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Horizon Scanning Technology Prioritising Summary

Robot-assisted therapy for long-term upper limb impairment after stroke

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PRIORITISING SUMMARY

REGISTER ID: 000527

NAME OF TECHNOLOGY: ROBOT-ASSISTED THERAPY

PURPOSE AND TARGET GROUP: FOR LONG-TERM UPPER LIMB IMPAIRMENT AFTER STROKE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---------------------------------------------|-------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|-----------------------------------------|-------------|
| <input type="checkbox"/> Yes | ARTG number |
| <input type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Italy	✓		
United Kingdom	✓		
Hungary	✓		
Germany	✓		

IMPACT SUMMARY:

Several companies manufacture robotic-assist devices including: the Mirror Image Motion Enabler; the InMotion robot (Massachusetts Institute of Technology, MIT-Manus); the Assisted Rehabilitation and Measurement Guide; the Robotic Rehabilitation System for upper limb motion therapy; the Neuro-Rehabilitation-Robot (NeRoBot); the Bi-Manu-Track; the robot-mediated therapy system GENTLE/S; and the Arm robot, ARMin (Mehrholz et al 2009). All of these systems aim to provide treatment for the recovery of movement and strength of limbs, specifically the upper limbs. The technology would be made available through specialised rehabilitation

centres for patients who have recently experienced a stroke event. None of these systems are registered on the TGA.

BACKGROUND

A stroke occurs when an artery supplying blood to a part of the brain suddenly bleeds (haemorrhagic stroke) or becomes blocked (ischaemic stroke) causing a loss of function of part of the brain. Ischaemic strokes are more common (85%) than haemorrhagic strokes, however both may affect functions including movement of body parts, vision, swallowing, communication, and may result in death. Nearly all patients are disabled immediately following a stroke event. Common disabilities include permanent paralysis of one side of the body, speech or swallowing difficulties, problems with memory, personality changes or a range of other difficulties. Depression, anxiety and cognitive impairment are also common after stroke. By the end of the first year, about half of all survivors of stroke remain dependent on others for activities of daily living. Stroke mainly affects older people with the rates of stroke increasing markedly with age from about 65 years, with the median age of patients having a stroke in Australia being approximately 79 years (Senes 2006).

Two-thirds of all patients admitted to hospital after experiencing a stroke will have arm paresis resulting in reduced upper extremity function. Approximately half of these patients will remain without arm function six months after the stroke (Mehrholz et al 2009). Therefore many stroke survivors require long-term rehabilitation which aims to improve and to prevent further deterioration of function, resulting in the highest degree of physical, psychological, social and financial independence. Rehabilitation may involve the coordination of medical, nursing and allied health practitioners, as well as using social, educational and vocational services. Early rehabilitation, beginning in hospital, is important, and should continue after the patient has been discharged (Senes 2006). Effective rehabilitation and therapy for stroke patients must be intense and prolonged, requiring practice of repetitive task-related movements and actions. It may be difficult to motivate the patient to complete this intensive therapy as it is often perceived as being boring. In addition, such therapy is expensive to implement (Crosbie et al 2007).

Robot-assisted therapy is a recent development used especially in the recovery of function of the upper extremities. This therapy uses computer-based instruments with moveable parts which patients can manipulate, allowing them to reach, push or pull in an active, active-assisted or passive setting. With robot-assisted therapies, the patient can perform more intense repetitions and does not require the constant supervision of therapists (Young & Tolentino 2009). Some devices may assist the active movement of an isolated joint, whilst others move multiple segments to perform reaching-like movements. Alterations in therapy may be achieved by altering the force required for movement, decreasing the assistance or increasing the resistance given by the device

and by altering the movement amplitude. In addition, some devices such as the Bi-Manu-Track move the affected limb passively, steered by the non-paretic limb in a therapy called “mirroring” (Figure 1). Most robotic systems would incorporate more than one modality (Mehrholz et al 2009).



