Horizon Scanning Technology
Prioritising Summary

Rehabilitation of stroke patients using virtual reality games

June 2010
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PRIORITISING SUMMARY

REGISTER ID: 000478

NAME OF TECHNOLOGY: REHABILITATION OF STROKE PATIENTS USING VIRTUAL REALITY GAMES

PURPOSE AND TARGET GROUP: TO IMPROVE RECOVERY IN STROKE PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒ Yet to emerge ☐ Established
☐ Experimental ☐ Established but changed indication or modification of technique
☐ Investigational ☐ Should be taken out of use
☐ Nearly established

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐ Yes ☐ ARTG number
☐ No ☒ Not applicable

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trials Underway or Completed</td>
</tr>
<tr>
<td>Australia</td>
<td>✓</td>
</tr>
<tr>
<td>Canada</td>
<td>✓</td>
</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
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<tr>
<td>Israel</td>
<td>✓</td>
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<tr>
<td>United States</td>
<td>✓</td>
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</tbody>
</table>

IMPACT SUMMARY:

Companies including Nintendo and Sony manufacture the virtual reality games Wii and Playstation EyeToy, respectively, with the aim of providing entertainment. However, a number of research groups have used these games for the rehabilitation of extremity motor functioning in patients who have experienced a stroke.

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. Risk factors for stroke are the same as for any cardiovascular disease: obesity, lack of physical activity, high blood cholesterol levels, high blood pressure and smoking. 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).

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 (Senes 2006).

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).

Virtual reality (VR) or a virtual 3D environment (VE) created by a computer, has been suggested as a means 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 (Crosbie et al 2007; Young & Tolentino 2009). VR rehabilitation, which has required the development of specialised VE, are expensive to purchase, therefore the efficacy of off-the-shelf and low cost video games, such as Wii and PlayStation EyeToy, have been investigated (Young & Tolentino 2009). The web site, Games4Rehab, has a number of video clips which demonstrate patients and therapists using these games.

The Nintendo® Wii became commercially available in 2006 and uses a remote with motion-sensing technology which allows the device to sense its position and movement in three-dimensional space. Using the Wii system patients have the potential to develop fine and gross motor function and co-ordination. With the development of the Wii balance board, the potential to improve a patient’s balance, strength and gait is added (Figure 1) (Butler & Willett 2010). These devices may be used in the home or a therapeutic environment.
CLINICAL NEED AND BURDEN OF DISEASE

Stroke poses a significant burden on patients and their families as well as on the health system and aged care services. In 2005, there were 8,195 deaths from stroke in Australia accounting for approximately 6.3 per cent of all deaths. 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 I69.0–I69.4). 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 2010).1

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 New Zealand during the year 2004-05, there were 7,783 public hospital separations for stroke (ICD-10 codes I60-I64) and 121 separations for the sequelae of stroke (ICD-10 codes I69.0–I69.4) (personal communication Analytical Services, New Zealand Ministry of Health).

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1 In the 2006 AIHW report by Senes, during 2002-03 there were 68,866 hospital separations with a principal diagnosis of stroke; its sequelae, and rehabilitation for stroke or its sequelae, accounting for 1,073,645 patient days. When accessing the same online data source for these years as those quoted above for public hospital separations, the total number of public hospital separations for stroke and its sequelae was 32,918 (I60-I64) plus 121 (I69), a total of 33,039. It is unclear whether the discrepancies in these numbers is due to private hospital separations.
DIFFUSION
The National Stroke Foundation draft clinical guidelines (updated 2010) have referenced the use of virtual training for stroke rehabilitation for both upper and lower limbs. The studies assessed described the use of robot-virtual reality systems, virtual reality games and virtual reality treadmill walking amongst others. For both walking and upper limb development more research was recommended (personal communication National Stroke Foundation).

One Australian group is investigating the use of the Wii balance board to assess balance in patients with dementia.

COMPARATORS
Rehabilitation therapies include constraint-induced movement therapy\(^2\) to improve motor function in the upper extremities, locomotor treadmill training with partial body-weight support to regain mobility, balance, gait symmetry and endurance\(^3\) and functional electrical stimulation\(^4\), a task orientated modality which aims to improve functional recovery in hemiparetic\(^5\) patients. 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 do not require the constant supervision of therapists (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 sufficient therapy for it to be effective (Crosbie et al 2007).

SAFETY AND EFFECTIVENESS ISSUES
The effectiveness of virtual reality exercises is being evaluated in a stroke rehabilitation randomised controlled trial (EVREST), which began in November 2008 and aims to assess the effect on the motor function of the upper extremity in stroke patients using a Wii compared to those who experience only recreational therapy (Clinical trials Register identifier NCT00692523). In Canada, rehabilitation is standard care for patients within 3-6 months of a stroke. A total of 22 eligible patients were enrolled and randomised 1:1 into either the active control or the experimental group. The mean age of enrolled patients was 61 years (range 41-83 years) and the mean time from experiencing a first-time haemorrhagic or ischaemic stroke was 25

\(^2\) 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.

