The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study

Shannon Watchman

Submitted in partial fulfillment of the requirements for the degree of
Bachelor of Physiotherapy (Honours)

22nd August 2016

School of Health Sciences
Division of Health Sciences
University of South Australia

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Glossary

Clinimetric properties: Properties and utility used to describe appropriateness of outcome measures applicable to a clinical setting (Streiner 2003).

Feasibility: An assessment of the practicality and ease of this project in terms of the clinical stroke context (Arain et al. 2010).

Pressure sensitivity: Ability to detect light touch (Auld et al. 2011).

Proprioception: Ability to detect the position of body in space (Hillier, Immink & Thewlis 2015).

Reliability: The reproducibility of a measure (Portney & Watkins 2009, p. 82).

Responsiveness: The ability of a measure to detect clinically important changes (Fitzpatrick et al. 1998).

Satisfaction: An assessment of one's expectations and needs, or the pleasured derived from this (Oxford University Press 2016).

Stereognosis: Ability to perceive and recognise an object in the absence of visual or auditory cues (Klingels et al 2010).

Stroke: An artery supplying blood to the brain either suddenly becomes blocked (ischaemic) or begins to bleed (haemorrhagic), reducing the amount of oxygen and nutrients reaching areas of the brain. This can result in parts of the brain dying, leading to sudden impairments (Australian Institute of Health and Welfare 2014, p. 128).

Tactile spatial acuity: Ability to perceive the smallest distance between two points of pressure on an area of skin, before the two points are perceived as one (Craig & Johnson 2000).

Utility: An assessment of the operationalisation of outcome measures to be useful within this project in a clinical stroke setting (Hardey 1994, p. 62).

Validity: The extent to which a test measures what it purports to measure in its applied context (Fitzpatrick et al. 1998).

List of abbreviations

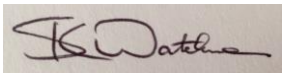
ADL	Activities of daily living
AIHW	Australian Institute of Health and Welfare
CI	Confidence interval
GODs	Grating orientation domes
GOT	Grating Orientation Task
HRC	Hampstead Rehabilitation Centre
MCAT	Measurement Critical Appraisal Tool
NHMRC	National Health and Medical Research Council
OGS	OrbIT Gaming System
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analysis
RASP	Rivermead Assessment of Somatosensory Performance
RCT	Randomised controlled trial
ROM	Range of movement
SD	Standard deviation
SDT	Spatial discrimination threshold
SWM	Semmes Weinstein Monofilament
UL	Upper limb
WMFT	Wolf Motor Function Test

Abstract

Following a stroke, people often present with persistent and debilitating upper limb impairments affecting their activities of daily living, however limited therapy time is spent on retraining the upper limb in a rehabilitation setting. Importantly, even less time is allocated to retraining of the somatosensory system, even though sensory deficits have been linked to poor motor outcomes. The evidence for the effectiveness of current sensory interventions in the stroke population is limited. To improve effectiveness and efficiency of interventions, and to engage stroke survivors in rehabilitation, robotics and gaming devices are being increasingly utilised. The OrbIT Gaming System has been successfully trialled with children with cerebral palsy and it is postulated that adults with stroke would benefit from this device. It is cognitively engaging and features a multi-dimensional controller to provide forced bimanual use and haptic (vibration) feedback aimed at improving sensation of the upper limb. Therefore, this pilot study is a randomised controlled trial to investigate the feasibility and utility of the OrbIT Gaming System in an inpatient stroke rehabilitation setting as an additional resource to usual therapy. Effectiveness of the system itself on sensation and motor outcomes was also investigated and compared to a historic control group. The study was conducted with two experimental groups. One group received the system with the haptic feedback setting, whilst the other received the system without the haptic feedback. Adults meeting the eligibility criteria received the system over a three-week intervention, and were allowed to determine their own participation in gaming sessions. All participants were assessed pre- and post-intervention by the Wolf Motor Function Test, Semmes Weinstein Monofilament test, proprioception assessed by the Rivermead Assessment of Somatosensory Performance, stereognosis assessed by Klingels' protocol and Grating Orientation Task. Additionally, questionnaires for both participants and staff, which were created specifically for this study, were completed post-intervention. The system also recorded all game usage. The results of the study were positive, indicating the system has feasibility and utility in an inpatient stroke rehabilitation setting, however modification to the research protocol is recommended including reducing outcome measures, adapting location of the OGS in regards to participants and creating effective relationships with staff directly involved in assisting participants to move around the ward. Sensory and motor outcome measures produced encouraging results with statistical differences found between pre- and post-intervention, and between haptic and non-haptic groups. Results however, must be viewed with caution due to the small sample size and lack of control group, limiting the generalisability of the results. Overall, participants and staff responded positively to the system and could see the benefits it provided in a rehabilitation setting. Further research is warranted to establish effectiveness of the system compared to a control group, and to improve feasibility.

Declaration

I declare that this thesis presents work carried out by myself and does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university. To the best of my knowledge it does not contain any materials previously published or written by another person except where due reference is made in the text; and all substantive contributions by others to the work presented, including jointly authored publications, is clearly acknowledged.



Signed ……..

Shannon Watchman

Acknowledgments

This study would never have been possible without Rachel Harling, Rachel Dempsey and Catherine Lieu from Hampstead Rehabilitation Centre expressing their interest in the OrbIT Gaming System. Furthermore, I would like to acknowledge all the time and hard work Sue Baxandall put into booking rooms, organising participant schedules and keeping track of eligibility. Lastly, thank you to all the staff at Hampstead Rehabilitation Centre who were involved in the recruitment and intervention phases of this study.

Thank you to my supervisor Susan Hillier for your patience, knowledge and continual cutting of words. Your guidance through this project allowed me to learn and develop my skills as a researcher.

To my other supervisor David Hobbs, thank you for introducing me to the fascinating world of robotics and Orby.

Thank you to Theo Niyonsenga for patiently helping me to understand and complete my statistical analyses, even if it took me four attempts.

Thank you to the Library staff who assisted in developing search strategies used in the systematic review.

I would also like to thank my family and friends for their support, patience and understanding.

Finally, thank you to my Mum for always being there for me.

Chapter 1: Review of the literature

1.1 Introduction

1.1.1 Stroke

Stroke is the second largest cause of mortality in Australia, accounting for 8 per cent of total deaths in 2011 (Australian Institute of Health and Welfare (AIHW) 2014, p. 19). Of stroke survivors, only 38 per cent who initially present with a plegic (paralysed) upper limb (UL) regain some functional use after six months (Kwakkel et al. 2003, p. 2184), and half of survivors report reduced arm function four years after stroke (Broeks et al. 1999, p. 359). Difficulties with performing dexterity-related motor skills and loss of sensation are commonly reported (Carey, Matyas & Oke 1993). These impairments lead to poor functional outcomes and a consequent loss of independence (AIHW 2014, p. 128).

1.1.2 Robotics and gaming devices

Automated devices are becoming increasingly used to improve UL rehabilitation outcomes in stroke. They aim to improve engagement of stroke survivors and maximise effectiveness and efficiency of interventions whilst decreasing therapist labour (Brackenridge et al. 2016). A literature review reported most robotic and mechanical devices concentrate on intensive, repetitive task training to facilitate motor activation (Brackenridge et al. 2016; Maciejasz et al. 2014). In the past decade, 141 UL devices were identified, but only seven reported their devices incorporated haptic feedback (Brackenridge 2015, p. 17).

1.1.3 The OrbIT Gaming System

Most haptic devices rely on force feedback to engage the impaired UL (Brackenridge et al. 2016). The OrbIT Gaming System (OGS) however, engages the participant in video gaming using a multidirectional controller driven by the user. This controller provides sensory stimulation and incorporates forced bilateral use (Figure 1.1 and 1.2). A Cochrane review by Laver et al. (2015) found that interactive video gaming might be beneficial in improving UL function and activities of daily living (ADL) alongside usual therapy and when compared to equivalent amounts of therapy.

Figure 1.1 The OrbIT Gaming System and controller


Figure 1.2 The OrbIT Gaming System in use

Following the successful trial of the OGS with children with cerebral palsy (Hobbs et al. 2015, p. 8), it was postulated that the OGS could have benefits for older adults undergoing stroke rehabilitation as they have a similar neurological condition.

The OGS is based on principles of neuroplasticity and rehabilitation protocols post-stroke which are (a) an active, cognitive involvement in the task at hand or 'focused attention', and (b) repeated, specific, and intense training (Daly & Ruff 2007; Hobbs et al. 2015, p. 4). This is combined with contextually relevant afferent stimulation in the form of haptic feedback to improve sensation, synchronised with game events through a range of vibration intensities and durations. In a clinical setting, Schabrun & Hillier (2009, p. 28) found sensation still remains poorly managed despite at least 60 per cent of stroke survivors presenting with sensory deficits that are linked to poor functional motor outcomes (Smania et al. 2003; Welmer et al. 2007). Limited use of the paretic limb then leads to a learned non-use pattern in the brain, and further secondary deterioration (Carey, Matyas & Oke 1993). In fact, sensation has

been shown to be much more influential on functional outcomes than spasticity in areas such as mobility and ADLs (Tyson et al. 2013).

The OGS does not rely on stereotypical repetitive movements like those in other robotic devices (Brackenridge et al. 2016). Instead, the spherical nature of the controller requires a variety of movement trajectories and forces use of both hands in similar though not identical motion. The brain is required to make decisions in accordance with visual cues and participants are unable to memorise how a game 'plays out', encouraging constant cognitive engagement. Forced-bimanual use is achieved through two proximity sensors built into the controller to monitor hand position, with the game pausing if a hand is removed for three seconds (Figure 1.3). This ensures users have their hands placed correctly and are paying attention to hand position on the controller throughout gameplay in a form of modified bilateral training. Literature does not report on forced-bimanual training as a common therapy but there is evidence on the effectiveness of bilateral training on the UL, however this is limited (Coupar et al. 2010; van Delden et al. 2012a).

Figure 1.3 Up-close view of controller's grey textured oval pad and proximity sensor

Despite stroke (Pollock et al. 2014; Veerbeek et al. 2014) and neuroplasticity literature (Dimyan & Cohen 2011; Pekna, Pekny & Nilsson 2012) indicating increased therapy time and activity will lead to improved functional recovery, people recovering from stroke only spend an average of 32.8 minutes of their physiotherapy session time being active (Kaur, English & Hillier 2012). This falls short of the current recommended guidelines of a minimum of 60 minutes active practice per day (National Stroke Foundation 2010, p. 80). Kaur, English & Hillier (2012) further reported that only 0.9 to 7.9 minutes per physiotherapy session were

directed at practice using the paretic UL. Furthermore, West and Bernhardt (2012) found that stroke patients spent most of their day inactive (48.1 per cent), in their bedroom (56.5 per cent), and alone (53.7 per cent). Enabling an increase in self-directed therapy with additional tools could be the key to improving activity and outcomes in patients post-stroke (West and Bernhardt 2012).

The OGS provides motivational therapy incorporating visual, motor and vibro-tactile feedback and can be a resource used in conjunction with usual therapy, thus increasing activity. This study aims to investigate the use of the OGS as a rehabilitation tool due to its focus on sensory input, forced-bimanual UL use and cognitive engagement.

1.1.6 Aims

1. To explore the feasibility and utility of using the OGS in an inpatient stroke rehabilitation setting.
    - 1.1 To record the participants experience (satisfaction) in using the OGS.
    - 1.2 To explore the staff experience (satisfaction) in administering the OGS.
2. To provide preliminary information about whether tactile sensory perception and/or motor function in post-stroke survivors can be improved by using the OGS in an inpatient stroke rehabilitation setting; from this preliminary effectiveness data, we can then provide an effect size for sample size calculations for potential future trials.

1.1.7 Research questions

1. What is the feasibility and utility of the OGS and controller as an additional therapy resource in a stroke inpatient rehabilitation setting?
    - 1.1 Do stroke survivors using the OGS in addition to usual therapy perceive it to be a positive experience (enjoyable and beneficial)?
    - 1.2 Do staff at an inpatient rehabilitation centre find administering the OGS beneficial and easy?
2. What is the effect of the OGS on tactile sensory perception and/or motor function for stroke survivors?

1.2 Systematic review on the clinimetric properties of the grating orientation domes

To expand the knowledge of stroke care and recovery, health practitioners need to accurately evaluate the effects of interventions. To date, systematic reviews on sensory measures for neurological conditions by Connell and Tyson (2012) and proprioception by Hillier, Immink and Thewlis (2015) have been conducted. However, no systematic review has been conducted on the clinimetric properties of the grating orientation domes (GODs), developed by Johnson, Van Boven and Phillips (Johnson & Phillips 1981), that are commonly used to assess tactile spatial acuity in stroke research.

1.2.1 Background

Traditionally, tactile spatial acuity has been assessed using the two-point discrimination test (Craig & Johnson 2000). However, it was determined this test is flawed as it does not measure spatial resolution, proposing participants discriminated one from two points using intensity, rather than spatial cues (Van Boven & Johnson 1994a). True spatial cues are based on the exact location of active neurons and are not affected by impulse rates (Johnson & Phillips 1981).

To replace this conventional, but possibly invalid test, the Grating Orientation Task (GOT) using the GODs was created in the 1990s (Van Boven & Johnson 1994a). The GOT accurately determines spatial resolution by using square-wave dome gratings in one of two orthogonal orientations (vertical or horizontal). The grating consists of alternating grooves and ridges of varying width (0.25mm to 3.5mm). The smallest grating orientation discriminated reliably (75% correct), provides a threshold estimate of the limit of spatial resolution. This is referred to as the spatial discrimination threshold (SDT) (Van Boven & Johnson 1994a).

Although use of the domes in a stroke population is not well studied, they have been used in clinical assessment and interventions in neurological conditions (Bleyenheuft & Thonnard 2011; Van Boven & Johnson 1994a), to assess the effects of blindness (Norman & Bartholomew 2011; Van Boven et al. 2000) and plasticity changes of spatial processing due to age (Bleyenheuft et al. 2006; Tremblay et al. 2000).

Thus, the aim of this systematic review was to:

1. Identify literature reporting on the clinimetric properties of the GOT using the GODs on the fingertip or hand in any population
2. Report and compare available clinimetric data
3. Provide recommendations on the appropriateness of the GODs for clinical use, and potential areas for future research.

1.2.2 Methods

Systematic review research question and eligibility

Using the PICOS framework (Harris et al. 2014), the parameters applicable and eligibility criteria for the systematic review are reported in Table 1.1.

Table 1.1 PICOS framework for review question and eligibility criteria

Acronym	Definition	Parameters/Inclusion criteria
P	Population	Any human population
I	Interventions (exposures)	GODs assessing tactile spatial acuity on the fingertips or hands (as relevant for UL rehabilitation)
C	Comparison	Any comparison
O	Outcomes measured	Clinimetric attributes
S	Study design	Not limited to a particular study design, however must be in English and peer-reviewed

Method for reporting systematic review

The PRISMA guidelines (Moher et al. 2009) were used to report methods, ensuring a comprehensive and transparent review. Validity and reliability results are summarised in tables, while responsiveness, feasibility, utility and normative data are summarised descriptively, due to the large variation of reporting in the original studies.

Information sources

A systematic search of Ageline, AMED, CINAHL, CIRRIE, Embase, ERIC, Meditext-Informit, Medline, OT Seeker, PEDro, Psycinfo, Scopus, SportDiscus, Cochrane Library and the Joanna Briggs Institute was conducted between December 4 and 6, 2015. No limits were placed on searches and databases were selected in consultation with an experienced physiotherapist and experienced search librarians at the University of South Australia.

Search

Two broad terms were searched: clinimetric properties and grating orientation domes, with appropriate Medical Subject Headings (MeSH), and appropriate truncations and wildcards used for specific databases (Appendix 1a). Terms were separated by the Booleans 'AND' and 'OR' where appropriate. The search was initially trialled in MEDLINE (Appendix 1b) and was adapted for other databases (e.g. PEDro and OT Seeker).

Study selection

The primary investigator reviewed titles and abstracts identified in the searches using the eligibility criteria. Studies that appeared to meet inclusion criteria, or had limited information, were retained for further full-text review. This assessment was performed independently by two reviewers (primary investigator and co-supervisor). Disagreements of eligibility were resolved by consensus. Refer to Appendix 2a and 2b for a summary of reasons for exclusion at both stages.

Data collection process and data items

The Measurement Critical Appraisal Tool (MCAT) (Appendix 3) was developed to extract clinimetric data. The clinimetric properties included in the MCAT were derived from clinical research literature (Fitzpatrick et al. 1998; Portney & Watkins 2009, pp. 77-113) and prior systematic reviews on assessment of stroke and other neurological conditions (Auld et al. 2011; Connell & Tyson 2012; Murphy et al. 2015; Santisteban et al. 2016). The MCAT was pilot-tested on two articles and refined by the review team. Two reviewers identified the clinimetric properties in individual studies. Data were then extracted by the primary investigator and entered into individual MCATs for each included study.

Risk of bias

Risk of bias assessment was not conducted for this systematic review. Evaluation of the methodological quality of studies is recognised to be a useful process (Harris et al. 2014), however studies assessing clinimetric properties, such as reliability and validity, often do not readily conform to typical study designs, such as those devised by the Centre for Evidence-Based Medicine (2016) and National Health and Medical Research Council (NHMRC) (2009). Additionally, previous systematic reviews on measures of sensation in neurological conditions did not provide resources for evaluating risk of bias (Auld et al. 2011; Connell & Tyson 2012; Hillier, Immink & Thewlis 2015).

Data synthesis

Individual MCAT study data were extracted and placed into one MCAT (Appendix 4). Items 1-6 in the MCAT were used to include or exclude relevant studies. Items 7-29 indicated the level of robustness of the clinimetric measures and clinical appropriateness using the GODs. To further summarise the data, evaluation of the clinimetric properties was performed using a guideline of accepted values (Appendix 5). Additional information, such as article title, author(s), aim(s), population and study design reported were included in individual MCATs but not transferred for data synthesis. Feasibility, utility and normative data reported were included in the MCAT to provide clinical context when considering the tool (Harris et al. 2014). All data were then collated for reporting in descriptive and narrative form.

1.2.3 Results

Study selection

The number of studies identified, assessed for eligibility and included in the review during the search process is summarised, as per a modified PRISMA flow diagram (Moher et al. 2009) (Figure 1.4).

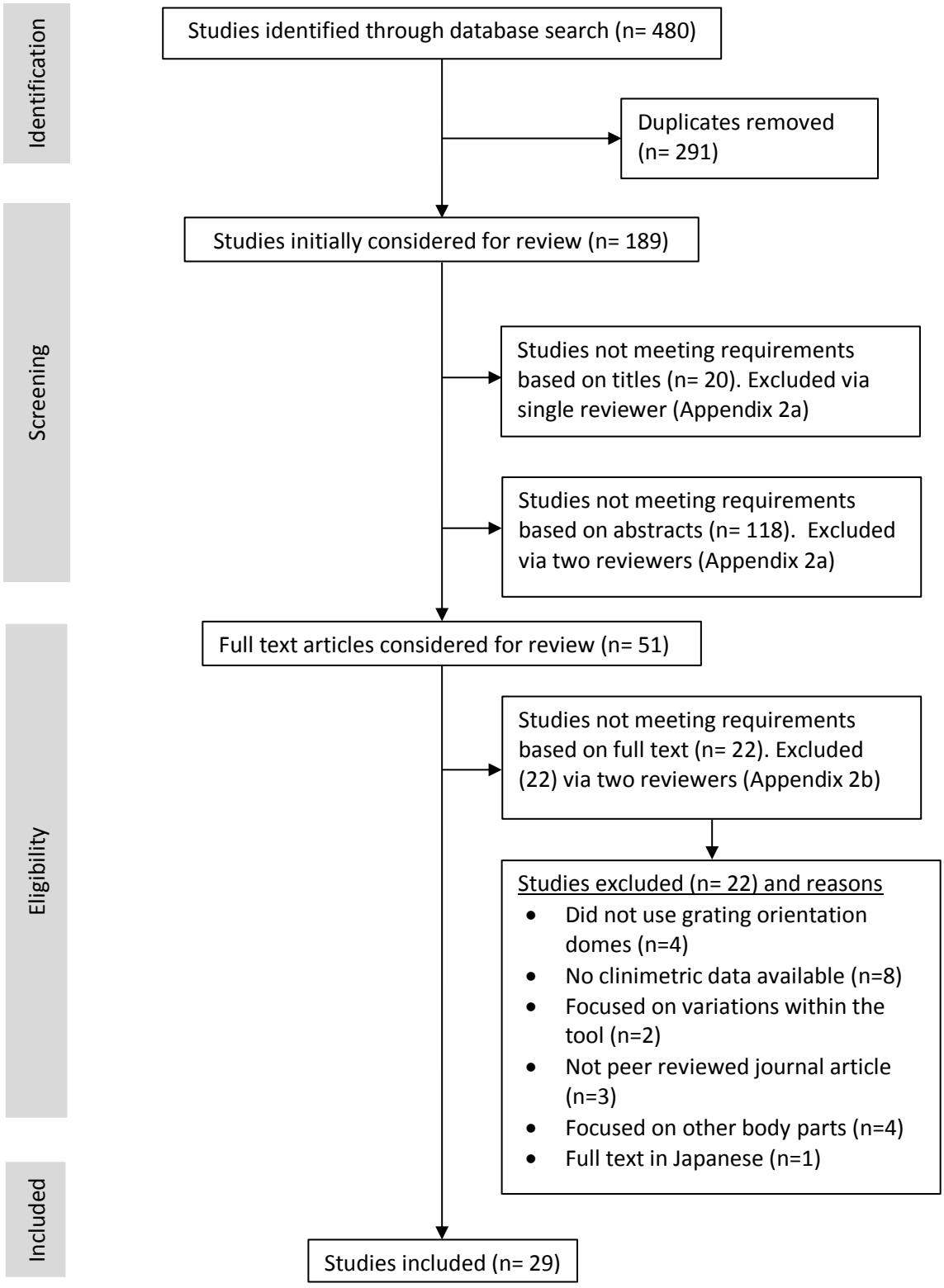


Figure 1.4 Flow diagram of search results

A total of 29 studies were included, with 14 studies reporting on validity, 3 on reliability and 24 on responsiveness. The literature indicated the GODs have proven reliability and validity, and acceptable clinical utility (Table 1.2). Appendix 6 summarises the characteristics of each study.