Figure 1 A patient using the Bi-Manu-Track device (Reha-Stim 2009)

The National Stroke Foundation Guidelines made the following recommendations for the assessment and management of the consequences of stroke:

Walking recommendations: One or more of the following interventions may also be used in addition to walking practice:

- cueing of cadence; (Grade B, Level I);
- mechanically assisted gait (via treadmill, automated mechanical or robotic device) (Grade B, Level I&II);
- joint position biofeedback; (Grade C, Level I); and
- virtual reality training; (Grade C, Level II).

Upper limb activity recommendations:

For people with difficulty using their upper limb one or more of the following interventions should be given in order to encourage using their upper limb as much as possible:

- constraint-induced movement therapy (Grade A, Level I);
- robot assisted training (Grade B, Level I); and

- repetitive task-specific training (Grade C, Level I) (National Stroke Foundation 2010).

CLINICAL NEED AND BURDEN OF DISEASE

In 2003, the number of Australians who had experienced a stroke at some time in their life was estimated to be 346,700 (AIHW 2010c). There is no national information on the incidence of stroke in Australia. It is expected that the ageing of the Australian population will result in an increase in the number of strokes in the future. Of those people who have experienced a stroke in their lifetime, almost half of survivors will experience a disability as a result of that stroke. Of those people who experience a first-ever stroke, one in five people will have died from it within one-month and one in three die within six-months. Within five years, one in six survivors of a first-ever stroke will experience another (Senes 2006).

In 2006, there were 8,484 deaths from stroke in Australia representing 18.6 per cent of all deaths from cardiovascular disease and approximately 6.3 per cent of all deaths. The majority of these deaths occurred in individuals who had experienced a haemorrhagic stroke. The age-standardised death rate for stroke decreased on average by 4.5 and 3.9 per cent per year during the period 1997–2006 for men and women, respectively. Recent declines have been greater for ischaemic stroke (8% per year) than for haemorrhagic stroke (2% per year) (AIHW 2010c; AIHW 2010a). The mean age at death from stroke was 80.3 years, and the majority of deaths (6,607, 81%) occurred in individuals aged >75 years (AIHW 2008). In Australia during 2007–08 there were 34,945 public hospital separations with a principal diagnosis of stroke (ICD-10 codes I60-I64), accounting for 352,916 patient days. During this same period there were only 67 public hospital separations for the sequelae of stroke (ICD-10 codes I69). However, the ICD-10 code I69.4 had 2,033 patient days associated with it, with an average length of stay of 63.5 days (AIHW 2010b).

In New Zealand during the year 2006-07, there were 7,815 public hospital separations for stroke (ICD-10 codes I60-I64). Of these, 690 and 381 separations were for individuals of Māori and Pacific Islander origin, respectively. Although there were only 37 separations for the sequelae of stroke (ICD-10 codes I69), these patients had a mean stay of 379.6 days (MoH 2010).

DIFFUSION

Robot-assisted therapy for the rehabilitation of stroke patients is not currently in routine use in Australia. At least one randomised controlled trial is being conducted in South Australia (ACTR Number: [ACTRN12609000777291](https://www.anzctr.org.au/Trial/Registration/TrialRegistration.aspx?ACTRN12609000777291)). Patients who have experienced either an ischaemic or haemorrhagic stroke will be randomised to either robotic or standard therapy. Robotic therapy will consist of 15 minutes of upper limb robotic therapy using the Bi-Manu-Track robot as part of 45 minute treatment session with standard treatment for the remaining 30 minutes. The robotic therapy consists of

150-250 repetitions of passive and/or active-passive program on Bi-Manu-Track robotic in both wrist flexion-extension, and pronation-supination positions and will be provided 5-days per week for 4-weeks. Standard treatment including bilateral training, relaxation, visualisation, grasp/release activities, passive range of motion with therapist, resisted strength training (eg with weighted cuffs), massage, and use of upper limb in functional tasks and will be given in 45 minute sessions, 5-days per week for 4-weeks. This trial is currently recruiting patients (n=60).

