SMART Arm with Outcome-Triggered Electrical Stimulation: A Pilot Randomized Clinical Trial

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Background: The SMART (SensoriMotor Active Rehabilitation Training) Arm is a nonrobotic device designed to allow stroke survivors with severe paresis to practice reaching. It can be used with or without outcome-triggered electrical stimulation (OT-stim) to augment movement. The aim of this study was to evaluate the efficacy of SMART Arm training when used with or without OT-stim, in addition to usual care, as compared with usual care alone during inpatient rehabilitation. **Methods:** Eight stroke survivors received 20 hours of SMART Arm training over 4 weeks; they were randomly assigned to either (1) SMART Arm training with OT-stim or (2) SMART Arm training alone. Usual therapy was also provided. A historical cohort of 20 stroke survivors formed the control group and received only usual therapy. The primary outcome was Motor Assessment Scale Item 6, Upper Arm Function. **Results:** Findings for all participants were comparable at baseline. SMART Arm training, with or without OT-stim, led to a significantly greater improvement in upper arm function than usual therapy alone ($P = .024$). There was no difference in improvement between training with or without OT-stim. Initial motor severity and presence of OT-stim influenced the number of repetitions performed and the progression of SMART Arm training practice conditions. **Conclusion:** Usual therapy in combination with SMART Arm training, with or without OT-stim, appears to be more effective than usual therapy alone for stroke survivors with severe paresis. These findings warrant further investigation into the benefits of SMART Arm training for stroke survivors with severe paresis undergoing inpatient rehabilitation during the subacute phase of recovery. **Key Words:** *electrical stimulation, recovery, rehabilitation, severe paresis, stroke, upper extremity*

Participation in intensive and repetitive task-oriented training promotes recovery of upper limb (UL) function after stroke.[1-4] However, a large proportion of stroke survivors have severe paresis and are thus unable to participate in task-oriented practice because of a lack of underlying movement.[5] Although one intervention option is robotic therapy, functional gains have been inconsistently reported in the literature,[6-8] and robotic therapy remains largely prohibitive because of cost and lack of availability.[9] More recently, a nonrobotic device, the SMART (SensoriMotor Active Rehabilitation Training) Arm, was developed to enable stroke survivors with severe paresis to undertake intensive and repetitive practice of reaching.[10]

Features of the SMART Arm design aim to make task-oriented practice possible. For instance, the device minimizes the mechanical degrees of freedom to be controlled; the hand is stabilized in a splint that is attached to a track, constraining the reaching movement to a straight-line trajectory that is consistent with a normal pattern of movement for reaching. The device can be used with electrical stimulation (ES) to augment movement through the full range of reaching. Continuous real-time visual and auditory feedback on the performance of reaching is provided via an interactive computer training program to engage and motivate the user. In addition, the device allows manipulation of a number of training elements, such as load, repetitions, and track elevation, to incrementally increase task difficulty. Thus, SMART Arm training

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attempts to drive recovery of reaching through structured and progressive task-oriented practice.

In a previous randomized clinical trial, SMART Arm training, with or without electromyogram (EMG)–triggered ES, was investigated in community-dwelling stroke survivors with severe and chronic arm paresis.[10] A significant reduction in impairment and improvement in activity was demonstrated after 12 hours of training over 4 weeks. However, the additional benefits derived when SMART Arm training was used with EMG-triggered ES were inconsistently expressed. In some instances, this may have been due to patterns of EMG activity, such as co-contraction of biceps and triceps, that triggered stimulation but were maladaptive with respect to the initiation of reaching. As a result of these findings, a new method of outcome-triggered ES (OT-stim) was developed, whereby the distance reached is used to define the stimulation threshold. Thus, assistance and reinforcement occur when the movement initiated is consistent with the desired outcome.

Early after stroke onset is the optimal time window for stroke rehabilitation. During the early stages of recovery from stroke, the brain is primed for recovery, and fewer secondary changes are likely to impede practice.[11,12] Therefore, in the current SMART Arm study, training was provided to adult stroke survivors with severe paresis during the inpatient (subacute) phase of recovery. The aim of the study was to evaluate the efficacy of SMART Arm training when used with or without OT-stim, in addition to usual care, as compared with usual care alone.