Table 1.2 Assessment of clinimetric properties and clinical utility and feasibility of the grating orientation domes

Clinimetric measures		Evidence
Reliability	Inter-rater	✓
	Intra-rater	✓
	Test-retest	++
	Internal consistency	0
Validity	Criterion	++/+
	Face	0
	Construct	+
	Content	✓
	Factor Analysis	0
Responsiveness	Sensitivity/specificity	0
	Floor/ceiling affects	0
	Factors affecting performance	✓
	Predictive power	0
Feasibility	Administration time	✓
	Cost of tool or additional equipment	X
	Additional training	✓
Utility	Age range	✓
	Method of administration	✓
	Scoring procedures	✓
	Interpretation of tool	✓

Key: +++ good evidence (reliability or validity scores ≥ 0.8), ++ moderate evidence (reliability or validity scores 0.6-0.8), + weak evidence (reliability or validity scores < 0.6), 0 no information, ✓sufficient reporting, X insufficient reporting

Validity

Fourteen studies reported on validity, however no studies explicitly reported face validity or factor analysis (Table 1.3). Eight studies reported on concurrent validity, with a range of correlations. The Landolt Ring Acuity Chart correlated the highest with the GODs (Bruns et al. 2014). Content validity of the GODs was acceptable as

they were reported to be not anisotropic (that is, not directionally dependent) at the fingertip (Gibson & Craig 2005).

Reliability

Inter-rater, intra-rater and test-retest reliability were reported across three studies, however internal consistency was not reported (Table 1.4). The GODs demonstrated good test-retest reliability in a single study (r=0.65) (Bruns et al 2014) and inter-rater reliability was proven with two studies reporting no significant difference between examiners (Bleyenheuft & Thonnard 2007; Van Boven & Johnson 1994b).

Table 1.3 Studies reporting on validity measurements

Author/date	Comparison used	Type of criterion-related validity	Content validity	Type of construct validity
Bleyenheuft & Thonnard (2011)	Purdue Pegboard	Poor (Paretic hand r = 0.126, p = 0.572; non-paretic hand r = 0.195, p= 0.377)	NR	NR
Bruns et al. (2014)	Landolt Ring Acuity Chart	Good to excellent (intercorrelation 0.78)	NR	NR
	Dot Pattern Acuity Chart	Moderate to good (intercorrelation 0.66)	NR	NR
	2 Point Discrimination	Poor (intercorrelation -0.02)	NR	NR
de Campos et al. (2014)	People with dystonia	NR	NR	Dystonia group SDT > CG (Dominant side p= 0.042; Non-dominant side p= 0.0001)

Gibson & Craig (2005)	Gap detection task	Described descriptively	Acceptable - not anisotropic (p=0.23)	NR
Grant et al. (2005)	IQ test	Poor (r=0.0068)	NR	NR
Grant, Thiagarajah & Sathian (2000)	People who are blind	NR	NR	No difference (CG, EOB, LOB; p= 0.33)
Libouton et al. (2012)	Unilateral carpal tunnel syndrome	NR	NR	Affected hand SDT < unaffected hand (p<0.05)
	Complete traumatic median nerve section (wrist)	NR	NR	Unable to perceive grating orientation on affected hand > 18 months postoperatively
Manning & Tremblay (2006)	Letter recognition task	Regression line r^2=0.65	NR	NR
Mueller et al. (2014)	New haptic threshold test	Poor (r=−0.390, p=0.150)	NR	NR
Norman & Bartholomew	Haptic 3D shape discrimination	NR	NR	Sighted participants had no relationship (r=0.083, p=0.76). Blind participants with

(2011)				poor SDT heightened ability to discriminate shapes (r=0.569, p = 0.021)
	People who are blind	NR	NR	No difference (CB, EOB, LOB; p=0.41)
Tremblay et al. (2003)	Grooved Pegboard test	Regression line of r = 0.66 (p<0.01)	NR	NR
Van Boven et al. (2000)	People who are blind	NR	NR	Blind group STD < sighted group (p=0.003).
Vega-Bermudez & Johnson (2001)	Letter recognition task	Moderate to good (NSR of-0.63 (p <0.001) and PPMC of -0.61 (p <0.001))	NR	NR
Veispak, Boets & Ghesquiere (2013)	Braille readers	NR	NR	Braille readers SDT > sighted reader (index finger p<0.0001; middle finger p=0.05)

Abbreviations: NR= not reported, SDT= spatial discrimination threshold, IQ= intelligence quotient, NSR= Nonparametric Spearman's rho, PPMC= Pearson product moment correlation, CG= control group, EOB= early onset of blindness, LOB= late onset of blindness, CB= congenital blindness

Table 1.4 Studies reporting on reliability measurements

Author/date	Test-retest	Inter-rater	Intra-rater
Bruns et al. (2014)	Good (r=0.65, p<0.1) Adults scored in two sessions, 5-8 days apart (mean 6.9)	NR	NR
Bleyenheuft & Thonnard (2007)	NR	No difference of SDT between 6 examiners (p=0.813)	No difference of force between examiners (p=0.836) No differences in timing of application between domes (p=0.077)
Van Boven & Johnson (1994b)	NR	SDT highly repeatable between sessions (SD 0.024 to 0.196mm (median 0.109))	NR

Abbreviations: NR = not reported, SDT = spatial discrimination threshold, SD = standard deviation

Responsiveness

The GODs have been used effectively in all healthy age groups, with normative data for all ages reported (Bleyenheuft et al. 2006; Tremblay et al. 2000; Van Boven & Johnson 1994b). Several factors were found to affect performance of the GODs (Table 1.5), with a majority of studies comparing data to normative data or control groups. No practice effects were found for the GODs (Bleyenheuft & Thonnard 2007; Bruns et al. 2014; Sathian & Zangaladze 1997). No studies reported on sensitivity/specificity, floor/ceiling affects or predictive power.

Table 1.5 Possible factors affecting performance of the grating orientation domes

	Factors affecting performance	
Main factors	Age	✓
	Gender	X
	Handedness	X
Vision	Vision of other objects	✓
	Short-term visual deprivation	X
	Handedness in blind people	✓
Body sites	Dorsum of the hand	✓
	Palm	✓
	Between digit fingertips	✓*
Trained	Trained fingers/palm	X /✓
	Pain state (chronic vs no pain) of musicians	X
Other	Gloves	✓
	Force applied	X
	Conformance	X
	Occupation related	X
	Hand symptoms (numbness)	X

Key: ✓= Affects performance, X = doesn't affect performance, * = unclear which digits differ

Main factors

Age was found to be a predictor of tactile SDT, with thresholds improving until 10-11 years old and then plateauing (Bleyenheuft et al. 2006). A general decline then occurred with age (Tremblay et al. 2000; Tremblay et al. 2003), with 55-86 year olds having twice the SDT as 21-26 year olds (2.5 ± 0.4 mm vs. 1.2 ± 0.3 mm, respectively) (Manning & Tremblay 2006). Gender was found to have no significant

effects on SDT for subjects aged between 6-16 years old and 60-95 years old (Bleyenheuft et al. 2006; Tremblay et al. 2000; Tremblay et al. 2003). However, a single study (n=45) found some evidence for a gender effect favouring males in adults aged 55-86 years old (Manning & Tremblay 2006). Handedness also had no effect on SDT (Sathian & Zangaladze 1996; Van Boven et al. 2000; Vega-Bermudez & Johnson 2001).

Vision

Participants who viewed their hand, or the experimenter's hand, relative to a neutral object had improved SDT (Cardini et al. 2012; Haggard 2006). Additionally, Wong et al. (2011) found short-term visual deprivation did not affect SDT and the effect of the eyelid state (open or closed) was not significant. A study by Grant, Thiagarajah & Sathian (2000) found people who become blind after the age of 10 had a 17 per cent higher mean threshold for the non-dominant hand (p=0.04).

Body Sites

The SDT varied between the fingertip (1.3mm) and dorsum of the hand (9.2mm or 7.8mm), and between the fingertip and the palm (ratio 7.4:1 or 6.2:1) (Craig & Lyle 2001; Schlereth, Magerl & Treede 2001). Significant differences were also reported between digits (Grant et al. 2006; Vega-Bermudez & Johnson 2001). However, Sathian & Zangaladze (1996) found thresholds between the first four digits did not differ significantly, but the fifth digit was significantly different.

Trained

When training fingers to improve tactile spatial acuity, Sathian & Zangaladze (1997) found the initial SDT was higher on the first trained finger, when compared to subsequent trained fingers, but the effect was of marginal significance (p=0.066). When using letter identification training on the palm, Craig and Lyle (2001) found a significant effect on SDT using an analysis of variance [$F(1,5) = 12.32$, $p < 0.05$]. Zamorano et al. (2015) found the SDT of musicians is similar in no-pain or chronic pain situations, in contrast to non-musicians.

Other

Wearing of a glove significantly increased SDT (decreased tactile acuity) at the fingertip, fingerbase and palm [$F(1,7)= 13.18$, $F(1,6) = 9.66$, and $F(1,7) = 17.48$, respectively, $ps < .05$] (Gibson & Craig 2002). Factors that had no significant effect included occupation related factors, hand symptoms (numbness/difficulty manipulating objects) (Mueller et al. 2014; Tremblay et al. 2000; Tremblay et al. 2003) and increasing force of application of the GODs at the fingertip or the finger base from 50g to 200g (Gibson & Craig 2006). Additionally conformance, the depth to which the skin invades the grooves of contactors, was not a good predictor of performance in the GOT (r^2=0.44) (Gibson & Craig 2006).

Feasibility and utility

Only one identified study reported on administration time, which was reduced to 15 minutes for children (Bleyenheuft et al. 2006). They cited studies from Sathian et al. (1997) and Van Boven et al. (2000) of administration time between 30-60 minutes. Method of administration was reported by all studies, with majority citing standardised procedures based on the instruction manual by Medcore (n.d.). No study reported on cost, additional training, the ease of interpreting test scores, nor relationship to clinically significant changes.

1.2.4 Discussion

The aims of this systematic review were to identify literature reporting on the clinimetric properties of the GODs, report and compare available data, provide recommendations on the appropriateness of the GODs for clinical use, and potential areas for future research. A total of 29 studies were identified that investigated the clinimetric properties of the GODs with studies dated from 1994 to 2015. Sample sizes ranged from 6 (Craig & Lyle 2001) to 222 participants (Bleyenheuft et al. 2006) for a total of 1,112 participants. Eleven populations were reported, with a wide range of characteristics including age ranging from 6 to 95 years, demonstrating that the GODs are used across populations, pathologies and age groups.

All aspects of reliability were reported, except internal consistency, as expected due to only one construct being measured (Fitzpatrick et al. 1998). Good test-retest

reliability was reported, and appropriate inter- and intra-reliability was reported. Whilst further research would be valuable, there is sufficient evidence for clinicians to assume reliability between and across testers.

Criterion validity ranged from good to weak evidence, dependent on the tool/construct being measured. Those tests, which were not correlated, clearly did not share the same physiological phenomenon. The GODs were able to determine differences in populations with unilateral brain lesions, median nerve problems, dystonia and people who are blind. Comparisons were made with control groups and between the impaired and non-impaired UL. Discriminatory validity was evident when compared to 3D shape discrimination, as it assessed a different underlying construct. Content validity was proven, whilst face validity and factor analysis were not reported. Further research is needed in all areas of validity, as well as sensitivity/specificity, floor/ceiling affects and predictive power as no identified studies reported these properties.

Clinical implications

For clinicians considering using GODs, there are several considerations. Firstly, an in-depth understanding of the population being tested is vital. It has been noted that general decline in tactile thresholds occurs with age; therefore appropriate kits including larger domes of 3.5mm and 4mm must be used when testing an older population, minimising a possible floor effect. Furthermore, trained fingers and palms using different applications, such as letter recognition, will result in different threshold levels compared to the normal population. Therefore when conducting experiments, researchers may need to exclude certain populations. Potential users also need to be aware that thresholds differ across body sites, with studies reporting differences between digits. Therefore, clinicians must be consistent with testing and record accurately to allow reproducibility. Gender, handedness and occupation related to manual therapy, repetitive movements and power tools do not appear to influence results.

There are no adverse reports on costs, or ease and safety of application, indicating the GODs are useful clinically. Factors such as pressure and skin conformance do no influence test results, however non-informative vision does improve results, and

therefore testing conditions need to be consistent with respect to visual input. No practice effects have been found to influence results.

Limitations

A limitation of this review was that heterogeneity of participants and inclusion of all types of statistical analysis restricted meta-analysis. The eligibility criteria may also have led to possible bias as studies were limited to English and peer-reviewed journals, meaning evidence may have been omitted. Although an extensive search of the databases was conducted, relevant articles may have been missed from other sources.

1.2.5 Conclusion

Tactile spatial acuity is reported as the most sensitive indicator of the integrity of the somatosensory system (Van Boven & Johnson 1994a); therefore it is important that clinicians can use readily available clinical measures. Use of the GODs to assess tactile spatial acuity is recommended, as they are a reliable and valid outcome measure easy to use in multiple populations. However, it is apparent from the review that further research is needed to strengthen the evidence of the use of GODs in a clinical setting.

Chapter 2: Methods

This section will justify the research design, confirm ethical approval, and outline protocols for recruitment, data collection and allocation procedures. The intervention is outlined, followed by the description of variables, reliability and validity of outcome measures, and statistical analysis.

2.1 Research design

A pilot study was undertaken to investigate the feasibility, utitlity and effectiveness of the OGS in an inpatient stroke rehabilitation setting based on understandings derived from an earlier pilot study with children with cerebral palsy (Hobbs et al. 2016, p. 28). The investigation used a double-blinded randomised controlled trial (RCT) research design. Perceived utility and feasibility of the OGS was obtained from participants and staff through questionnaires, as well as data recorded by the system. To determine effectiveness of the OGS, participants were allocated to one of two intervention groups. Both groups participated in individual computer gaming sessions using the OGS. One group received active (vibration) haptic input targeted to the more impaired hand whilst the comparison group did not receive any haptic input. Due to low recruitment numbers, data were compared to historic cohort data from the Hampstead control group arm of the CIRCUIT trial conducted by English et al. (2015).

A pilot study was chosen to establish reliable and valid procedures, and gather information to inform future larger-scale studies of the OGS (Portney & Watkins 2009, p. 94). An RCT was used to establish a cause and effect relationship and is considered a gold standard study design for interventions in health research (NHMRC 2009). It allows researchers to provide a context similar to clinical practice (Jadad 1998, p. 12), whilst controlling for variables. Pseudo-qualitative data to inform feasibility and utility was obtained from participants and therapists involved in the study, using questionnaires to develop an initial understanding, and identify and explain behaviours, beliefs or actions (Hennink, Hutter & Bailey 2011, p. 16). This allows influences and motivations regarding the OGS in this clinical inpatient setting to be understood.

2.2 Ethical approval

Ethical approval was obtained from the Royal Adelaide Hospital Human Research Ethics Committee on 1 October 2015 and from the Human Research Ethics Committee of the University of South Australia on 8 October 2015 (Appendix 7a and 7b). The study was conducted in accordance with the National Statement on Ethical Conduct in Human Research 2007 Guidelines (NHMRC 2015) and was registered with the Australian New Zealand Clinical Trials Registry (Appendix 8).

2.3 Recruitment protocol

2.3.1 Participants

Patients who were admitted into the Stroke Unit at Hampstead Rehabilitation Centre (HRC) over a 7-month period (December 2015 and June 2016) were considered for recruitment (sample of convenience). Eligibility criteria were developed as seen in Table 2.1. To reduce risk of bias and to increase generalisability to the greater population, all possible patients were invited to participate over an adequate time period (Portney & Watkins 2009, p. 154; Stannard 2012).

Table 2.1 Eligibility criteria

Inclusion Criteria	Exclusion criteria
• Aged over 18 years old • Diagnosed with a first time stroke; either ischemic or hemorrhagic • Willing and capable to give informed consent • Able to place impaired hand on the side of the controller, either by themselves or with their hand supported by a positioning strap • Sufficient shoulder range of movement (ROM) and control of their hand to be strapped; approximately 70 degrees shoulder flexion, neutral wrist and mid pronation/supination (assessed by goniometer) • Able to focus and respond to screen-based games	• Significantly reduced vision or perception – were unable to see/read computer screen • Behavioral issues that preclude participation in seated computer gaming tasks • Epileptic • Fixed contracture that prevented passive opening of the hand to place on the controller • Could not follow instructions and answer written questions in English

Power calculations for sample size estimate

An estimate of sample size was not applicable for this pilot study, however results obtained allowed a preliminary effect size to be calculated.

Recruitment procedures

Adults that matched the eligibility criteria were consecutively recruited on admittance to the Stroke Unit at HRC. The HRC physiotherapists and occupational therapists initially approached eligible participants with study information, including information sheet (Appendix 9a) and consent form (Appendix 9b). After consent was received, details were given to the researchers as seen in a flow diagram in Appendix 10.

2.3.2 Equipment

Feasibility and utility measures included questionnaires and gaming system data. A range of physical outcome measures, focused on UL sensation and functional ability, were used to best capture effectiveness of the intervention.

Feasibility and utility outcome measures

OGS usage

The OGS recorded all game activity including length of time spent engaging with the system, days played, number of games played and amount of vibration (if any) was received (Hobbs et al. 2015, p. 4).

Participant and staff questionnaires

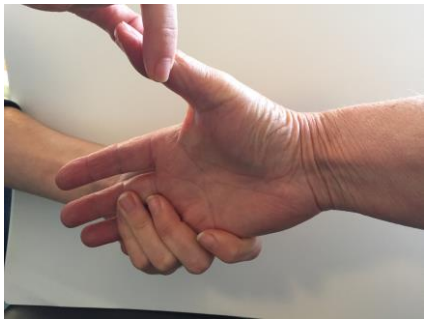
No standardised questionnaire was found in the literature applicable to the customised OGS. Therefore, an indication of feasibility and utility from both participant and staff perspectives was obtained through two specifically adapted questionnaires (Appendix 11a and 11b), based on private correspondence on 16 October with David Hobbs regarding his 2016 study. A co-supervisor and an experienced physiotherapist assessed face validity. Participant and staff perceptions were recorded on a five point Likert type scale ranging from 'strongly agree' to 'strongly disagree', a 1-10 scale with 1 representing 'very poor' and 10 representing 'brilliant', as well as open-ended questions.

Physical outcome measures

Five physical outcome measures were used (Table 2.2) with a more detailed explanation on the application in Appendix 12.

Table 2.2 Characteristics of physical outcome measures

	Outcome Measure	Variable	Type and level of variable	Operational-isation	Measurement tool	Procedural reference	Image
Motor Function	WMFT	Time taken to complete hierarchy of 15 functional tasks of the UL	Dependent Interval	Median time (secs) of 15 tasks	WMFT kit	Standardised protocol (Taub et al. 2011)	
Sensory Function	SWM	Pressure sensitivity - light touch detection of the hand	Dependent Ordinal	Force in grams	5 nylon monofilaments precisely calibrated and equal length. Levels 2.83, 3.61, 4.31, 4.56 and 6.65	Operation manual (Stoelting Co. 2001)	

Sensory Function	RASP	Proprioception of the metacarpal-phalangeal joint of the thumb	Dependent Ratio (interval)	Score of success	Assessor moved the thumb in a random sequence of 'up or down' directions 10 times	Standardised protocol (Winward, Halligan and Wade 2002)	
	Klingels Protocol	Stereognosis of the hand	Dependent Ratio (interval)	Score of success	6 common shapes and 6 everyday objects	Standardised protocol (Klingels et al. 2010)	

Sensory Function	GOT	Tactile spatial acuity of hand	Dependent Ordinal	Millimeters	10 spherical domes with equidistant bar and groove widths (0.25, 0.50, 0.75, 1.00, 1.20, 1.50, 2.00, 2.50, 3.00, 3.50 mm) 10 trials were conducted for each dome	Standardised protocol (Medcore n.d.)	

Abbreviations: WMFT= Wolf Motor Function Test, SWM= Semmes Weinstein Monofilaments, RASP= Rivermead Assessment of Somatosensory Performance, GOT= Grating Orientation Task, UL= upper limb

Data Collection Protocol

The primary investigator was responsible for all data collection and storage, and was trained in the use of the five physical outcome measures by an experienced co-supervisor. All outcome measures were administered in the same order for each participant; Semmes Weinstein Monofilaments (SWM), Rivermead Assessment of Somatosensory Performance (RASP), Klingels protocol, Grating Orientation Task (GOT) and Wolf Motor Function Test (WMFT) for both pre- and post-assessment administration. This order reflected a hierarchy of perceptual difficulty for the brain, from the least demanding to the most demanding outcome measure (Shumway-Cook & Woollacott 2017, pp. 126-127). Participants were assessed prior to the introduction to the OGS and re-assessed at the completion of the three-week intervention. Individual data was documented on a data collection sheet (Appendix 13) and later transferred into a Microsoft Excel spreadsheet for analysis. The participant questionnaire was completed during the post-assessment with instructions given to each participant by the primary investigator. The day and time of each pre- and post-assessment varied due to the clinical setting, however all participants were assessed in the same quiet room by the primary investigator who was blinded to group allocation. The staff questionnaire was completed at the end of the data collection period and was given to all staff involved in the recruitment process.

2.3.3 Randomisation and allocation procedures

Simple randomisation using a computer-generated randomised sequence was allocated by an independent researcher at a central administration site. The primary investigator and participants were blinded to allocation, however staff at HRC could not be blinded. The primary investigator scheduled times for pre- and post-assessments, however was not involved in the system set up to maintain blinding. Refer to Appendix 14 for a flow diagram of the allocation procedure.

