Virtual reality in the rehabilitation of the upper limb after hemiplegic stroke: a randomised pilot study

J H Crosbie[1], S Lennon[1], M C McGoldrick[1], M D J McNeill[2], J W Burke[2] and S M McDonough[1]

[1]Centre for Rehabilitation Research, University of Ulster, Belfast, N. IRELAND

[2]School of Computing and Engineering Science, University of Ulster, Coleriane, N. IRELAND

j.crosbie@ulster.ac.uk, *s.lennon@ulster.ac.uk*, *mc.mcgoldrick@ulster.ac.uk*, *s.mcdonough@ulster.ac.uk*, *mdj.mcneill@ulster.ac.uk*, *dj.burkey@gmail.com*

http://php.infc.ulst.ac.uk/vr-therapy

ABSTRACT

The aim of this study was to assess the feasibility of an RCT to investigate VR mediated therapy in comparison to standard physiotherapy alone in the motor rehabilitation of the upper limb following stroke, and to provide data to inform a power analysis to determine numbers for a future trial. A single blinded randomised controlled trial was conducted. Participants were recruited from two hospital stroke units and members of local Northern Ireland Chest, Heart and Stroke Association clubs. The Upper Limb Motricity Index, Action Research Arm Test were completed at baseline, post-intervention and 6 weeks follow-up. 18 participants were randomised to either a VR mediated upper limb therapy group or a standard therapy group. No significant between group differences were noted. Both groups reported some small changes to their upper limb activity levels. Both interventions seemed to have been acceptable to participants. This study demonstrated the feasibility of a randomised controlled trial of virtual reality mediated therapy for the upper limb compared to standard therapy. Forty-eight participants (24 per group) would be needed to complete an adequately powered study.

1. INTRODUCTION

It has been suggested that underutilisation of the affected limb can occur after stroke (Taub et al, 1993) and people tend to compensate with the intact limb rather than attempting to use the more affected limb (DeLuca et al, 2003). Virtual reality (VR) may hold some solutions to these problems. It has been shown to be an interactive and enjoyable medium that, with sufficient use, may improve upper limb motor function in adults with stroke (Holden et al, 2007). VR technology can be used to produce an environment in which intensity of practice and feedback on performance can be manipulated to provide tailored motor training (Merians et al, 2006) (Reid, 2002). However, reviews in this field have indicated that although very promising there are still problems relating to sample size and the variety of methodologies used (Crosbie et al, 2007). More recent studies continue to report the variety of set-up and design of the VR technology. Examples of such are a novel upper limb system consisting of three-dimensional tracker, custom forearm support, workstation and library of Java 3D exercises (Kuttuva et al, 2006) and a haptic master-slave set-up (Houtsma et al, 2006).

Two recent trials have been reported (Jang et al, 2005; Fischer et al, 2007) comparing VR mediated therapy for the upper limb to no intervention and to alternative digital applications. In the trial reported by Jang et al (2005) significant improvements were found in the Box and Block Test; the Fugl-Meyer Assessment and manual function test. This study also reported a novel demonstration of VR induced neuroplastic changes associated with motor recovery as indicated through the use of FMRI. Fischer et al (2007) also report significant changes on the Box and Block Test and the Fugl-Meyer Assessment, along with a significant change in Wolf Motor Function Test score. However, the authors indicated that overall gains were small. At the time of commencing this work no trials had been reported comparing VR therapy to standard therapy. There remain a limited number of trials which compare standard therapy to VR based therapy. However, in the last year one study (Piron et al, 2007) has been completed in which 25 subjects received reinforced feedback in a virtual environment for the upper limb, with 13 subjects in the control group receiving conventional rehabilitation, however no detail of the content of these sessions is given.

2. AIMS AND OBJECTIVES

The aim was to assess the feasibility of an RCT to investigate the effectiveness of VR based therapy compared to standard physiotherapy in the motor rehabilitation of the upper limb following stroke. Objectives were (i) to pilot the methodological procedures; (ii) to assess the effects of VR therapy on the upper limb impairment and activity levels of people with stroke; and (iii) to provide data to inform a power analysis to determine sample size for a future trial.