Methods

A pilot single-blind randomized clinical trial was conducted at a rehabilitation unit (20-bed) in a large regional hospital in Australia between February 2008 and August 2010. Comparison was made between groups of stoke survivors who received SMART Arm training with or without OT-stim and a historical control group of 20 stroke survivors who had received usual UL therapy at the study site with the same therapists.[13] Ethical approval was received from the Townsville Health Service District Human Research Ethics Committee (48/07) and James Cook University Human Research Ethics Committee (H2839), and informed consent was obtained from all participants. The trial was registered on the Australian New Zealand Clinical Trial Registry (ACTRN12611001075976) and was conducted in accordance with the Declaration of Helsinki.

Participants

Stroke survivors admitted to the acute stroke or inpatient rehabilitation unit were invited to participate in the study. The inclusion criteria were as follows: (1) diagnosis of a first-time stroke less than 3 months previously; (2) age greater than 18 years; (3) triceps muscle strength grade less than 3 (or 8/15 on triceps manual muscle testing); (4) inability to complete a standardized supported reaching task (push a 25-g sandbag off the edge of a table displaying 90° to 180° elbow extension); (5) ability to understand single-stage commands; and (6) ability to provide written informed consent. If the stroke survivor was physically unable to write, the legal guardian could sign on his or her behalf. Exclusion criteria consisted of (1) UL comorbidities that premorbidly limited function (eg, arthritis, neurologic disorders); (2) inability to tolerate ES or presence of a contraindication to cutaneous ES; or (3) a medically unstable condition. Members of the control group were subject to identical inclusion criteria; however, they were recruited based on severity of active wrist extension movement (ie, inability to actively extend the wrist past neutral) rather than elbow extension movement, and persons with language, comprehension, or cognitive problems were excluded.

Protocol

Participants were randomly allocated to 1 of 2 training groups: (1) SMART Arm training with OT-stim (SMART Arm OT-stim) and usual therapy, or (2) SMART Arm training without OT-stim (SMART Arm alone) and usual therapy. Participants in the control group received only usual therapy. Usual therapy consisted of individual and group sessions, which focused on both passive (eg, stretching, cyclic electrical stimulation) and active (eg, range of movement, strengthening, modified task practice with ES) practice when possible.

Randomization was performed by using sealed opaque envelopes that contained participant allocation. The randomization sequence, drawn up by a computerized number generator, and group allocation were concealed from all study personnel except participants, their usual therapists, and trainers throughout the entire study. After baseline testing was performed, participants and treating therapists were informed of group allocation by the study coordinator.

Intervention

SMART Arm groups were offered 20 training sessions of 60 minutes' duration, 5 days per week for 4 weeks, in addition to usual therapy. Participants in the control group were offered usual therapy 5 days per week for 4 weeks. Occupational therapists, physiotherapists, and therapy assistants (trainers) delivered the SMART Arm intervention in addition to their daily workload. Researchers (K.H. and R.B.) provided one-on-one and group (maximum 6 trainers per group) training sessions in the use of the SMART Arm with OT-stim to trainers as appropriate to individual skill levels. Researchers (K.H. and R.B.) provided assistance with the delivery of SMART Arm training as required.

The training set-up and procedure replicated the SMART Arm training protocol that had been previously established.[10] The only differences in this current trial were the type of stimulation provided during training (OT-stim as compared with EMG-triggered ES), the orientation of the hand splint (mid pronation-supination as compared with pronation), and the duration of training (20 sessions over 4 weeks vs 12 sessions over 4 weeks).

Each training session began with the participant seated in a chair beside the SMART Arm (see **Figure 1**), restrained by a harness to restrict compensatory trunk movement.[14] The affected arm was positioned in 90° elbow flexion and the forearm in mid pronation-supination and wrist extension (0° to 45°), which was achieved by placement in a customized thermoplastic splint. The splint was mounted on a linear slide that measured displacement and provided continuous visual feedback to the participant by means of a bar displayed on a computer screen. The height

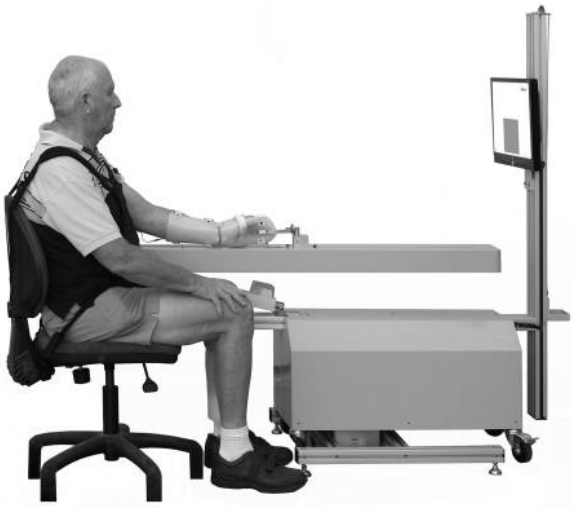

Figure 1. The SMART Arm device.

