

The efficacy of interactive, motion capture-based rehabilitation on functional outcomes in an inpatient stroke population: a randomized controlled trial

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Abstract

Objective: To compare the efficacy of novel interactive, motion capture-rehabilitation software to usual care stroke rehabilitation on physical function.

Design: Randomized controlled clinical trial.

Setting: Two subacute hospital rehabilitation units in Australia.

Participants: In all, 73 people less than six months after stroke with reduced mobility and clinician determined capacity to improve.

Interventions: Both groups received functional retraining and individualized programs for up to an hour, on weekdays for 8–40 sessions (dose matched). For the intervention group, this individualized program used motivating virtual reality rehabilitation and novel gesture controlled interactive motion capture software. For usual care, the individualized program was delivered in a group class on one unit and by rehabilitation assistant 1:1 on the other.

Main measures: Primary outcome was standing balance (functional reach). Secondary outcomes were lateral reach, step test, sitting balance, arm function, and walking.

Results: Participants (mean 22 days post-stroke) attended mean 14 sessions. Both groups improved (mean (95% confidence interval)) on primary outcome functional reach (usual care 3.3 (0.6 to 5.9), intervention 4.1 (–3.0 to 5.0) cm) with no difference between groups ($P=0.69$) on this or any secondary measures. No differences between the rehabilitation units were seen except in lateral reach (less affected side) ($P=0.04$). No adverse events were recorded during therapy.

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Conclusion: Interactive, motion capture rehabilitation for inpatients post stroke produced functional improvements that were similar to those achieved by usual care stroke rehabilitation, safely delivered by either a physical therapist or a rehabilitation assistant.

Keywords

Feasibility, self-management, technology, exercise, virtual reality

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Introduction

Stroke leaves a high physical burden that can be addressed by engaging patients in repetitive rehabilitation exercises.¹ However, the dose of rehabilitation activity needs to be high to drive neural remodeling and improve function.² This is not commonly achieved in standard rehabilitation.³ Innovative technological solutions, including virtual reality with motion capture capability, have the potential to engage patients in the doses of repetition required to improve outcomes in rehabilitation, without the cost and burden of increased therapy time.⁴ As well, these technologies provide visual feedback of movement in real time, thereby increasing engagement in and enjoyment of rehabilitation tasks.⁵ However, the use of such technology to support rehabilitation in the subacute setting is very limited.

While reviews across different types of technological interventions provide positive evidence for efficacy in stroke rehabilitation, results from meta-analyses vary depending on the type of technology included and outcomes measured.^{6–9} An updated Cochrane review suggests that overall upper limb function can be improved with a range of virtual reality options; however, the evidence on lower limb function and balance is less clear.¹⁰ Much evidence for virtual reality rehabilitation is based on multiple small studies (7 studies of less than 20 participants).¹¹ This suggests that caution in considering the applicability of this technology as a viable therapeutic modality in subacute stroke rehabilitation is warranted.

The development and broader availability of sophisticated controller-free motion capture and inertial sensing devices for measuring body movement and human–computer interaction has only

recently shifted from expensive and dedicated laboratory facilities to clinical settings. The ability for people after stroke to use their less affected upper limb to communicate with the computer via gesture and progress at their own pace through their exercise program at a self-directed rate demonstrates potential for improving the way in which clients can work through their rehabilitation program with greater independence. Although their potential in rehabilitation is evident, and multiple usability, feasibility,^{12–16} and validation trials^{17,18} have been conducted; the reporting of interactive motion capture-based rehabilitation (iMCR) technology in large, well-designed clinical trials in subacute rehabilitation is absent from the literature.

The purpose of this single-blind two-group, parallel, randomized controlled trial was to compare the efficacy of novel iMCR using commercially available software (Jintronix™) on physical function in participants less than six months after stroke. An additional aim was to compare outcomes on two units in subacute hospital settings.

In addressing the primary hypothesis, we anticipate that participants allocated to the iMCR intervention will demonstrate greater improvements in standing balance, compared to participants allocated to the control group, as measured by functional reach prior to discharge. We also wanted to explore whether units with different staff supervision produced the same or different results.