2.3.4 Intervention

Outline

On completion of the pre-assessment of the physical outcome measures, participants were introduced to the OGS. The set up of the OGS was standardised (Appendix 15), as well as standardised instructions, demonstration and practice with the OGS completed for each participant by a co-supervisor (Appendix 16). The intervention time period for each participant was three weeks, and participants were instructed to use the OGS as much and as long as they wanted. There was no time or day constraint as the OGS was set-up in the dining room in the Stroke Unit, a communal area that is used frequently on weekdays and weekends (Figure 2.1). Selected staff were trained in the use of the system and helped participants if needed.

Figure 2.1 Two OrbIT Gaming Systems set up side-by-side in the dining room at HRC

Rationale

Participants were given a free choice method of playing the OGS as feasibility and utility were key aims of this study. If participants were given specific time periods to play, data reflecting engagement and enjoyment would be limited. Additionally, active patient management was chosen in response to research suggesting increasing patient control is important in rehabilitation outcomes (Eng et al. 2014). Free choice may encourage participants to engage, thereby increasing their personal control of their rehabilitation. Movement in and between wards is also considered to be beneficial to the rehabilitation process (Eng et al. 2014), thus the

OGS was located in the communal dining room in the ward. Therapy rooms were not considered an appropriate location due to their unavailability after therapy hours and on weekends (Janssen et al. 2014). A three-week intervention period was chosen as this was close to the average hospital length of stay in a rehabilitation setting (English et al. 2015), and was supported by HRC therapists.

2.3.5 Control group

Due to low recruitment numbers, an historic cohort was used as a usual therapy control group. This cohort was part of a previous trial assessing functional ability of the UL using the WMFT over a similar time period and received usual therapy only in the same inpatient rehabilitation unit (English et al. 2015). This provided control for the effect of time and usual rehabilitation alone. Participants from both studies were matched for baseline WMFT scores, age and gender. Change in scores for WMFT for participants in both studies were calculated for comparison.

2.4 Variables

Independent variables

Use of the OGS with and without active haptic input (as recorded by the system).

Dependent variables

Upper limb motor function assessed using the WMFT and hand sensation assessed using SWM, proprioception (RASP), stereognosis (Klingels' protocol) and GOT.

Extraneous variables

Environment and staff were kept consistent, however assessment and intervention times were variable due to the clinical context. Discharging of participants and transfers between wards were also variables. Assessment explanations, sequence and length for each participant were standardised. To avoid fatigue, a glass of water was given to each participant at the start of testing, and breaks were given between tests if needed. Introduction to the OGS via explanation and demonstration was also standardised and conducted by the same investigator for all participants.

Confounding variables and internal validity

The main variables identified include:

- Variation in usual therapy received
- Staff support for use (requires assistance for mobility, or placing hand on controller with strap)
- Previous interest/experience with computers and gaming or lack thereof
- Age
- Cognitive function and concentration
- Joint pain
- Comorbidities that affect sensation in the UL (e.g. diabetes)
- Learning effect of outcome measures

Randomisation of groups and blinding of the primary investigator assisted in controlling confounding variables and increasing internal validity. Furthermore, participants consented knowing they would be using video gaming and were willing to do so. To control for the learning effect, there were 21 days between pre- and post-assessments. HRC staff were actively involved in ensuring the intervention was adhered to and facilitated transportation of participants. Extraneous variables mentioned above such as inconsistent timeframes for interventions, participant discharge from hospital and transfers between units within the hospital were monitored and recorded.

2.5 Reliability and validity

Reliability and validity of outcome measures

All outcome measures were found to be reliable (inter and intra-rater) and valid in either stroke or a similar population (refer to Appendix 17). The purpose-designed questionnaires were determined to have face validity, and there was no attempt to establish test-retest reliability. Attitudes are a dynamic concept (Shrigley, Koballa & Simpson 1988), and have the ability to change over time. Therefore this study sought to capture a 'point in time' attitude of both therapists and participants.

External validity

This study is generalisable to a population of people with stroke who are recovering in an inpatient setting. The primary investigator administered all assessments and participants determined the intervention dosage by playing in accordance with their skills and motivation. Environment for assessment and intervention was kept consistent and was reproducible due to the clinical setting.

2.7 Statistical analysis

All data were entered directly into a Microsoft Excel spreadsheet following pre- and post-assessment, and questionnaire completion. Data of the physical outcome measures were analysed using the Statistical Package for Social Sciences (SPSS) computer software (version 21 for windows; SPSS Inc., Chicago, IL), whilst data of the feasibility measures were analysed using Microsoft Excel. A Shapiro-Wilk test of normality was conducted on the physical outcome measures data due to its appropriateness for small samples (<50 participants) (Ghasemi & Zahediasl 2012). It revealed data were not normally distributed, therefore nonparametric statistics were applied. Whole cohort pre- and post-assessment scores were analysed by Wilcoxon Signed Ranks Test as the test evaluates differences within paired scores, examining both relative amount and direction of difference (Portney & Watkins 2009, p. 516). Data comparing between groups (haptic vs non-haptic) were analysed by Mann-Whitney U test as it allows two independent samples to be compared, without requiring the groups to be of equal size (Portney & Watkins 2009, p. 506). The median score of the WMFT was used, so as not to skew the data if participants were not able to complete tasks (Taub et al. 2011). Statistical significance was set at $p<0.05$. Descriptive statistics were calculated for participant and staff questionnaires (mean, SD, range and agreement percentage), as well as participants' demographics (mean, SD, range). Open-ended questions were reported descriptively.

Chapter 3 Results

This section will report on data and analyses obtained from this study. The flow of participants through the study, including a descriptive analysis of the final population, will be reported. Descriptive analysis is conducted for the questionnaires and usage of the OGS is reported. Statistical data from the physical outcome measures are included, effect size is calculated and comparison is made to the historic control group.

3.1 Results of recruitment

Consistent recording of participant eligibility could only occur between 19 April and 31 May 2016 due to staff circumstances. During this time period 55 patients were admitted into HRC Stroke Unit and assessed for eligibility. In total, 12 were eligible; 7 people consented and 5 did not consent (planned length of stay less than 3 weeks (n= 2), transferred into another ward (n= 2) and cognitive deficit (n= 1)). Refer to Table 3.1 for reasons of ineligibility for the study.

Table 3.1 Reasons for ineligibility for the intervention

Ineligibility reasons	**Number of participants**
No UL deficit	16
Limited ROM	10
Cognitive deficit	8
Insufficient UL power	6
Transferred to another ward or hospital	5
Planned length of stay < 3 weeks	3
English as a second language	1
Wrist fracture	1
Enrolled in another research trial	1

Final sample of participants

A total of 11 participants agreed to participate. One participant was subsequently excluded, five were allocated to the haptic group, and five to the non-haptic group.

One haptic group participant was discharged prior to completion, but all available data were included in the analyses, as seen in a modified flow diagram as per Consort reporting for RCTs (Schulz, Altman & Moher 2010) (Figure 3.1). For flowchart purposes, the recruitment time period is split; Cohort 1 was recruited between 1 December 2015 and 18 May 2016, whilst Cohort 2 was between 19 May and 24 June 2016.

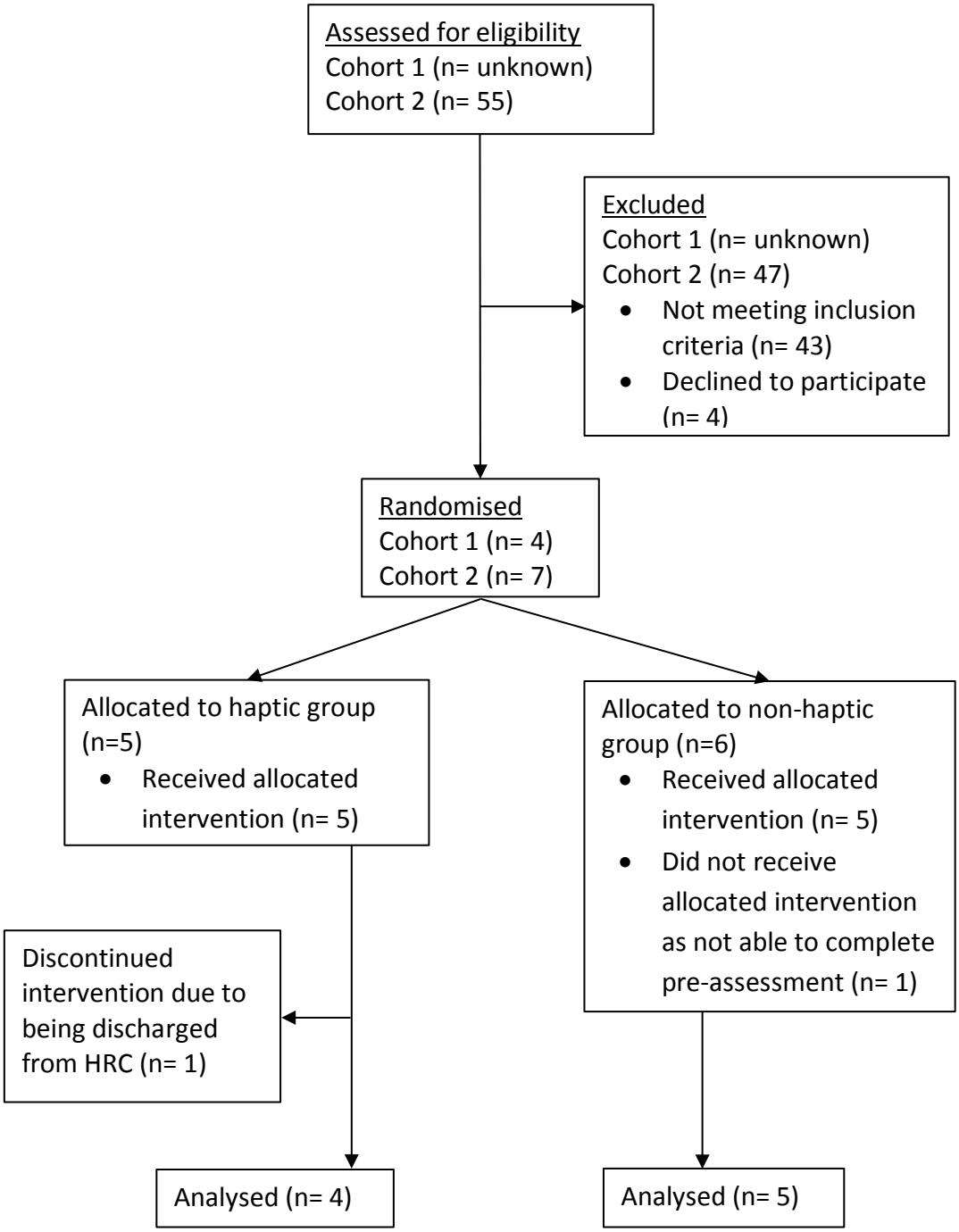


Figure 3.1 Modified flow diagram of the progression of the participants through the study

Demographic details of the ten participants who commenced the intervention, at baseline, can be seen in Table 3.2 and raw demographic data for independent participants are presented in Appendix 18. Eight were stroke infarcts (two middle cerebral artery, anterior cerebral artery, cerebral (exact location unknown), prefrontal cortex, brainstem, lacunar and multi-territorial) and two had other neurological conditions (neuroma and chronic inflammatory demyelinating polyneuropathy). These were included outside of the criteria as they presented with classic hemiparesis and were non-progressive at the time of the trial.

Table 3.2 Participant demographic details at baseline

Characteristics at baseline	**Whole group (n=10)**	**Haptic group (n=5)**	**Non-haptic group (n=5)**
Age in years (mean ± SD, range)	65.56 ± 9.76, 45.92-82.75	67.30 ± 13.43, 45.92-82.75	63.85 ± 5.17, 56.25-68.92
Gender (male; female %)	70; 30	60; 40	80; 20
Stroke affected UL (L; R %)	70; 30	40; 60	100; 0

3.2 Feasibility results

3.2.1 Participant questionnaire results

Nine participant questionnaires were completed. One participant was discharged during the intervention and was unable to provide data. See Appendix 19 for raw data of the participant responses. Questions one and three had the highest average agreement (mean score of 3.67 out of 5) and conversely, question seven had the lowest average agreement (mean score of 6.11 out of 10). Table 3.3 includes questions and their corresponding mean, standard deviation (SD) and agreement.

Table 3.3 Mean, standard deviation and agreement of Likert type scale questions for participant responses in the questionnaire

Question	Mean	SD	Range	Agreement (%)
1. The OGS was easy to use	3.67	1.25	1-5	73.40
2. The OGS was enjoyable to use	3.11	1.20	1-5	62.20
3. The OGS was beneficial for you	3.67	0.47	3-4	73.40
7. What score would you rate the OGS (10=brilliant, 1=poor)	6.11	2.42	1-8	61.10

Summary of open-ended questions

Five participants were motivated to play the OGS during their rehabilitation, one was moderately motivated and three were not. Four participants stated they preferred playing the OGS in the middle of the day and afternoon, four participants played it on the weekends, four participants had no preference and one commented they were not at hospital during the weekends.

Positive comments regarding computer gaming and stroke included 'I enjoyed playing it' and 'Believe it is helpful'. Critical comments included **'**Found I would have liked one or two more challenging games', 'Personally found it frustrating as not a gaming person. Frustrating in understanding the concept of computer games and knowing what to expect with movements' and 'Structure of ball to keep hands on. Need to hit red button to activate and kept changing'.

3.2.2 Staff questionnaire results

Four staff questionnaires were completed. See Appendix 20 for raw data of the staff responses. Question three had the highest average agreement (mean score of 4.5 out of 5) and conversely, question two had the lowest average agreement (mean score of 3.25 out of 5). Refer to Table 3.4 for each Likert type scale questionnaire and their corresponding mean, SD and agreement.

Table 3.4 Mean, standard deviation and agreement of Likert type scale questions for staff responses in the questionnaire

Question number	Mean	SD	Range	Agreement (%)
1. The OGS was easy to set up for people with stroke	4.00	0.82	3-5	80.00
2. The OGS was easy for people with stroke to use	3.25	0.96	2-4	65.00
3. I could see the benefits for the OGS	4.50	0.58	4-5	90.00
9. What score would you rate the OGS (10=brilliant, 1=poor)	7.25	0.96	6-8	72.50

Summary of open-ended questions

Subpopulation identified

Staff thought younger clients with previous gaming experience would benefit most from using the OGS. One staff member identified males predominately, however another staff suggested both genders would benefit.

Feasibility

Staff also thought the system was feasible due to ease of access and use. One staff member commented it was more feasible for younger patients and for those who could independently mobilise to the controller.

Problems or issues identified

Issues identified include:

- Improving location of the OGS to increase interest and/or making it portable
- Some games were complex and required higher levels of cognition
- Position of the button made it difficult selecting games especially when the muscle strength of the proximal limb is <3/5 as the controller would tend to move when trying to select games
- Needing a more secure strap for the impaired UL
- Older population seemed ambivalent towards the OGS

Recommendations for future

Staff thought the console and laptop was user friendly, easy to set up, a good way to improve UL function, and engaged patients in independent rehabilitation. Two out of four staff members thought that trialing with a younger population would be beneficial. Two out of four staff also felt that the technology should be closer to the patients' rooms/be portable.

Additional comments

Only one staff member had additional comments suggesting a supervised system in a gym environment may boost participation and competition/comradery between inpatients.

3.2.1 The OrbIT Gaming System usage over 3-week intervention

The OGS usage was analysed using a box and whiskers plot. Values for the median, quartile ranges and whiskers for each box and whiskers plot are shown in Appendix 21. The median total time played for the haptic group was 27.83 minutes compared with 121.22 minutes for the non-haptic group (Figure 3.2). However this was not significant as there is overlap of range between the two groups.

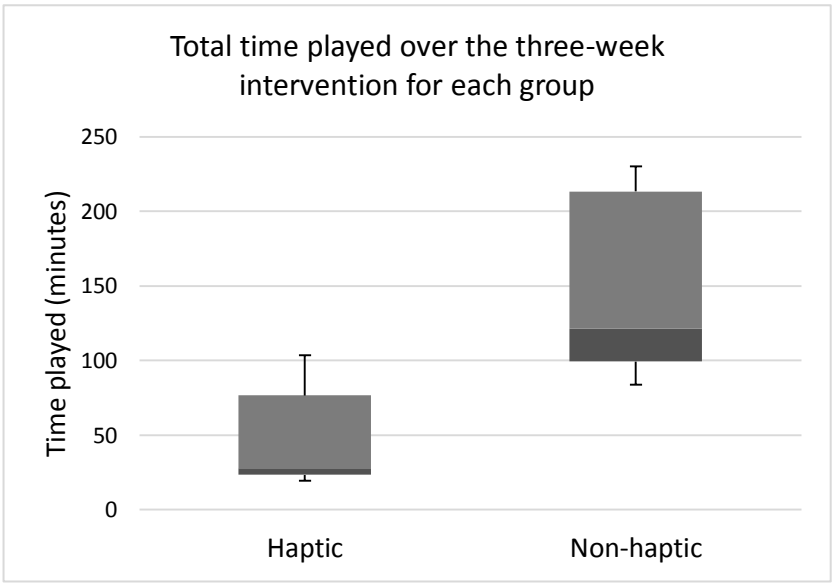


Figure 3.2 Total time played of the OrbIT Gaming System by each group over the intervention

The non-haptic group also played the OGS for a greater number of days (Figure 3.3). The median number of days played was double for the non-haptic group.

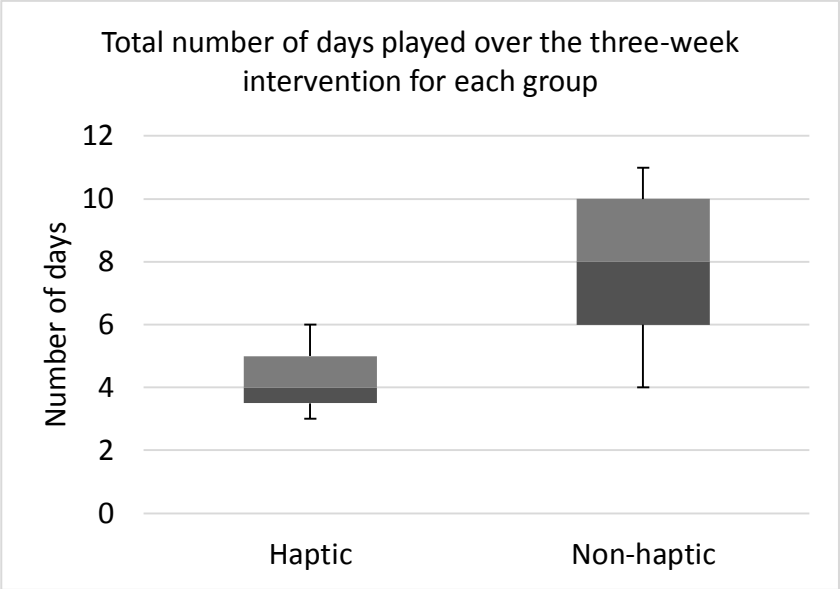


Figure 3.3 Total number of days played of the OrbIT Gaming System by each group over the intervention

3.3 Physical outcome measure results

Whole cohort

A significant difference was found for the whole cohort between the means of baseline and post-intervention scores for pressure sensitivity on the first finger (p= 0.041) and thumb (p= 0.026), and functional ability of the impaired UL (p= 0.017) using Wilcoxon Signed Rank tests (Table 3.5). All other outcome measures had no statistical difference. Raw data for the more impaired UL can be seen in Appendix 22.

Table 3.5 Whole cohort scores between baseline and post-intervention for each outcome measure

Outcome measure	Pre-Assessment			Post-Assessment			P value
	Mean	**SD**	**Range**	**Mean**	**SD**	**Range**	
SWM first finger (g)	4.62	1.14	3.61-6.65	4.26	0.96	3.61-6.65	0.041*
SWM thumb (g)	4.41	0.88	3.61-6.65	4.00	0.37	3.61-4.31	0.026*
Proprio-ception (S/10)	8.30	2.06	4.00-10.00	9.11	1.70	5.00-10.00	0.235
Stereo-gnosis (S/6)	3.50	2.07	0.00-6.00	4.22	2.05	1.00-6.00	0.107
GOT (mm)	3.30	0.42	2.50-3.50	3.28	0.44	2.50-3.50	0.317
WMFT (secs)	29.03	47.98	2.84-120.00	20.61	38.98	1.91-120.00	0.017*

Abbreviations: SWM= Semmes Weinstein Monofilament, GOT = Grating Orientation Task, WMFT= Wolf Motor Function Test, SD= standard deviation, g= grams, S/6= score out of 6, S/10= score out of 10, mm= millimeters, secs= seconds

Key: *= signifies statistical difference

Haptic vs non-haptic groups

A significant difference was found between the two groups (haptic vs non-haptic) for stereognosis (p=0.029) using a Mann-Whitney test. All other outcome measures resulted in no statistical difference. Refer to Appendix 23a for data analysis and Appendix 23b for raw data.

3.3.1 Effect sizes

The effect size (standardised mean difference, equivalent to Cohen's d) was calculated for each outcome measure. Effect size scores were calculated using the mean of the change in scores and standard deviation for haptic and non-haptic groups. No statistical difference was found for the outcome measures, however stereognosis approached significance with an effect size of -1.56. Refer to Appendix 24a for data analysis and Appendix 24b for raw data.

3.3.2 Comparison with historic control

A comparison between the change scores of the historic cohort (CIRCUIT) and the present study showed both groups improved with a mean change in score of -17.64 and -4.76 respectively. Refer to Appendix 25a for the comparison data and 25b raw data.

Chapter 4 Discussion

Feasibility and effectiveness data will be discussed in light of other literature. Limitations and further recommendations for future studies will also be considered.