and color of the bar varied in accordance with the displacement of the arm, that is, the extent of reach. The trainer also provided verbal encouragement as required. On commencement of each training session, the participant's active reach distance (or personal best) and maximum passive reach distance (goal) were recorded. When prompted by an audible tone, the participant was required to push his or her hand along the linear track to reach the goal, represented by a gold line on the computer screen. When the goal was achieved, the computer screen burst into gold. If all 10 reaching movements for a set surpassed the goal distance, the goal for movement increased to a distance that equated to the average reach distance of the previous set. Based on a training dose previously established,[10] a minimum of 60 repetitions were performed during the first 5 training sessions (6 sets of 10), and a minimum of 80 repetitions (8 sets of 10) were performed during each of the remaining 15 sessions. Up to 60 seconds of rest was provided after each set. Practice could be progressed by altering the rest period duration, degree of load, number of repetitions performed, and reaching range by means of elevation or reorientation of the training track. At the end of each session, training details were recorded in the participant's logbook.

Participants allocated to SMART Arm OT-stim received ES to the lateral head of the triceps. ES was delivered via a Respond Stim unit (Empi, St Paul, Minneapolis, MN) through 2 surface electrodes

(diameter of 50 mm) applied above the area of the triceps brachii motor point (lateral head) and at the muscle insertion. Stimulation intensity was set at a level sufficient to achieve the overall movement goal, that is, full elbow extension to enable practice of reaching. The threshold distance for delivery of ES was each participant's personal best distance, recorded on commencement of each training session. As a participant's reach attempt surpassed his or her personal best distance (threshold), ES to triceps brachii was automatically triggered. If the threshold distance was successfully achieved during 8 of 10 consecutive trials within a set, the threshold distance was automatically increased on the third repetition of the subsequent set. If the threshold distance was not achieved, the unit was programmed to automatically decrease the threshold distance on the subsequent repetition. Stimulus parameters consisted of a 1-second ascending ramp, 4 to 10 seconds of a 200-μs pulse width biphasic stimulation at 50 Hz, followed by an 8- to 20-second rest period between trials. Active stimulation and rest period duration were set, as appropriate, for each participant.

Measurement

Before initial assessment, demographic information consisting of age, sex, stroke onset, site of lesion, stroke-related impairments (eg, cognition, communication, and sensory), level of disability on admission to rehabilitation unit as measured by the Functional Independence Measure (FIM), and medical comorbidities were collated from the medical chart. All participants (n = 28) were evaluated at baseline (0 week) and after training (4 weeks) by 1 of 3 experienced physiotherapists who were blinded to group allocation. Standardized testing procedures were used to administer all measures across the cohorts investigated. The order of measurement was consistent for the duration of the study.

The primary outcome measure was Motor Assessment Scale Item 6, Upper Arm Function (MAS6). This measure was chosen because of its known validity and reliability[15] and for comparison with the previous SMART Arm study and population-based studies undertaken in Australia. Secondary outcome measures included MAS Item 7, Hand Movements, and Item 8, Advanced Hand Activities, which enabled analysis of any carryover improvements in hand function.[16] All MAS items were administered to experimental and control participants. Other secondary outcome measures were administered to SMART Arm participants only, with the aim to quantify the presence of and change (either positive, negative, or no alteration) in impairments during SMART Arm training. Measures included: (1) triceps brachii muscle power using manual muscle testing[17,18]; (2) resistance to passive elbow extension using the Modified Ashworth Scale and spasticity of elbow flexors using the Tardieu Scale[19,20]; and (3) joint tenderness with passive shoulder movement using the Ritchie articular index.[21,22] The Stroke Impact Scale (SIS), a self-report measure of important consequences of stroke, was administered to determine the effect of SMART Arm training on quality of life and overall participation.[23]

Statistics

An intention-to-treat analysis was performed using Microsoft Excel. SMART Arm training characteristics were compared between persons receiving SMART Arm training with versus those receiving SMART Arm training without OT-stim using Cohen's *d* effect size index.[24] A small effect size is considered by convention to be indicated by a *d* value of 0.2 to 0.3, a medium effect size by a *d* value of 0.5, and a large effect size by a *d* value of greater than 0.8. Normality of the distribution of mean change scores for the primary outcome measure across the groups was assessed using a Wilks-Shapiro test. On this basis, the SMART Arm and usual care groups were compared across time points using the Mann-Whitney *U* test. Nonparametric descriptive measures of median and interquartile range (IQR) were also calculated for all participant groups.