3. METHOD

A single blind randomised controlled trial was conducted. The outcome assessor was blind as to group allocation and the research therapist was blind to outcome scores. Participants were recruited from two stroke units and via local stroke support clubs, all in the Greater Belfast area. Individuals were considered for inclusion if they were up to 24 months following their first stroke; and if they were: medically stable; could follow a two-step command; and had a score of 25 or above on the upper limb Motricity Index (MI) (Demeurisse et al, 1980). All participants were formally screened for confusion; excluded with a mental score of less than 7/10 (Hodkinson, 1972); and neglect; excluded with a Star Cancellation Score of less than 48/52 (Wilson et al, 1987). Participants were also excluded if they had co-morbid conditions, for example, cardiac, respiratory or orthopaedic conditions, affecting their rehabilitation potential and severe arm pain of < 7/10, as assessed by a visual analogue scale. People who had been fitted with a cardiac pacemaker were excluded, as the electromagnetic motion tracker used within the VR system may interfere with such devices. Participants did not report any sensory deficits. These extensive exclusion criteria were employed in an effort to recruit as homogenous a sample as possible form this population. Participants were randomised to either a standard therapy (ST) or VR based therapy. Randomisation was stratified within each group according to age (old = 72 years or more; young = 71 years or less). The Queen's University Belfast and the Northern Ireland Office for Research Ethical Committees approved the study.

4. INTERVENTIONS

Our research group has built a system for use in stroke rehabilitation (Crosbie et al, 2005) which gives the user the ability to move around a world composed of simple and familiar objects, and to interact with these objects by touching, grasping and moving their upper limb. The user wears a head mounted display unit (HMD), a mono Cy-Visor DH-4400VP. A 5DT stretch Lycra data glove facilitates manual interaction in the virtual world. An Ascension Flock-of-Birds magnetic sensor system provides real-time 6-degrees of freedom (position and orientation) tracking of up to four points on the user's body. A virtual environment (VE) has been created with a series of reaching and grasping tasks. The user sees a stylized representation of their arm and hand in the VE. Three sensors are attached to the major upper limb joints (shoulder, elbow and wrist) and the fourth is attached to the HMD to facilitate the sense of immersion in the VE.

4.1 VR Training

The VR group underwent a three-week VR intervention period. This consisted of nine sessions over a 3-4 week period. Each session was approximately one hour in duration, and consisted of participant set up; physical practice using the VR based system to encourage the user to produce specific upper limb activities and functions. The research therapist operated the system from a PC based station in the same room as the user. A few users required some assistance to don and doff the apparatus (HMD and data glove) and the researcher applied the motion tracking sensors to the upper limb. Once the set-up had been applied the user was free to choose upper limb exercises from the range of pre-programmed task and game activities. These involved the arm and hand reaching to a target(s); wrist extension exercises and functional reach and retrieve tasks. An element of choice was open to the user in terms of number of targets; height and distance placement; and speed of task performance. A game activity 'whack the mouse' was also incorporated into the sessions. Auditory and visual mechanisms provided feedback on the users' performance. Gaming aspects included: visualisation of the number of 'hits' in a score box; the addition of levels of difficulty, with adaptations to the users' speed and accuracy of performance. High scores were entered onto a 'leader board'. An element of problem solving was introduced to the game in level 3, where the user had to contact the virtual mouse, with the hammer, whilst avoiding a virtual dog (See Figure 1a and 1b for a screen shot of the mouse game and components of the system).