Methods

This single-blinded randomized controlled trial was conducted on two rehabilitation units of a

secondary referral hospital (Launceston General Hospital, Tasmania, Australia). Randomization was performed at the unit level. Participants were recruited between November 2014 and July 2016. All patients admitted to both units were screened by a senior rehabilitation physical therapist. Potential participants were included if they had reduced mobility post-hemorrhagic or infarct stroke of recent onset (less than six months), with a clinician-assessed capacity for improvement in mobility. Participants of any level of mobility were included. These potential participants were excluded if they had either severe receptive or expressive dysphasia which impacted their ability to communicate with the research staff or provide consent, marked cognitive impairment as determined by the screening clinician and the ability to follow two step commands, medical condition that precluded exercise, a severe visual impairment, or an anticipated length of stay of less than five days. All participants provided written informed consent. Ethical approval for this study was received from the Tasmanian Health and Medical Human Research Ethics Committee (approval number H0013769). This trial was registered with the Australian and New Zealand Clinical Trials Network (ACTRN12614000427673) and the protocol of this trial has been published.¹⁹

All participants attended two measurement sessions: one on entry into the study (baseline and prior to randomization) and one after the 8-week period (post-test) or immediately prior to discharge if discharged before eight weeks. The assessors were physical therapists blinded to group allocation at both time points. Allocation into iMCR intervention or control group used a computer-generated random number schedule with variable block sizes of two to six. The randomization sequence was generated by a researcher not involved in recruitment or assessment. Group allocation was concealed using consecutively numbered opaque sealed envelopes, opened after completion of baseline assessment in the presence of the participant.

The primary outcome of standing balance was assessed by observing participants' ability to reach forward with the less affected arm using the Functional Reach Test. This is a reliable²⁰ and

valid²¹ measure in the stroke population. A mix of upper limb function, balance, and gait measures were used as secondary outcomes. The Upper Arm Function component of the Modified Motor Assessment Scale was used to reliably measure progression of proximal arm strength²² and gross uni-manual dexterity was assessed using the timed Box and Block test.²³ Both are valid measures in the stroke population.^{21,24} The ability to maintain a static sitting position unsupported was assessed using the four-point rating scale and the Sitting Balance Test.^{21,25} Dynamic standing balance ability of side to side reach was measured using the Lateral Reach Test²⁶ to both sides. Measurement was taken from the shoulder to account for any loss of upper limb motion. The Step Test,²⁷ a validated measure of dynamic balance in individuals with stroke, was used to measure ability to repetitively step and tap each foot on to a 7.5-cm step over a 15-second time period.

Gait parameters of velocity calculated from the number of steps taken over time were measured over 10 m of a 14-m walkway at both a comfortable and fast pace.²⁸ Functional mobility was also assessed using the Timed Up and Go test.²⁹ These clinical gait measures have been validated in stroke populations.^{21,30,31}

Adverse events (e.g. an injury or fall) during therapy were recorded by the treating physical therapist, documented in the risk management system and reported to the research ethics committee. Further detail regarding these methods has been published as a protocol document.¹⁹

Participants in both groups were scheduled to receive two sessions of therapy per day. Both groups received individually prescribed physical therapy targeting functional outcomes on a daily basis. For the control group, the second session, participants received individualized prescription of repetitive exercises (functional retraining, strength, balance, and endurance). Each participant worked through the exercises at their own pace with guidance and supervision for the more challenging exercises as required. Exercises were performed in both seated and standing positions. These were delivered in group sessions on unit A (short stay rehabilitation unit) or by individual session with a

rehabilitation assistant on unit B (longer stay rehabilitation unit) for up to 1 hour per day on weekdays, depending on the endurance of the participant. The intention was to dose match the iMCR intervention and the control groups. For the iMCR intervention arm, the second session consisted of an individualized prescription of repetitive exercises using software from the Jintronix Rehabilitation System™ (JRS WAVE) (<http://www.jintronix.com/>). These game-based activities aimed to enhance standing and sitting balance, functional retraining, upper and lower limb strength, and endurance, as relevant to each client and were based on their clinical assessments. The iMCR intervention, lasting up to 1 hour in duration on weekdays, was dependent upon the endurance of the participant. Specifically, the iMCR intervention included arm activities targeting the more affected side and bilateral arm tasks to bring both hands to the midline, sitting and standing tasks that move the center of mass over the base of support and toward the limits of stability, and seated and standing leg activities to promote directional stepping and gait. Assistance was available to participants during balance-challenging activities.