4.1 Feasibility and utility

Study population

The OGS was successfully integrated into the HRC Stroke Unit population and was feasible in an inpatient rehabilitation setting. Overall, participants agreed that the system was easy to use, enjoyable and recognised benefits from use. Four of the nine participants did not find computer gaming motivational yet commented positively on benefits. Staff rated the system more beneficial than participants, found it easy to set up, and perceived it easy to use. From a research perspective, the population was appropriate as they met the eligibility requirements, engaged with the OGS and showed improvement against a majority of the outcome measures.

Acceptability of trial design

Overall, the trial design was acceptable however modifications are needed for future research studies. Eligibility criteria were effective as participants could physically and cognitively use the system. Some participants who had minimal active ROM and functional movement against gravity in their impaired UL struggled maneuvering the controller. Cognitive and physical challenges are important in rehabilitation (Yekutiel 2000, p. 47) so this does not indicate the need for exclusion, rather that the strapping and positioning of the system can be improved. Language difficulties excluded one participant who withdrew from the study, as receptive dysphasia prevented him completing the initial assessment. It is important to note that receptive dysphasia did not restrict the ability to play the OGS, only the research assessment.

The feasibility and possible high up-take of the system in a larger research trial is reinforced as all eligible participants consented to participation but five discontinued for pragmatic reasons, such as ward transfer. This aligns with current literature that supports the concept that the older population is initially open-

minded to new rehabilitation techniques incorporating technology (Laver et al. 2011), indicating enthusiasm for this study.

The trial design was semi-feasible in terms of sensory and motor outcome measures. Firstly, completion of assessments was lengthy, ranging from 30-80 minutes, often tiring participants. Most outcome measures were sensitive to change, with a trend of improvement. The GOT was the only outcome measure to result in no change over the intervention, due to a possible floor effect. Adults following a stroke have a mean threshold of 5.68mm (SD 3.06mm, range 3.19mm to 11.25mm) in the impaired UL (Bleyenheuft & Thonnard 2011), which this study was unable to accurately measure due to using a standardised kit. A modified kit containing GODs of up to 11.25mm is recommended for future studies.

The length of intervention corresponded with the average length of stay at HRC meaning minimal participants had to withdraw. The intervention relied on patient choice encouraging personal control, but the short intervention time lessened patient opportunity to use the system. Incorporating OGS into a structured timetable may promote greater participant activity in future studies (Tyson, Burton & McGovern 2016). The effectiveness of the trial relied on good communication between staff and researchers to allow commencement for each participant in a timely manner.

The system itself proved robust. Over the 7-month time period, no major technical issues occurred that restricted participant use. One issue arose with respect to incorrect shut-down of the system, however instructions were given to override this error, with no direct effect on the intervention. Proof of concept and and Phase I trials of the OGS found no technical issues (Hobbs et al. 2016, p.28; Walker & Hobbs 2014), establishing the robustness of this system over lengthy periods.

Challenges emerging from the trial

Use of the OGS was not as high as staff members or researchers had anticipated. The haptic group's individual usage ranged from 19.54 minutes to 103.65 minutes, compared to 83.68 minutes to 230.33 minutes in the non-haptic group. Both total-time-played and total-days-played were greater in the non-haptic group. The small

sample size may explain this variance (Portney & Watkins, p. 146) as there is no logical explanation why amounts varied – there were no reports of the haptic input being noxious (i.e. reducing player enjoyment/engagement) in the previous study (Hobbs et al. 2016, p. 28), nor did our participants report this. Age and previous use of computer gaming were highlighted by staff members as main factors that may have influenced usage results. Although this current study used a small sample, the trend of decreased up-take of technology by older adults is in line with other large-scale studies (Adler 2006; Smith 2014). Hobbs et al. (2016, p. 28) reported high usage results by children, further supporting the notion that a younger population may engage more with computer gaming. Several other inhibiting factors were suggested, including the complexity of games, the restraint of the impaired UL on the controller and location of the OGS.

The accessibility to the OGS was another unforeseen feasibility issue. The study relied on staff commitment to help participants engage as they largely relied on assistance to mobilise around the ward (Eng et al. 2014; Janssen et al. 2014). Time constraints and lack of labour allocated to embedding the use of the OGS into 'normal practice' likely played a role in the usage pattern (Eng et al. 2014; Tyson et al. 2016). This is supported by a participant who expressed frustration as they 'Normally [played the OGS] on weekends in the afternoon because it would fit in structurally with other factors in the ward'. This does not truly reflect the participant's willingness to play the system, but rather the inpatient clinical setting. Weekend leave also reduced time for system use. Positioning of the OGS for future studies needs to take into account reasonable accessibility but should not reduce the social and physical activity involved in mobilising to the system (Eng et al. 2014; West & Bernhardt 2012).

Appropriateness of timelines

Overall the short recruitment window of 7 months impacted on sample size. This was also confounded by another research study at the hospital site. Larger hospitals, increased recruitment window period, and/or multiple hospital sites will need to be considered to ensure larger sample sizes in future studies.

Partnerships to implement trial

Physiotherapists and occupational therapists were very supportive of the trial and comments supported its feasibility. The essential partnership that needed improvement was with the nursing staff. Due to time constraints, established daily routines (Eng et al. 2014; Janssen et al. 2014) and less commitment to the OGS trial, it was not prioritised. Reliance on nursing staff assistance impacted on participant ability to engage. The recruitment process also needs further consideration as researchers could conduct both eligibility and recruitment at the hospital site. This was not permitted for ethical reasons in this pilot study.

4.2 Sensory and motor improvement

4.2.1 Whole cohort comparison

Significant differences were found for light touch detection on the first finger ($p=0.041$) and thumb ($p= 0.026$), as well as functional ability for the more impaired UL ($p=0.017$) between baseline and follow up for the whole cohort ($n=10$). These positive results are encouraging however the small sample size reduces the likelihood that it reflects a true significant difference (Button et al. 2013). The tactile nature of the controller, and the forced bimanual use required to manipulate it (Hobbs et al. 2015, p. 6) may explain these results. However, spontaneous recovery and continued usual therapy received throughout the intervention were not controlled for, so cannot be excluded as explanations for these results (Cramer 2008). Therefore, further research is required with a control group, of usual therapy only, to explore the impact of the OGS. Similar results were found in children with cerebral palsy, with a significant difference found for UL function for the more involved hand after using the OGS (Hobbs et al. 2016, p. 28).

4.2.2 Haptic and non-haptic group comparison

A significant difference was found for stereognosis between the two groups over time ($p= 0.029$). Stereognosis is a composite measure, incorporating fine motor skills, and cues from texture, spatial properties, size and temperature, as well as cognition (Yekutiel, Jariwala & Stretch 1994). Therefore, it is plausible to suggest if any one of these components improves, stereognosis may improve, especially as the whole cohort improved in light touch detection and UL function over time. The effect size calculated for stereognosis was large: -1.56 (95% CI -3.19, 0.07, $p= 0.06$) however there was a small probability that chance may have influenced these

results. Interestingly, the non-haptic group had the greatest improvement in scores between pre- and post-assessment, resulting in this statistically significant result. This would suggest that the active vibration does not improve function, but greater usage may have likely played a role. The effect of increased activity on the brain due to its high degree of plasticity may have led to these improvements (Pollock et al. 2014; Smania et al. 2003). Whether this increase in activity of the OGS translates into better outcomes is yet to be determined and requires further investigation. All participants in the non-haptic group were left arm impaired, warranting further investigations. Once again, the lack of a control group and small sample size make it difficult to determine a direct cause of these results and they cannot be generalised to the greater stroke population (Button et al. 2013).

Similar trends were identified in this study and the previous study by Hobbs et al. (2016, p. 28). Haptic and non-haptic groups in both studies improved in UL function, and non-haptic groups improved in proprioception and UL function. In contrast, this current study identified improvements in light touch detection in both groups, as well as spatial discrimination and proprioception improving in the non-haptic group, whereas Hobbs et al. (2016, p. 28) found no improvements of light touch detection. On average, the non-haptic group played for a greater time period in both studies, indicating the need to further assess the effects of the haptic function.

4.2.3 Historic group comparison

Study data were matched to usual therapy historic cohort WMFT data (English et al. 2015) because of similarities in population and setting, and its recent publication. These were found to be somewhat comparable, however the CIRCUIT group improved more (mean -17.64 seconds) compared to the OGS (mean -4.76). This is partially explained by the historic group receiving 4 weeks intervention compared to 3 weeks with the OGS, and only a small number of participants could be compared. It is important to note that the OGS data showed a 41.4 per cent improvement, higher than the minimally clinical important difference of 16 per cent (Lang et al. 2008).

4.3 Evidence from previous studies

This study was the first to explore the effects of a haptic device, with vibration targeted at the UL, in an inpatient stroke population. The focus on sensory outcomes was also a significant difference to previous studies. These reported on haptic systems incorporating force feedback combined with either virtual reality games and/or robot assistance (Adamovich et al. 2009; Fluet et al. 2009, p. 190; Johnson et al. 2005; Mali & Munih 2006; Merians et al. 2006; Simkins et al. 2013, p. 2; van Delden et al. 2012b).

Clinical settings differed, with other studies including participants with chronic (outpatient) stroke, due to their more stable impairments (Adamovich et al. 2009; Johnson et al. 2005; Merians et al. 2006; van Delden et al. 2012) and children with cerebral palsy (Fluet et al. 2009, p. 189). In these studies, motor outcomes associated with device quality were the focus. Two studies reported on some improvement of functional arm movement (Fluet et al. 2009, p. 191; Merians et al. 2006) corresponding with the OGS study results. Another reported conflicting evidence for improvement in the UL and could not establish the efficacy of their system (Adamovich et al. 2009). Simkins et al. (2013, p. 3) reported improvement in shoulder ROM. Overall the lack of reporting on sensory outcomes meant comparison with the OGS could not be conducted.

Other studies concentrated on trials to assess the device itself and to make improvements (Johnson et al. 2005), and some did not report on any clinical results (Mali & Munih 2006; van Delden et al. 2012). Only one study assessed feasibility of their device with children with cerebral palsy, and experienced similar difficulties in establishing feasibility due to small sample sizes (Fluet et al. 2009, p.191). Overall, feasibility was not well discussed.

4.4 Limitations

A small sample size and lack of control group limited the results from this study. Although population homogeneity was maximised by taking participants from one rehabilitation hospital, the results are subject to specific stroke and stroke-like conditions, therefore extrapolating these results for other rehabilitation hospitals or other stroke settings should be done with caution. In addition, this current

population was representative of a sample of convenience so improvements in motor and sensory function obtained may or may not be representative of the entire population. Due to the clinical setting, the three-week intervention time period may not have been long enough to show true, significant changes of the motor and sensory systems, and several confounding factors including discharge of participants, movement of participants between wards and staff motivation to recruit eligible participants for this current study, may have affected these results.

4.5 Recommendations for future studies

This pilot study contributed to the development of a feasible protocol for the implementation of the OGS into an inpatient rehabilitation setting.

The following recommendations are provided to improve the clinical use of the OGS in a future trial. Firstly, consideration will need to be given to the location of the system both geographically, and within the routines of the rehabilitation centre to enable the most effective access. The physical position needs to be in a multi-use room to encourage social and physical activity. The use of the OGS should be structured into routines so that it is valued as a therapy and given the appropriate time allocation. It is therefore important to develop effective relationships with staff most directly involved in providing participant access to the system. Improvements to the controller need to be made in regards to a more secure restraint of the impaired UL to encourage independent usage.

A greater sample size is required as well as the inclusion of a control group. The assessment time should be decreased, by reducing the range of sensory outcomes. The GOT should only be used if suitable domes for stroke participants are available (Bleyenheuft & Thonnard 2011). Amount of usage is an area of study that warrants further investigation (dose-response) along with recording of participant characteristics to determine motivating factors.

4.6 Conclusion

The results from this pilot study support the feasibility and utility of the OGS in an inpatient stroke rehabilitation setting with both participants and staff reporting satisfaction. The study identified trends for sensory and motor improvements that warrant further high quality research. Despite these encouraging outcomes, the results should be viewed cautiously due to the uncontrolled study design and the small sample size.

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Appendices

Appendix 1
Systematic review search

1a) Search terms used in systematic review

Clinimetric terms	Grating dome terms
• Clinimetric* • Psychometric* • Valid* • Reliab* • Responsive* • Sensitiv* • Specific* • Feasib* • Accura* • Scalab* • Dimension* • Factor analys* • Threshold performance* • Reproduce* • Level* of measurement • Degree* of measurement • /Sensitivity and specificity • /Reproducibility of results	• Grating orientation* • Grating dome* • JVP dome* • Johnson Van Boven Phil?ips dome*

Key: * = Truncations; ? = Wildcards; / = MeSH headings

Appendix 1b) Initial MEDLINE search

Number	Searches	Results	Search Type
1	(clinimetric* or psychometric* or valid* or reliab* or responsive* or sensitiv* or specific* or feasib* or accura* or scalab* or dimension* or factor analys* or threshold performance* or reproduce* or "level* of measurement" or "degree* of measurement").mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	5361959	Advanced
2	exp "Sensitivity and Specificty"/	465661	Advanced
3	Exp "Reproducibility of Results"/	309459	Advanced
4	1 or 2 or 3	5441885	Advanced
5	(grating orientation* or grating dome* or JVP dome* or Johnson Van Boven Phil?ips dome*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	193	Advanced
6	**4 and 5**	**115**	**Advanced**

Appendix 2
Reasons for study exclusion

2a) Number of studies excluded in title and abstract review and reasons

Studies were excluded on first reason that became apparent

Exclusion 1 = articles excluded due to study on visual detection

Exclusion 2 = articles excluded due to study on animals

Exclusion 3 = articles excluded due to being unrelated e.g. CSF notches

Databases	**Exclusion reasons**			
Studies excluded from:	**Ex 1**	**Ex 2**	**Ex 3**	**TOTAL**
Ageline	0	0	0	**0**
AMED	0	0	0	**0**
CINAHL	0	0	0	**0**
CIRRIE	0	0	0	**0**
Embase	**8**	**1**	0	**9**
ERIC	0	0	0	**0**
Meditext-Informit	0	0	0	**0**
Medline	**55**	**12**	**3**	**70**
OT Seeker	0	0	0	**0**
PEDro	0	0	0	**0**
Psycinfo	**14**	**2**	**1**	**17**
Scopus	**31**	**2**	**9**	**42**
SportDiscus	0	0	0	**0**
Cochrane Library	0	0	0	**0**
The Joanna Briggs Institute	0	0	0	**0**
TOTAL	**108**	**17**	**13**	**138**

2b) Number of studies excluded in full-text review and reasons

Studies were excluded on first reason that became apparent

Exclusion 1 = articles excluded due to not assessing tactile spatial acuity using Grating Orientation Domes

Exclusion 2 = articles excluded due to not reporting on any clinimetric data

Exclusion 3 = articles excluded due to focusing on variations within the tool

Exclusion 4 = articles excluded due to not being a peer reviewed journal

Exclusion 5 = articles excluded due to reporting on brain areas

Exclusion 6 = articles excluded due to reporting on other body parts

Exclusion 7 = articles excluded due to reporting in languages other than English

Databases	**Exclusion reasons**							
Studies excluded from:	**Ex 1**	**Ex 2**	**Ex 3**	**Ex 4**	**Ex 5**	**Ex 6**	**Ex 7**	**TOTAL**
Ageline	0	0	0	0	0	0	0	**0**
AMED	0	0	0	0	0	0	0	**0**
CINAHL	0	0	0	0	0	0	0	**0**
CIRRIE	0	0	0	0	0	0	0	**0**
Embase	0	**3**	0	**2**	0	0	0	**5**
ERIC	0	0	0	0	0	0	0	**0**
Meditext-Informit	0	0	0	0	0	0	**1**	**1**
Medline	**2**	**4**	**2**	0	**1**	0	0	**11**
OT Seeker	0	0	0	0	0	0	0	**0**
PEDro	0	0	0	0	0	0	0	**0**
Psycinfo	0	**1**	0	**1**	0	0	0	**2**
Scopus	**2**	0	0	0	0	**1**	0	**3**
SportDiscus	0	0	0	0	0	0	0	**0**
Cochrane Library	0	0	0	0	0	0	0	**0**
The Joanna Briggs Institute	0	0	0	0	0	0	0	**0**
TOTAL	**4**	**8**	**2**	**3**	**1**	**3**	**1**	**22**

Appendix 3
Measurement Critical Appraisal Tool (MCAT)

The following table is a template of the MCAT used to extract data from identified studies in the systematic review.

1. Article title		
2. Author/s		
3. Aim of study		
4. Population of study		
5. Type of study		
6. Reports on at least one psychometric property listed below		Y / N / not reported Continue?
External Validity		
7. Tool has been validated on healthy population		Y / N / not reported
8. Normative values available	i. Populations:	Y / N / not reported
Internal Validity		
9. Criterion validity		Y / N / not reported
10. Face validity		Y / N / not reported
11. Content validity		Y / N / not reported
12. Construct validity		Y / N / not reported
13. Factor Analysis undertaken		Y / N / not reported
Reliability		
14. Internal consistency		Y / N / not reported

15. Test-retest reliability		Y / N / not reported
16. Inter-rater reliability		Y / N / not reported
17. Intra-rater reliability		Y / N / not reported
Responsiveness		
18. Sensitivity/specificity		Y / N / not reported
19. Floor/ceiling effects		Y / N / not reported
20. Factors affecting performance	i. Age	Y / N / not reported
	ii. Sex	Y / N / not reported
	iii. Handedness	Y / N / not reported
	iv. Body site	Y / N / not reported
	v. Other…	Y / N / not reported
21. Practice effects		Y / N / not reported
22. Predictive power		Y / N / not reported
Feasibility & Utility		
23. Administration time		Y / N / not reported

24. Cost of tool or additional equipment required		Y / N / not reported
25. Additional training needed		Y / N / not reported
26. Age range reported		Y / N / not reported
27. Method of administration described		Y / N / not reported
28. Scoring procedures clearly described		Y / N / not reported
29. Interpretation of tool score is clear		Y / N / not reported

Appendix 4
Completed MCAT

All data from identified studies in the systematic review were placed in this MCAT

External Validity

NORMATIVE VALUES:

Healthy Individuals: (Van Boven & Johnson 1994b)

0.98mm for the finger (SD 0.121, range 0.73 to 1.17)

Children between 6-16 Years Old: (Bleyenheuft et al. 2006)

Children 10-16 years old have a lower tactile spatial threshold than children aged 6-9 years old (Table 5.1)

Table 5.1 Spatial threshold of 6-16 year olds

Age groups (years)	Threshold (mm)
6-7	1.12
8-9	0.97
10-11	0.73
12-13	0.78
14-16	0.71

Elderly adults: (Tremblay et al. 2000)

With an increasing age, there is a decline in tactile spatial thresholds (Table 5.2).

Table 5.2 Spatial threshold of 60-80+ year olds

Age groups (years	Threshold (mm)
60-69 (mean 64.1)	2.63 (SD 0.34, range 2.0 to >3.0
70-79 (mean 73.5)	2.90 (SD 0.19, range 2.43 to >3)
80+ (mean 83.8)	3 (SD 0)

Internal Validity	**<u>CRITERION VALIDITY:</u>** **Concurrent Validity of GODs and Purdue Pegboard:** (Bleyenheuft & Thonnard 2011) Poor correlation between the GODs and digital dexterity (Purdue Pegboard) in patients with unilateral brain lesions (Spearman's correlation; r = 0.126, p = 0.572 and r = 0.195, p= 0.377; for paretic and non-paretic hand, respectively). **Concurrent Validity of GODs and Dot Pattern Acuity Chart:** (Bruns et al. 2014) Moderate to good intercorrelation of 0.66 in a healthy population. **Concurrent Validity of GODs and Landolt Ring Acuity Chart:** (Bruns et al. 2014) Good to excellent intercorrelation of 0.78 in a healthy population. **Concurrent Validity of GODs and 2 Point Discrimination:** (Bruns et al. 2014) Poor intercorrelation of -0.02 in a healthy population. **Concurrent Validity of GOT and Gap Detection:** (Gibson & Craig 2005) The GODs used the same spatial cues as the gap detection task in the presence of a glove on the hand. No statistical analysis was included. **Concurrent Validity of GOT and IQ:** (Grant et al. 2005) The Pearson correlation was poor (0.0068) between Full Scale IQ and temporal lobe epilepsy subject's baseline performance on the hand ipsilateral to side of seizure onset.

