The Feasibility and Acceptability of Virtual Reality Gaming Technologies for Upper-Limb Stroke Rehabilitation: A Mixed-Methods Study

A Thesis Submitted for the Degree of Doctor of Philosophy

By

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Abstract

Background: Evaluation of virtual-reality gaming technologies for upper-limb stroke rehabilitation has focused on those with mild to moderate impairment. This mixed-methods study details the development and evaluation of the feasibility, acceptability and preliminary efficacy of the custom-developed, Personalised Stroke Therapy (PST) system, in stroke-survivors with mild to moderately-severe levels of impairment.

Methods: The PST system was iteratively designed with input from stakeholders. Twelve stroke-survivors (nine females, mean age 58 years, median stroke chronicity 42 months, stroke severity 14-25 for shoulder and elbow on the Motricity Index) aimed to complete nine, 40-minute sessions on the PST system over three-weeks. Feasibility and acceptability were assessed though semi-structured interview, recording of adverse effects, adherence, enjoyment and perceived exertion. Assessments of impairment, activity and participation, were completed at baseline, immediately post-intervention and 4-weeks post-intervention. Data were analysed using Thematic Analysis of interview transcripts and field-notes, and Wilcoxon Signed Ranks. Side-by-side displays were used to integrate quantitative and qualitative findings.

Findings: Integrated findings of safety and ability to use the PST system suggested system feasibility. Themes of the need for personalisation of activities and the necessity of a hands-free system helped explain findings of feasibility. Integrated findings of enjoyment, the acceptability of using the system in different settings and the importance of feedback provided evidence of acceptability. Themes of physical and psychological benefits were supported by improvements in measures of impairment, activity and participation between baseline and immediately post-intervention ($p<0.05$ for all measures).

Conclusion: Personalisation of activities and use of a hands-free system resulted in feasibility and acceptability of the PST system in a group of community dwelling stroke-survivors including those with moderately-severe disability. Therapists should consider using such technologies as an adjunct to traditional rehabilitation, particularly in those with greater stroke severity for whom a lack of suitable alternatives are available.

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List of Abbreviations

ADL	Activities of Daily Living
ARAT	Action Research Arm Test
CI	Confidence Interval
FMA-UE	Fugl-Meyer Assessment- Upper Extremity
ICF	International Classification of Functioning, Disability and Health
IPQ	iGroup Presence Questionnaire
IQR	Inter Quartile Range
MAL	Motor Activity log
mAS	modified Ashworth Scale
MCID	Minimal Clinically Important Difference
MDC	Minimal Detectable Change
MI	Motricity Index
MRC	Medical Research Council
mRS	modified Rankin Scale
NHPT	Nine Hole Peg Test
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
PST	Personalised Stroke Therapy
QUEST	Quebec User Evaluation of Satisfaction with Assistive Technology
RCT	Randomised Control Trial
SD	Standard Deviation
SIPSO	Subjective Index of Physical and Social Outcome
SMD	Standardised Mean Difference
SPSS	IBM Statistical Package for the Social Sciences
SR	Systematic Review
UK	United Kingdom
VAS	Visual Analogue Scale
VR	Virtual Reality
WHO	World Health Organisation
WMFT	Wolf Motor Function Test

Dissemination

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Key Oral Presentations

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Chapter 1: Introduction to Thesis

1.1 Introduction

Evaluation of virtual-reality gaming technologies for upper-limb stroke rehabilitation has focused on those with mild to moderate impairment. This study details the development and mixed-methods evaluation of the feasibility, acceptability and preliminary efficacy of the custom-developed, Personalised Stroke Therapy (PST) system in stroke-survivors with mild to severe levels of impairment. In this chapter, a brief overview of stroke with an emphasis on upper-limb impairment is initially presented, followed by a discussion of the use of virtual reality (VR) gaming technologies in rehabilitation. The chapter concludes with an overview of the overall thesis structure.

1.2 Stroke

Approximately 17 million people suffer a new stroke every year (Feigin et al., 2014) making stroke the leading cause of disability worldwide (Langhorne et al., 2009). In the United Kingdom (UK) over 100,000 strokes occur annually (Stroke Association, 2018) resulting in 85,000 hospital admissions (Royal College of Physicians, 2016) and an estimated annual economic burden of £26 billion (Stroke Association, 2018) including £3 billion in direct National Health Service (NHS) costs (Department of Health, 2010). With incidence of stroke increasing, improving survival rates and longer life expectancy in general, the burden of caring for and rehabilitating stroke survivors is predicted to increase (Hughes et al., 2014; McHugh et al., 2014) placing further strain on healthcare systems. The need for treatment interventions that are both effective and cost-effective is therefore of paramount importance (Intercollegiate Stroke Working Party, 2016; Ward, 2017).

Severity of stroke depends on the location and extent of the lesion. However, it is estimated that of the 1.2 million stroke survivors living in England, 300,000 experience moderate to severe levels of disability (Stroke Association, 2015). Symptoms include limb and trunk weakness (apparent in 80% of stroke survivors), alterations in muscle tone, sensory changes, pain, impairment in coordination, communication, vision, cognition, swallowing, alterations in mood and fatigue as well as secondary problems such as soft tissue shortening, contracture, depression, balance problems, falls and physical deconditioning (Intercollegiate Stroke Working Party, 2016). Together these symptoms result in problems performing everyday functions and tasks and reduce participation in everyday life. While

82% of stroke survivors achieve independent mobility by six months (Kwakkel et al., 1999) to date, upper-limb recovery has been less successful (Kwakkel and Kollen, 2015; Subramanian et al., 2010).

1.2.1 Incidence of Upper-Limb Impairment Post Stroke

Eighty-five percent of stroke survivors will initially experience upper-limb deficits (Stroke Association, 2016). Of these only 5 to 34% will make a full recovery (Kong et al., 2011; Kwakkel and Kollen, 2015). While walking is the highest treatment priority identified by patients (Intercollegiate Stroke Working Party, 2016), lack of upper-limb recovery has a major impact on function and ability to participate in life roles and therefore lack of recovery results in significant dependence and a reduced quality of life (Nichols-Larsen et al., 2005; Ward, 2017; Wyller et al.,1997). Moreover, lack of upper-limb recovery has been found to be one of the strongest predictors of reduced psychological well-being following stroke (Nichols-Larsen et al., 2005; Wyller et al., 1997). Effective upper-limb treatment interventions have therefore been identified as a priority for stroke research by stroke survivors, their carers and clinicians (James Lind Alliance, 2011; Rankin et al., 2012).

Poor upper-limb recovery is associated with visual inattention, hemianopia, urinary incontinence and somatosensory deficit (Ward, 2017). However, the most significant predictor of upper-limb recovery is the degree of the initial impairment (Coupar et al., 2012). Rondina et al., (2017) describe the 'proportional recovery rule' which maintains that those with moderate to mild upper-limb impairment as a result of stroke tend to have a good recovery, typically improving by 70% of their initial impairment by three months. The prognosis for those with more severe deficits is less certain with only half achieving proportional recovery (again improving by 70% of their initial impairment), while the other half show minimal improvement at three months. However, recovery from motor problems can be seen in those with severe upper-limb deficits even after a year following stroke (Subramanian et al., 2010; Taub et al., 2013) suggesting those with severe stroke have different recovery patterns and mechanisms than those with milder initial deficits.

