $n = 23$	T1 $n = 15$	T2 $n = 15$	T0 $n = 22$	T1 $n = 17$	T2 $n = 13$				
Body function and structure										
FMA-UE (%)	32.4 (25.4)	51.9 (30.9)	57.1 (33.8)	31.6 (27.0)	42.4 (32.6)	41.6 (34.5)	< 0.001	0.224	0.058	0.47
BBT (blocks/min)	3.0 (8.3)	9.5 (14.3)	12.7 (17.3)	3.8 (7.5)	6.9 (11.7)	5.1 (9.8)	< 0.001	0.227	0.021	0.63
Activity										
S-WMFT FAS (%)	16.4 (21.4)	32.6 (30.1)	39.0 (36.6)	18.6 (23.6)	24.9 (33.1)	24.8 (32.5)	< 0.001	0.394	0.024	0.59
Abilhand (%)	36.9 (15.6)	47.1 (20.2)	53.1 (14.1)	41.6 (25.3)	46.6 (21.1)	47.8 (18.8)	< 0.001	0.947	0.165	0.48
Activlim (%)	38.9 (19.8)	56.2 (21.4)	63.3 (19.1)	44.8 (20.7)	56.6 (25.3)	59.4 (22.3)	< 0.001	0.881	0.150	0.88
Participation										
Stroke impact scale (%)	36.3 (21.4)	50.0 (21.4)	59.4 (24.1)	45.2 (26.6)	50.9 (34.7)	47.5 (31.5)	< 0.001	0.923	0.011	0.88

Data are mean (SD). ICF: International Classification of Functioning, Disability and Health; RAT: Robotic-Assisted Therapy; CT: Conventional Therapy; T0: inclusion; T1: after the 9-week intervention; T2: 6 months post-stroke; FMA-UE: Fugl Meyer Assessment Upper Extremity; BBT: Box and Block Test; S-WMFT FAS: Functional Ability Scale of the streamlined version of the Wolf Motor Function Test.