	Concurrent Validity of GOT and Letter Recognition Task: (Manning & Tremblay 2006) Highly correlated with a regression line of $r^2 = 0.65$. **Concurrent Validity of GOT and Grooved Pegboard Test:** (Tremblay et al. 2003) Highly correlated with a regression line of r=0.66, p<0.01. **Concurrent Validity of GOT and Letter Recognition Task:** (Vega-Bermudez & Johnson 2001) Moderate to good correlation of -0.63 measured by the nonparametric Spearman's rho ($p < 0.001$) (rankings between the methods), and -0.61 measured by the Pearson product moment correlation ($p < 0.001$) (based on the values) with negative correlation implying consistency. **Concurrent Validity of GOT and New Haptic Threshold Test:** (Mueller et al. 2014) A poor correlation of $r = -0.390$, p=0.150. **Predictive Validity:** Not reported. **FACE VALIDITY:** Not reported. **CONTENT VALIDITY:** (Gibson & Craig 2005) The GODs and Gap task test similar underlying neural mechanisms as there was no significant anisotropy between proximal and lateral orientations at the fingerpad. Post hoc Bonferroni analysis further supported this as no significant difference in performance between the lateral and proximal orientations or between the proximal and oblique

	orientations for the fingerpad (p=0.23; p=0.53, respectively). **<u>CONSTRUCT VALIDITY:</u>** **Known Group Method - Dystonia:** (de Campos et al. 2014) The dystonia group compared to the control group had a higher SDT (dominant side: dystonia mean 11.21; control mean 6.39; P = 0.042; and non-dominant side: mean dystonia 12.64; control mean 5.28; P = 0.0001, respectively) using a Mann-Whitney U test. **Known Group Method - Unilateral Carpal Tunnel Syndrome:** (Libouton et al. 2012) There is a significant reduction in SDT in the affected hand of Carpal Tunnel Syndrome patients, relative to the unaffected hand (paired t-test, $t = -2.21$; $p < 0.05$). **Known Group Method - Complete Traumatic Median Nerve Section at the Wrist:** (Libouton et al. 2012) Participants were unable to perceive grating orientation on the index finger pad of the affected hand for >18 months postoperatively. The reproducibility of the GODs for the unaffected hand was very high across time points (1 week, 3 months, 6-9 months, >18 months) ($p > 0.5$). The mean SDT score was 2.15 mm (±0.72 mm) in the normal subjects (age 31±11). **Known Group Method - Unilateral Brain Lesions:** (Bleyenheuft &Thonnard 2011) Children with congenital hemiplegia and adults following a stroke both had higher SDT in their paretic

	hand compared to their non-paretic hand (Wilcoxon test, w = 247, $p < 0.001$). There was no significant difference between these two groups (paretic hand Mann–Whitney test, T=104, p=0.489; non-paretic hand t-test, t = 0.106, p = 0.971). **Known Group Method - People who are blind:** (Grant, Thiagarajah & Sathian 2000) There was no significance difference between groups [control, early blind, and late blind; F(2,44) = 1.14, p = .33] as determined by a repeated-measures ANOVA. **Known Group Method - People who are blind:** (Norman & Bartholomew 2011) There was a significant differences between blind participants' thresholds and their age- and sex-matched sighted controls using-sample t test [t(15) = −3.12, p = .007, two-tailed]. A large effect was found (Cohen's d=0.78). An ANOVA found no significant difference between the three types of blindness [congenital vs. early onset vs. late onset: F(2, 13) = 0.95, p = .41]. **Known Group Method - People who are blind:** (Van Boven et al. 2000) Post hoc comparisons revealed blind subjects performed significantly better at each individual finger tested compared to sighted subjects (right index finger, t = -7.28, df = 84, p < 0.001; left index finger, t = -4.63, df = 84, p < 0.001; right middle finger, t = -5.31, df = 84, p < 0.001; left middle finger, t = -3.08, df = 84, p = 0.003). Neither age (r = 0.13, p = 0.64), hours per day of Braille reading (greater than or less than 1.5 hours per day [two- tailed t-test, t = 1.03, df =

	11, p = 0.33]) or number of years of Braille reading (r = - 0.17, p = 0.57) were found to relate to thresholds. **Known Group Method - Braille Readers:** (Veispak, Boets & Ghesquiere 2013) Braille readers have significantly more sensitive fingers than sighted print readers as found in ANCOVAs of their index finger (F(1,51) = 20.61, p<.0001) and middle finger (F(1,51) = 4.08, p=.05). **Discriminatory Validity of GOT and Haptic 3D shape discrimination:** (Norman & Bartholomew 2011) For the sighted participants, there was no relationship between SDT and shape judgment (r = .083, p = .76). However, for blind participants, there was a significant correlation between SDT and shape judgment (r = .569, p = .021, two-tailed). Reductions in tactile acuity were accompanied by improvements in haptic 3-D shape discrimination. **Convergent validity:** Not reported. **FACTOR ANALYSIS:** Not reported.
Reliability	**INTERNAL CONSISTENCY:** Not reported. **TEST-RETEST RELIABILITY:**(Bruns et al. 2014) Good test-retest repeatability (r = 0.65, p<0.1, SD = 0.43) with adults scored in two sessions, 5 to 8 days apart (mean 6.9). **INTER-RATER RELIABILITY:** (Bleyenheuft & Thonnard 2007) No significant difference was detected between 6 examiners (Friedman repeated measures analysis on

	ranks; p = 0.813). **<u>INTER-RATER RELIABILITY</u>:** (Van Boven & Johnson 1994b) The SDT in single subjects were highly repeatable between seven test sessions at least 24 hours apart. The SD of the thresholds values in individual subjects ranged from 0.024 to 0.196mm (median 0.109) at the finger; with values all within expected range. **<u>INTRA-RATER RELIABILITY</u>:** (Bleyenheuft & Thonnard 2007) Repeated-measures analysis of variances (ANOVA) found forces applied were very reproducible for each examiner as no differences in forces were detected from one dome to another (p = 0.836), and also no differences in timing (p=0.077) were detected from one dome to another.
Responsiveness	**<u>SENSITIVITY AND SPECIFICITY:</u>** Not reported. **<u>FLOOR/CEILING EFFECTS:</u>** Not reported. **<u>FACTORS AFFECTING PERFORMANCE:</u>** **Age:** (Bleyenheuft et al. 2006) The SDT improved with the age until 10–11 years old and then plateaued with a significant global age effect (p<0.001) found by using a Kruskall–Wallis test. A Mann-Whitney Rank Sum test found children 6-9 years old were less sensitive than children above 10 years old (6-7 years old p<0.012; 8-9 years old p<0.021; no difference between these groups p= 0.894). No significant differences were reported between the 10–11 years old, 12–13 years old, and

	14–16 years old group (all p> 0.711). There are highly signigicant difference between 6-9 and 10-16 years old (p<0.001). **Age:** (Manning & Tremblay 2006) A general decline in SDT occurred with the older age as 55-86 year olds group, compared to 21-26 years old had double the SDT (2.5 ± 0.4 mm vs. 1.2 ± 0.3 mm, respectively). **Age:** (Tremblay et al. 2000) An ANOVA found a significant effect of age on SDT ($F(2, 29) = 5.83$, $p < 0.01$) with adults between 60-80+ years of age. It was concluded the older a person was, the poorer their SDT. **Age:** (Tremblay et al. 2003) A multiple linear regression analysis found age to be a significant predictor of SDT measured at the index finger (partial r = 0.55, p= 0.022). People 60-71 years had mean SDT of 2.7 ± 0.6mm and people 74-95 years old had a mean SDT of 3.4 ± 0.4mm. **Gender:** (Bleyenheuft et al. 2006) A Mann-Whitney Rank Sum test found no significant difference between genders for subjects aged between 6 and 16 years old, however no statistical analysis was reported. **Gender:** (Manning & Tremblay 2006) An ANOVA found a small gender effect ($F_{1, 23} = 5.1$, $p = 0.04$) in the older group (mean 67.2 year olds) compared to the younger group (mean 23.5 years old).

	Gender: (Tremblay et al. 2003) A multiple linear regression analysis found gender to have no significant effect (partial r = 0.05, p=0.845). **Gender:** (Tremblay et al. 2000) States gender had no significant effect on grating resolution thresholds (no statistics reported). **Handedness:** (Sathian & Zangaladze 1996) A repeated-measures ANOVA found no major differences between hands (F=1.24, p=0.2738). An individual subject analysis using paired t testing (a = 0.05) further confirmed the lack of significant lateralization. **Handedness:** (Vega-Bermudez & Johnson 2001) An ANOVA found there no difference between hands (1.46mm and 1.44mm SDT for left and right hands; F[1,35] = 0.038, p = 0.78) and no interaction between hand and certain digits (p = 0.85). **Handedness in sighted and blind people:** (Van Boven et al. 2000) Mean SDT for digits in the right hand was not significantly different from the left hand for sighted subjects (ANOVA, F = 2.66, df = 1,14, p = 0.13) or blind subjects (ANOVA, F = 0.88, df = 1,14, p = 0.36). **Handedness in sighted and blind people** (Grant, Thiagarajah & Sathian 2000) A repeated-measures ANOVA found no significant difference between hands within subjects (dominant vs. non-dominant; F(1,44) = 1.31, *p* =0.26). The mean

	threshold on the non-dominant hand was 17% higher compared to the dominant hand for people who became blind after the age of 10. This difference was significant using a paired t test *(p* = 0.04). No significant difference was found between hands for people who became blind before the age of 5 *(p = 0*.38) or for the sighted controls *(p* = 0.27). **Body Sites:** **Palm Compared to Fingerpad:** (Craig & Lyle 2001) The threshold for the fingerpad was determined as 1.25 mm. Thus, the ratio of sensitivity between palm and finger pad is either 7.4:1 or 6.2:1 (using the initial and final threshold estimates from the palm respectively). **Between Digits:** (Grant et al. 2006) There was a significant within-subjects effect of finger tested (Digit 2 vs. Digit 4, F = 37.7, p < .0005). The mean GOT was 1.12 at Digit 2 and 1.65mm at Digit 4. **Between Digits:** (Sathian & Zangaladze 1996) Mean thresholds at the fifth digit were significantly different from those on the first through fourth digits, while thresholds on these four digits did not differ significantly from one another as determined by a post hoc comparisons of mean thresholds at different locations using the Scheffe test (a = 0.05). **Between Digits:** (Vega-Bermudez & Johnson 2001) An ANOVA found a difference between fingers (F[2,35] = 17.6, p < 0.001). Post hoc test of SDT found individual fingers differed from one another (sign tests, p < 0.001 for digits 2 and 3 and digits 2 and 4, p

= 0.004 for digits 3 and 4.

Dorsum of hand compared to finger tip: (Schlereth, Magerl & Treede 2001)

Mean dorsum of the hand SDT was 18.9 mm, compared to 1.3 mm for the fingerpad of the index finger.

Trained fingers: (Sathian & Zangaladze 1997)

The SDT was lower on subsequently trained fingers than on the first-trained finger; the effect was of marginal significance *(p* = .066).

Trained palm: (Craig & Lyle 2001)

An ANOVA showed a significant effect of pre- vs post-testing on the palm after receiving training on letter identification task [$F(1,5) = 12.32$, $p < 0.05$]. The mean SDT was 9.2mm in initial measure, and 7.8mm in the final measure.

Body Site + gloves: (Gibson & Craig 2002)

A repeated-measures ANOVA found a glove on the hand had a significant effect on performance at the fingertip, fingerbase, and palm [$F(1,7)= 13.18$, $F(1,6) = 9.66$, and $F(1,7) = 17.48$, respectively, $ps < .05$] (Table 5.3).

Table 5.3 Spatial thresholds with and without a glove on the hand

Location	No Glove (mm)	With Glove (mm)	% Increase
Distal fingerpad	1.24	1.69	36
Proximal fingerpad	4.35	4.93	13
Palm	5.73	6.98	22

Body Site and Force: (Gibson & Craig 2006)
A repeated-measures ANOVA found no significant difference between 50 and 200-g force at the fingerpad or the fingerbase. [F(1,4)=0.26, P=0.64; F(1,4)=0.16, P=0.71, respectively] (Table 5.4).

Table 5.4 Spatial resolution at different force conditions

	Force	
	50g	200g
Fingerpad	1.01mm	1.02mm
Fingerbase	2.93mm	3.32mm

Conformance (Gibson & Craig 2006)
Conformance is not a good predictor of the performance in the GODS. The average conformance for the fingerpad and fingerbase, separately result in reasonably high r^2 values, 0.66 and 0.86, respectively. Combining data, the r^2 value falls considerably to 0.44.

Vision: (Cardini et al. 2012)
T-tests found judgments of GODS were significantly above chance both after viewing the hand (65% correct), [$t(32)= 7.98$; $p<0.0001$] or the object (62% correct), [$t(32)=5.39$; $p<0.0001$]. The SDT was superior after briefly viewing the hand compared to after briefly viewing the object [$t(32)= 2.46$; $p < 0.05$, 2-tailed].

Vision: (Haggard 2006)
Viewing one's own hand or viewing the experimenter's hand significantly enhanced SDT relative to viewing a neutral object, $t(29)= 3.15$,

	p< .005; t(29)= 2.15, p< .05, respectively. Conversely, there was no significant difference between viewing one's own and viewing another person's hand, t(29)= 1.28. **Short –term Visual Deprivation:** (Wong et al. 2011) An ANOVA found significant effects of ambient lighting (p = 0.010). Although the effect of eyelid state was not significant (p = 0.077), participants tended to perform better with eyes opened than closed. One-way repeated-measures ANOVA found no significant change in SDT indicating performance in the dark and light were equivalent. Additionally, a one-way repeated-measures ANOVA found no significant change in SDT of participants in the visually deprived group (p = 0.435) or the non- deprived group (p = 0.115). Thus, visual deprivation did not affect SDT. **Occupation-related:** (Mueller et al. 2014) One-way ANOVA revealed no significant differences between SDT of employed physiotherapists, osteopathic manual therapists or the control group ($F(2, 76) = 2.89$, $p = .062$). **Occupation-related:** (Tremblay et al. 2000) Occupation related factors (repetitive movements or power tool used) had no significant effect on SDT. No statistics were reported. **Occupation-related:** (Tremblay et al. 2003) A multiple linear regression analysis found occupational factors (previous or current) had no significant effect on SDT (partial r = -0.40, p=0.117).

	Hand symptoms: (Tremblay et al. 2000) Reported hand symptoms (numbness/difficulty manipulating objects) had no significant effect on SDT. No statistics were reported. **Hand symptoms:** (Tremblay et al. 2003) A multiple linear regression analysis found hand symptoms (numbness) and difficulties with manipulations to have no significant effect on SDT (partial r = -0.36, p=0.158; partial r = 0.12, p=0.637, respectively). **Pain and learned tactile sensitivity:** (Zamorano et al. 2015) Post hoc mean comparisons revealed pain-free individuals displayed lower SDT than chronic pain patients within non-musicians ($p < 0.01$), but not within musicians. **PRACTICE EFFECTS:** (Bleyenheuft & Thonnard 2007) No trial effect emerged within five consecutive testing sessions (Friedman repeated measures analysis on ranks; p = 0.116). **PRACTICE EFFECTS**: (Bruns et al. 2014) The GODs repeatability decreased for high mean thresholds values over two sessions of 5 to 8 days (mean 6.9 days). (r= 0.70, p = .001). **PRACTICE EFFECTS**: (Sathian & Zangaladze 1997) No significant difference between first- and subsequently trained fingers (mean of 3.1 sessions for the first trained finger, and 1.9 sessions for the subsequent trained fingers *(p* = .49).

	PREDICTIVE POWER: Not reported
Feasibility	**ADMINISTRATION TIME:** Ranged from 30-60 minutes (Sathian et al. 1997; Van Boven et al 2000). It was adapted for children, reducing the time to 15 minutes (Bleyenheuft 2006). **COST OF TOOL OR ADDITIONAL EQUIPMENT REQUIRED:** No studies reported cost or additional equipment. **ADDITIONAL TRAINING NEEDED:** No studies reported additional training needed.
Utility	**AGE RANGE REPORTED:** Has effectively been used in all age groups. Please refer to normative data above. **METHOD OF ADMINISTRATION DESCRIBED:** Yes, most studies followed a standardized procedure based on the instruction manual by Medcore (n.d.) and from the literature (Sathian & Zangaladze 1996; Van Boven & Johnson 1994a; Van Boven et al. 2000). Slight variations were made to each study method including the amount of trials for each grating being administered and whether to use manual application or application through use of a device. Grant et al. 2006 found that there was no statistical significant difference between the method of constant stimuli (MCS) and the staircase method (SC), therefore both methods produce a meaningful measure of SDT. MCS involves each grating being applied in a block of 20-50 consecutive trials, whereas the subject in the SC method is never exposed to a single grating

	consecutively for more than two trials. **<u>SCORING PROCEDURES CLEARLY DESCRIBED</u>:** All studies clearly described their scoring procedures, with majority citing the manual provided by Medcore (n.d.). **<u>INTERPRETATION OF TOOL SCORE:</u>** No studies commented on the interpretation of the scores.

Appendix 5
Guidelines for clinimetric evaluation

Following are the definitions and accepted values used in the evaluation of the grating orientation domes. All references are reported below the table.

Clinimetric Property	Definitions	Clinimetric Measures
Validity	Refers to the extent to which a test measures what it purports to measure in its applied context (Fitzpatrick et al. 1998).	
	External validity Refers to the extent the results of the measure can be generalised beyond the internal specifications of the study population. It looks at how useful the information is outside of the experimental situation. Threats to this involve the interaction of treatment with the specific study population, the specific setting the measure was conducted in and the time in history when the study was conducted (Fitzpatrick et al. 1998).	• Qualitative reports. Based mostly on population and methodology
	Internal validity Reflects the extent to which items measure aspects of the same characteristic and nothing else. Eg tactile acuity (Portney & Watkins 2009, p. 176).	• Cronbach's coefficient alpha • Item-to-total correlation via the Pearson product-moment correlation coefficient
	Face validity Examines whether an instrument appears to be measuring what it is intended to measure. Assessed as all or none (Portney & Watkins 2009, p. 100).	• Qualitative reports

Content validity Examines the extent to which the domain of interest is sampled by the items within the instrument. Indicates that the items that make up an instrument covers all important areas of the health components to be measured. It will be free from the influence of factors that are irrelevant to the purpose of the measurement (Portney & Watkins 2009, p. 101).	• Qualitative. Usually reviewed by a panel of experts
Criterion-related validity The new measure correlates with a measure accepted as a more accurate or criterion variable. Often the measure will be congruent with an acknowledged 'gold standard' measure. Is inclusive of concurrent and predictive validity (Portney & Watkins 2009, p. 102).	• Correlation coefficients • Correlation occurs with available gold standard assessments or a criterion measure already established and shown to be valid
Concurrent validity Establishes validity when the tool to be validated and the criterion measure are administered at relatively the same time, signifying the same incident of behavior. Used most often when the tool to be validated is considered more efficient than the gold standard, thus can be used instead of the gold standard (Portney & Watkins 2009, p. 103).	
Predictive validity Establishes that a measure will be a valid predictor of a future criterion score or outcome (Portney & Watkins 2009, p. 104).	

Construct validity Reflects the ability of a tool to measure an abstract concept or construct. It aims to assess functional issues, rather than directly observable incidences. For example, decreased tactile spatial acuity. Common methods include convergent and discriminatory validity (Portney & Watkins 2009, p. 105). ***Convergent validity*** Indicates the degree in which two different instruments are able to measure the same construct. They will correlate highly (Portney & Watkins 2009, p. 107). ***Discriminatory validity*** Indicates that different results will be yielded when instruments are believed to assess different constructs. There will be a low correlation (Portney & Watkins 2009, p. 107). ***Known group methods*** Indicates a test can discriminate between individuals who are known to have a particular trait/condition, and those that do not (Portney & Watkins 2009, p. 107). **Factor analysis (part of construct validity)** Refers to the analysis of patterns of items that go together to assess single underlying constructs. It is based on the idea that a construct contains one or more underlying component (Portney & Watkins 2009, p. 108).	• Correlation coefficients • Area under receiver operating characteristics (ROC or AUC) curve

Reliability	Refers to the reproducibility of a measure. Vital to establish that any changes observed during an experiment are due to the intervention itself and not the measuring instrument or persons conducting intervention (Portney & Watkins 2009, p. 82).	
	Internal consistency Refers to the degree of consistency within an instrument. It reflects the extent to which several items measure the same construct. Also referred to as the homogeneity of the items (Portney & Watkins 2009, p. 89).	• Cronbach's coefficient alpha • Split half or Spearman-Brown reliability coefficient • Item-to-total correlation • Pearson Product-Moment correlation coefficient
	Test-retest reliability Evaluates whether an instrument yields the same results on repeated applications over a various length of time (Portney & Watkins 2009, p. 85).	• Correlation coefficients (Intraclass correlation coefficient (ICC) and Pearson Product-Moment correlation coefficient) Cohen's Kappa coefficient
	Inter-rater reliability Consistency of administration and scoring across various raters (Portney & Watkins 2009, p. 87).	• ICC • Cohen's Kappa coefficient • Correlation coefficient
	Intra-rater reliability Consistency of administration and scoring within individual raters (Portney & Watkins 2009, p. 87).	• ICC • Cohen's Kappa coefficient

Responsiveness	Refers to the ability of an instrument to detect clinically important changes (Fitzpatrick et al. 1998).	Many different methods to evaluate responsiveness, with main one being: • Effect size
	Sensitivity and specificity (Portney & Watkins 2009, p. 620). Sensitivity refers to the ability to detect true change within a clinical setting (true positive) Specificity refers to the ability to detect true stability (true negative)	Area under receiver operating characteristics (ROC or AUC) curve
	Floor/ceiling effect Refers to a measurement limitation where the instrument's scale is unable to determine an increased performance or decreased performance beyond a certain level. This means the measure may be too easy (ceiling) or too hard (floor) for subjects, not truly assessing their appropriate function (Portney & Watkins 2009, p. 111).	• Percentage
	Factors affecting performance Any known factors that will have some affect on the scores of the instrument e.g. gender or age (Fitzpatrick et al. 1998).	• ANOVAs • T-tests • Graphically plotted
	Practice effects What the effect of the first test is on the outcome of the second test (Fitzpatrick et al. 1998).	• Friedman repeated measures analysis on ranks

	Predictive power Refers to the ability to define the operation of an instrument's test score, when the score is known, but the condition has not yet been diagnosed (Portney & Watkins 2009, p. 622). This is very clinically relevant as it allows allied health practitioners to determine whether a patient has a condition or not.	Area under receiver operating characteristics curve
Feasibility	How easy an instrument is to administer and process. Includes time, cost and level of training needed (Fitzpatrick et al. 1998).	Subjective reports from studies
Utility	Refers to how clinically meaningful scores from an instrument are. Includes if it is age appropriate, method of administration, scoring process, and score interpretation and relevance (Fitzpatrick et al. 1998).	Subjective reports from studies

Key to main categories for clinimetric data

Cronbach's alpha	**Validity coefficients using Cohen's r**	**Area under receiver operating characteristics (ROC)**	**ICC**	**Reliability correlation coefficients**	**Cohen's Kappa**	**Effect size**	**Floor and Ceiling effects**
α = 0.70-0.90 adequate α = 0.60-0.70 α < 0.60 inadequate (>0.90 may indicate redundancy)	r > 0.6 excellent r = 0.30-0.59 moderate r < 0.30 poor	0.75 = high 0.50- 0.75 = moderate <0.50 = low	Widely varies, but miniminum of 0.70 suggested	>0.75 excellent 0.50 – 0.75 good 0.25 – 0.50 fair <0.25 poor	K 0.81 – 1.00 = strong K 0.61 -0.80 = moderate K 0.40 -0.60 = weak K <0.40 = poor	Large ≥ 0.80 Medium 0.50-0.79 Small < 0.50	<20% of participants receiving scores of either 0% or 100% were regarded as sufficient

References

Fitzpatrick, R, Davey, C, Buxton, MJ & Jones DR 1998, 'Evaluating patient-based outcome measures for use in clinical trials', *Health Technology Assessment,* vol. 2, no. 14 pp. 1-74.