1.2.2 Mechanisms of Recovery

The term "recovery" is widely used in neurorehabilitation to indicate improvement in impairment or function. In stroke, recovery can broadly be considered as to whether improvements seen are due to spontaneous biological recovery, neural restitution or use of behavioural strategies (Buma et al., 2013; Kleim and Jones, 2008; Levin et al., 2009).

1.2.2.1 Spontaneous Biological Recovery

In the aftermath of stroke, deficits seen are due to a combination of cell death and compromised cell function in areas immediately surrounding the area of damage due to oedema. In addition, reduced function in areas functionally related to, but distal to the area of damage can occur due to loss of input (diaschasis). While cell death is permanent, resolution of oedema and reversal of diaschasis occurs irrespective of treatment and will lead to some spontaneous recovery (Pekna et al., 2012).

1.2.2.2 Neural Restitution

Neural restitution refers to the re-establishment of movement behaviours that were used prior to the stroke through restoration of neural components (Bernhardt et al., 2017). This so called “true recovery” requires neuroplastic change, that is the alteration of nerve structure and function in response to experience and system demands (Kleim and Jones, 2008; Pekna et al., 2012). Changes occur at structural and neuronal network levels.

While not all processes have been observed in adult humans (Ward, 2017) structural changes including axonal sprouting, dendritic spine branching, synaptogenesis, increase in post synaptic receptor density, neurogenesis and gliogenesis have been suggested as neuroplastic phenomena occurring after stroke (Pekna et al., 2012; Ward, 2017). In addition to structural changes, changes in neuronal pathway activation and cortical maps have also been observed and can additionally account for changes in movement (including restoration of movement and function) seen following stroke (Buma et al., 2013). Structural changes resulting in neural repair are believed to result in a more complete recovery of movement then changes in neuronal networks whereby secondary areas (i.e. areas which usually only assist the primary brain area responsible for a particular function) become the main locus of movement (Bernhardt et al., 2017).

It has been proposed that a ‘critical window’ of neuroplasticity exists in the weeks following stroke when areas surrounding the lesion are in a hyper-excited state (Biernaskie et al., 2004; Cortes et al., 2017; Krakauer, 2015; Krakauer et al., 2012; McDonnell et al., 2015). These researchers propose that this phenomenon should be exploited by focusing rehabilitation interventions during this three-month window period. Other researchers have argued that while less dramatic, plasticity can also contribute to recovery in chronic stages of stroke (Gauthier et al., 2008; Taub et al., 2013; Wolf et al., 2016) and therefore rehabilitation should not be limited to the peri-stroke window period.

Neuroplasticity can enhance or impede recovery. Kleim and Jones (2008) emphasised the importance of experience in driving the direction of neuroplastic change and describe ten principles of experience dependent plasticity as presented in Table 1.1.

Table 1.1 Principles of Experience-Dependent Neuroplasticity (Kleim and Jones, 2008, pS227)

Principle	Description
1. Use it or lose it	Failure to drive specific brain functions can lead to functional degradation
2. Use it and improve it	Training that drives a specific brain function can lead to an enhancement of that function
3. Specificity	The nature of the training experience dictates the nature of the plasticity
4. Repetition matters	Induction of plasticity requires sufficient repetition
5. Intensity matters	Induction of plasticity requires sufficient training intensity
6. Time matters	Different forms of plasticity occur at different times of training
7. Salience matters	The training experience must be sufficiently salient to induce plasticity
8. Age matters	Training-induced plasticity occurs more readily in younger brains
9. Transference	Plasticity in one training experience can enhance the acquisition of similar behaviours
10. Interference	Plasticity in response to one experience can interfere with the acquisition of other behaviours

While some degree of plasticity is likely following stroke, it rarely results in complete restoration to the premorbid state (Bernhardt et al., 2017) therefore some form of behavioural compensation is likely.

1.2.2.3. Behavioural Strategies

Functional recovery from stroke can also occur through use of compensatory strategies whereby the stroke survivor uses approaches alternate to those used prior to their stroke to achieve successful completion of a functional task (for example using their mouth and unaffected hand to open a packet, using one hand to button a shirt or tie a shoelace or side) (Cortes et al., 2017). While use of compensation can be the best strategy when the prognosis for recovery at a neural level is poor, such movements tend to be inefficient, can cause pain and can lead to learnt non-use of the affected side (Cirstea and Levin, 2007). Compensation should therefore be discouraged in those with mild to moderate deficits especially in the early stages of recovery as this hinders restoration processes and

consequently impedes recovery of the affected side (Cirstea and Levin, 2007; Kleim and Jones, 2008; Levin et al., 2009). As restitution has the potential to lead to a better recovery, rehabilitation interventions which exploit plasticity are considered to be the most effective.

1.3 Physiotherapy Interventions Post Stroke

Historically physiotherapy interventions for stroke focused on the use of named approaches (e.g. Bobath, Rood, Brunnstrom etc). More recently, therapists have embraced a more eclectic approach, using a variety of interventions that aim to exploit the ability of the central nervous systems to plastically adapt and reorganise in response to experience (Arya et al., 2011; Intercollegiate Stroke Working Party, 2016; Langhorne et al., 2009). The most convincing evidence is for interventions (such as constraint induced movement therapy, electro-myographic biofeedback, mental practice with motor imagery and task specific practice) which are characterised by high intensity and repetitive practice of a meaningful task (Arya et al., 2011; Langhorne et al., 2009; Pollock et al., 2014; Veerbeek et al., 2014). These characteristics are believed to enhance neuroplasticity (as described in Table 1.1) and have also been recognised as key to motor learning (Arya et al., 2011).

1.3.1 Motor Learning

Motor learning has been defined as the “acquisition and/or modification of a skilled action” (Shumway-Cook and Woollacott, 2017, p22). It occurs through both unconscious and explicit means (Subramanian et al., 2010) and is reliant on a combination of feedback and practice (Arya et al., 2011).

1.3.1.1 Feedback

The provision of feedback is a key concept in motor learning, as practice without feedback can increase the use of compensatory strategies, resulting in maladaptive plastic phenomena hindering recovery through restitution (Cirstea and Levin 2007; Michaelsen et al., 2006). Feedback can be considered in terms of knowledge of results (knowledge about the outcome of the movement) or knowledge of performance (knowledge about the nature of the movement pattern used and what to do to improve it) (Subramanian et al., 2010). In many instances knowledge of results can be gained without external help (i.e. the patient knows whether they successfully managed a task or not). However, knowledge of performance is harder to achieve, especially in conditions such as stroke where internal feedback mechanisms may be damaged (Van Vilet and Wolf, 2006). It is therefore recommended that knowledge of performance is provided by an external source (usually by clinicians) in stroke rehabilitation (Cirstea and Levin 2007; Piron et al., 2010; Subramanian et

al., 2010). However, as it has been suggested that an over-reliance on feedback can impede motor learning, frequency of feedback should be faded to avoid dependence (Cirstea and Levin 2007).