COMPARATORS

Rehabilitation therapies include constraint-induced movement therapy¹ to improve motor function in the upper extremities, locomotor treadmill training with partial body-weight support to regain mobility, balance, gait symmetry and endurance² and functional electrical stimulation³, a task orientated modality which aims to improve functional recovery in hemiparetic⁴ patients (Young & Tolentino 2009). These targeted therapies are expensive in terms of time, money and resources and to be effective, therapy must be prolonged and intensive. With limited resources and a large patient group, many patients do not receive an adequate volume of therapy for it to be effective (Crosbie et al 2007). New therapeutic modalities include the use of virtual reality to provide patients with controlled, safe and individualised therapy that is multisensory, multidimensional and functional. Therapy with VR allows for the intensive therapy required for effective rehabilitation using task-related activities such as reaching for a utensil in the kitchen or making a cup of coffee (Young & Tolentino 2009; Crosbie et al 2007). Virtual reality rehabilitation has required the development of specialised virtual environments which are expensive to purchase, however the efficacy of off-the-shelf and low cost video games, such as Wii and PlayStation EyeToy, have been investigated for use in the home or a therapeutic environment (Young & Tolentino 2009).

SAFETY AND EFFECTIVENESS ISSUES

A 2009 Cochrane Review included randomised controlled trials (RCTs) and randomised controlled cross-over trials (level I intervention evidence). Many were conducted on mixed populations of brain injured and stroke patients, however only those studies that had a population exceeding 50 per cent of stroke patients were included (n=11). The first analysis included all patients regardless of the elapsed time between stroke event and enrolment, however a subgroup analysis was later conducted

¹ Constraint-induced movement therapy involves constraining the “good” limb for a number of hours and hoping that the affected limb will begin to compensate and function.

² Treadmill training involves the patient being placed on a treadmill with an overhead harness which assists with weight bearing. The patient attempts to walk with the assistance of therapists.

³ Electrical stimulation is given via electrodes placed on the paretic limb at the same as patients are directed by a therapist to perform tasks such as grasping and releasing objects.

⁴ Hemiparetic: muscular weakness or partial paralysis restricted to one side of the body

on patients in the acute and subacute phase of their stroke (≤ 3 months) and those in the chronic phase (>3 months duration). The primary and secondary outcomes of the included studies were an improvement in daily living activity and changes in arm motor function impairment, respectively. The methodological quality of the included studies was assessed using the PEDro scale.⁵ As blinding of the therapist and patient was not possible the maximum possible score on the PEDro score was eight. The PEDro score ranged from two to seven with a median value of six (2 studies scored 7, 4 studies scored 6, 3 scored 5 and one study each were poor quality scoring 2 and 4). The sample sizes of the included studies ranged from 12 to 56 patients, with a mean age of 55 years to 68 years. The duration of the treatment program ranged from three to 12-weeks, with most studies using a five or six week intervention period, however the frequency of treatment in all trials was five times per week with a duration of therapy of 30-90 minutes (Mehrholtz et al 2009).

No adverse events relating to the use of robot-assisted therapy were reported by any of the included studies.

Six studies assessed the impact on daily living activities of electromechanical or robot-assisted arm training compared to other interventions, including physiotherapy alone. The pooled standardised mean difference (random effects model) was 0.29 (95% CI [-0.47, 1.06], $p=0.45$), indicating that robot-assist training did *not* improve daily living activities. In addition, no improvement in daily living with the use of robot-assist therapy was noted after a sub-group analysis was conducted on acute and subacute, and chronic stroke patients. However, there was a high level of heterogeneity ($I^2= 85\%$ ⁶) suggesting a large degree of variation between the included studies, possibly due to the trial design, the participant characteristics or the treatment given. Seven studies reported on changes in arm motor function impairment. The pooled standardised mean difference (random effects model) was 0.68 (95% CI [0.24, 1.11], $p=0.002$), indicating an improvement in motor function. There was less heterogeneity between these studies with an I^2 of 56 per cent. Five studies reported on changes to motor strength with the use of robot-assisted therapy compared to other interventions. Although there was an improvement in motor strength with a pooled standardised mean difference of 1.03 (95% CI [0.29, 1.78], $p=0.007$), there was a high degree of heterogeneity ($I^2= 79\%$) (Mehrholtz et al 2009).