Results

Participants

Participants were compared at baseline to check for group differences. All participants (n = 28) were severely disabled with an MAS6 score of

Table 1. Baseline participant characteristics

Participant characteristics	SMART arm all (n=8)	SMART arm OT-stim (n=4)	SMART arm alone (n=4)	Control (n=20)
Mean age, years (SD)	63 (17.5)	69 (10)	56 (24)	62 (17)
Sex, female, n	3	2	1	7
Mean DSS (SD)	36 (9)	46 (12)	26 (6)	35 (44)
Hemiplegic side, right, n	5	4	1	10
Stroke location, MCA, n	5	4	1	–
Admission to rehabilitation documented				
Total FIM, range	30–82	30–35	32–82	–
Motor-FIM, range	13–47	13–25	15–47	–
Cognitive-FIM, range	8–35	8–17	16–35	–
Altered sensation, n	2	1	1	–
Altered communication, n	2	2	0	–
Altered perception, n	4	4	0	–
MAS6, Upper Arm Function (0-6), median (IQR)	0 (0)	0 (0.25)	0 (0)	0 (1)
MAS7, Hand Movements (0-6), median (IQR)	0 (0)	0 (0)	0 (0)	0 (0)
MAS8, Advanced Hand Activities (0-6), median (IQR)	0 (0)	0 (0)	0 (0)	0 (0)
Modified Ashworth scale (0-4), median (IQR)	1.5 (3.25)	0 (0.5)	0 (0.25)	–
Tardieu scale (0-3), median (IQR)	0 (0.25)	1 (2)	0.5 (1.25)	–
Triceps muscle grade (0-15), median (IQR)	0.5 (2)	2 (4.25)	1.5 (1.5)	–
Ritchie articular index (0-3), median (IQR)	1 (1.25)	1.5 (1)	0 (0.25)	–

Note: DSS = days since stroke; FIM = Functional Independence Measure; IQR = interquartile range; MAS = Motor Assessment Scale; MCA = middle cerebral artery; OT-stim = outcome-triggered electrical stimulation; ROM = range of movement.

≤1 (unable to maintain elevation of their arm in the supine position) (see **Table 1**). There were no significant differences between participants at baseline with respect to age or days since stroke onset ($P > .05$). At baseline, those allocated to received SMART Arm training with OT-stim were more disabled and were more likely to have cognitive, language, and perceptual impairments than those allocated to receive SMART Arm training alone. Two participants dropped out of the trial during its course because of severe medical complications or the presence of multiple strokes (see **Figure 2**).

SMART Arm training

The characteristics of SMART Arm training were compared between persons who received training with and without OT-stim (see **Table 2**). The SMART Arm OT-stim group completed more repetitions during training than the SMART Arm alone group ($d = 1.05$). With regard to progression of training, the SMART Arm alone group performed training under conditions of greater load ($d = -0.65$) and elevation ($d = -0.66$) than the SMART Arm OT-stim group. No adverse events were reported.

Effectiveness of SMART Arm training

There was no significant difference in upper arm function (MAS6) between persons who received SMART Arm training with or without OT-stim at baseline or after 4 weeks of SMART Arm training ($P > .05$). In light of the small number of participants, all SMART Arm participants were pooled for comparison with the control group.