Figure 1a. S*creen shot of mouse game.*

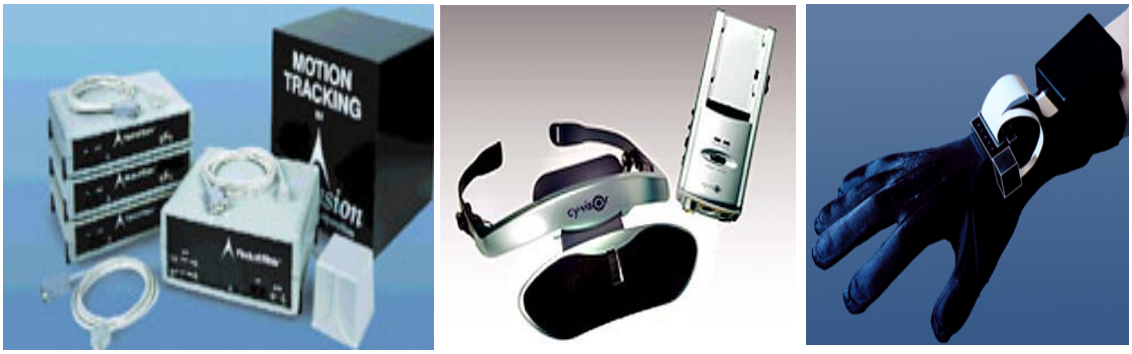

Figure 1b. *Components of the University of Ulster VR rehabilitation system.*

4.2 Standard Therapy Training

The standard therapy (ST) group received therapy, focusing on the upper limb, to control for any dose effects in terms of the amount of intervention between the two groups i.e. both groups received therapy for the same length of time. This was delivered by a physiotherapist and followed a programme of conventional rehabilitation techniques, which included muscle facilitation techniques, stretching exercises, strengthening activities (Winstein et al, 2004) and the inclusion of the more affected upper limb in functional tasks. The content of standard therapy was recorded for each session using a treatment checklist As the same therapist treated both VR and ST groups, a physiotherapist with expertise in neurological rehabilitation, and who was not involved in the delivery of the intervention, verified that the therapy offered to the ST group was in line with current practice. One session each for six participants was video recorded to facilitate this process.

5. OUTCOME MEASURES

Upper Limb Motricity Index (Demeurisse et al, 1980) and Action Research Arm Test (ARAT) (Lyle 1981) were completed at baseline, post-intervention and 6 weeks follow-up. The Upper Limb Motricity Index was used as a method of assessing the level of impairment and has been described earlier in this paper. This measure was chosen as it has been shown to be a valid measure of motor impairment after stroke (Collin and D Wade, 1990; Parker et al, 1986). Further advantages of this measure are that it is short, easily applied and does not require specialist training for its use. The MI grades motor activity and is based on the MRC Oxford Classification of muscle action, assessing whether there is a muscle contraction, if movement is present and if movement is possible against gravity or resistance. The upper limb section is scored out of a possible 100, with 0 indicating no muscle contraction palpable. A score of 0-25 out of 100 indicates very severe impairment; 26-50 is severe; 51-75 is moderate and 76-99 is mild impairment (Sanchez-Blanco et al, 1999).

The ARAT was constructed for assessing recovery of upper limb function following cortical brain injury. Motor actions, including arm movements and hand functions, are graded on a 4-point ordinal scale. The test is divided into four domains – grasp, grip, pinch and gross movement – and items are arranged in order of difficulty. Items within each subscale are ordered in such a way that if the person accomplishes the most difficult item, this predicts success with all less difficult items (Hsieh et al, 1998). This measure was chosen as it has been validated for use in people with stroke and has been shown to have high inter-rater and test-retest reliability (Platz et al, 2005). The ARAT provides meaningful information about functional recovery after stroke (Hsueh et al, 2002).

6. DATA ANALYSIS

All data were analysed using the Statistical Package for the Social Sciences (Windows 12) according to the intention to treat principle. Descriptive statistics compared baseline characteristics. Non-parametric tests were used due to the small sample size of this pilot study. The Friedman test was used to determine any differences between values measured across the three time points (baseline, post-intervention and follow-up). The Mann-Whitney U Test was used to identify whether the difference lay within or between groups. The Mann-Whitney U tests the assumptions about differences between median values in two groups. Missing data points were dealt with by the simple mean imputation method. The mean score of the group replaced missing values at a particular time point.