The most recent RCT conducted by Lo et al (2010) randomised 149 patients who had experienced a stroke event at least 6-months prior to enrolment. Patients were randomised to receive a maximum of 36 one-hour intensive robot-assisted therapy

⁵ Items of the PEDro scale include: specification of eligibility criteria, random allocation to groups, concealment of allocation, treatment groups similar in characteristics at baseline, blinding of participants, assessors and therapists, follow-up of more than 85% of participants, an intention to treat analysis, reporting of results of between group statistical comparisons and reporting of point measures and measures of variability.

⁶ The I^2 statistic describes the percentage of variation across studies that is due to heterogeneity rather than chance. If there is little variation between trials then I^2 will be low.

(RT) sessions over a period of 12-weeks (n=49), intensive comparison therapy including assisted stretching, arm exercises and functional reaching exercises (n=50) or usual care which may or may not include rehabilitation services (n=28) (level II intervention evidence). The robot used was the MIT-Manus device; training consisted of four training blocks each lasting three weeks (9 training sessions per block). The program was designed to train movements of the shoulder, elbow, wrist and hand (Lo et al 2009). The intensive comparison therapy (ICT) had the same schedule as the robot-assist therapy and was delivered by the same staff. Patients were assessed for any changes in motor function as measured by the Fugl-Meyer Assessment of Sensorimotor Recovery after Stroke⁷ at 6, 12, 24 and 36 weeks post-randomisation. There was no difference between the baseline characteristics of all the three treatment groups with a mean overall age of 64.6 ± 11.3 years and the majority of patients having experienced an ischaemic stroke. The time from index stroke to randomisation did, however, differ significantly between the groups ($p=0.04$ for all comparisons): 3.6 ± 4.0 years for RT patients, 4.8 ± 4.0 years for ICT patients and 6.2 ± 5.0 years for the usual care patients. Of importance, there was no significant difference between baseline Fugl-Meyer scores, Wolf Motor Function Test scores⁸ or Stroke Impact Scale scores⁹ (Lo et al 2010).

There were no major treatment-related adverse events, with 12 patients (24%) in the RT group and nine patients in the ICT (18%) reporting transient muscle soreness.

The changes in outcomes scores at 12 and 36-weeks are summarised in Table 1. The mean Fugl-Meyer score improved for patients who received robot-assist therapy compared to those who received usual care, but was decreased compared to intensive care therapy. However, both of the between group differences of the means were non-significant. The reverse situation was true between group differences in the speed of motor-task performance as measured by the Wolf Motor Function Test, with a decrease in time to complete a task for patients who received robot-assist therapy compared to usual care, and an increase in time when compared to intensive care therapy, with both mean differences being non-significant. There was, however, a

⁷ The Fugl-Meyer Assessment is a validated 226-point multi-item Likert-type scale developed as an evaluative measure of recovery from hemiplegic stroke. It is divided into 5 domains: motor function, sensory function, balance, joint range of motion, and joint pain. Each domain contains multiple items, each scored on a 3-point ordinal scale (0 = cannot perform, 1 = performs partially, 2 = performs fully). The motor domain includes items measuring movement, coordination, and reflex action about the shoulder, elbow, forearm, wrist, hand, hip, knee, and ankle. The motor score ranges from 0 (hemiplegia) to a maximum of 100 points (normal motor performance), divided into 66 points for the upper extremity and 34 points for the lower extremity (Gladstone et al 2002).

⁸ The Wolf Motor Function Test measures proximal and distal upper-limb motor control on 15 timed functional tasks, with an upper limit of 120 seconds per task. The tasks are averaged to produce a score that ranges from 0 to 120 seconds, with higher scores indicating worse functioning.