Murphy, MA, Resteghini, C, Feys, P & Lamers, I 2015 'An overview of systematic reviews on upper extremity outcome measures after stroke', *BMC Neurology,* vol. 15, no. 29, pp. 1-15.

Portney, LG & Watkins, MP 2009, *Foundations of Clinical Research: Applications to Practice,* 3rd edn, Pearson Prentice Hall, Upper Saddle River, NJ.

Santisteban, L, Teremetz, M, Bleton, JP, Baron, JC, Maier, MA & Lindberg, PG 2016, 'Upper limb outcome measures used in stroke rehabilitation studies: a systematic literature review', *PLoS One,* vol. 11, no. 5, p. e0154792.

Note: Refer to Appendix 4 for other accepted values for clinimetric data in cited references

Appendix 6
Study characteristics of included studies

The following is a table of relevant characteristics of all included studies. The studies are listed alphabetically by first author's name and year. The study design was not included in the table as it was determined that all studies were of comparative, experimental nature. Gender and handedness were also characteristics not included as they were found to have no effect on the performance of the domes.

Author/Date	Sample size	Mean age (range) [years]	Selection Bias/population	Clinimetric properties reported		
				Validity measures	Reliability measures	Responsiveness
Bleyenheuft et al. (2006)	222	10.9 (6 -16)	Representational of Belgian school children, but not randomly selected	Normative values	NRNR	FAP
Bleyenheuft & Thonnard (2007)	12	NR (22-40)	Representative of general population	NR	Inter-rater Intra-rater	Practice effects
Bleyenheuft & Thonnard (2011)	22	35.8 (10-81)	Children with congenital hemiplegia and adults following a stroke, excluded cognitive deficits. Used normative sample as control	Concurrent Known groups	NR	NR
Bruns et al.	18	23.4	Sighted volunteers via	Concurrent	Test-retest	Practice effects

(2014)		(19-30)	convenience sampling (Germany)			
Cardini et al. (2012)	33	24.2 (21-37)	Paid healthy volunteers via convenience sampling (UK)	NR	NR	FAP
Craig & Lyle (2001)	6	NR	Paid healthy university student volunteers via convenience sampling (USA)	NR	NR	FAP
de Campos et al. (2014)	16	13.2 (8-19) Controls 17 (12-22)	Diagnosis of perinatal stroke and evidence of dystonia, and healthy volunteer controls	Known group	NR	NR
Gibson & Craig (2002)	8	NR	Paid healthy university student volunteers via convenience sampling (USA)	NR	NR	FAP

Gibson & Craig (2005)	12	NR	Paid healthy university student volunteers via convenience sampling (USA) and data from Gibson & Craig (2002)	Concurrent Content	NR	NR
Gibson & Craig (2006)	11	NR	Paid healthy university student volunteers via convenience sampling (USA)	NR	NR	FAP
Grant, Thiagarajah & Sathian (2000)	63	39.8 (18-75)	Blind adults with age-matched sighted controls (USA)	Known group	NR	FAP
Grant et al. (2005)	34	34.7 (20-63)	Adults with medically intractable unilateral temporal lobe epilepsy with age-matched healthy controls (USA)	Concurrent	NR	NR
Grant et al. (2006)	16	23.5 (18-30)	Representative of general population	NR	NR	FAP
Haggard (2006)	30	NR (14-45)	Representative of general population	NR	NR	FAP

Libouton et al. (2012)	26	50 (20-80)	Adults with unilateral carpal tunnel syndrome, surgically repaired complete traumatic median nerve section at the wrist and healthy volunteers	Known group	NR	NR
Manning & Tremblay (2006)	45	45.4 (21-86)	Representative of general population	Concurrent	NR	FAP
Mueller et al. (2014)	100	41.2 (34-50)	Adult manual therapists (PT, PT student and OMT) and healthy volunteers	Concurrent	NR	FAP
Norman & Bartholomew (2011)	32	57.8 (30-77)	Adults who are blind with age- and sex-matched sighted controls	Known group Discriminatory	NR	FAP
Sathian & Zangaladze (1996)	7	NR	Convenience sampling of healthy population	NR	NR	FAP
Sathian & Zangaladze (1997)	8	NR	Paid healthy volunteers via convenience sampling	NR	NR	FAP Practice effects

Schlereth, Magerl & Treede (2001)	12	28 (22-47)	Healthy volunteers via convenience sampling	NR	NR	FAP
Tremblay et al. (2000)	32	71.6 (60-88)	Healthy volunteers (<1/3 reporting hand symptoms) via sampling of convenience	Normative values	NR	FAP
Tremblay et al. (2003)	30	76.3 (60-95)	Representative of general population	Concurrent	NR	FAP
Van Boven & Johnson (1994b)	15	NR (23-25)	Healthy medical students via sampling of convenience	Normative values	Inter-rater	NR
Van Boven et al. (2000)	30	42 (25-55)	Blind adults with age- and sex-matched sighted controls	Known group	NR	FAP
Vega-Bermudez & Johnson (2001)	8	35 (22-57)	Healthy male volunteers	Concurrent	NR	FAP
Veispak, Boets & Ghesquiere (2013)	56	15.6 (9.5-25.6)	Dutch braille children readers with age-, sex- and educational level-matched sighted print readers	Known group	NR	FAP

Wong et al. (2011)	158	20.5 (18.1-25.8)	Appears representational but unclear	NR	NR	FAP
Zamorano et al. (2015)	85	29.7 (18.6-41.5)	Representative of general Spanish population	NR		FAP

Abbreviations: FAP = Factors affecting performance, NR = Not reported

Appendix 7
Ethical approval from respective sites

7a) Ethical approval letter from the Royal Adelaide Hospital Human Research Ethics Committee

Government of South Australia
SA Health

Central Adelaide Local Health Network
Royal Adelaide Hospital Human Research Ethics Committee
Level 4, Women's Health Centre Royal Adelaide Hospital North Terrace Adelaide, South Australia, 5000
Telephone: +61 8 8222 4139 Email: rah.ethics@health.sa.gov.au

Approval Date: 1 October 2015

A/Prof Susan Hillier
Centre for Allied Health Evidence
School of Health Sciences
University of South Australia,

Dear A/Prof Hillier

HREC reference number: **HREC/15/RAH/406**

Project Title**: "The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.**

RAH Protocol No: 150916

Thank you for submitting the above project for ethical review. This project was considered by the Chairman of the Royal Adelaide Hospital Human Research Ethics Committee. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the National Statement on Ethical Conduct in Human Research. The documents reviewed and approved include:

- **LNR Submission: AU/15/9661211 Sites covered by this approval:** o **Royal Adelaide Hospital: CPI – A/Prof Susan Hillier**
- **Protocol, dated 10 September 2015**

Please quote the **RAH Protocol Number, 150916** and the **HREC number, HREC/15/RAH/406** allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each anniversary of the above approval date, within 10 workings days, using the Annual Review Form available at: http://www.rah.sa.gov.au/rec/index.php
- The REC must be advised with a report or in writing within 30 days of completion.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea on 08 8222 4139, or rah.ethics@health.sa.gov.au .
You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

This Committee is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research* (2007). The HREC wishes you every success in your research.
Yours sincerely,

for
A/Prof A Thornton
CHAIRMANRAH
HUMAN RESEARCH ETHICS COMMITTEE

7b) Ethical approval email from the Human Research Ethics Committee of the University of South Australia

-----Original Message-----
From: no_reply@unisa.edu.au [mailto:no_reply@unisa.edu.au]
Sent: Thursday, 8 October 2015 11:58 AM
To: Susan Hillier; Human Ethics
Subject: Human Ethics: Application approved

Dear Applicant

Re: Ethics protocol "The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study." (Application ID: 0000034926)

Thank you for submitting your ethics protocol for consideration. Your protocol has been considered by the E1 Committee Review Group.

I am pleased to advise that your protocol has been granted ethics approval and meets the requirements of the National Statement on Ethical Conduct in Human Research. Please note that the E1 Committee Review Group's decision will be reported to the next meeting of the Human Research Ethics Committee for endorsement.

Please regard this email as formal notification of approval.

Ethics approval is always made on the basis of a number of conditions detailed at http://www.unisa.edu.au/res/forms/docs/humanresearchethics_conditions.doc; it is important that you are familiar with, and abide by, these conditions. It is also essential that you conduct all research according to UniSA guidelines, which can be found at http://www.unisa.edu.au/res/ethics/default.asp

Please note, if your project is a clinical trial you are required to register it in a publicly accessible trials registry prior to enrolment of the first participant (e.g. Australian New Zealand Clinical Trials Registry http://www.anzctr.org.au/) as a condition of ethics approval.

Best wishes for your research.

Executive Officer
UniSA's Human Research Ethics Committee CRICOS provider number 00121B

This is an automated email and cannot be replied to. Please direct your query to humanethics@unisa.edu.au.

Appendix 8
Registration with the Australian New Zealand Clinical Trials Registry

Below is an email confirmation of registering the OGS clinical trial with the Australia New Zealand Clinical Trials Registry

Dear Shannon Watchman,

Re: The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.

Thank you for submitting the above trial for inclusion in the New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12616000157471

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12616000157471.aspx
Date submitted: 6/02/2016 3:55:35 PM
Date registered: 10/02/2016 10:00:09 AM
Registered by: Shannon Watchman

****Please note that as your trial was registered after the first participant was enrolled, it does not fulfil the criteria for prospective registration and will therefore be marked as being Retrospectively Registered on our website.****

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).
Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial's Primary Sponsor or their representative (the Registrant).
The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.
The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 9565 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

Appendix 9
Recruitment forms

9a) Participant information sheet

Title of the project
The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.

Researcher Shannon Watchman
Supervisors Dr Susan Hillier
David Hobbs

What is this project about?
Rehabilitation can be a long process for people after stroke. Computer gaming is proposed as a way for people to spend time in enjoyable activities during their rehabilitation stay. This project will investigate if computing gaming, through the use of the OrbIT Gaming System, has benefits for people during their stroke rehabilitation.
Particularly, we are interested in finding out if participation in computer gaming will improve movement and sensation in the affected upper limb following a stroke. The study will also ask participants and staff about their experiences using this system. This study is being conducted as part of a Physiotherapy student honours project.

You are invited to participate in this research project, but you do not have to be involved. Whether you wish to or not is entirely up to you and you have the right to withdraw from the study at any time without giving a reason. Whether you take part or not, or if you withdraw from the study, your medical and rehabilitation care will not be affected in any way.

Summary of procedures
The reason you have been invited to participate in this study is because you have had a stroke and are currently receiving inpatient stroke rehabilitation at Hampstead Rehabilitation Centre. If you agree to participate, you will be allocated (by chance) to one of two groups. Both groups will participate in computer gaming with the use of a controller and laptop, which will be readily available over a three-week period. This will be used as an additional rehabilitation tool during your stay at Hampstead Rehabilitation Centre, allowing as much use as you choose.
The games have been designed to be of broad appeal and easy to play (no experience required). You will also receive the usual rehabilitation sessions scheduled for you. All participants (regardless of group) will be asked to undergo assessment at the beginning of the study and after the three-week period (1 hour for each assessment). All participants will be asked specific questions after the three-week intervention through a written questionnaire. This will enable us to compare the effects of computer gaming.

Confidentiality and Data Security
All records containing personal information will remain confidential and no information which could lead to your identification will be released, except as required by law. The

outcomes of this project will be published in conference papers, journals or other venues as appropriate, but your individual results and information will be kept confidential at all times. Data obtained from the research will only be accessible by the researchers and will be kept in a locked cabinet within the University of SA (P5-06F-65) for 7 years, before being destroyed securely.

a. In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures.
b. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected.

Benefits, risks and adverse effects

This study is designed to determine what benefits there might be in computer gaming – we cannot make any claims at this stage. However this project does not involve any known risk to you, beyond that which is usually associated with rehabilitation. Participants in this study are insured under the University of South Australia and the Royal Adelaide Hospital. The study will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007).

Outcomes

If you would like a copy of the final report of the study, please indicate this on the consent form and we will mail it to you when the study has finished.

Expenses and payments

You will not receive any payment for participation in this study.

Contact

If you would like any further information about this study and your involvement in it, please do not hesitate to contact:

Shannon Watchman (Physiotherapy Hons student), School of Health Sciences, City East Campus, University of South Australia, North Tce, Adelaide SA 5000. T: 0401451739 E: watsk002@mymail.unisa.edu.au

Susan Hillier, BAppSc, PhD; international Centre for Allied Health Evidence, School of Health Sciences, City East Campus, University of South Australia, North Tce, Adelaide SA 5000. T: 83022544, F: 83022766, E: susan.hillier@unisa.edu.au

David Hobbs, BSc(Physics), BSc/BEng(Biomedical)(Hons), Medical Device Research Institute, School of Computer Science, Engineering and Mathematics, Flinders University, 1284 South Road, Tonsley, SA, 5042. T: 8201 3167, E: david.hobbs@flinders.edu.au

This study has been reviewed by the Royal Adelaide Hospital (RAH) Research Ethics Committee and the University of South Australia (UniSA) Human Research Ethics Committee. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Chairman of the RAH Research Ethics Committee on 8222 4139 or the executive officer of the UniSA Ethics Committee on 8302 3118 or email Vicki.allen@unisa.edu.au.

9b) Consent form

I, ... hereby give consent to

my involvement in the research project: *The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.*

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by

..... (full name of recruiter) and my consent is given voluntarily.

I acknowledge that the details of the following have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time; and the frequency with which they will be performed:

1. I will receive the OrbIT Gaming System and use of the controller over a 3 week period, during which I will use it at my own free will, whilst an inpatient at Hampstead, in addition to my regular rehabilitation.
2. I understand that I can use the gaming system as frequently as I wish to both during the week and on weekends
3. I will complete assessment testing at the beginning of the study, and at the end of the three-week intervention (approx. 1 hour each)
4. I will complete a questionnaire about my satisfaction with using the controller and the end of the three-week intervention (approx. 5 mins).
5. There are no risks involved that differ from usual rehabilitation.

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect. Information from this study may be published, however individual participants will not be identified and information will be kept confidential.

I declare that I am over the age of 18 years

☐ I would like to receive a copy of the final report of the study

If ticked yes, please print postal address
.....

Signature of Research Participant : .....

Date: .....

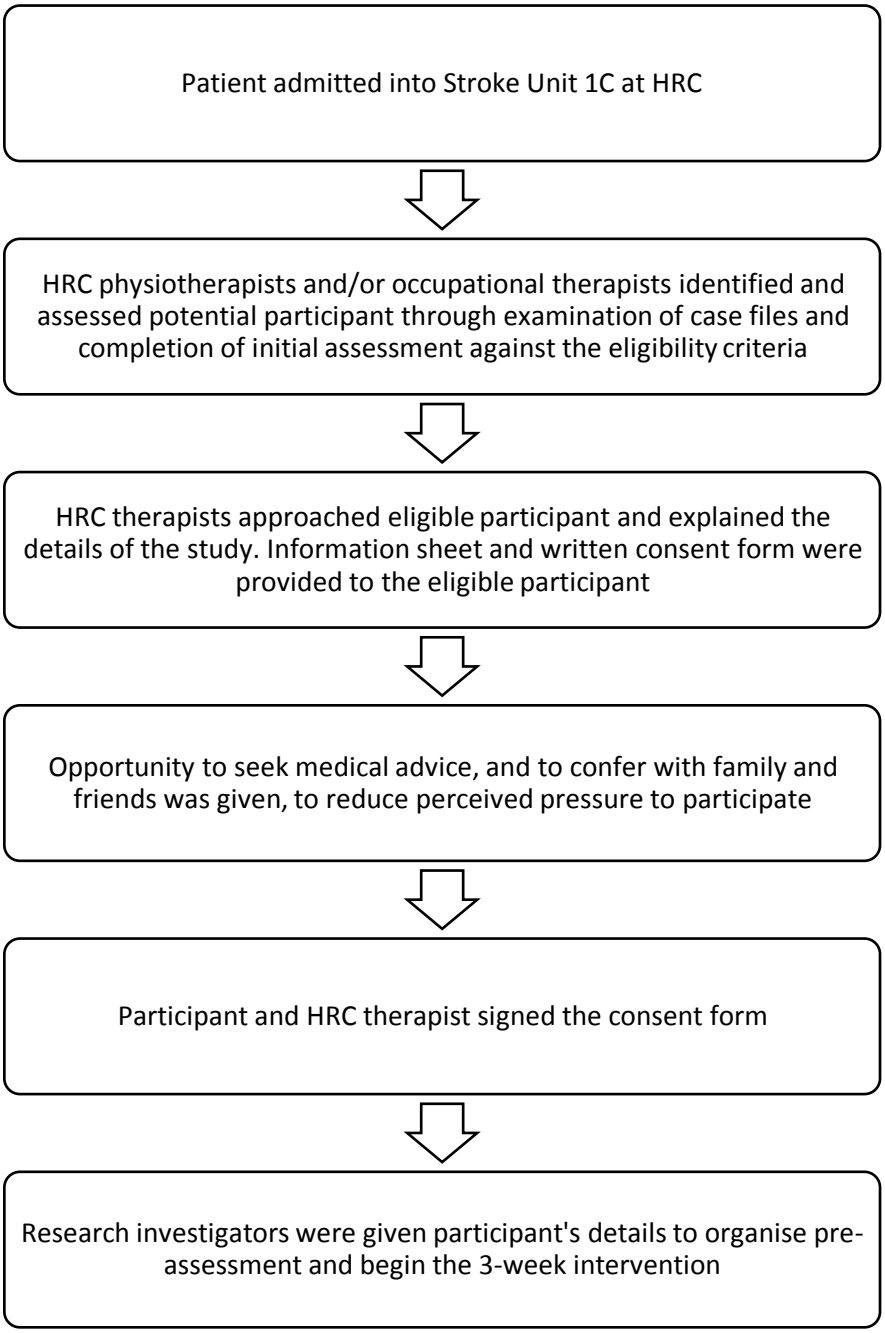
I, ... have described to .....

the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: .....
Date:.....

Status in Project:
.....

Appendix 10
Flow diagram of recruitment procedure



Appendix 11
Questionnaires

Appendix 11a) Participant questionnaire

University of South Australia

OrbIT Gaming System and Stroke

Bachelor of Physiotherapy - Honours Project

Participant

This survey was completed by: patient / staff member / family member on behalf of the patient

Thank you for participating in our study looking at the feasibility and utility of using the OrbIT Gaming System to improve motor and sensory function in people recovering from stroke. Please fill in this survey to provide further information for our research. This questionnaire should only take 5 minutes to fill in. Thank you in advance.

Please circle the following in accordance with your belief of the statement.

1. The OrbIT Gaming System was easy to use

Strongly agree Agree Neutral Disagree Strongly disagree

2. The OrbIT Gaming System was enjoyable to use

Strongly agree Agree Neutral Disagree Strongly disagree

3. The OrbIT Gaming System was beneficial for you

Strongly agree Agree Neutral Disagree Strongly disagree

Please answer the following questions:

4. Were you motivated to try computer gaming during your stroke rehabilitation?

---

5. Did you have a preferred time of the day that you liked to use the OrbIT Gaming System? Did this differ between weekday and weekend use? (E.g. morning, middle of the day, evening, other times? Please provide details)

P.T.O

6. Do you have any other comments regarding computer gaming and stroke rehabilitation?

   ---

7. What score out of 10 would you rate the OrbIT Gaming System? (10 = brilliant, 1 = very poor)

   1 2 3 4 5 6 7 8 9 10

Appendix 11b) Staff questionnaire

University of South Australia

OrbIT Gaming System and Stroke

Bachelor of Physiotherapy Honours Project

Staff

Thank you for participating in our study looking at the feasibility and utility of using the OrbIT Gaming System to improve motor and sensory function in people recovering from stroke. Please fill in this survey to provide further information for our research. This questionnaire should only take 5 minutes to fill in. Thank you in advance.

Please circle the following in accordance with your belief of the statement.

1. The OrbIT Gaming System was easy to set up for people with stroke

Strongly agree Agree Neutral Disagree Strongly disagree

2. The OrbIT Gaming System was easy for people with stroke to use

Strongly agree Agree Neutral Disagree Strongly disagree

3. I could see the benefits the OrbIT Gaming System provided for people with stroke

Strongly agree Agree Neutral Disagree Strongly disagree

Please answer the following questions:

4. Were you able to distinguish a certain sub-population that benefited from the OrbIT Gaming System? (e.g. type of stroke, gender, age)

---

5. Do you think this system was feasible? If not, how could it be more feasible?

---

6. Were there any overall problems/issues you identified with the OrbIT Gaming System?

P.T.O

7. Is there anything you would you recommend for the future regarding computer gaming and stroke rehabilitation?

   ---

8. Do you have any other comments regarding computer gaming and stroke rehabilitation?

   ---

9. What score out of 10 would you rate the OrbIT Gaming System? (10 = brilliant, 1 = very poor)

   1 2 3 4 5 6 7 8 9 10

Appendix 12
Detailed explanation of application for physical outcome measures

All participants were in a comfortable seated position for the completion of all primary outcome measures. Pre- and post-assessment was conducted in the same room, with the same equipment.