The iMCR intervention replaced either the group sessions on one unit (unit A) or individual therapy supervised by rehabilitation assistants on the second unit (unit B). Each participant worked through their program at their own pace, using gestures with their less affected side to progress through the pre-set program with spotting or supervision as required to ensure safety. Functional and repetitive exercise programs for all study participants were reviewed daily in order to optimize rehabilitation potential.

Analysis

A priori sample size calculation was based upon previously published data on the Functional Reach outcome measures (baseline mean (standard deviation) data of 25.6 (7.4) cm).³² A clinically relevant between-group difference of 3.7 cm required a sample size of 63 ($P < 0.05$, power 80%). A total of 79 participants were recruited to allow for a 20% dropout rate.

Intention-to-treat analysis was used to compare the change (baseline vs. postintervention) in the outcome measures between the iMCR intervention group and control group using mixed effects linear regression corrected for repeated measures (STATA software, version 12, College, Texas). Study characteristics for both groups were compared using Student's *t*-test (for continuous variables) or chi-square test (for categorical values). The two units were also compared to determine if the outcomes varied between them. For asymmetrical activities (lateral reach, box and block, and Step Test), data were grouped to more and less affected sides. For analysis of timed up and go and the walking tasks, data from participants who were unable to complete the tests at baseline were removed from the analysis of those variables.

Results

No adverse events were recorded by the iMCR intervention or control groups while in therapy. In all, 81 people consented to participate in this study and data from 79 participants were collected at baseline as two people withdrew before baseline data were collected. Complete data for 73 individuals were recorded (Figure 1). The age of participants, average time since stroke, length of stay, and number of sessions were not different between the two groups (Table 1).

There were no between-group differences for the primary outcome of standing balance Functional reach ($P = 0.69$) (Table 2). No between-group differences were observed for any of the other outcome variables measured (Table 2).

Over time, participants improved in standing balance, sitting balance, upper limb function, and timed up and go (all $P < 0.04$). No changes in time for 10-m walk velocity (comfortable $P = 0.08$ or fast $P = 0.33$) were observed. Furthermore, 13 people who were unable to perform the task at baseline were able to perform the Timed Up and Go at the postintervention point (baseline $n = 50$, postintervention $n = 63$).

Analysis of the unit A and B comparisons demonstrated no differences in any of the outcome measures (all $P > 0.1$) except for lateral reach to the less