1.3.1.2 Practice Regime

The most important factor to aid plasticity and enhance motor learning is intensive repetition of a specific functional task (Arya et al., 2011; Han et al., 2013; Intercollegiate Stroke Working Party, 2016; Veerbeek et al., 2014). Animal models of practice induced plasticity indicate that 250-300 repetitions per session are necessary for neuroplastic changes to occur (Teasall and Hussain, 2016). While the number of repetitions required to drive long term neuroplastic change in humans is uncertain, studies have shown that intensive protocols, providing three hours or more of additional therapy each day, resulted in better performance in measures of impairment and function than studies employing an hour of therapy (Han et al., 2013; McCabe et al., 2015; Ward, 2017). While intensive task specific practice is a key factor to enhance neuroplastic phenomena and drive motor learning, evidence suggests that there are considerable challenges in delivering this clinically (McHugh and Swain, 2013; Stroke Association, 2016).

1.3.2 Issues with Delivery of Therapy

Current guidelines recommend that stroke survivors who are able to tolerate such a dose, should receive a minimum of 45 minutes of 'active treatment' daily of each relevant therapy for five days minimum a week (Intercollegiate Stroke Working Party, 2016; National Institute for Health and Care Excellence [NICE] 2013). While it has been argued that 45 minutes is insufficient to drive long term neuroplastic change (Ward, 2017), significant problems in delivering this level are nonetheless apparent (Royal College of Physicians, 2016). McHugh and Swain (2013) found that only 32% of patients who needed physiotherapy achieved the 45-minute target; while McHugh et al. (2014) noted patients received an average of only five hours of physiotherapy during their entire hospital stay. The situation for upper-limb rehabilitation is worse. Lang (2009) noted that interventions for the upper-limb occurred in only 51% of rehabilitation sessions with an average of only 32 repetitions, far below the threshold of 250-300 repetitions suggested by animal studies (Kleim et al., 1998; Nudo et al., 1996). More recently, Serrada et al. (2016) found a similar pattern, with an average of just 7.9 minutes a day of combined occupational therapy and physiotherapy for the upper-limb during the first four weeks after stroke. While patient fatigue may limit therapy input with some patients (Kluger et al., 2013), a lack of treatment intensity and the greater focus on walking have been suggested in part explanation for lack of upper-limb recovery following

stroke (Barker and Brauer, 2005; Levin et al., 2009). The situation is compounded by early adoption of compensatory strategies to achieve function, in effect, promoting a learned non-use of the affected side and facilitating neuroplastic changes in favour of the less affected side (Levin et al., 2009; Taub et al., 2006).

In addition, an ageing population, and people living for longer with more complex conditions, has placed additional demand on NHS resources (Stroke Association, 2018). While demand for physiotherapy has increased, physiotherapy budgets have been reduced (Chartered Society of Physiotherapy, 2012). This mismatch between supply and demand has resulted in 60% of hospitals in the UK operating below the recommended physiotherapy staffing levels suggested by the Royal College of Physicians (Royal College of Physicians, 2017). Furthermore, changes in infrastructure and government policies such as the Early Supported Discharge Scheme (Department of Health, 2007) have reduced the length of hospital admission enabling earlier discharge than in the past (reducing from a mean length of stay of 40 days in 2001 to 20 days in 2017 [Royal College of Physicians, 2017]). While the Royal College of Physicians (Intercollegiate Stroke Working Party, 2016) recommend that rehabilitation provision following early discharge should continue at a similar level to inpatient rehabilitation, this is rarely the case. McHugh et al. (2014) found stroke survivors, on average, received just 7.1 hours of physiotherapy in total in community settings (how much of which was spent on rehabilitating the upper-limb was unclear). As therapy typically reduces over time and rarely continues after six months (Subramanian et al., 2010), Ward (2017) asserts that in the chronic stage, rehabilitation for stroke survivors is practically non-existent.

With demand for therapy outstripping available resources, there is a greater emphasis on stroke survivors exercising independently (Intercollegiate Stroke Working Party, 2016). Provision of home exercises for continuation of rehabilitation is common following stroke (Connell et al., 2014; Langan et al., 2018). However, McHugh et al. (2014) found that while 94% of patients with mild upper-limb impairment were offered home upper-limb exercise programmes, this figure fell to 82% for those with moderate impairment and fell to just 44% for those with severe deficits. In addition, the effectiveness of such programmes is dependent on exercise adherence which is notoriously poor, particularly over time (Jurkiewicz et al., 2011; Peek et al., 2016). Lack of support, lack of feedback, lack of confidence and boredom with exercises are the most frequently cited factors associated with poor adherence (Barker and Brauer, 2005; Disler and Wade, 2003; Hung, 2016; Jurkiewicz et al., 2011; Langan et al., 2018; O'Brien et al., 2011). It has been suggested that the use of

VR gaming technologies can be a useful adjunct to improve exercise adherence without the need for additional therapy input and in doing so, facilitate upper-limb recovery following stroke (Ballester et al., 2015; Turolla et al., 2013).

1.4 Virtual Reality Gaming Technologies

Different terms are used to describe VR based gaming technologies for use in rehabilitation fields including serious games for health, video games, gaming technologies, interactive video gaming, e-rehab, augmented reality and virtual reality. The term *VR gaming technologies* is used throughout this thesis. This is in keeping with the terminology most commonly used by therapists and refers to both immersive and non-immersive gaming technologies.

VR gaming systems use technology to generate life-like environments in which users can interact and practice tasks and movements in real time (Man, 2010). VR can be considered in terms of the level of immersion provided, that is the degree the user feels present in the virtual world due to the technical aspects of the VR environment. More immersive systems generate life scaled, three-dimensional images, surround sound auditory feedback and haptic feedback (sensory feedback such as vibration, pressure or temperature or resistance to movement) using visual display units, curved screens, head mounted displays, speakers and data-gloves or body suits (Man, 2010). Such systems are associated with inducing a high sense of presence in the virtual world (that is the subjective experience of being in the virtual world as a result of the level of immersion experienced). However, while providing a more life-like experience, such systems are expensive, require considerable space, and are often complex to set-up (Man, 2010; Pastor et al., 2012; Prashun et al., 2010) thereby limiting use for rehabilitation purposes. Less immersive systems involve the production of two-dimensional images, typically viewed on a computer or television screen, with system interaction via controller-based systems (such as computer keyboards, joysticks, balance boards and hand-held controllers and inertial measurement units) or via camera-based tracking systems (Anderson et al., 2015). The smaller space requirements, reduced expense and fewer side effects (such as cyber-sickness) compared with more immersive devices have made them a popular choice for rehabilitation purposes (Prashun et al., 2010; Rosa et al., 2016).