\(^3\) 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.

\(^4\) 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.

\(^5\) Hemiparetic: muscular weakness or partial paralysis restricted to one side of the body.
days (range 10-56 days). The control group received eight recreational therapy sessions over a 2-week period with no more than two sessions being completed on any one day. Recreational therapy, in addition to standard therapy, included leisure activities such as playing cards or the game Jenga.\(^6\) Patients in the experimental group received an intensive program consisting of eight, 60 minute Wii gaming sessions over a 2-week period with no more than two sessions being completed on any one day. Patients continued to receive all other standard medical and physiotherapy treatments while enrolled in the study (level II intervention evidence).

Baseline disability of all patients was measured using a modified Rankin Scale and the Barthel Index for activities of daily living. Baseline motor function was measured using the Wolf Motor Function Test (WMFT\(^7\)) and the Box and Block Test. Measures were repeated at the end of the intervention and at four weeks follow-up.

Only preliminary results, reported at the Canadian Stroke Congress (2009) of this study were available. Of the 22 enrolled patients, the interventions were successfully delivered in 9/10 (90\%) of the patients in the Wii group and 8/10 (80\%) of the rehabilitation therapy group. No adverse events were reported. After adjustment for age, baseline functionality and stroke severity, the patients in the Wii arm had a significant average motor function improvement of seven seconds compared to the rehabilitation group (WMFT \(-7.4\) seconds, 95\% CI \([-14.5, -0.2]\)), representing a 30 per cent improvement in motor function (Saposnik et al 2010, Saposnik et al 2009). The change score of an individual patient has to reach 4.36 on the WMFT time to indicate a real change. To be regarded as clinically important changes the mean change scores of a stroke group on the WMFT time should achieve 1.5 to 2 seconds (Lin et al 2009).

Further results from the EVREST study will be presented at the European Stroke Conference (Barcelona May 25-27) and will also be published soon in STROKE Journal (personal communication with the author, Saposnik).

Playstation EyeToy is a video-capture system which enables participants to interact with virtual objects displayed on a TV screen. Twenty patients (mean age 61.1 years) with hemiparesis after first-time stroke (mean time since stroke 3.9 months) were randomised to either the control group or the EyeToy intervention, with assessors

\(^6\) Jenga is played with 54 wooden blocks. To set up the game, a tower of 18 levels is constructed consisting of 3 blocks placed adjacent to each other along their long side and perpendicular to the previous level. Once the tower is built, a player takes one and only one block from any level (except the one below the incomplete top level) of the tower, and placing it on the topmost level in order to complete it using one hand at a time. The game ends when the tower falls.

\(^7\) The WMFT used to assess upper-extremity function in stroke rehabilitation studies. It is an impairment-based test which quantifies upper extremity movement ability through timed single or multiple joint motions and functional tasks. The test progresses from proximal to distal joint movement. It consists of 15 timed items, 2 strength measures, and a quality of motor function scale for each of the timed items. The WMFT starts with simple items, such as placing the hand on a table top, and progresses to more challenging fine motor tasks, such as stacking checkers or picking up a paper clip.
blinded to allocation (level II intervention evidence). Patients were eligible if they had no severe cognitive disorders, were able to understand simple verbal instructions and had a Brunnstrom stage\textsuperscript{8} score between one and four. Both patient groups participated in conventional stroke rehabilitation\textsuperscript{9}, five days per week, for 2-5 hours per day over a four week period. Patients randomised to the EyeToy group received an additional 30 minutes of virtual reality therapy. Games selected for patients included “Kung-Foo”, “Goal Attack”, Mr Chef” and “Home Run”, all of which required flexion and extension of the paretic or paralysed shoulder, elbow and wrist as well as the abduction of the paretic shoulder. The control group watched the virtual reality games but did not join in physically. The primary outcome measure was the Brunnstrom stages, reflecting underlying motor control, and the Functional Independence Measure (FIM), measured at baseline, immediately post-treatment (4 weeks) and at three months follow-up.