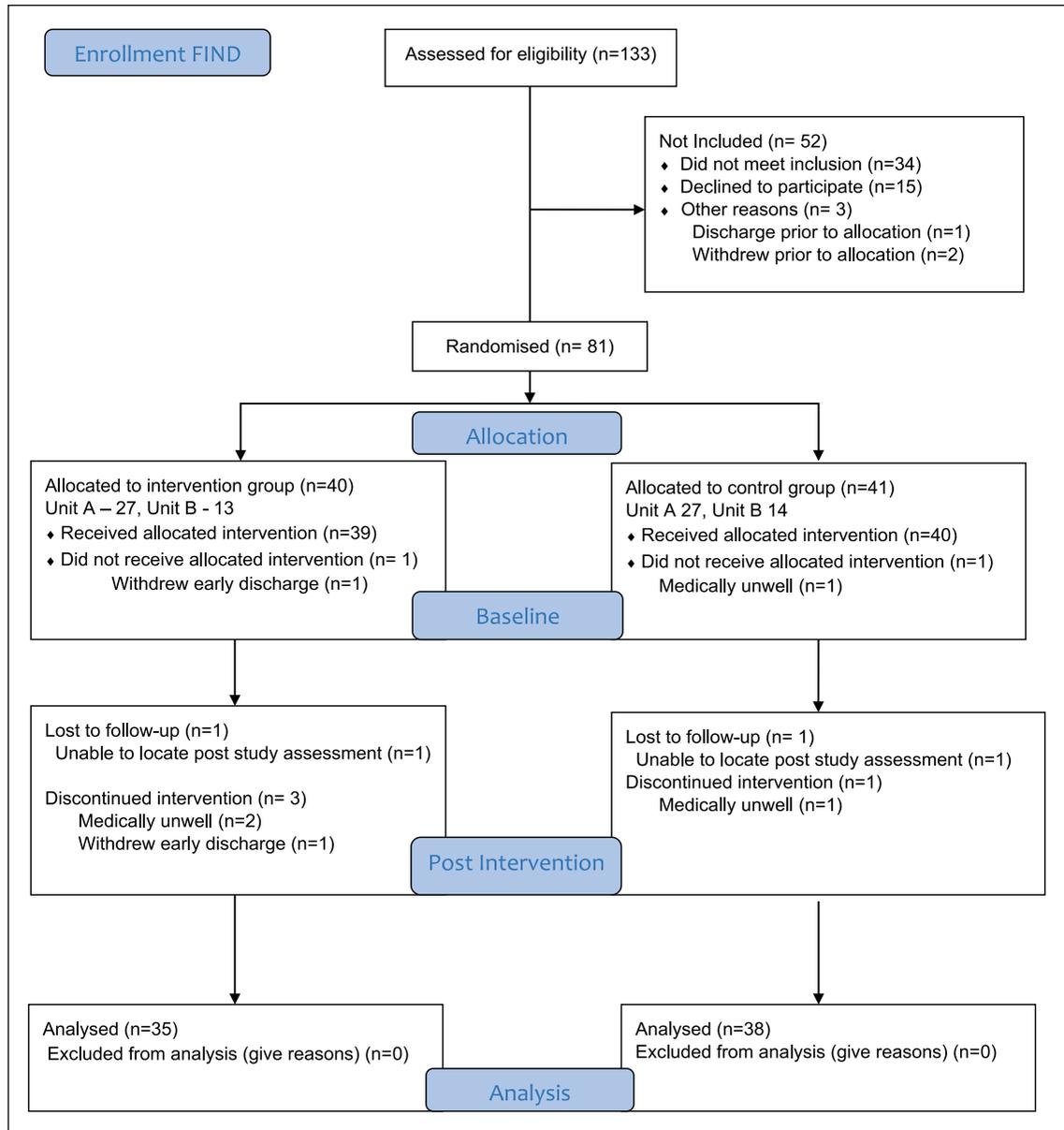


Figure 1. Participant flow through the study.

affected side. For lateral reach to the less affected side, larger improvements (i.e. change from baseline to postintervention) were observed for people in unit B (mean difference 3.7 (95% CI: 15 to 7.3)) ($P=0.041$; Table 3). However, this variable was also different between the two units at baseline: unit

A (12.8 (SD, 1.16)) compared to unit B (5.0 (SD, 2.0), $P=0.001$). Baseline Functional Independence Measure (FIM) scores were also different between units indicating that people enrolled in the study from unit B (35.9 (14.7)) had lower FIM scores than in unit A (57.9 (16.0); $P<0.001$).

Table 1. Characteristics of the study participants in control and iMCR intervention groups.

Characteristic	Control group Mean (SD)	iMCR intervention Mean (SD)	P value of difference
Number of participants	40	39	
Age (years)	74.8 (11.9)	72.8 (10.4)	0.42
Gender (F, M)	15, 25	23, 16	0.06
Height (cm)	165.9 (10.7)	166.0 (12.0)	0.96
Weight (kg)	77.5 (17.8)	72.6 (21.1)	0.27
Right side most affected	21	13	
Left side most affected	18	23	0.12
Both sides affected (right worst)	1	3	
Time since stroke (days)	19 (13)	26 (27)	0.14
Length of stay on rehabilitation unit (days)	41 (30)	42 (38)	0.89
Length of stay in hospital (days)	55 (35)	60 (47)	0.59
Number sessions	13 (9)	15 (11)	0.38
Functional independence measure	51.6 (17.6)	48.6 (19.7)	0.48

iMCR: interactive motion capture-based rehabilitation.

Discussion

This study found that the iMCR was not superior to control intervention, and no differences in the primary and other outcome measures between these groups were found. Clinically meaningful improvements in standing balance across both groups were not accompanied by improvements in usual and fast walking velocity. Across the two units, where the iMCR intervention was delivered by a physical therapist in one unit and a rehabilitation assistant on the other unit, no differences in functional outcomes between the two delivery modes were observed.