Comparison of SMART Arm training (with or without OT-stim) with usual therapy alone was performed. There was no significant difference in arm function (MAS6) at baseline for SMART Arm and control participants ($P > .05$). Changes in MAS6 scores for the control group (n = 20) were not normally distributed (Wilks-Shapiro, $P < .01$); therefore, a nonparametric inferential approach was used. The improvement in MAS6 score was significantly greater for the SMART Arm groups (mean rank, 20.063; n = 8) than for the

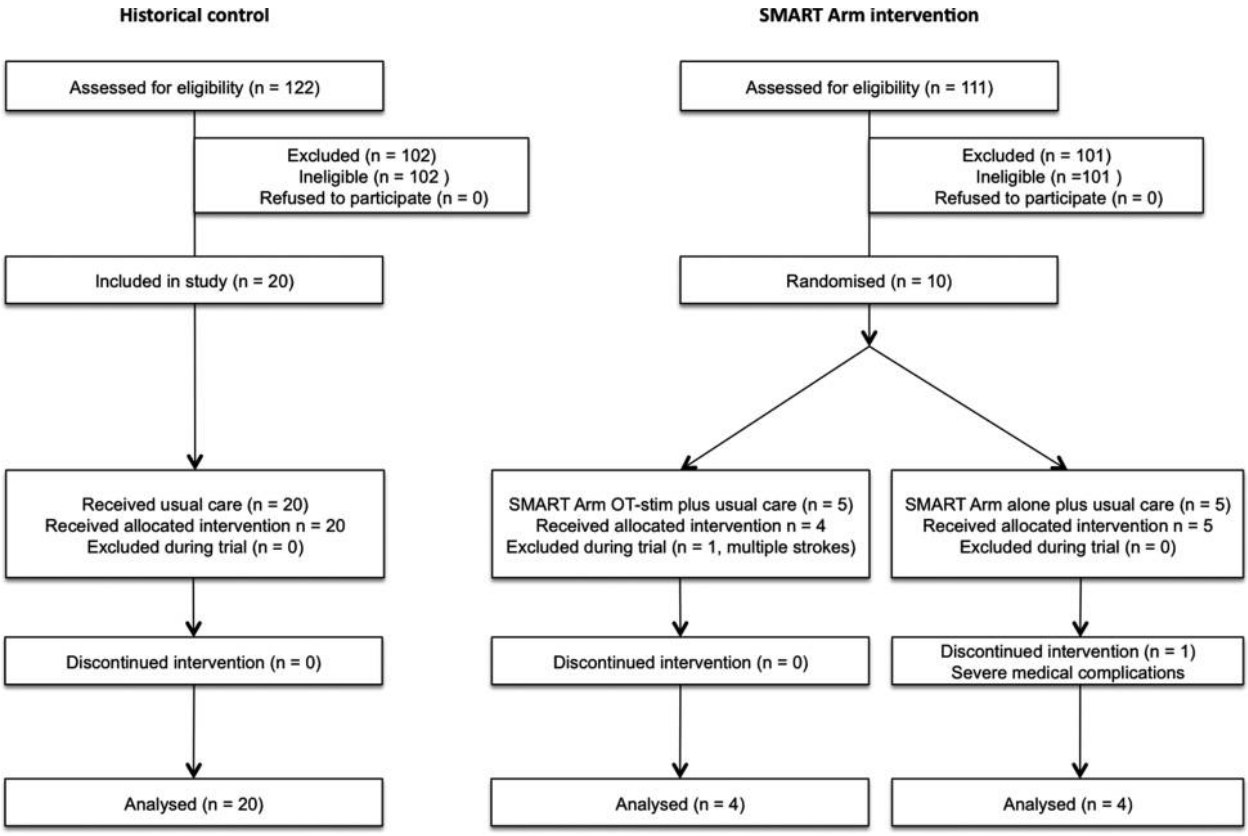

Figure 2. Flow diagram for patient screening and randomization.

Table 2. SMART Arm training characteristics

Training	SMART Arm OT-stim (n=4)	SMART Arm alone (n=4)	Cohen's *d*
SMART Arm sessions, /20	20 (0)	17 (0)	∞
Usual therapy sessions, /20	17 (0)	12 (0)	∞
Total repetitions	1,760 (400)	1,275 (518)	1.05
Average load, ounces	1.5 (3.0)	6.7 (10.9)	−0.65
Average elevation, degrees	1 (4)	4 (5)	−0.66

Note: Values are given as mean (SD). OT-stim = outcome-triggered electrical stimulation.

control group (mean rank, 12.275; n = 20) (Mann-Whitney $U = 35.5$, $P = .024$). **Figure 3** shows that 6 of the 8 individuals who received SMART Arm training exhibited a change in MAS6 score that exceeded the upper inner fence of the distribution obtained for the control group.