1.4.1 Proposed Mechanism of Action of VR Gaming Technologies

It is suggested that gaming technologies can help deliver more rehabilitation with fewer resources through provision of a motivating means to deliver treatment that is not reliant on

increased therapist contact time, (Taylor, 2015; Teasell and Hussian, 2016; Turolla et al., 2013; Veerbeek et al., 2014). The enjoyable and challenging nature of such activities may help address issues of boredom frequently experienced in rehabilitation (Langan et al., 2018; Poltawski et al., 2015; Subramanian et al., 2010; Taylor, 2015) and in doing so, augment user-engagement and enhance motor learning (Levin et al., 2015). In addition, the ability to provide feedback may further enhance enjoyment and increase motor learning through provision of knowledge of performance and knowledge of results (Arya et al., 2011; Cirstea and Levin, 2007; Kiper et al., 2011; Langan et al., 2018; Piron et al., 2010; Subramanian et al., 2013). Together these factors help promote self-management and improve exercise adherence (Fung et al., 2012; Peek et al., 2016, Taylor, 2015) and thereby help provide the high intensity, repetitious task practice necessary to drive positive neuroplastic change and recovery (Ayra et al., 2011; Saposnik et al., 2010; Teasell and Hussain, 2016). Moreover, evidence from imaging studies (Zhang et al., 2018) demonstrating increased activation in 'mirror neurones' (brain cells involved in performing a movement which also "fire" when observing a movement) (Rizzolatti and Craighero, 2004) suggests that the provision of visual feedback via an on-screen character (avatar) can help prime the central nervous system (Stoykov and Madavan, 2015). This motor priming prepares the motor system for action (Stoykov et al., 2017) and by doing so is thought to increase responsiveness to rehabilitation interventions thereby aiding recovery (Adamovich, 2009; Celnik et al., 2006; Ertelt et al., 2007; Franceschini et al., 2012; Pekna et al., 2012; Stoykov and Madavan, 2015; Thieme et al., 2012).

1.4.2 Uptake of VR Gaming Technologies in Rehabilitation

VR gaming technologies are increasingly being used for rehabilitation purposes (Iruthayarajah et al., 2017; Langan et al., 2018; Liu et al., 2015; Mat Rosly et al., 2017; Nitz et al., 2010; Ravenek et al., 2016; Thomson et al., 2016) in clinical specialities such as paediatrics (Deutsch, 2008; Gordon et al., 2012; Salem et al., 2012), rehabilitation of older people (Fung et al., 2012; Laver et al., 2012), intensive care rehabilitation (Kho et al., 2012), and amputee rehabilitation (D'Angelo et al., 2010). In addition, the use of such technologies in neurorehabilitation has become more established, particularly for upper-limb stroke rehabilitation (Langan et al., 2018; Laver et al., 2017; Mendes et al., 2012; Pietrzak et al., 2014; Veerbeek et al., 2014).

A systematic review by Proença et al. (2017) identified 35 different gaming technologies for use in upper-limb neurorehabilitation. These included commercially available, VR gaming technologies, developed primarily for entertainment purposes (such as the Nintendo Wii

[Nintendo, Kyoto, Japan] , Sony Playstation Eyetoy [Sony Computer Entertainment Group, California, USA], Microsoft X-box Kinect [Microsoft Corp. Washington, USA] and Leap Motion [Leap Motion, California, USA]), those developed specifically for rehabilitation purposes (such as GestureTek [GestureTek Corp. Toronto, Canada] IREX [GestureTek Corp. Toronto, Canada], Jintronix [Jintronix Corp. Seattle, USA], CAREN (Motek Medical, Amsterdam, Netherlands] Music Glove [Flint Rehabilitation Devices LLC, California, USA], HandTutor [MediTouch Ltd, Israel]) and modified versions of commercially available VR gaming devices (whereby commercially available systems developed primarily for entertainment purposes, have been adapted to enable use in rehabilitation) (Barrett et al., 2016; Tsekleves et al., 2014). However, while many different systems have been proposed, evaluation of the acceptability and feasibility of using these VR gaming technologies for rehabilitation purposes has been limited (Thomson et al., 2014).

1.4.3 Preliminary Work

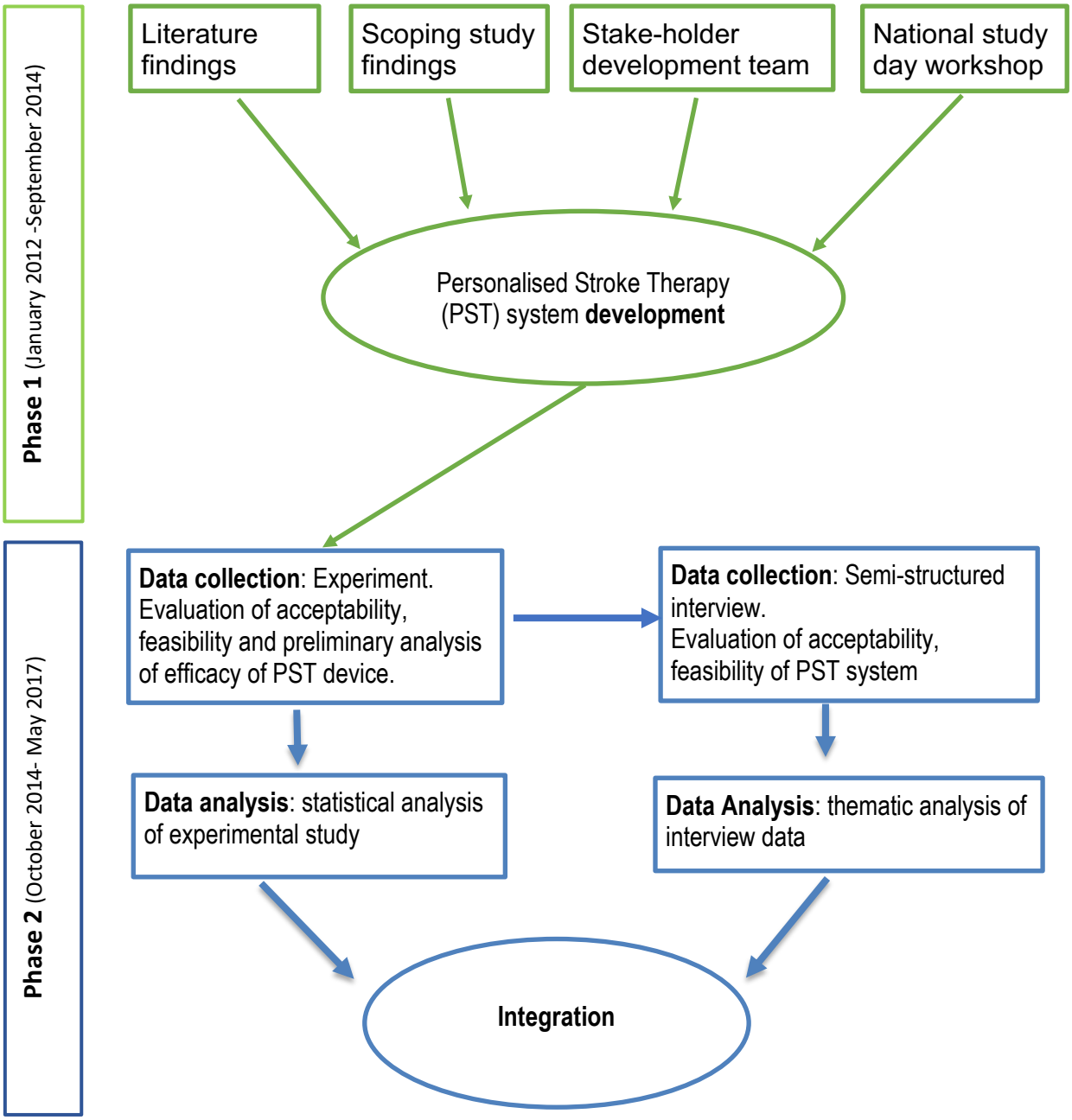
In a preliminary scoping study, the concept of using off-the-shelf, VR gaming technologies in rehabilitation was explored in four NHS Trusts within the clinical specialities of lower-limb amputee, musculoskeletal outpatient rehabilitation and neurorehabilitation (Warland et al., 2012; Appendices 1.3 and 2). Findings indicated that the commercially available, VR gaming system, the Nintendo Wii, was largely acceptable and feasible to use for lower-limb amputee, musculoskeletal outpatient and neurological balance rehabilitation. However, use was severely limited in upper-limb neurorehabilitation due to the large range of movement, coordination and speed required to play the games, the degree of coordination, strength and dexterity necessary to use the controller and the demoralising effect of negative feedback. Moreover, findings demonstrated the need for gaming technologies to be easy to set-up, affordable and suitable for those with more severe upper-limb impairment. These findings suggested the need for development of purpose-built systems for upper-limb neurorehabilitation. **The overarching aim of this thesis was therefore to design and evaluate a VR gaming technology for upper-limb stroke rehabilitation.**