Semmes Weinstein Monofilaments *(pressure sensitivity -light touch)*

Assessment was conducted in accordance with an established protocol in the operation manual developed by Stoelting Co. (2001). The participants placed their forearms on the surface of the table in a supine position. The palmar surface of the index finger and thumb was used to evaluate the median nerve function. Each filament was applied to the first pad of the index finger or thumb, with three attempts on each site being randomly applied across the four sites (both hands were tested). The filament was pressed against the skin at a 90degree angle until the filament bows. It was then held in place for 1.5 seconds and then removed. The participant had to respond firstly if they felt the stimulus, and where they felt it. The smallest filament (2.83) was applied first, and if the participant was able to detect it, then there was no procession to the other filaments. If they were unable to detect it, the next largest filament was applied (3.61), and this was continued until they were successfully able to detect all three attempts (100%) was successfully. The participant had a blindfold on, or had their eyes closed during the assessment.

RASP *(proprioception)*

Test was conducted in accordance with the standardised protocol by Winward, Halligan and Wade (2002). The participants' non-impaired upper limb and hand were rested comfortably on a table, and held in a neutral forearm and wrist position. The lateral borders of the thumb were grasped and 'up or down' movements were performed at the metacarpalphalangeal joint of the thumb. Initial demonstration with eyes open was completed first. Eyes were then closed and 10 small amplitude smooth movements in a random sequence of 'up or down' were completed. Movements were over a distance of approximately 2cm. Participants

were scored out of 10 for correct perception of movement and identifying direction. This process was then conducted on the impaired hand.

Klingels Protocol *(stereognosis)*

Assessment was conducted in accordance to the standardised protocol in a study conducted by Klingels and colleagues (Klingels et al. 2010) which evaluated the ability to perceive and recognise an object in the absence of visual information. This involved the tactile identification of twelve familiar objects. Of the twelve objects, six were matched in pairs with objects being of similar size and shape (paperclip/safety pin, pen/pencil, coin/button) and the other 3 objects clearly differing from each other (marble, comb, peg, key, tennis ball, spoon). For each hand, six objects were randomly selected, of which three were from the paired objects, and three from the non-similar objects. In this assessment, a box with a cloth was used to prevent visual interference, allowing participants to place their hand inside the box, and also keep their eyes open (Figure 11.1). The non-impaired hand was placed inside the box, and from a cut out hole on the opposite side of the box, the first object was handed to the participant. They then had to respond in what they thought the object was this. This was recorded, and the second object was handed to the participant and so on. Once the participant had identified all 6 objects, they swapped hands and the more impaired hand was placed inside the box. The same process was conducted.

The number of objects correctly identified was recorded for both hands, with the total score ranging from 0-6.

Figure 11.1 The box used during stereognosis assessment

Grating Orientation Domes *(tactile spatial acuity)*

The participant's non-impaired forearm was placed on the table in a supine position. The index finger lay on the table and was immbolised by the assessor. With eyes open, the largest groove width was placed on the palmar surface of the subject's index finger to allow subject to identify horizontal (down) and longitudinal (across) orientations. Participant then wore a blindfold, or closed their eyes, and the largest groove width dome was manually applied perpendicular to the skin for 1-2 seconds. The dome was aligned randomly in one of two directions (down or across) and the participant had to identify the orientation. This was conducted 10 times with equal number of horizontal and longitudinal applications, with the answer of each trial recorded. The next smallest groove width was then applied and so on until the participant responded correctly to 7 or less. Two smaller groove widths were then applied to confirm the tactile threshold. This process was then conducted on the impaired hand.

Wolf Motor Function Test *(functional ability of the upper limb)*

Assessment was conducted in accordance with the standardised protocol in the WMFT manual by Taub et al. (2011). The instructions provided by the manual were read to the participant, with two demonstration of each activity was performed. The participant was instructed that they had to 120 seconds to complete each of the 17 tasks, however they were told to perform the task as quickly as they could. Timing was carried out using a stopwatch and the starting cue for each task was 'ready, set, go'. Only the more impaired upper limb was tested, as it was assumed that the non-impaired upper limb could be compared to as normal.

Appendix 13
Data collection sheet

The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.

Date of assessment: _____ Location: ___
_____

Assessors name: _____

Assessment type: **First (pre)** **Second (post)**

Participant's study number: _____ Gender: ____
_____

Participant's initials: _____

Participant's date of birth: _____

Stroke type: _____

Side of hand/arm affected: _____

Project contact:

If you have any questions, queries or problems about anything to do with the study, please contact Shannon Watchman (mobile: 0401 451 739).

Sensory Assessment Test Results: ***(5 piece kit)***

1. Test for tactile detection (Semmes-Weinstein monofilaments) (Blind fold required)

(Note: begin with the 2.83 filament – if they can feel this, then you don't need to proceed to the other colours. If they can't, choose the next largest filament and repeat the process).

Each filament is applied to the **first pad** of the index finger or thumb. The order can be random. Tick (√) the circle if they detect the colour at that site, cross (X) if they fail to detect – three attempts on each site but randomly applied across the four sites. Highest detection level is 100% correct.

Detection	(R) Finger 1	(R) Thumb	(L) Finger 1	(L) Thumb
2.83	O O O	O O O	O O O	O O O
3.61	O O O	O O O	O O O	O O O
4.31	O O O	O O O	O O O	O O O
4.56	O O O	O O O	O O O	O O O
6.65	O O O	O O O	O O O	O O O

Highest detection level (R): _____ (finger) _____ (thumb)

Highest detection level (L): _____ (finger) _____ (thumb)

Comments (if any):

_____
_____
_____
_____

2. Test of proprioception (by moving the distal thumb either up or down) (Blind fold required)

Non-hemiparetic hand: Total number correct _____ /10

Hemiparetic hand: Total number correct _____ /10

Comments (if any):

_____
_____
_____
_____

3. Test of stereognosis (Klingels Protocol) <u>(Use of box/Blind fold required)</u>

When choosing objects, ensure that 3 are chosen from the 'similar pairs' group of 6 and that 3 are chosen from the 'non-similar' group of 6 objects. Randomly choose the objects so that there is some overlap between the non-dominant and dominant hand, but that some new objects are also used.

Object chosen by therapist (e.g.: pen)	***Non-Hemi.: Object identified correctly?*** (Y or N)	***Object chosen by therapist*** (e.g.: pen)	***Hemi.: Object identified correctly?*** (Y or N)
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	

Non-hemiparetic hand: Total number correct _____ /6

Hemiparetic hand: Total number correct _____ /6

Comments (if any):

_____
_____
_____
_____

4. Grating Orientation Domes **(Blind fold required)**

With eyes open, place largest groove width on the palmar surface of the subject's index finger and allow subject to identify horizontal (down) and longitudinal (across) orientations.

With eyes closed, starting with the largest groove width, conduct 10 trials with equal number of horizontal and longitudinal applications (in random order). Subject must respond to more than 7 correct responses to continue to the next groove. Once the subject responds to 7 or less correct responses, this will be their tactile threshold. Two smaller groove widths are then applied to confirm the tactile threshold.

Groove width	***Non-Hemi: No. of correct guesses (out of 10***)	***Groove width responded to 7/10 times correctly (place X)***	***Hemi: No. of correct guesses (out of 10***)	***Groove width responded to 7/10 times correctly (place X)***
1. 3.5	/10		/10	
2. 3.0	/10		/10	
3. 2.5	/10		/10	
4. 2.0	/10		/10	
5. 1.5	/10		/10	
6. 1.2	/10		/10	
7. 1.0	/10		/10	
8. 0.75	/10		/10	
9. 0.50	/10		/10	
10. 0.25	/10		/10	

Comments (if any):

5. The Wolf Motor Function Test (WMFT) (NO blind fold)

The maximum time allowed for any task below is **120 seconds** (2 mins). If they cannot complete the task in that time (they run out of time), score them a value of '120 secs'. If a adult cannot complete the task at all, assign them the value of '120 secs', but write a note below that they couldn't attempt or complete the task at all.

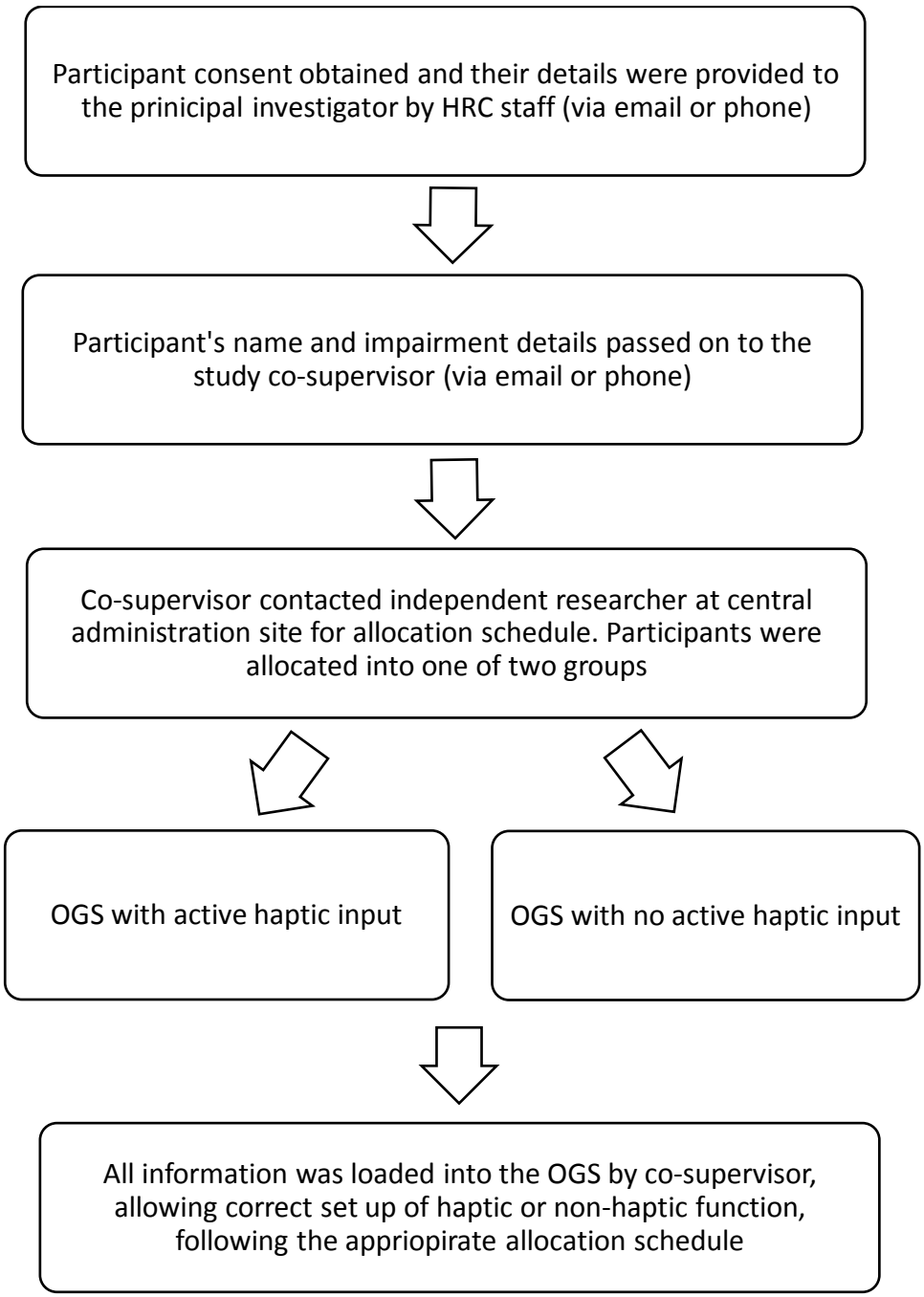
Task	***Hemi hand***	***Please tick as appropriate***		***Functional Ability***
		Attempted	***Not attempted***	
Forearm to table (side)	sec			
Forearm to box (side)	sec			
Extend elbow (side)	sec			
Extend elbow (weight)	sec			
Hand to table (front)	sec			
Hand to box (front)	sec			
Weight to box	lbs			
Reach and retrieve	sec			
Lift can	sec			
Lift pencil	sec			
Lift paper clip	sec			
Stack checkers	sec			
Flip cards	sec			
Grip strength	Kgs			
Turn key in lock	sec			
Fold towel	sec			
Lift basket	sec			

Comments (if any):

Grating Orientation Dome Random Sequence Allocation

Hemi / non hemi L / R	Hemi / non hemi L / R
Random schedules	Random schedules
1. 1 2 2 1 2 1 1 2 1 2	1. 1 2 2 1 2 1 1 2 1 2
2. 1 1 2 1 2 2 1 2 2 1	2. 1 1 2 1 2 2 1 2 2 1
3. 2 1 2 2 1 2 1 1 2 1	3. 2 1 2 2 1 2 1 1 2 1
4. 2 1 1 2 1 1 2 2 2 1	4. 2 1 1 2 1 1 2 2 2 1
5. 1 2 1 1 2 1 2 2 1 2	5. 1 2 1 1 2 1 2 2 1 2
6. 2 2 2 1 1 2 1 1 2 1	6. 2 2 2 1 1 2 1 1 2 1
7. 2 1 2 1 2 2 1 2 1 1	7. 2 1 2 1 2 2 1 2 1 1
8. 1 2 1 2 2 1 2 1 1 2	8. 1 2 1 2 2 1 2 1 1 2
9. 1 2 2 2 1 2 1 1 2 1	9. 1 2 2 2 1 2 1 1 2 1
10. 2 2 1 2 2 1 1 1 2 1	10. 2 2 1 2 2 1 1 1 2 1
*horizontal = 1 vertical = 2	*horizontal = 1 vertical = 2

Appendix 14
Flow diagram of allocation procedure



Appendix 15
Standardised equipment and system requirements for the OrbIT Gaming System

Standardisation of pre- and post-assessment

The setting for pre- and post-assessment was standardised for the intervention (Figure 16.1).

Figure 16.1 Standardised set up of pre- and post-assessment room at HRC

<u>Equipment dimensions</u>

Table: 152cm x 60 cm x 74 cm

Participant chair: 51cm x 57cm x 80cm Armrest on chair: 41cm x 4cm x 19cm

Note: participants who mobilised in a wheelchair, stayed in their wheelchair for the pre- and post-assessment as required

Standardisation of the OGS set up in communal dining room

Two available OGS were used in the intervention (Figure 16.2). No more than two participants enrolled in the intervention at a single time however, if more participants had been included, the OGS could have been set up for multiple users. If one participant was enrolled, they would use the OGS set up on the left side of the Figure 16.2, as the table adjusted in height, allowing researchers to accommodate use of a wheelchair. The height was set appropriately during the standardised protocol and demonstration conducted by the co-supervisor, before the trial had began.

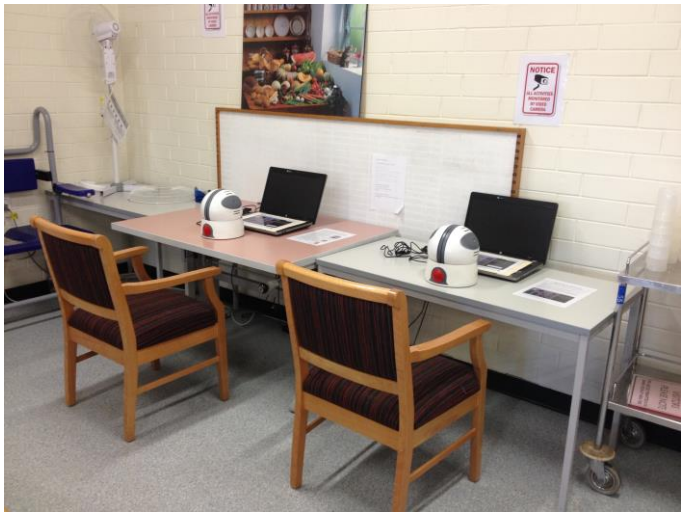


Figure 16.2 Standardised set up of two OGS set up side-by-side in the dining room at HRC

Equipment dimensions

OrbIT controller: 21cm in diameter, 23cm in height and 66cm in circumference around the base

HP Pavilion dv7-6107tx Entertainment Notebook: 41.6cm x 27.5cm x 3.6 cm

Table on left-hand side of Figure 16.2: 1200cm x 90cm x 73cm

Table on right-hand side Figure 16.2: 1200cm x 60cm x 72cm

Participant chair: 35cm x 48.5cm x 90cm Armrest on chair: 46.5cm x 4.5cm x 21.5cm

System use

The OGS required the participant to sit at a desk, either on a chair or in their wheelchair, as shown in Figure 16.1. The participant turned on the laptop by pressing the 'ON' button situated in the top left hand corner of the keyboard. This automatically started the gaming system. Typically, the system would be already turned on for the participant. Both hands were placed on the oval pads of the controller (at approximately th 10 and 2 o'clock positions). Hand position allowed the participant to move the controller in all four directions to play the computer games: forwards, backwards, left and right. To log in using the accessible controller they selected their name on the screen with the controller and pushing the big red button on the front of the controller to confirm the selection. A guest login was also made available, allowing family members and friends to become involved. Explicit instructions were given to the participant that only they were allowed to log in to their name, and no one else.

The System provided 15 2-D and 3-D games to choose from. However, initially only five games were available to play, with the remaining ten games 'locked'. The system required participants to play for certain time periods to unlock new games (e.g. 30 minutes, 1 hour). During use of the system, both hands had to maintain contact with the oval pads on the controller. Failure to do so automatically stopped the game until both hands were back on the controller. An infrared proximity sensor mounted beneath each oval pad monitored hand position. Functional movements required during game play were dependent on the participant's physical abilities, with possible movements of radial and ulnar deviation of the wrist, supination and pronation of the forearm, and elbow and shoulder flexion and extension. Trunk use was discouraged.

To turn off the system, the participant used the controller to select the 'off button' on the screen and pushed the red button.

Figure 16.3 A trial participant using the OrbIT Gaming System appropriately at HRC

Appendix 16
Standardised protocol and demonstration for the OrbIT Gaming System

Study Protocol Document:

The feasibility and utility of using an accessible controller to improve motor and sensory function in people recovering from stroke through computer gaming: A randomised controlled pilot study.

Hi, my name is David and I work at Flinders University. Thank you for agreeing to be a part of our computer gaming trial – we really appreciate your involvement.

Because this is a proper scientific study, I'm going to give you a demonstration and overview of the system and read the following instructions to you. This way every person gets the same introduction from me. If you have any questions, please ask me. I want you to have fun and enjoy using it over the next 3 weeks.

Firstly, this is your new computer gaming system – it consists of a computer (touch the laptop) and a specially-designed controller (touch the controller) that we call 'Orby'.

The system is very easy to use – let me show you. To start it, all you do is open the laptop and press the 'on' button. This turns the computer on and the gaming system automatically starts, as you can see (games system will load up in the background).

To use the system and play the games, rather than use a small and fiddly X-Box controller, all you need to do is use this new controller we've made for you. It's very easy to use – you place your hands here on the oval pads to use it (demonstrate by putting hands on the oval pads), and move the controller in one of 4 directions to play any of the games: forward, backward, left or right.

As you can see, the gaming system has just loaded for us (point to laptop screen). The first thing that you need to do, and you need to do this **every time**, is log in. This is where you choose **your name**, shown here on the screen. To log in, just press this big red button on the front of the controller (point to the button).

If your friends or family want to play one of the games, that is absolutely fine and we encourage it. However, you need to ask them to **always** log in using the 'guest' name (point to the guest name on the screen).

So, if you're playing the system, always log in with **your name**, but if someone else plays the system, they need to use the '**guest' log in**. Please don't let anyone log in with your name. For now, I'm going to log in using this 'demo' name so I can show you how to use the system (move the controller to the 'demo' log in).

Do you want to press the big red button to log me in? (Adult presses button).

Ok, as you can see we're now logged in. Look at all these games – every cube or box that you can see represents a game; there are 15 of them in all. Let me demonstrate how some of them work and then you can explore the rest – how does

that sound? Are you ready to see what we've made for you?

The first game I would like to show you is called 'Alex Adventure'. To choose this game I need to move across until the 'Alex Adventure' box is highlighted – you can see the box is now spinning around and has a glow around it. This means it's been selected.

At the same time, you can see over here on the right hand side, on what we call the smartphone, that a video is showing you a preview of the game (point to the smartphone and the video). So every time you move through the games menu, you can look on the smartphone for a preview, to see what the game looks like.

Once you play a game, the bottom part of the smartphone (point to the bottom part) will show you the high scores from playing that particular game, and the name next to it is the person who has that high score. Hopefully when the trial finishes you have lots and lots of high scores here for all the games!

Let's now play the game. Do you want to press the red button for me? Thank you.

With all our games the idea is that you don't need a button to play any of them – all you need to do is move the controller forward, backward, left or right to move your character in the game. So as long as you keep your hands on the controller, you're ready to play.

With this particular game, there is an introductory story that you can read to understand the background to the game. I'll let you read through the game story at another time, but I can show you how to play this game.

The aim of the game is to collect as many carrots as you can, while jumping over or ducking under obstacles. To jump, because there is no button, all you do is move forward or 'up' – and you can see that Alex jumps (demonstrate this). To move right, you move the controller right, to move left, you move the controller left – what do you think you do to duck under objects? (See if adult knows they need to move the controller down to duck, but don't let them wait more than a few seconds if they can't answer).

Let me show you the first level (demonstrate first level). As you can see Alex, celebrates by dancing a jig at the end if you win the level.

Let me show you what happens if you haven't collected any carrots, and you run into an enemy (purposefully run into an enemy to show the child what happens when the game ends).

As you can see, when the game ends, the next screen you see is the log in screen again. This will happen every time, so you always have to select your name each time so the computer knows who is playing the games.

Now, the next game I want to show you is 'Driving Maniac'. This one is obviously a car racing game. Do you want to press the red button for me to start the game? Thank you.

As you can see, this game starts straight away. The aim of this game is to drive as far as you can while avoiding all the other cars and road works on the road. Every now and then you'll see objects on the road, like fuel cans and extra lives, which you should collect by running over them. Watch what happens if I take my hands off the controller (take hands off controller – wait for 3 seconds and see that the system stops and provides a pop-up telling me to put my hands back on).