While this study was powered to detect differences between the iMCR and control groups and found none, we cannot assume that improvements of similar magnitude across both groups indicate exact equivalence. While improvements of similar values for the primary functional outcome were observed, there were large, although non-significant, differences in these values at baseline. These differences provide additional impetus to suggest that replication in a larger study is required. This study provides valuable data for calculating the sample size for such a study in a similar population.

The frequency and duration of the iMCR intervention and control groups were designed to be

dose-matched and pragmatic, reflecting research in practice, with the dose set between 8 and 40 sessions. The mean number of sessions was quite low (14), reflecting the current reality of short duration hospital stays due to planned early discharge. The low number of actual sessions may be another reason why between-group differences were not seen in this study. A larger dose over a longer intervention period may potentially produce a different result. Future research aimed at novel iMCR interventions in subacute rehabilitation should address the issue of short stays in care and include investigation of continuation of rehabilitation at home.

While the delivery of an iMCR intervention in a subacute inpatient setting is novel, this setting and population may be further reasons for the lack of between-group differences reported in this study. In the subacute setting, there is a large degree of variability in the functional level of participants at study entry, as evidenced by the range of SD values recorded in this study. This impacts the ability to determine between-group differences. As well, the natural recovery of participants at this short time period following stroke may further hamper detection of these differences.

This study demonstrates rehabilitation assistants can supervise established iMCR programs which are monitored and progressively modified as

Table 2. Comparison of outcomes for both groups (control and iMCR intervention).

Variable	Control group Pre mean (SE)	Control group Post mean (SE)	iMCR intervention Pre mean (SE)	iMCR intervention Post mean (SE)	Difference (95% confidence intervals)	P value
Functional reach (cm)	17.1 (1.8)	20.4 (1.3)	13.8 (2.6)	17.9 (1.4)	0.77 (-3.0 to 4.6)	0.69
Lateral reach (more affected) (cm)	9.3 (1.3)	12.8 (1.1)	8.2 (1.9)	11.8 (1.6)	0.2 (-3.0 to 3.4)	0.90
Lateral reach (less affected) (cm)	12.1 (1.4)	13.6 (1.2)	8.9 (2.0)	11.1 (1.8)	0.7 (-2.8 to 4.1)	0.71
Sitting balance (number)	3.6 (0.1)	3.9 (0.1)	3.7 (0.2)	3.9 (0.2)	-0.1 (-0.5 to 0.2)	0.46
Motor assessment (number)	3.8 (0.4)	4.6 (0.2)	3.6 (0.3)	4.4 (0.3)	0.0 (-0.7 to 0.6)	0.89
Box and block (more affected) number in 60 seconds	18.3 (2.6)	27.8 (1.7)	15.8 (1.7)	23.5 (2.7)	-1.9 (6.7 to 2.9)	0.44
Box and block less affected	35.3 (1.9)	41.8 (1.8)	34.8 (2.7)	41.8 (2.7)	-0.7 (-5.9 to 4.5)	0.80
Step test more affected (number in 15 seconds)	5.3 (1.0)	7.2 (0.6)	4.0 (1.3)	5.8 (0.9)	-0.1 (-1.9 to 3.1.7)	0.91
Step test less affected (number in 15 seconds)	5.6 (1.0)	6.5 (0.8)	4.4 (1.3)	6.4 (1.1)	1.1 (-1.1 to 3.4)	0.32
Timed up and go ^a (seconds) (n = 50)	26.7 (3.9)	22.9 (5.3)	28.6 (6.1)	27.6 (6.1)	3.1 (-12.9 to 19.1)	0.71
Velocity comfortable ^a (m/s) (n = 50)	0.66 (0.1)	0.74 (0.08)	0.6 (0.9)	0.65 (0.1)	-0.01 (-0.03 to 0.2)	0.92
Velocity fast ^a (m/s) (n = 50)	0.92 (0.1)	0.95 (0.1)	0.8 (0.1)	0.83 (0.2)	-0.02 (-0.4 to 0.3)	0.91

iMCR: interactive motion capture-based rehabilitation.

^aData were not included if participant was unable to perform task at baseline.