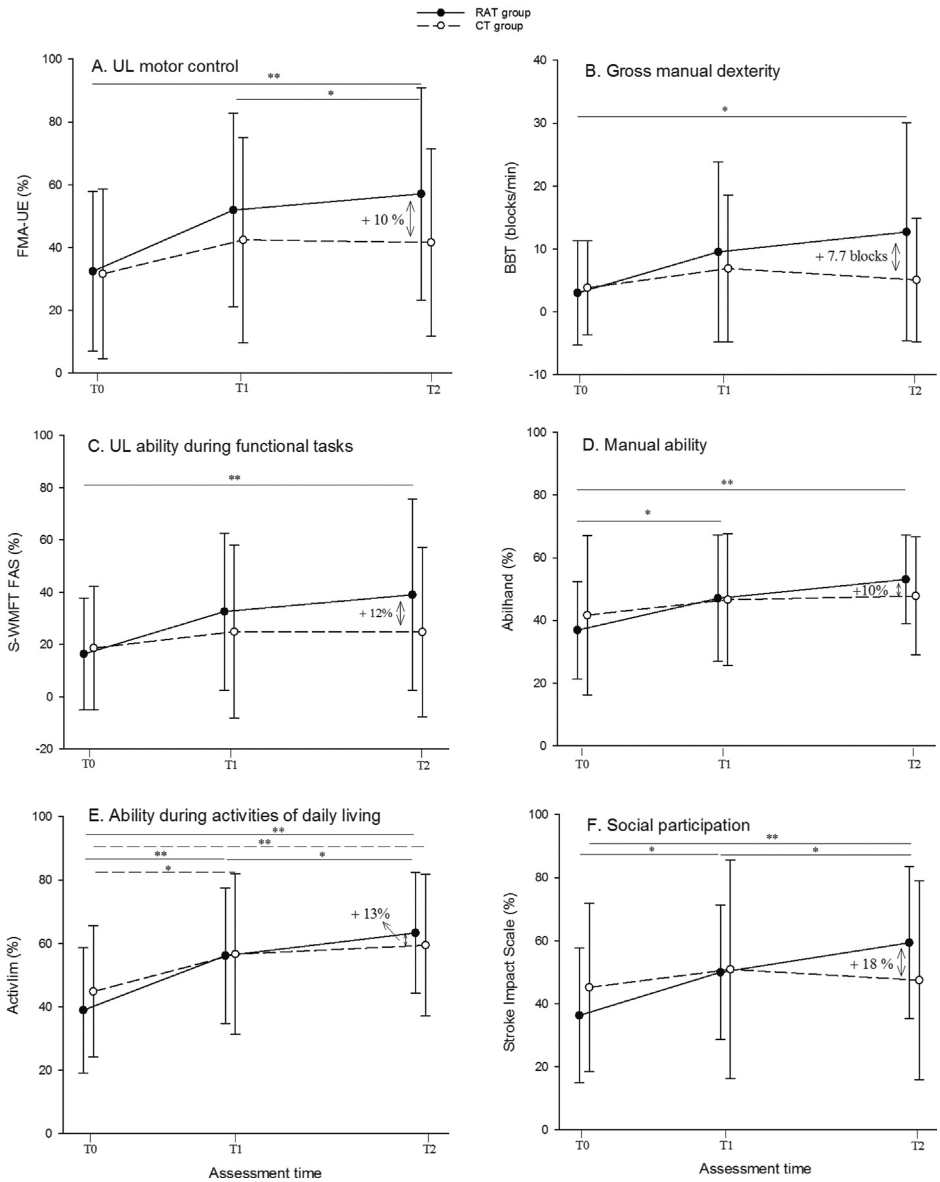

Fig. 2. Data for each assessment time for the (A) Fugl Meyer Assessment Upper Extremity test (FMA-UE), (B) Box and Block Test (BBT), (C) Functional Ability Scale of the streamlined version of the Wolf Motor Function Test (S-WMFT FAS), (D) Abilhand questionnaire, (E) Activlim questionnaire and (F) Stroke Impact Scale. T0, inclusion; T1, after the 9-week intervention; T2, 6 months post-stroke. Data are mean (SD). $_{RM}$ANOVA ($^{*}P < 0.05$; $^{**}P < 0.001$).

ties and social participation domains was also high. Furthermore, all participants with improvement in social participation showed improvement in motor control and manual ability. These results are consistent with Peter et al. [36] who showed improvement in FMA-UE before functional recovery. Therefore, early rehabilitation should focus on motor control.

4.3. Study strength

This study can be considered a pragmatic study [15] because it included a population that is relevant (recruited in rehabilitation centres, with moderate to severe motor impairments), and the CT group received a conventional therapy adapted to their personal needs. Outcomes were meaningful, including patient-reported outcome measures, and relevant in clinical practice for stroke patients [37]. This study shows the real-world effectiveness of RAT in the early rehabilitation phase.

4.4. Study limitations

This study has several limitations. First, the sample was relatively small. These preliminary results should be confirmed by a future multicentric study involving more participants. Second, the number of patients who dropped out (37%) was higher than in previous studies at the same phase of rehabilitation (10–15%) [33,36]. However, these dropouts did not stop the study because of the intervention. Rather, they dropped out due to worsening health, stroke recurrence, etc. (Fig. 1). Results could be influenced by the dropout of 4 patients in the CT group between T1 and T2, because 3 of them had better motor control than the CT group mean (> 42% for the FMA-UE). Finally, in Belgium, patients commonly pursue physical therapy to maintain their functional abilities after discharge, but we did not have precise information on the therapy between T1 (end of the intervention) and T2 (6 months post-stroke).

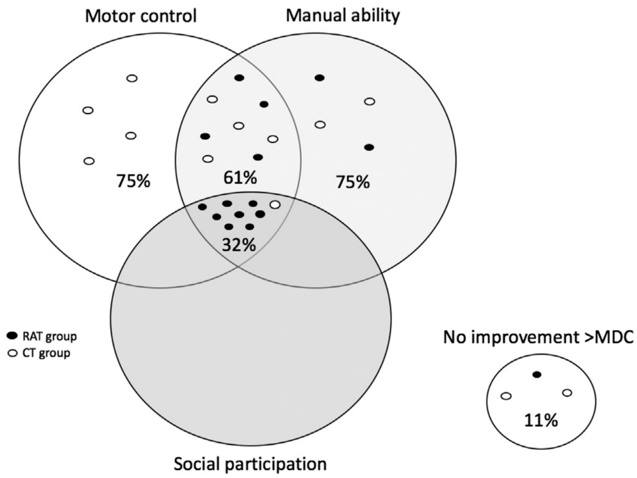

Fig. 3. For each International Classification of Functioning, Disability and Health (ICF) domain, illustration of participants from both groups with improvement more than the minimal detectable change (MDC) or the clinically important difference (CID) between T0 (inclusion) and T2 (6 months post-stroke). Each patient is represented by one circle. Percentages are calculated for both groups.

5. Conclusion

The present RCT showed that post-stroke, for the same duration of daily rehabilitation, motor UL RAT combined with CT was more effective than CT alone for gross manual dexterity, UL ability during functional tasks and patient social participation in the early rehabilitation phase. To allow for generalisation, our findings should be confirmed by further studies involving a larger sample. Then, RAT could be used in clinical practice to increase the number of movement repetitions and motor recovery.

Disclosure of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.rehab.2019.04.002.

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