1.5. Thesis Structure

This thesis consists of two study phases (Figure 1.1). Contextual information regarding stroke and gaming technologies has been presented in this chapter. **Chapter 2** details the methodology and justifies the use of a mixed-methods approach and service-user participation. **Chapter 3** provides a critical analysis of literature regarding efficacy, acceptability and feasibility of using VR gaming technologies for upper-limb stroke rehabilitation. Phase 1, involving the iterative co-design and preliminary evaluation of the

Personalised Stroke Therapy (PST) system for use in upper-limb stroke rehabilitation, is described in **Chapter 4.** Phase 2 methods and findings are reported in **Chapters 5-8.** These chapters detail the mixed-methods approach (using a within subject, pre-test, post-test study design and semi-structured interviews) used to explore the feasibility, acceptability and preliminary efficacy of the PST system. **Chapter 9** provides a discussion of overall findings, clinical implications of findings, study strengths and limitations and suggestions for future research.

Figure 1.1 Diagram of Study Phases



Chapter 2: Methodological Approach

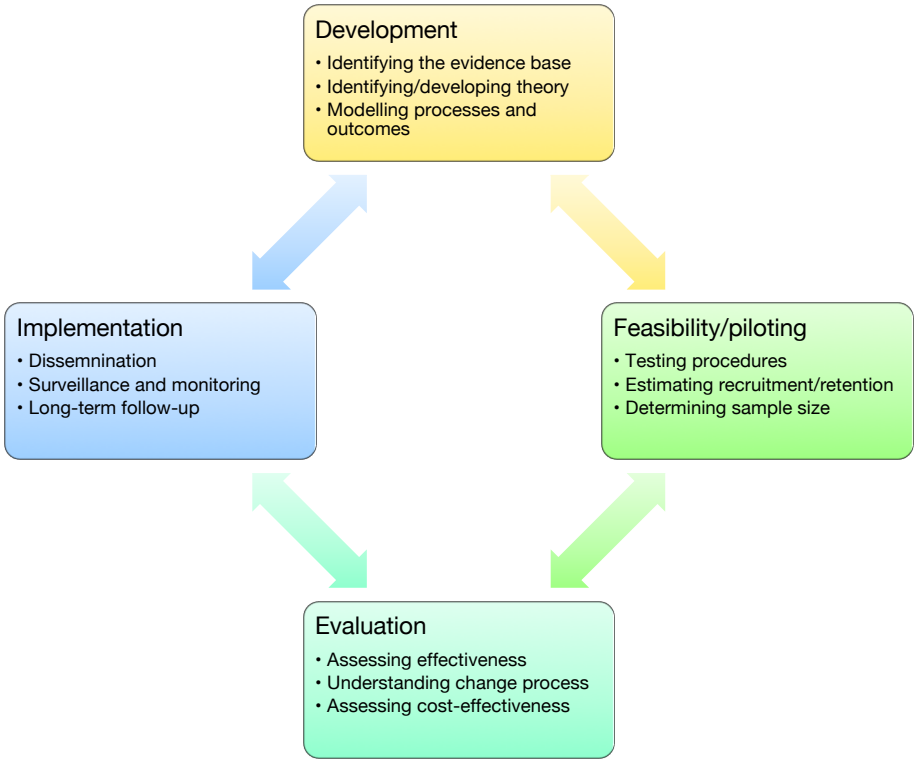
2.1 Introduction

This chapter details the methodological approach and justifies the use of a mixed-methods study design. The chapter begins with a summary of the Medical Research Council (MRC) Framework for Complex Interventions (Craig et al., 2008) which has informed the design and structure of the thesis. In addition, the importance of server-user participation in research is discussed to further justify study methodology. This is followed by an overview of mixed-methods followed by discussion of the philosophical approach of pragmatism employed across thesis phases, again justifying the use of mixed-methods.

2.2. Structural Underpinning to the Thesis

In order to assess whether an intervention is effective or not in everyday practice, careful evaluation is required. This is particularly the case with complex interventions, such as those employed in the rehabilitation of individuals following stroke, where the wide variability in patient presentation, variation in the implementation of treatment and contextual factors can all influence outcome (Moore et al., 2015).

Figure 2.1 MRC Framework for Complex Interventions: Key Elements of the Development and Evaluation Process (Craig et al., 2008).



In recognition of this, the MRC developed a framework for the systematic development and evaluation of treatment interventions (Medical Research Council, 2000). This was updated in 2008 (Craig et al., 2008) (Figure 2.1) placing greater flexibility in the perceived order of stages, greater emphasis on the development stage, and earlier assessment of feasibility. The updated framework was used to guide the structure of this study. Table 2:1 maps key study activities onto the framework, namely the Development and Feasibility / Piloting phases. As evaluation and implementation of the intervention were not the focus of the study, these phases are not included in this thesis.

Table 2:1 Aligning Study Phases and Activities onto the MRC Framework (Craig et al., 2008)

MRC Framework phase	Thesis study phase	MRC element	How and where addressed within thesis
Development	Study phase 1	Identifying the evidence base	• Identification and review of VR gaming technology and rehabilitation literature (Chapter 3)
		Identifying / developing theory	• Review of literature regarding stroke rehabilitation, recovery and VR gaming technologies (Chapters 1 and 3) • Preliminary research involving service-users and clinicians (Appendix 2) • Findings from a National World Café Study Workshop (Chapter 4)
		Modelling processes and outcomes. Provides information about the design of the intervention and design of evaluation. Barriers and facilitators	• Identification of suitable study methodology and methods (Chapters 2, 4, and 5) • Iterative co-design and development of the PST system (Chapter 4) • Preliminary system evaluation (Chapter 4).
Feasibility/piloting	Study phase 2	Testing procedures for acceptability using a combination of qualitative and quantitative methods	• Testing the PST system for feasibility, acceptability and preliminary efficacy (Chapters 5-8)
		Estimating recruitment and retention	• Recruitment and retention assessed using qualitative and quantitative measures (Chapters 6-8)
		Determining sample size	• A sample size calculation (Chapter 6)

However, the MRC Framework has been criticised for failing to define acceptability and feasibility and a lack of guidance as to how to evaluate these constructs (Bowen et al., 2009; Moore et al., 2015; Sekhon et al., 2017; Wuest et al., 2015).