Table 3. Comparison of change in unit A (pre-post) to change in unit B (pre-post) (change in unit A subtracted from change in unit B).

Variable	Change in unit A (n=51)	Change in unit B (n=22)	Difference (95% confidence intervals)	P value
Functional reach (cm)	3.3 (1.2)	4.2 (1.7)	0.9 (-3.1 to 5.0)	0.65
Lateral reach (more affected) (cm)	1.8 (1.0)	4.2 (1.4)	2.4 (-0.9 to 5.7)	0.15
Lateral reach (less affected) (cm)	0.5 (1.1)	4.2 (1.5)	3.7 (-0.9 to 5.7)	0.04
Sitting balance (number)	0.2 (0.1)	0.4 (0.2)	0.2 (-0.17 to 0.6)	0.28
Motor assessment (number)	0.8 (0.2)	0.7 (0.3)	-0.1 (-0.17 to 0.6)	0.75
Box and block (more affected) number in 60seconds	9.4 (1.5)	7.2 (2.1)	-2.2 (-7.8 to 3.0)	0.41
Box and block less affected	6.1 (1.6)	6.4 (1.7)	0.3 (-5.3 to 5.7)	0.93
Step test more affected (number in 15seconds)	2.0 (0.6)	1.5 (0.8)	-0.5 (-2.3 to 1.4)	0.61
Step test less affected (number in 15seconds)	1.8 (0.7)	0.6 (1.0)	-1.2 (-3.5 to 1.2)	0.32
Timed up and go (seconds) (n=50)	-8.3 (2.4)	-13.2 (6.0)	-4.9 (-15.4 to 5.3)	0.36
Velocity comfortable (m/s) (n=50)	0.16 (0.03)	0.21 (0.07)	0.05 (-0.09 to 0.19)	0.50
Velocity fast (m/s) (n=50)	0.14 (0.04)	0.20 (0.07)	0.07 (-0.12 to 0.25)	0.49

required by a physical therapist. As monitoring and progression can be done remotely, there is potential to meet the needs of clients in rural or remote sites, who may not have access to a full-time physical therapist. The cost-effectiveness of this model of rehabilitation delivery is worth investigating, especially as this potentially adds another therapy option for people undergoing rehabilitation.

Technology can be used to engage clients in specific, targeted practice in rehabilitation. The visual feedback from the screen provides encouragement to improve movement quality and performance; this biofeedback is identified as helping to induce neuroplasticity.³³ As repetitions of part practice or functional tasks are the focus of subacute rehabilitation, clients interacting with technology can become engaged in the activity, thereby promoting higher levels of active participation,³⁴ concentration, and repetitions while being less aware of the number of repetitions already completed. As well, using gestures from the non-affected side to control the pace of their exercise program may encourage more independence within a therapy session. Future research is needed to guide clinicians in identifying the types of clients that prefer and benefit most from using this technology in rehabilitation.

There are some limitations. In the subacute setting, participants had a wide range of capabilities at

entry to the study. This influences the ability to find statistical significance between the groups in the results as the variability was larger than the data the sample size calculation was based on. The sample size then was not adequate to detect inferiority in either arm and subsequently provides a need for replication with a much larger group. The lack of any long-term follow-up prevents us from determining if one or other arm of this trial is more effective. Some improvements in function, that is, changes in gait aids used for clinical walking tests, have not been captured in these results.

Interactive, motion capture-based rehabilitation for mobility-limited people with stroke in subacute rehabilitation produced improvements in functional outcomes that were not superior to usual stroke rehabilitation. Clients can perform targeted functional activities designed by physical therapist using iMCR but supervised by rehabilitation assistants, using gesture control to set the pace of their exercise program. This has implications for service delivery, expanding the effective interventions delivered under the supervision of physical therapists or rehabilitation assistants. Replication of this study, with a long-term intervention providing a home-based component and follow-up, is recommended to determine whether technology-assisted rehabilitation produces sustained improvements in

functional outcomes and engages clients to participate actively and independently in their rehabilitation.

Clinical Messages

- Interactive motion capture-based rehabilitation can be delivered by physical therapists and rehabilitation assistants.
- This study found the clinical change associated with it was similar to and not superior to the change associated with routine care.

Declaration of Conflicting Interests

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