7. RESULTS

Seventy-seven potential participants were contacted. See Figure 2 for flowchart of study according to CONSORT statement (Moher et al, 2001). Three people were deceased at time of contact. 56 people were excluded for the following main reasons: unwillingness to participate (n = 23) non-response (n = 4) and ineligibility according to the inclusion criteria (n = 29). 15 people (20%) were unwilling to participate. Three people were attending formal rehabilitation and did not want to join the study; two people identified time constraints and three people identified problems with travelling to the research setting. 39% of potential participants did not meet the inclusion criteria: co-morbidity (n = 15); more than 85 years (n = 2); MI score of less than 25 (n = 3); longer than 2 years post stroke (n = 6) and having a history of more than one stroke (n = 3). Outcome data was therefore obtained from 18 participants at baseline and from 17 at post-intervention and follow-up. One participant dropped out after baseline measures and one treatment session, despite efforts to reschedule appointments and to acquire further outcome data. 18 participants were recruited and randomised into either a VR mediated upper limb therapy group or the standard therapy group. See Table 1 for baseline characteristics. There were no significant differences between the groups at baseline. Outcome data were obtained from 95% of participants at the end of treatment and at follow-up. One participant withdrew consent after one VR session. Compliance in both groups was high, with all 17 participants completing all nine therapy sessions. Only two people reported side effects of transient dizziness and headache from VR exposure.

Group median scores indicated an improvement in MI scores for both groups, with the VR group sustaining that improvement during follow-up. Each intervention appeared to have been equally effective post intervention, with respect to the MI score. There was a positive trend in MI score in favour of the VR group at follow-up, with the ST group dropping back to baseline level. However for the functional test (ARAT) there was a positive trend in favour of the ST group at discharge from intervention. At follow-up the VR group had improved their performance on the ARAT. Both groups showed a similar level of change in ARAT by follow-up.

Table 1. *Baseline Characteristics of Participants.*

	VR Group	**ST Group**
Age (years) Mean (SD)	56.1 (14.5)	64.6 (7.4)
Sex	5 male, 4 female	5 male, 4 female
Time since stroke (SD)	10 months (6.4)	11.7 months (7.8)
Side most affected	4 left, 5 right	3 left, 6 right

The Friedman test indicated significant differences within both groups across the time points of the study for the upper limb MI score ($p = 0.008$) and the ARAT score ($p = 0.01$). The Mann-Whitney U test indicated no

significant differences between the groups. There was a change of between 7-8 points for each group in the MI score, and of 3-4 points for the ARAT. The minimally clinical important difference for the MI has not been published; however other studies have identified a change of 10% in an outcome score as being clinically relevant (Brønfort and Bouter, 1999). This would represent a change of 10 points on the MI score. Thus the trend in these results would not be clinically significant. The MCID for the ARAT is 6 points [26], and likewise these results were not clinically significant.

Four of the nine VR participants reported that movement of the more affected arm had improved and that following participation in the trial could undertake some tasks that they had not been able to do previously e.g. driving a car; opening kitchen cupboards. Seven of the nine who received standard therapy reported that the movement in their more affected arm had improved. Difficulties were encountered in recruiting people with moderate to severe levels of disability.

8. CONCLUSION

This study demonstrated the feasibility of a randomized controlled trial of VR based therapy for the upper limb compared to standard therapy. The trial design was acceptable to participants. A power calculation for a larger trial indicated that 24 participants would be required in each arm in order to have the power to demonstrate statistically significant changes to both impairment and function of the more affected upper limb. This was calculated by using the MCID for the MI and the ARAT, and the standard deviations from this data.

The small sample sizes and the lack of sensitivity of the outcome measures for the population recruited are likely to have affected the results. It was disappointing not to have been able to recruit participants with a wider range of disabilities, with most scoring towards the ceiling of both outcome measures at baseline. Based on these preliminary results it is not yet possible to definitively advocate VR over standard therapy for the rehabilitation of the upper limb.

Acknowledgements: Northern Ireland Chest, Heart and Stroke Association, 6th Floor, 22 Great Victoria Street, Belfast BT2 7LX (Application number: 2002004). Dr L. Pokluda and Dr M. Ma for developing and supporting the technical aspects of this work.