⁹ The Stroke Impact Scale is a self-reported measure of quality of life in the domains of hand function, activities or instrumental activities of daily living, mobility, and social participation. Scores range from 0 to 100, with higher scores indicating better functioning and greater social participation.

significant improvement in motor function as measured by the Stroke Impact Scale for robot-assisted therapy compared to usual care. At 36-weeks, patients receiving robot-assisted therapy had significant improvements in Fugl-Meyer scores and Wolf Motor Function Test times compared to those patients who received usual care but not when compared to intensive therapy. Although significantly poorer performance scores were associated with longer interval times between stroke onset and therapy, the inclusion of interval time in the adjusted model (data not given) did not alter the treatment effects (Lo et al 2010).

Table 1 Changes in outcome scores

	Robot-assisted therapy vs Usual care		
	Robot-assist	Usual care	Mean difference [95% CI] At 12-weeks At 36-weeks
Change in F-M score	1.11 ± 1.01	-1.06 ± 1.00	2.17 [-0.23, 4.58] p=0.08 2.88 [0.57, 5.18] p=0.02
Change in time on WMF	3.13 ± 2.96	7.54 ± 2.97	-4.41 [-11.52, 2.7] p=0.22 -8.10 [-13.61, -2.60] p=0.005
Change in SIS score	4.61 ± 2.36	-3.03 ± 2.34	7.64 [2.03, 13.24] p=0.009 5.95 [0.34, 11.56] p=0.04
Change in pain scale	-0.81 ± 0.39	0 ± 0.38	-0.81 [-1.73, 0.11] p=0.08
	Robot-assisted therapy vs Intensive comparison therapy		
	Robot-assist	Intensive therapy	Mean difference [95% CI] At 12-weeks At 36-weeks
Change in F-M score	3.87 ± 1.05	4.01 ± 1.06	-0.14 [-2.94, 2.65] p=0.92 -0.58 [-2.97, 1.81] p=0.63
Change in time on WMF	-3.96 ± 3.00	-4.89 ± 3.00	0.93 [-7.03, 8.89] p=0.82 -2.13 [-9.2, 4.93] p=0.55
Change in SIS score	6.31 ± 1.68	5.77 ± 1.67	0.54 [-3.87, 4.94] p=0.81 1.19 [-2.74, 5.12] p=0.55
Change in pain scale	-0.61 ± 0.29	0.24 ± 0.30	-0.84 [-1.62, -0.06] p=0.03

F-M = Fugl-Meyer score, WMF = Wolf Motor Function Test, SIS = Stroke Impact Scale

Two other case series were identified which reported on before and after measures of small groups of stroke patients treated with the MIT-Manus (n=20) and the ReoGo™ (n=14). An in-depth report of the results of these case series has not been included, however preliminary results indicated a favourable decrease in motor disability in the upper limbs of these patients (Posteraro et al 2009; Bovolenta et al 2009)

COST IMPACT

There are several robot-assist devices on the market, however at least one, the Bi-Manu-Track is currently in trial in South Australia. The Bi-Manu-Track is manufactured and distributed by the German company, Reha-Stim. The current 2010

list price for this device is €15,299¹⁰ excluding customs charges and taxes (personal communication Reha-Stim).

The RCT by Lo et al (2010) as described above, compared three arms of therapy: robot-assisted therapy, intensive comparison therapy and usual care and presented a basic cost-analysis of this study. The purchase price of each robot (assuming full depreciation over 5 years) was used to estimate the cost per session of robot-assisted therapy. Costs were standardised to 2008 US dollars with the use of the general consumer price index. The average per-patient cost of therapy was US\$9,977 for patients receiving robot-assisted therapy and \$8,269 for patients receiving intensive comparison therapy. After 36 weeks, the average total cost (therapy plus the cost of all other health care use) was \$15,562 for robot-assisted therapy, \$15,605 for intensive comparison therapy, and \$14,343 for usual care. There was no difference in the non-log-transformed costs between treatments, however the costs for the two active-therapy groups were significantly more than the cost for usual care when log-transformed cost models were used ($p < 0.01$ for both comparisons) (Lo et al 2010).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