2.3. Operationalisation of Acceptability and Feasibility Within the Thesis

For the purposes of this study, feasibility was defined as “the possibility that something can be made, done or achieved, or is reasonable” (Cambridge Advanced Learner’s Dictionary and Thesaurus. n.d). Feasibility was evaluated in terms of feasibility of the intervention and feasibility of the study protocol. Acceptability was defined as “the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention” (Sekhon et al., 2017, p.2). Evaluation of the acceptability of the study protocol and acceptability of the intervention were based on a model proposed by Sekhon et al. (2017), Details of how these constructs were operationalised within the thesis is provided in Table 2.2.

Table 2:2 The Operationalisation of Feasibility and Acceptability Within Thesis

Construct		How operationalised within thesis
Feasibility	Intervention	Occurrence of adverse effects
		Rates of study inclusion
		Feasibility of independent use
		Feasibility of gameplay
		System costs
	Study protocol	Recruitment
		Rates of exclusion
		Study attrition
		Adherence to study protocol
Acceptability	Intervention	Attitudes towards the intervention (e.g. effects of the intervention on levels of enjoyment, motivation, engagement and satisfaction)
		Burden (effort/difficulty of use)
	Study protocol	Attitude towards the study (e.g. indications of enjoyment, boredom)
		Burden

Furthermore, in recognition of what and for whom research is for, service-user participation in research is being increasingly advocated and is recommended at all stages of the MRC framework (Craig et al., 2008).

2.4 Service-User Participation

Given their unique insight, it has been argued that service-user involvement in research enables the achievement of better, more pertinent and acceptable interventions and therefore should lead to a greater uptake of findings (Haywood et al., 2006; NHS England, 2015; Whitstock, 2003). Additionally, service-user input provides greater insight as to how an intervention can deliver change (Craig et al., 2008; Moore et al., 2015), and moreover, can improve research study retention and recruitment (NHS England, 2015). There are five levels of participant involvement (Table 2.3), ranging from provision of information, through

to full control where service-users control decision making ranging (NHS England, 2015. Adapted from Arnstein, 1969).

Table 2:3 Five Levels of Service-User Involvement (NHS England, 2015)

Information	**Consultation**	**Participation**	**Partnership / Co-production**	**Control**
Service-users are told what is happening. No influence over decision making	Service-users are asked their views. Limited influence over decision making	Service-users' views are sought and considered. They have no direct impact on decision making	Working as equals, service-users share decisions and responsibility, influencing and determining outcomes	Service-users control decision making
The Promise to Service-Users				
The information service-users receive will be balanced, accurate and up to date	Feedback received will be taken seriously, and they will be informed of the influence they have had	Service-users will be able to shape the process. They will have influence over decisions	Service-users and service-providers make decisions together	Service-users will have sufficient resources to enable effective decision making and what they decide will happen

In this study service-users participated at various levels at different times.

- **Phase 1**: service-users were integrated into the design team and participated at a *partnership / co-production level,* testing and providing direct feedback about each version of the PST system. Decisions regarding design and features of the PST system were made jointly between team members.
- **Phase 2**: service-users were initially involved at a *partnership / co-production level,* deciding, in conjunction with the lead researcher, about wording of questions for the semi-structured interviews and about key features for the study design such as attendance requirements. Later, service-users were again involved at a *partnership / co-production level,* with findings from a mixed-methods study evaluating the PST system for upper-limb stroke rehabilitation, being used in the development and evaluation of the Neurofenix platform (Neurofenix.com) for home-based upper-limb stroke rehabilitation (Section 9.11).

As well as service-user input to evaluate interventions, Moore et al., (2015) also recommends the use of mixed-methods to improve understanding, identify barriers and facilitators and ultimately to improve interventions.

2.5 Mixed Methods Research

Mixed-methods research has been advocated as a powerful tool to explore complex issues in healthcare (Curry and Nunez-Smith, 2015; Fetters et al., 2013) and has been described as:

> *"An approach to research…in which the investigator gathers both quantitative (closed question) and qualitative (open-ended) data, integrates the two, and then draws interpretations based on the combined strength of both sets of data to understand research problems".* (Creswell, 2015, p2).

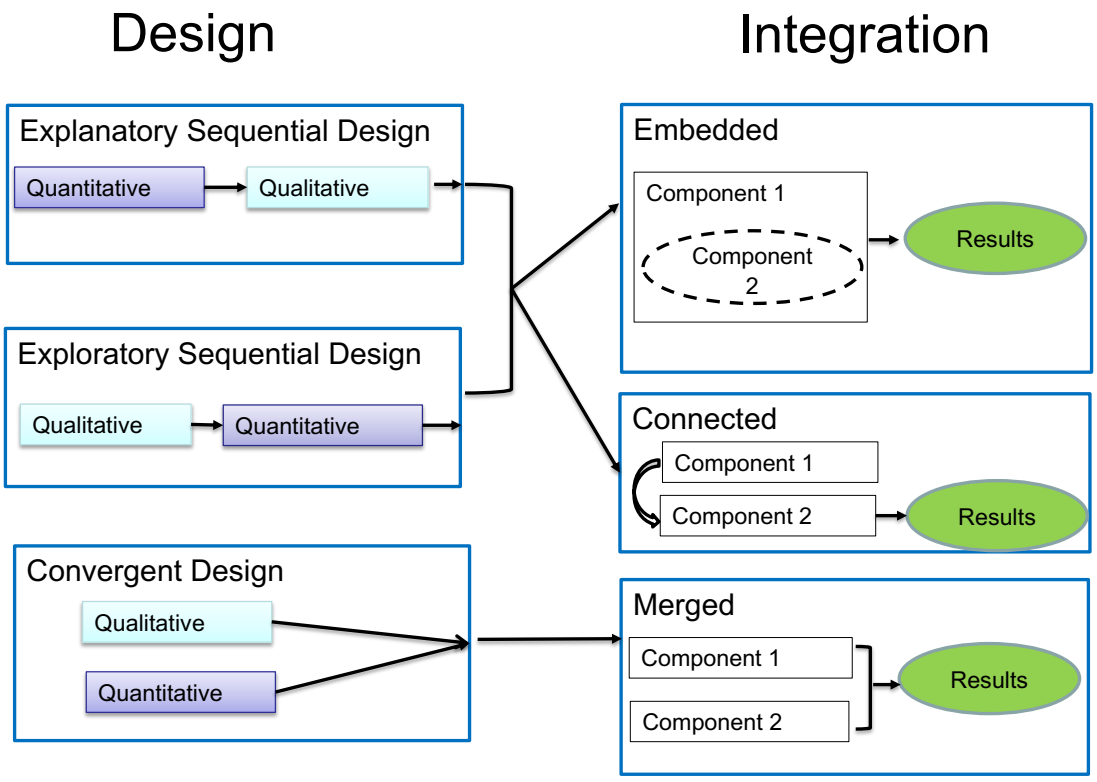
It has been argued that the use of mixed-methods can provide greater insight into phenomena, with agreement between data sets, strengthening study findings and where data sets disagree or where data is lacking, qualitative findings may help explain quantitative results (Creswell, 2015; Teddie and Tashakkori, 2009). Moreover, the use of both quantitative and qualitative methods allows the strengths of both types of study to off-set the methodological weaknesses inherent in each approach (Creswell, 2015).