Secondary outcome measures

Participants who received SMART Arm training displayed an improvement in triceps muscle strength after training (median improvement 4 out of 15 points; IQR = 3.5) (see **Table 3**). There was no reliable alteration in tone, spasticity, or pain on completion of training. Participants who were able to complete the SIS, a measure of stroke-specific quality of life, demonstrated an improvement in all subscales.

Discussion

This is the first study to evaluate the effect of usual therapy when delivered in combination with SMART Arm training as part of inpatient rehabilitation during the subacute phase of recovery, as compared with usual therapy without SMART Arm training. The findings of this study are promising, because they indicate that usual

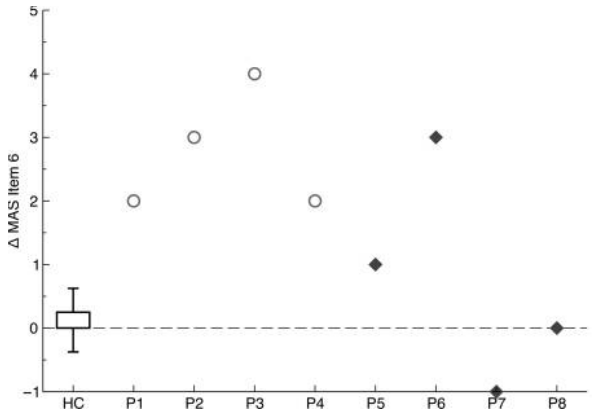

Figure 3. Change in upper arm function (Motor Assessment Scale [MAS] Item 6). Box and whisker values represent values obtained for the historical cohort (HC). Upper and lower whiskers correspond to the inner fence upper and inner fence lower, respectively. Upper and lower bounds of the box correspond to upper and lower quartiles, respectively. The horizontal dashed line is drawn at the median value of the HC (n = 20). P1 to P8 represent changes in MAS Item 6 exhibited by individuals who received SMART Arm training (*circles* = SMART Arm training alone; *diamonds* = SMART Arm training with outcome-triggered electrical stimulation).

therapy in combination with SMART Arm training, with or without OT-stim, is more effective than usual therapy alone for stroke survivors with severe paresis during inpatient rehabilitation. SMART Arm training enabled participants to intensively and repetitively practice reaching, which has been previously considered difficult to achieve.[5] Participants with multiple impairments were also able to complete the intervention protocol. This is an important outcome, because the eligibility criteria for a large proportion of studies investigating stroke survivors with severe paresis often exclude those with multiple impairments. Because stroke survivors with severe paresis and multiple impairments were included in this study, the findings have increased relevance for clinical therapists.

Training logs highlighted differences between the 2 SMART Arm groups with respect to the conditions under which training occurred. SMART Arm OT-stim participants performed a greater number of repetitions in comparison with SMART Arm alone participants, despite having greater initial stroke severity and the presence of multiple impairments. The presence

Table 3. Outcome measures collected throughout the trial

Measure	SMART Arm all (n = 8)		SMART Arm OT-stim (n = 4)		SMART Arm alone (n = 4)		Control group (n = 20)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
MAS6, Upper Arm Function	0 (0)	2 (2.25)	0 (0.25)	0.5 (1.5)	0 (0)	2.5 (1.25)	0 (1)	0 (1)
MAS7, Hand Movements	0 (0)	0 (0.25)	0 (0)	0 (1.25)	0 (0)	0 (0.25)	0 (0)	0 (0)
MAS8, Advanced Hand	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Triceps strength (0-15)	1.5 (3.25)	7.5 (5)	2 (4.25)	3 (1.5)	1.5 (1.5)	8 (0.25)	NA	NA
Modified Ashworth scale (0-5)	0 (0.25)	0 (1)	0 (0.5)	0.5 (1)	0 (0.25)	0 (0.25)	NA	NA
Tardieu scale (0-4)	0.5 (2)	1 (2)	1 (2)	2 (0.5)	0.5 (1.25)	0 (0.5)	NA	NA
Ritchie articular index (0-3)	1 (1.25)	1 (2)	1.5 (1)	2 (0.5)	0 (0.25)	0.5 (1)	NA	NA
SIS, Total (0-315)	–[a]	–[a]	–[b]	–[b]	149 (27.5)	183.5 (42.25)	NA	NA
SIS, Impairment (0-155)	–[a]	–[a]	–[b]	–[b]	88.5 (12.5)	107 (17.75)	NA	NA
SIS, Activity (0-120)	–[a]	–[a]	–[b]	–[b]	41.5 (8)	55.5 (12.25)	NA	NA
SIS, Participation (0-40)	–[a]	–[a]	–[b]	–[b]	13 (7)	18.5 (14.25)	NA	NA

Note: Values given as mean (interquartile range). MAS = Motor Assessment Scale; NA = not available; OT-stim = outcome-triggered electrical stimulation; SIS = Stroke Impact Scale.