All patients completed the study and all those in the virtual reality group reported that they found it enjoyable, whilst all those in the control group expressed a wish to become physically involved rather than just watching. There was a significant between groups difference from baseline to post-treatment for motor recovery and upper extremity related motor functioning, however this difference was not evident from post-treatment to 3-month follow-up (Table 1).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Between group differences for motor recovery</th>
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<tbody>
<tr>
<td></td>
<td>Baseline – Post-treatment, mean (± SD)</td>
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<tr>
<td></td>
<td>EyeToy group</td>
</tr>
<tr>
<td>Brunnstrom hand</td>
<td>0.9 (0.5)</td>
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<tr>
<td>Brunnstrom upper extremity</td>
<td>0.6 (0.5)</td>
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<tr>
<td>FIM self care</td>
<td>3.2 (0.9)</td>
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<tr>
<td></td>
<td>Post-treatment-3-month follow-up, mean (± SD)</td>
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<tr>
<td></td>
<td>EyeToy group</td>
</tr>
<tr>
<td>Brunnstrom hand</td>
<td>0.1 (0.1)</td>
</tr>
<tr>
<td>Brunnstrom upper extremity</td>
<td>0.2 (0.1)</td>
</tr>
<tr>
<td>FIM self care</td>
<td>2.5 (1.5)</td>
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</tbody>
</table>

A significant between groups difference did however, persist for the Functional Independence Measure scores (p=0.018). Similarly, the difference between groups in

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\textsuperscript{8} Brunnstrom stages – 7 stages of recovery following stroke from Stage 1: Flaccidity, no voluntary movements on the affected side, through to Stage 4: Some movement, decrease in spasticity, to Stage 7: normal function is restored.

\textsuperscript{9} Including neurodevelopment facilitation techniques, physiotherapy, occupational therapy and speech therapy if required.
mean change in score from baseline to follow-up was only significant for the FIM self care score. This small study demonstrates that virtual reality games may be of some benefit for upper extremity motor functioning but has no beneficial effect on motor recovery. However, the short-term nature of the study, with only 10 hours of intervention, and the small number of participants, may not be sufficient to see a change in motor recovery (Yavuzer et al 2008).

An earlier, non-comparative study assessed the use of EyeToy in 12 stroke patients, seven of whom were at a chronic stage of rehabilitation (1-5 years post-stroke) and five were at the subacute stage of rehabilitation (1-3 months post-stroke). No meaningful outcome data were reported, including before and after measures, therefore the results of this study are not reported in this summary (Rand et al 2008).

**Cost Impact**

The price of a Wii console + Wii sport (including four remotes) ranges from A$350-400. The Wii Fit and Wii balance board costs approximately A$110-130. Both items would be required. It would appear that Playstation 2 EyeToy has been superseded by Playstation 3, with the console costing approximately A$580.

No cost-effectiveness studies were identified.

**Ethical, Cultural or Religious Considerations**

No issues were identified/raised in the sources examined.

**Other Issues**

An Australian trial is currently underway at the Prince of Wales Hospital, Sydney, comparing the Wii to constraint induced movement therapy for stroke patients with poor upper limb function (personal communication Director Sacred Heart Rehabilitation Services & St Vincent's Pain Service).

Another Australian group are currently investigating the validity of using the Wii balance board to quantify a patient’s centre of pressure, compared to the standard practice, a laboratory-grade force platform. Patients with an impaired standing balance have an increased risk of falling. An initial study reported on the 30 young, injury-free individuals (mean age 23.7 ± 5.6 years) who underwent four standing tasks on each platform on two separate days (level III-3 intervention evidence). Both platforms had good within device and between device test-retest reliability. The minimal detectable change values for the Wii did not exceed those of the force platform in three of the four tasks, leading the authors to conclude that the Wii is a potentially valid tool for the assessment of standing balance. The advantage of the Wii is that it is not only portable but costs a fraction of the force platform (Clark et al 2010).

An RCT examining the use of Wii-Fit for improving activity, gait and balance in people with Alzheimer's dementia will be recruiting patient (n=30) in the near future,
with the study aiming to be finalised by late 2011 (Clinical Trials identifier NCT01002586)

SUMMARY OF FINDINGS
There is limited published information on trials and studies which examined the use of virtual reality for the rehabilitation of stroke patients. Those included in this summary are of a high level of evidence but involved small numbers of patients who underwent rehabilitation with virtual reality for only a short period of time. Some patient benefits were observed, especially in motor functioning rather than motor recovery. Larger, well-designed randomised trials to investigate the benefits and the potential risks of introducing virtual reality therapy into patient rehabilitation are required, especially to identify those patients who would benefit most from this therapy. The benefits of virtual reality therapy is that it can be delivered at home or in a therapeutic environment and can be delivered at low cost, however caution should be used in the introduction of this therapy in an ad-hoc manner without evidence to support its beneficial effects.

HEALTHPACT ASSESSMENT:
The evidence assessed is high-level but limited in amount. However, further studies reporting long-term outcomes are required to ascertain the potential for clinical benefit and to assess whether these benefits are maintained over time. Therefore HealthPACT does not intend to further review this technology.

NUMBER OF INCLUDED STUDIES
Total number of studies: 2
Level II intervention evidence: 2

REFERENCES:


SEARCH CRITERIA TO BE USED:

- Stroke/*rehabilitation
- Computer Simulation
- Video Games
- Disability Evaluation
- Exercise Therapy
- Recovery of Function
- Therapy, Computer-Assisted/instrumentation/*methods
- Paresis/physiopathology/*rehabilitation