There are many possible designs of mixed-methods studies. Teddie and Tashakkori (2009) describe the impossibility of defining an exhaustive list, due to the flexibility inherent in the method and the need for researchers to design a study best-suited to their particular question. However, based on the relative timing of data collection phases and the method of integration, three basic mixed-methods designs have been identified (Creswell, 2015; Curry and Nunez-Smith, 2015; Fetters et al., 2013) (Figure 2.2). In explanatory sequential designs, quantitative data is initially collected and analysed prior to the collection and analysis of qualitative data. In this design qualitative findings are used to explain quantitative results. Curry and Nunez-Smith (2015) advocate this approach when quantitative results are incomplete or difficult to interpret. In the exploratory sequential design, qualitative data is initially collected and analysed, and results are used to generate an instrument (such as a questionnaire) or a new intervention (such as a treatment) to be tested in a follow-up quantitative study. Creswell (2015) describes this as the most sophisticated and rigorous basic mixed-methods design but warns of the lengthier time frame required. The third basic mixed-methods design, the convergent design was used in this study. In this design, both qualitative and quantitative data is collected and analysed separately before being integrated. Creswell (2015) argues that this approach enables researchers to gain multiple perspectives of a problem but notes challenges in integrating two different kinds of data.

A key aspect of mixed-methods studies is the integration of datasets (Figure 2.2). This is primarily achieved through embedding, connecting or merging datasets. Embedding qualitative data from a secondary study method within the primary aim has been advocated

for use in intervention and sequential study designs. Connecting is more appropriate for use in sequential designs, where one dataset builds on another (Creswell, 2015; Curry and Nunez-Smith, 2015). Merging is particularly well suited to convergent study designs where datasets are compared and assessed for concordance, dissonance or silence between datasets (Curry and Nunez-Smith, 2015). Different methods of data merging have been suggested including transformation of one type of data into the other before direct comparison, integration through narrative or side by side visual displays (Creswell, 2015; Fetters et al., 2013).

Figure 2.2 Mixed-Methods Basic Designs and Ways of Integration (Adapted from Curry and Nunez-Smith, 2015)



2.6 Methodological Approach to Mixed- Methods

2.6.1 Approach to Mixed-Methods in This Study

Following on from phase 1 development and preliminary evaluation of the PST system, a convergent mixed-method study design was used in phase 2, with integration through merging of datasets using side by side visual displays. Side-by-side displays were adopted in this thesis as the researcher felt the use of visual displays facilitated data analysis and helped identify the level of agreement between datasets.

2.6.2 Approach to Reporting Mixed-Methods

The Good Reporting of a Mixed Methods Study (GRAMMS) guideline (O'Cathain et al., 2008) was used as a framework to guide reporting of the mixed-methods studies (see Table 2.4).

Table 2.4 The Good Reporting of a Mixed Methods Study (GRAMMS) Guideline (O'Cathain et al., 2008)

1. Describe the justification for using a mixed methods approach to the research question
2. Describe the design in terms of the purpose, priority and sequence of methods
3. Describe each method in terms of sampling, data collection and analysis
4. Describe where integration has occurred, how it occurred and who participated in it
5. Describe any limitation of one method associated with the present of the other method
6. Describe any insights gained from mixing or integrating methods

As research methodology (as well as the methods used, and the research questions asked) must align with a researcher's philosophical beliefs about the nature of reality, what they believe constitutes knowledge and what kind of knowledge is important, it is essential that researchers state their research paradigm (Morgan, 2007; Shannon-Baker, 2016; Teddie and Tashakkori, 2009).

2.7 Philosophical Considerations

A research paradigm has been defined as a "worldview, complete with the assumptions associated with that view" (Mertens, 2003. p139). These assumptions can be considered in domains of ontology (that is the nature of reality, and whether the researcher believes in a single or multiple reality) and epistemology (that is the nature of knowledge and how it can be gained) (Teddie and Tashakkori, 2009). Traditionally, paradigms have been considered to be either positivist or constructivist in nature (Muncey, 2009) and these are briefly reviewed next.

2.7.1 Positivism

Positivism is grounded in a realist ontology, emphasising a single reality, where knowledge is believed to exist independent of the knower and that natural laws regarding the world not only exist, but are absolute (Teddie and Tashakkori, 2009). The positivist paradigm has been the dominant paradigm from 1900 until the 1970s (Muncey, 2009; Teddie and Tashakkori, 2009). While later versions of positivism (such as post-positivism) employ a less rigid interpretation (acknowledging the role researcher values play in data collection and analysis), positivists continue to mainly employ quantitative methodologies (favouring

experimental, quasi-experimental and survey research methods), emphasising objectiveness in data collection and analysis and generalisability of results (Teddie and Tashakkori, 2009). While recognised as an effective means of identifying cause and effect (Bowling, 2014), methods used in quantitative methodologies have been criticised as creating artificial situations with limited relevance to real-world situations (external validity) and limited consideration of how a phenomenon effects an individual (Bowling, 2014; Muncey, 2009). These issues have been highlighted as being particularly pertinent when interventions involve a degree of behaviour change such as those frequently employed in the management of complex long-term conditions (Muncey, 2009).

2.7.2 Constructivism

Constructivism is grounded in the ontology of idealism, that is a belief that reality is constructed by the mind and can only be understood through socially constructed meanings (Snape and Spencer, 2003). Unlike the absolutism purported in positivist paradigms, idealists believe in the existence of multiple realities and that knowledge and truth are dependent on time, place and person and that in the case of research, that knowledge is constructed through collaboration between the researcher and the researched (Snape and Spencer, 2003; Teddie and Tashakkori, 2009). A resurgence in the popularity of the constructivist paradigm during the 1970s to the 1990s (Teddie and Tashakkori, 2009) occurred in reaction to criticisms of the positivist stance and an increasing recognition of the importance of contextual factors (Miles et al., 2014; Muncey, 2009).

Constructivists tend to use qualitative methodologies focusing on naturally occurring events in natural settings, employing methods such as semi-structured interviews and focus groups which concentrate on the subjective viewpoint (Miles et al., 2014; Teddie and Tashakkori, 2009). Constructivism allows the researcher to consider the most appropriate approach for a specific patient in a particular situation. In addition, Miles et al., (2014) argue that qualitative methods can address causation through greater understanding of the ‘what’ and ‘why’ behind interventions. Provision of ‘thick description’ of the research context and the development of theories, aid transferability of findings (Lewis and Ritchie, 2003; Teddie and Tashakkori, 2009), while techniques of prolonged engagement, persistent observation, triangulation and respondent validation, aid credibility (Teddie and Tashakkori, 2009). However, a lack of necessary detail in reporting studies and a lack of transferability to other situations, has led to the criticism of using qualitative methodologies in isolation (Miles et al., 2014; Scotland, 2012).

It is argued that pragmatism reconciles positivist and constructivist paradigms (Morgan, 2007; Teddie and Tashakkori, 2009).