Do you see that? The system knows I've taken my hands off the controller, and it's stopped the game and is telling me to put my hands back on. This will happen for every game, so you need to make sure that you always have both hands on the controller or else the games will keep stopping, which can get annoying.

Look what happens when I put my hands back on the controller – see the arrows are going away and the system says 'thank you' as it knows my hands are in place and that I'm ready to play (demonstrate this feature of the system). The system also counts me back into the game, so you have time to get ready before the game restarts.

If you ever want to pause the game you are playing, all you have to do is push the red button (demonstrate this) – and this menu pops up. To restart, just select the 'resume' function (point to this) or to exit the game completely, select exit (point to this). You can also adjust the volume of the system from this menu as well. Or, as we've just seen, you can also pause the game by taking your hands off the controller.

Let me show you a little bit more of this game (demonstrate 'Driving Maniac' for a little longer – deliberately crash the car to end the game).

Here we are back at the log in screen, and I'll select my 'demo' name again.

This time, let me show you a few other things. If you select this yellow icon here (point to the top left yellow icon) you can shut down or turn off the system and also change a few things (select the yellow icon). Notice that the smartphone will tell you what each icon does each time you move from icon to icon, so if you want to know what anything does, just look at the smartphone for more information (point to the information).

You can change the background colour for the system here (demonstrate this) and also the system volume, in case things get too noisy and you want to turn the volume down (demonstrate this).

If you want to find out who made the gaming system for you, then select this icon here (point to the relevant icon), and you can see all the names of the people who helped design, build, supervise and make the games and the controller, as well as who funded the project.

Lastly, when you've finished playing with the system for the day, or if you need to shut the system down, you just need to select this icon here (point to the shutdown icon). This will automatically log you out and turn off the whole system. Then all you have to do is close the computer lid, and the system is packed away.

Let me get out of this menu by selecting the blue 'back' arrow, and here we are back at the main games menu. There are two more games I'd like to quickly show you, and then it's your turn!

The next game to show you is 'Squaretris' (point to the 'Squaretris' game cube and select it) – this is our newest and latest game.

'Squaretris', as you can probably guess, is a twist on 'Tetris' – so if you're a Tetris fan I think you'll like this game as well. Something that I want to highlight is that when you select 'Squaretris' (select the 'Squaretris cube') you'll see this 'Unity' logo pop up on the screen – this is part of the game and you don't need to worry about it.

(Play 'Squaretris' and demonstrate what happens when the board flips, etc. Highlight how the game then returns to the games menu).

Ok, the last game to show you is called 'Space Stuntz'. This is a 3D flying spaceship game (move down to the 'Space Stuntz' cube) – do you want to push the button for me to select it? The aim of this game is to fly as far as you can in space and to fly through as many rings as possible. If you miss a ring, you lose a point, and if you miss 10 rings the game is over. You can read about how to play the game from the start menu here.

You also have to look after your spaceship and the protective shield around it, and avoid asteroids and ice storms that damage your craft. Here's where the game instructions are (move controller left and right) and now let's start the game (press the red button).

(Play the game, but deliberately miss rings or fly into objects).

So – you have 15 games here to play and explore, and you use Orby to control all the games and to move within the menu. Now I think it's your turn. Let me log in for the last time and go into the settings so I can start your trial (log in, select the settings icon, then select the 'Start Trial' button. This logs me out and takes away the 'demo' profile).

However, there is one more thing to tell you. When you first start the system you can only play 5 of the games – the rest are locked. This means you can't play them right away.

However, unlocking the games is easy! All you have to do to unlock a game is to play the other games for at least 30 minutes – and every 30 minutes a new game is unlocked. Does that make sense (pause to see if there are any questions? The system keeps track of how long you play for so knows when to unlock the games for you – this is automatic. I'll show you how this works when you log in.

Here you go – let me move out of the way, and it's your turn. Make yourself comfortable and it's time to select your name and to log in as you. Are you ready?

Before I hand control over, just a reminder that you need to ensure that you and only you log into your name when you play the games, and that any friends and family use the guest log in. Also, because this is a scientific study, please don't discuss the specifics of your trial with other families. Do you have any final questions?

(Let them get set up and in position, and watch them log in and get started. Explain how the 'unlocking' of games works and how it looks in the main menu, and how the system keeps track of when a particular game will be unlocked. Stay for a little while (around 5-10 mins) to see how they go and to answer any questions they might have).

And one final reminder – your 3-week trial starts today.

Today's date is: _____

However, if you have any questions or if something goes wrong, feel free to contact me. My details are here (show them the 'Gaming System Instructions Sheet') and I'll also be leaving this System Overview Sheet with you as well (point to this). My number is also on the bottom of 'Orby' the controller.

Appendix 17
Reliability and validity of outcome measures

The following table outlines the reliability and validity of physical and feasibility outcome measures in the stroke population. The OrbIT Gaming System was not included, as it has not yet been used in the stroke population prior to this pilot study.

Construct	O.M	Reliability	Validity	Clinically Acceptable
Motor Function	**WMFT**	Excellent test-retest and inter-rater for functional ability r= 0.95; r= 0.0.88 (Morris et al. 2001)	Validated against Upper Extremity Fugl-Meyer: r = 0.86–0.89 (Whitall et al. 2006)	Clinically responsive in acute stroke population (Edwards et al. 2012)
Sensory Function	**SWM**	NSSL Inter-rater ICC = 0.965 in CP population (Novak et al., cited in Auld et al. 2011)	NSSL Sensitivity 100%, specificity 77.7% in diabetic patients (Kumer et al., cited in Auld et al. 2011). Strong correlation with neurological examination in diabetic patients PCC = 0.69-0.83 (Valk et al., cited in Auld et al. 2011)	Frequent clinical use - some evidence with hand therapy (Kitsos et al. 2011).

Sensory Function	**Proprioception (RASP)**	Excellent inter-rater reliability PCC 0.92 Good test-retest PCC 0.50 (direction) (Winward, Halligan & Wade 2002)	Acceptable face and content validity Discriminated significantly between people with and without brain damage ($p<0.001$) Concurrent validity with Motricity Index (SCC r=0.31 and 0.32, both significant) and with Barthel ADL Index (r=0.35 and r=0.41) (Winward, Halligan & Wade 2002)	Acceptable clinically and for research participants (Hillier, Immink & Thewlis 2015)
	Stereognosis (Klingels protocol)	NSSL Inter-rater ICC = 0.78 Test re-test ICC = 0.86 in CP population (Klingels et al. 2010)	NSSL NR in CP population	NSSL Systematically used in UL intervention studies (Auld et al. 2011)
	GOT	NSSL Good test-retest (r = 0.65, $p<0.1$, SD = 0.43) (Bruns et al. 2014) Inter-rater acceptable with no difference found between 6	NSSL Validated against: Grooved Pegboard Test r = 0.66 (Tremblay et al. 2003) Good to excellent correlation with Landolt Ring Acuity Chart	NSSL Adequate for examining spatial sensitivity in a clinical and research setting (Craig 1999)

Sensory Function		examiners (Friedman repeated measures analysis on ranks; p = 0.813) in healthy populations (Bleyenheuft & Thonnard 2007)	intercorrelation 0.78 in healthy populations (Bruns et al. 2014)	
Feasibility & Utility	**Purpose-designed questionnaires**	N/A	Face validated by two experienced researchers	Used frequently, e.g. Stroke-Specific Quality of Life Scale (Williams et al. 1999)

Abbreviation: O.M= Outcome measure, NSSL = Non-Stroke Specific Literature, WMFT= Wolf Motor Function Test, SWM= Semmes Weinstein Monofilaments, RASP= Rivermead Assessment of Somatosensory Performance, GOT= Grating Orientation Task, PCC = Pearson Correlation Coefficient, ICC = Intraclass correlation, CP = cerebral palsy, N/A = not, available

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Appendix 18
Raw data of participant demographics

Participant number	Age (years)	Gender	Upper limb impaired	Type of stroke/location/other condition
1	70.75	F	R	MCA
2	66.25	M	R	Cerebral
3	82.75	F	L	ACA infarct
4	64.58	M	L	MCA infarct
5	68	M	L	Prefrontal cortex infarct
6	45.92	M	R	Brainstem with extension of 4th ventricle and dual AV fistula
7	68.92	F	L	Post recision of basal ganglia neuroma
8	56.25	M	L	Lacunar infarct
9	61.5	M	L	CIDP
10	70.83	M	L	ACA, PCA and MCA infarcts

Abbreviations: M = male, F = female, L = left, R = right, MCA = middle cerebral artery, ACA = anterior cerebral artery, CIDP = chronic inflammatory demyelinating polyneuropathy, PCA = posterior cerebral artery

Appendix 19
Raw data of participant questionnaires

Participant No.	Questions						
	Q1	Q2	Q3	Q4	Q5	Q6	Q7
1	4	4	4	While I was there, I did. I didn't play it as much as I should've. I liked the dragonfly game.	Afternoons. During weekdays.	I enjoyed playing it.	8
2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	4	4	4	Something completely different and enjoyable.	Afternoon and weekends when no therapy available. Mornings full of therapy.	A games room available to patients especially evenings.	7
4	2	2	4	No.	Anytime.	NC	3
5	4	3	3	Moderately.	No particular time.	NC	7
6	5	2	3	No.	No.	No.	5
7	5	5	4	Yes.	Middle of the day mostly. Not here on weekends.	Believe it is helpful.	8

8	4	4	4	Yes.	On weekends when occupational therapy and physio sessions were not on.	Found I would have liked one or two more challenging games.	8
9	4	3	4	Not computer gaming per say. Was motivated to do this. Wanted to challenge myself and develop strength and coordination in my upper limb.	Dependent on how therapy sessions were planned. Normally on weekends in the afternoon because it would fit in structurally with other factors in the ward.	Personally found it frustrating as not a gaming person. Frustrating in understanding the concept of computer games and knowing what to expect with movements.	8
10	1	1	3	Not really.	Not really.	Structure of ball to keep hands on. Need to hit red button to activate and kept changing.	1

Abbreviations: N/A= not available, NC= not completed

Appendix 20
Raw data of staff questionnaires

Staff No.	Questions								
	Q1	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**
1	4	4	5	Younger male patients who had some experience with video games in the past	The uptake wasn't as much as I'd anticipated. The system was certainly feasible for the younger patients and those who could get themselves to the controller location	• Older population – seemed ambivalent about gaming systems • Location of Orbit was tucked out of sight, this could've been better located to ↑ interest	• Console and laptop system were user friendly and easy to set up • May need to set up closer to patient rooms • Try to establish with younger population	A supervised system in a gym environment (similar to the Wii with a large screen) may boost participation and competition/comradery between inpatients	8
2	5	3	5	Younger clients and those with >3/5 motor power proximally in the UL	Semi feasible. The set up could be enhanced eg. A trough to support the hemi limb and a more secure fixation for the hand	• Some of the games were quite complex/required high cognition levels – even for staff	• Definitely has a role. Maybe use of a large screen and ↑portability of the gaming tool	No	8

3	4	2	4	Younger people who had previous exposure to gaming consoles	There were issues regarding the strap for holding weaker hands in place, as possible improvement may be a glove that is fitted to the control orb	• Hand control – keeping it in the right place. • Position of the button – people with weak UL, the orb moved as soon as they tried to press the button with the stronger hand	I think if you were able to repeat this study in 10 years time you would get more participants as the concept would be more familiar	NC	6
4	3	4	4	• Better for younger generation <65 as they are more computer literate • Gender neutral • Difficult for R) MCA – more cognitive issues	Yes, easily accessible and when understood easy to follow	-	Good way to improve UL function, engages pt's to independently rehab	NC	7

Abbreviations: UL = upper limb, R) = right, MCA = middle cerebral artery, pt = patient, NC= not completed

Appendix 21
Raw data of the OrbIT Gaming System usage

Appropriate values calculated for whiskers and boxplot for total time played over three-week intervention for haptic and non-haptic groups

Group	Box plot and whiskers					Outliers		
	Min	**Q1**	**Median**	**Q3**	**Max**	**IQR**	**Lower limit**	**Upper limit**
Haptic	19.54	23.41	27.83	76.70	103.65	53.29	-56.53	156.64
Non-haptic	83.68	99.45	121.22	213.40	230.33	113.96	-71.49	384.33

Abbreviations: Min= minimum, Q1= lower quartile, Q3= upper quartile, Max= maximum, IQR= inter-quartile range

Appropriate values calculated for whiskers and boxplot for total amount of days played over three-week intervention for haptic and non-haptic groups

Group	Box plot and whiskers					Outliers		
	Min	**Q1**	**Median**	**Q3**	**Max**	**IQR**	**Lower limit**	**Upper limit**
Haptic	3	3.5	4	5	6	1.5	1.25	7.25
Non-haptic	4	6	8	10	11	4	0	16

Abbreviations: Min= minimum, Q1= lower quartile, Q3= upper quartile, Max= maximum, IQR= inter-quartile range

Appendix 22
Raw data of physical outcome measures involving the more impaired upper limb

All raw data is of the more impaired limb only. The following abbreviations were used in all tables: UL= upper limb, R)= right, L)= left, Pre-Ax= pre-assessment, Post-Ax= post-assessment, N/A= not available

Semmes Weinstein Monofilament First Finger

Subject	UL affected	Group	Pre-Ax	Post-Ax	Change in score
1	R	1	3.61	3.61	0
2	R	1	3.61	N/A	N/A
3	L	1	4.31	3.61	-0.70
4	L	2	6.65	4.31	-2.34
5	L	2	6.65	6.65	0
6	R	1	3.61	3.61	0
7	L	2	4.31	4.31	0
8	L	2	4.31	3.61	-0.70
9	L	2	4.56	4.31	-0.25
10	L	1	4.56	4.31	-0.25

Semmes Weinstein Monofilament Thumb

Subject	UL affected	Group	Pre-Ax	Post-Ax	Change in score
1	R	1	4.56	4.31	-0.25
2	R	1	3.61	N/A	N/A
3	L	1	4.31	3.61	-0.70
4	L	2	4.31	4.31	0
5	L	2	4.56	4.31	-0.25
6	R	1	3.61	3.61	0
7	L	2	3.61	3.61	0
8	L	2	4.31	3.61	-0.70
9	L	2	6.65	4.31	-2.34
10	L	1	4.56	4.31	-0.25

Proprioception of the Thumb					
Subject	**UL affected**	**Group**	**Pre-Ax**	**Post-Ax**	**Change in score**
1	R	1	8	10	2
2	R	1	10	N/A	N/A
3	L	1	10	10	0
4	L	2	7	10	3
5	L	2	9	10	1
6	R	1	10	5	-5
7	L	2	6	9	3
8	L	2	10	10	0
9	L	2	4	8	4
10	L	1	9	10	1

Stereognosis					
Subject	**UL affected**	**Group**	**Pre-Ax**	**Post-Ax**	**Change in score**
1	R	1	4	4	0
2	R	1	5	N/A	N/A
3	L	1	6	5	-1
4	L	2	0	2	2
5	L	2	2	6	4
6	R	1	5	6	1
7	L	2	5	6	1
8	L	2	5	6	1
9	L	2	1	2	1
10	L	1	2	1	-1

Grating Orientation Task					
Subject	**UL affected**	**Group**	**Pre-Ax**	**Post-Ax**	**Change in score**
1	R	1	3.5	3.5	0
2	R	1	2.5	N/A	N/A
3	L	1	2.5	2.5	0
4	L	2	3.5	3.5	0
5	L	2	3.5	3.5	0
6	R	1	3.5	3.5	0
7	L	2	3.5	3.5	0
8	L	2	3.5	3.5	0
9	L	2	3.5	3.5	0
10	L	1	3.5	2.5	-1.0

Wolf Motor Function Test					
Subject	**UL affected**	**Group**	**Pre-Ax**	**Post-Ax**	**Change in score**
1	R	1	120.00	120.00	0
2	R	1	7.81	N/A	N/A
3	L	1	5.06	2.1	-2.96
4	L	2	8.28	3.35	-4.93
5	L	2	6.56	6.97	0.41
6	R	1	2.84	2.22	-0.62
7	L	2	8.56	6.03	-2.53
8	L	2	3.72	1.91	-1.81
9	L	2	7.50	4.90	-2.60
10	L	1	120.00	38.03	-81.97

Appendix 23
Haptic and non-haptic comparison

Appendix 23a) Haptic and non-haptic comparison analysis

This table outlines the haptic and non-haptic sum of change in score for each physical outcome measure, with the p value being stated.

Outcome measure	Mean	SD	Range	P value
SWM first finger (g)	-0.47	0.76	-2.34-0.00	0.606
SWM thumb (g)	-0.50	0.74	-2.34-0.00	0.899
Proprioception (S/10)	1.00	2.65	-5.00-4.00	0.137
Stereognosis (S/6)	0.89	1.54	-1.00-4.00	0.029*****
GOT (mm)	-0.11	0.33	-1.00-0.00	0.264
WMFT (secs)	-10.78	26.75	-81.97-0.41	0.806

Abbreviations: SWM= Semmes Weinstein Monofilament, GOT = Grating Orientation Task, WMFT= Wolf Motor Function Test, SD= standard deviation, g= grams, S/6= score out of 6, S/10= score out of 10, mm= millimeters, secs= seconds

Key: *****= signifies statistical difference

Appendix 23b) Raw data for between group comparison

This table represents haptic and non-haptic scores used in the analysis for each physical outcome measure, with the p-value once again being stated.

Outcome measure	Pre-assessment						Post-assessment						P value
	Haptic group			Non-haptic group			Haptic group			Non-haptic group			
	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	
SWM first finger (g)	3.94	0.46	3.61-4.56	5.30	1.24	4.31-6.65	3.79	0.35	3.61-4.31	4.64	1.17	3.61-6.65	0.606
SWM thumb (g)	4.13	0.49	3.61-4.56	4.69	1.15	3.61-6.65	3.96	0.40	3.61-4.31	4.03	0.38	3.61-4.31	0.899
Proprioception (S/10)	9.40	0.89	8-10	7.20	2.39	4-10	8.75	2.50	5-10	9.40	0.89	8-10	0.137
Stereognosis (S/6)	4.40	1.52	2-6	2.60	2.30	0-5	4.00	2.16	1-6	4.40	2.19	2-6	0.029*
GOT (mm)	3.10	0.55	2.5-3.5	3.5	0	All 3.5	3.00	0.58	2.5-3.5	3.5	0	All 3.5	0.264
WMFT (secs)	51.14	62.88	2.84-120.00	6.92	1.95	3.72-8.56	40.59	55.58	2.10-120.00	4.63	2.03	1.91-6.97	0.806

Abbreviations: SWM= Semmes Weinstein Monofilament, GOT = Grating Orientation Task, WMFT= Wolf Motor Function Test, SD= standard deviation, g= grams, S/6= score out of 6, S/10= score out of 10, mm= millimeters, secs= seconds, Key: *****= signifies statistical difference

Appendix 24
Effect size calculations

Appendix 24a) Effect size data analysis

This table outlines the effect size scores calculated for each physical outcome measure.

Outcome measure	Effect size	CI	P value
SWM first finger	0.52	-0.83, 1.87	0.45
SWM thumb	0.42	-0.92, 1.76	0.54
Proprioception	-0.84	-2.25, 0.57	0.24
Stereognosis	-1.56	-3.19, 0.07	0.06
GOT	-1.17	-2.67, 0.33	0.13
WMFT	0.04	-1.27, 1.36	0.95

Abbreviations: SWM= Semmes Weinstein Monofilament, GOT = Grating Orientation Task, WMFT= Wolf Motor Function Test, CI= confidence interval

Appendix 24b) Raw data for effect size calculation

The weight for each calculation was 100%

	Haptic group			Non-haptic group		
Outcome measure	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**
SWM first finger	-0.24	0.33	4	-0.69	0.98	5
SWM thumb	-0.30	0.29	4	-0.66	0.98	5
Proprioception	-0.50	3.12	4	2.2	2.64	5
Stereognosis	-0.25	0.96,	4	1.8	1.3	5
GOT	3.00	0.58	4	3.5	0.00	5
WMFT	-5.02	5.29	4	-5.27	5.06	5

Abbreviations: SWM= Semmes Weinstein Monofilament, GOT = Grating Orientation Task, WMFT= Wolf Motor Function Test, n= number of participatns, SD= standard deviation

Appendix 25
Historic cohort data comparison

Appendix 25a) The OrbIT Gaming System compared to historic cohort control analysis

The following table compares scores of the WMFT between the OGS study and the CIRCUIT trial study by English et al. (2015), including the mean change in scores in seconds. Participants were matched with baseline WMFT scores, age and sex.

	Baseline WMFT median ± IQR (range) (secs)	**3-week WMFT median ± IQR (range (secs)**	**Mean change in score (secs)**	**Improvement in median scores (%)**
OGS data	15.92 ± 20.04 (5.68-99.19)	9.33 ± 20.83 (3.01-97.21)	-4.76	41.4
Historic conventional therapy data	15.66 ± 20.48 (6.00-98.70)	4.5 ± 11 (3.00-54.00)	-17.64	71.3

Abbreviations: WMFT= Wolf Motor Function Test, OGS= OrbIT Gaming System

Appendix 25b) Raw data of individual participants matched for both the OrbIT Gaming System and historic cohort studies

The following table outlines the raw data used to calculate comparisons mean change in score for both studies.

The OGS pilot study				Historic conventional therapy data			
Age (years)	**Sex**	**Baseline WMFT mean time (secs)**	**3-week WMFT mean time (secs)**	**Age (years)**	**Sex**	**Baseline WMFT mean time (secs)**	**4-week WMFT mean time (secs)**
70.75	F	99.19	97.21	83	F	98.70	54
70.83	M	66.25	59.79	75	M	69.42	3
82.75	F	15.97	4.18	89	F	15.79	5
68.92	F	15.86	15.48	64	F	15.53	14
64.58	M	18.84	6.24	57	F	17.54	3
68	M	9.99	7.62	80	F	7.40	14
45.92	M	10.88	11.04	60	M	10.77	3
56.25	M	5.68	3.01	76	M	6.00	4