[a] Incomplete sample.

[b] SIS was unable to be completed because of the presence of significant aphasia.

of OT-stim appears to have enabled stroke survivors with severe and multiple impairments to perform errorless practice of a task directed at bridging the "no function"' gap. In contrast, the SMART Arm alone group completed more difficult training, as evidenced by greater use of load and elevation. Principles of exercise prescription suggest that increased task difficulty can lead to reduced performance.[25] Therefore, as a trade-off to maintain performance, SMART Arm trainers reduced the number of repetitions to be completed. This also highlights that the SMART Arm device has the capacity to progress practice and promote continued improvements in function. Therefore, the training logs provided useful insight into the role of SMART Arm training to help stroke survivors not only "get going with exercise," but also to progress practice to drive recovery of arm function.[5]

Despite variations in training volume and conditions, the provision of SMART Arm training in addition to usual therapy increased upper arm function to a significantly greater degree than usual therapy alone. The findings of this study confirm that upper arm function can be improved when task-oriented practice is made physically possible for stroke survivors with severe paresis. After 20 hours of SMART Arm training, upper arm function improved by a score of 2 out of 6, which is consistent with previous research.[10] Thus, results of this study suggest that a beneficial effect in the chronic phase of recovery is also achievable during the inpatient rehabilitation phase of recovery. An improvement in upper arm function is perhaps not surprising, considering that key principles of motor learning are exploited within this intervention, such as multi-joint movement performance, repetitive practice, minimization of the mechanical degrees of freedom, and real-time visual and auditory feedback of performance.[10] Unfortunately, the benefits derived from augmentation of movement with OT-stim were somewhat inconsistently expressed. This finding is similar to that achieved with EMG-triggered ES.[10] Although there may be systematic grounds for variations in the efficacy of ES across individuals, these cannot be identified on the basis of the results of this study. In view of the improved outcomes in relation to usual therapy alone, further detailed evaluation of the utility of SMART Arm training in a larger cohort during the inpatient rehabilitation phase is warranted to give consideration to any additional advantage that may be bestowed by OT-stim.

This study is limited by the use of a historical cohort as a control group. In principle, use of a historical cohort raises a possible confounder in relation to the content and intensity of usual therapy. However, because there was a high degree of standardization across the 2 data collection periods and participants were comparable at baseline for both demographic and performance-related characteristics, it is unlikely that the large effect we have ascribed to the training intervention can be attributed to chance or variations in usual therapy alone. However, it is possible that SMART Arm training enabled stroke survivors to achieve the critical intensity of training required to demonstrate a functional improvement. A recent systematic review has suggested that the gains derived from robotic therapy are largely due to the dose of therapy, with similar gains being achievable during usual therapy if an adequately matched dose is administered.[8] However, current reports indicate that routine usual therapy is unlikely to be able to match this dose.[26,27] Therefore, if SMART Arm training can enhance the dose and remain cost-effective, its use may be warranted. Exploration of the cost-effectiveness of SMART Arm training is therefore required.

Conclusion

In summary, SMART Arm training with or without OT-stim enabled stroke survivors with severe and multiple impairments to intensively and repetitively practice reaching during the inpatient rehabilitation phase of recovery. The results of this study suggest that SMART Arm training has a role to play in bridging the "no function" gap early after stroke in persons with severe paresis and multiple impairments. These findings require further exploration within the context of a larger trial. Such a trial should evaluate the optimal SMART Arm training parameters and how best to include SMART Arm training within usual therapy to

promote greatest functional improvements in persons with severe paresis and multiple impairments after stroke.

Acknowledgments

Conflict of interest: K. S. Hayward, R. N. Barker, S. G. Brauer, D. Lloyd, and R. G. Carson are currently involved in commercialization of the SMART Arm device.

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Clinical trial registration information: Australian and New Zealand Clinical Trial Registry unique identifier ACTRN12611001075976.

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