There are several studies currently underway assessing the use of robotics for limb training in stroke patients. An RCT (ClinicalTrials.gov Identifier: [NCT00975156](https://clinicaltrials.gov/ct2/show/study/NCT00975156)) being conducted by The University of Texas Health Science Center commenced in 2008 and expects to be finalised by the end of 2010. This study randomised chronic stroke patients (expected enrolment $n=20$) to either conventional physiotherapy or robotic assisted therapy with the Lokomat device and assessed improvements in ambulation and gait. Another RCT being conducted in Trento, Italy, is currently recruiting patients (ClinicalTrials.gov Identifier: [NCT01102309](https://clinicaltrials.gov/ct2/show/study/NCT01102309)). The study commenced in 2008 and expects to be finalised in 2011. Acute and subacute stroke patients ($n=40$) will be randomised to receive either conventional physiotherapy of the affected arm for 5-weeks, five times weekly for 120 minutes or to therapy with the NeRebot for 5-weeks, five times weekly for 40 minutes, plus 80 minutes of conventional therapy. A large RCT ($n=127$) conducted by the US Department of Veterans Affairs is nearing completion and is no longer recruiting patients. Patients with a single new focal unilateral stroke were randomised to one of three treatment arms: 1) usual care, 2) intensive comparison therapy, or 3) robotic training. Robotic training (12-weeks divided into 4 consecutive blocks, with 9 training sessions per block) with the MIT-MANUS robot consisted of four modules to train the entire upper limb: module A: shoulder-elbow; module B: anti-gravity; module C: wrist, and

¹⁰ €15,299 = \$ 21,529 as of 2nd November 2010

module D: hand-unit (ClinicalTrials.gov Identifier: [NCT00372411](#)). The National Taiwan University Hospital is about to commence an RCT, aiming to recruit 120 patients 3-24 months after the onset from a first-ever unilateral stroke (ClinicalTrials.gov Identifier: [NCT00917605](#)). Patients will receive therapy (20 training sessions: 1.5 hours/day, 5 days/week for 4 consecutive weeks) with the robot-assisted arm trainer, Bi-Manu-Track, which enables the symmetrical practice of 2 movement patterns: forearm pronation-supination and wrist flexion-extension. A non-randomised comparative study by the Prasat Neurological Institute in Thailand is also starting to recruit patients (n=80) who have experienced a subacute first-time stroke (haemorrhage and ischemic). Patients will receive conventional therapy or conventional therapy in addition to robotic therapy (ClinicalTrials.gov Identifier: [NCT01187277](#)). A smaller RCT (n=40) conducted by the US Kessler Foundation is currently recruiting patients who have experienced a unilateral ischemic stroke (onset < 15 days) that has resulted in arm weakness (ClinicalTrials.gov Identifier: [NCT00785343](#)).

SUMMARY OF FINDINGS

There is an extensive body of literature regarding the use of robot-assisted therapy for the rehabilitation of stroke patients. Inconsistencies in the baseline characteristics of patients included in comparative arms of trials make it difficult to make objective comparisons between groups. From the evidence assessed it would appear that robot-assist therapy has better outcomes in terms of improved motor function and decreased time to perform tasks when compared to usual care but not when compared to intensive therapy. However, intensive therapy is costly to perform, requiring one-to-one patient-therapist time. Therefore the addition of robot-assist therapy may deliver the same patient benefits as intensive therapy at a reduced cost, however a full cost-effectiveness analysis would be required to ascertain the true benefits of robot-assist therapy.

HEALTHPACT ASSESSMENT:

There is limited evidence regarding the effectiveness of this technology for stroke patients therefore further review of this technology by HealthPACT at this time is not warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies
Level I intervention evidence
Level II intervention evidence

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SEARCH CRITERIA TO BE USED:

Physical Therapy Modalities/instrumentation

Recovery of Function

Robotics

Stroke/physiopathology/*rehabilitation/complications/therapy

Upper Extremity/*physiopathology

Brain Injuries/*rehabilitation

Self-Help Devices

Task Performance and Analysis

Therapy, Computer-Assisted/methods