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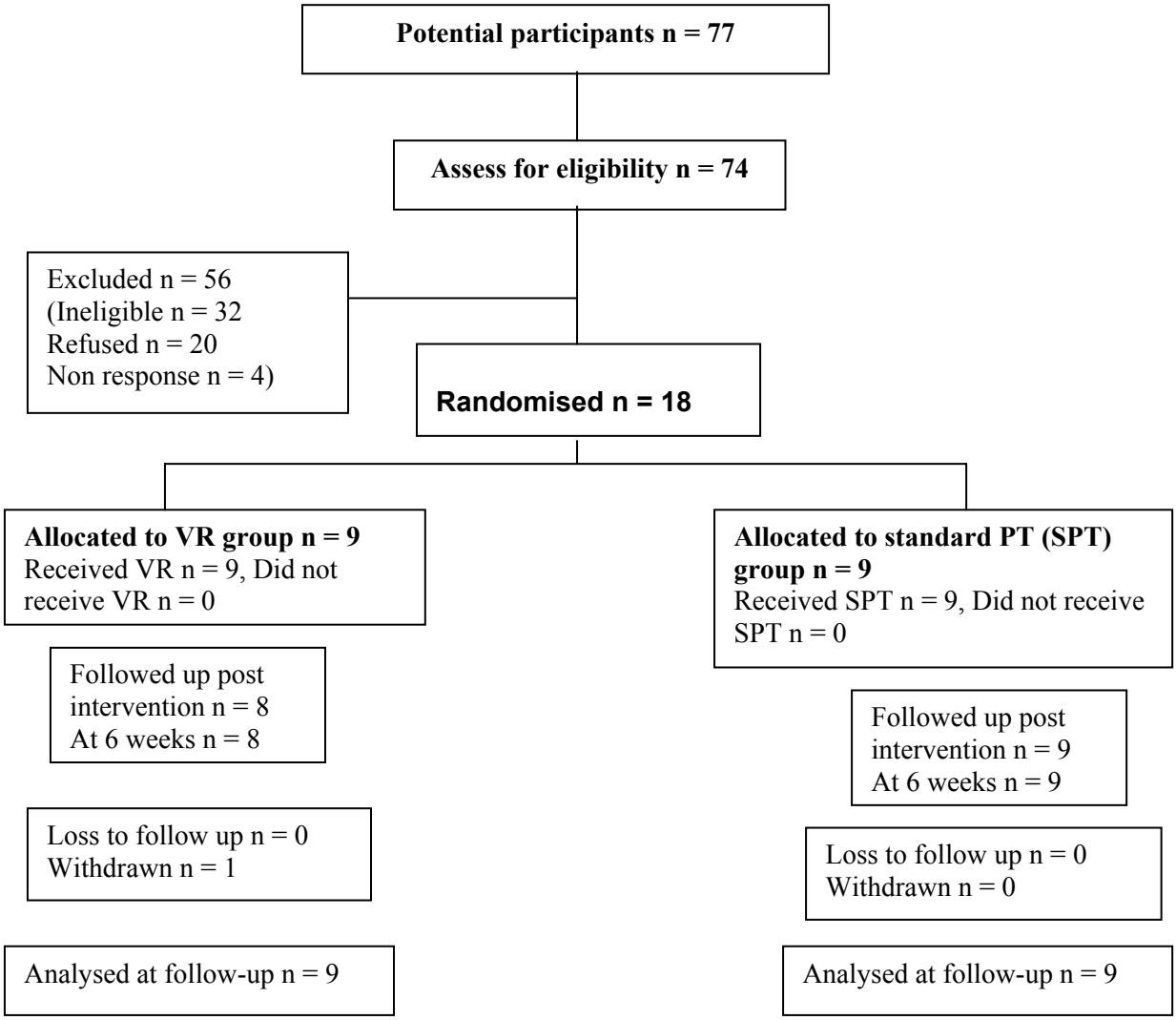

Figure 2. The flow chart of the trial according to the CONSORT statement (Moher et al, 2001).