2.7.3 Pragmatism

Pragmatism has been defined as a:

> *"...paradigm that debunks concepts such as "truth" and "reality" and focuses instead on "what works" as the truth regarding the research question under investigation. Pragmatism rejects the either/or choices associated with the paradigm wars, advocates for the use of mixed methods in research and acknowledges that the values of the researcher play a large role in the interpretation of results"* (Tashakkori and Teddie, 2003, p.713)

Pragmatism supports the use of both quantitative and qualitative methodologies, and as noted in the quote above, advocates for mixed-methods research through the collection of both subjective and objective viewpoints, depending on which is best suited to address a specific research issue at a particular time (Teddie and Tashakkori, 2009). While pragmatism has been criticised for failing to articulate 'what' works (Hall, 2013), researcher values, and for whom the research is for (Mertens, 2003), Teddie and Tashakkori, (2009) argue that these are misconceptions, stating that pragmatism recognises the values of the researcher in interpreting results and that it aims to find 'workable solutions' to problems. Additionally, while Morgan (2007) in agreement with Mertens (2003) notes that results cannot be generalised to every situation, Morgan argues that the assumption of a middle-ground between positivist and constructivist paradigms means that results are rarely so unique to a specific context to totally lack transferability (Morgan, 2007).

While some researchers have maintained that mixed-methods research can be conducted without a paradigm, through alternate paradigms or through multiple paradigms (Hall, 2013; Shannon-Baker, 2016), the author of this thesis, in agreement with other mixed-methods researchers (Creswell, 2015; Teddie and Tashakkori, 2009), assumes a pragmatic stance.

2.7.4 The Researcher as a Pragmatist

While socialised as a physiotherapist into a positivist paradigm, the author of this thesis gradually assumed a pragmatic stance. This was through recognition of limitations of the 'scientific method', often noting that samples included in quantitative studies were not representative of the variety of patients seen in clinical practice due to restrictive inclusion criteria and selection and volunteer bias (Salkind, 2010). In addition, clinical experience taught that contextual factors were often key to the success or failure of a treatment intervention and again this was often overlooked when interpreting results from clinical trials

(Treweek and Zwarenstein, 2009). However, while qualitative studies provide relevant contextual information, they are unable to address whether a treatment works or not. Consequently, the need for a mixed-methods approach to address the complexities of rehabilitation, ensuring interventions were feasible, acceptable *and* effective was apparent from clinical practice and endorsed by the literature (Craig et al., 2008; Haywood et al., 2006; NHS England, 2015; Whitstock, 2003). A further facilitator of the move towards a pragmatic stance was in acknowledgement that that our understanding of neuroscience and mechanisms of neurological recovery is incomplete. As our understanding of the brain, and theories of recovery are likely to change with technical developments and new knowledge, a pragmatic stance allows for flexibility in approach recognising that what is considered to be true is likely to change over time (Biesenthal, 2014).

2.8 Research Governance

Good Clinical Practice and the Research Governance Framework for Health and Social Services (2005) and Data Protection Act (1998) were used throughout all study phases to ensure ethical practice.

2.9 Summary

In summary, this chapter provided the justification for the structure, methodological approach and methods used in this thesis.

Chapter 3: Review of the Literature

3.1 Introduction

This chapter presents a mixed-methods review of the literature regarding the effectiveness, acceptability and feasibility of using VR gaming technologies in the rehabilitation of the upper-limb following stroke. An initial review of the (at the time) most prevalent VR gaming system, the Nintendo Wii, for motor rehabilitation was undertaken in January 2012 (Tsekeleves et al., 2014). Engagement with new literature continued throughout the thesis process. However, considerable advances in technology, the launch of rival gaming systems (such as the Microsoft Kinect, launched in November 2010), increasing development of purpose-built VR-based rehabilitation systems, combined with an upsurge in technology use in everyday life (Taylor, 2015), necessitated an updated examination of the literature. An additional literature review was therefore undertaken in March 2018. Review topics of efficacy, acceptability (as defined in Section 2.3) and feasibility (as defined in Section 2.3) were developed in-line with MRC Framework recommendations (Craig et al., 2008). Specific review questions were:

1. Does the use of VR gaming technologies improve measures of upper-limb impairment, activity or participation for adults following stroke compared with conventional treatment or no treatment?
2. Are VR gaming technologies acceptable for use in upper-limb rehabilitation in adults following stroke?
3. Are VR gaming technologies feasible for upper-limb rehabilitation in adults following stroke?

This review adds to the current body of knowledge through the inclusion of systems using modified versions of commercial VR gaming devices as well as up to date literature. Moreover, to the best of the author's knowledge, this is the first review which synthesises the findings of feasibility and acceptability with efficacy of different types of VR system.

3.2 Review Design

In order to address review questions (Section 3.1), a mixed-methods review was undertaken with both qualitative, quantitative and mixed-methods studies being included in the search strategy. Combining different methodological approaches within a review has been proposed as a means of providing a more holistic and complete understanding of a topic than the use

of a single methodology in isolation (Grant and Booth, 2009). Moreover, the inclusion of qualitative and quantitative studies within a review has been advocated when multiple questions are asked within one review (Harden, 2010).

The main body of the review is organised into three key sections, starting with evidence of VR system efficacy, secondly, evidence of acceptability is presented and thirdly, evidence of feasibility is presented. Within each of these sections, evidence is presented by device type with devices being classified as off-the-shelf systems (developed for commercial gaming purposes), purpose-built systems (those built specifically for rehabilitation purposes) and modified versions of commercially available systems (those modifying commercially available gaming devices for rehabilitation purposes).

3.3 Eligibility Criteria

The review questions and eligibility criteria were defined using the PICOT framework (detailing the **P**opulation, **I**ntervention, **C**omparator and **O**utcome, **T**ype of study):

- **Population**. The population of interest was adult stroke survivors with upper-limb motor deficits as a result of stroke. Participants of all stroke chronicity and severity of initial upper-limb impairment were included.
- **Intervention**. The interventions of interest were virtual reality or video gaming technologies used to rehabilitate upper-limb motor deficits after stroke (regardless of level of immersion or study setting but excluding interventions using VR in combination with robotics, exoskeletons and interventions not commonly used in clinical practice).
- **Comparator**. The comparator of interest was conventional therapy or no therapy where studies examined efficacy or effectiveness. Where acceptability and feasibility were explored, studies without a comparator were included.
- **Outcome**.
    - Where studies examined efficacy, outcomes of interest were:
        - recognised measures of impairment, activity or participation.
    - Where studies examined acceptability outcomes of interest were:
        - Attitudes toward the intervention (e.g. effects of the intervention on enjoyment, motivation, engagement, satisfaction).
        - Burden of use (indications of effort or difficulty of use)
        - Attrition
    - Where studies examined feasibility, outcomes of interest were:
        - Occurrence of adverse effects
        - Rates of study inclusion

        - Feasibility of independent use
        - Feasibility of gameplay
        - System Costs
- **Type of study**.
    - Where studies examined efficacy, SRs and additional research papers omitted from SR's were included. As few RCTs examine the use of purpose-built and modified systems, no limit on study design was imposed.
    - Where studies explored acceptability or feasibility both quantitative and qualitative studies were included.

3.4 Search Strategy

The following databases were searched from January 2013 to March 2018: Association for Computing Machinery [ACM] Digital Library, Institute of Electrical and Electronics Engineers [IEEE], Allied and Complementary Medicine Database [AMED], the Cochrane Central Register of Controlled Trials [CENTRAL], the Cochrane Database of Systematic Reviews, the Cumulative Index to Allied Health Plus [Cinahl Plus], Medical Literature Analysis and Retrieval System Online [Medline], Physiotherapy Evidence Database [PEDro], PsycARTICLES, Psychological Database for Brain Impairment Treatment Efficacy [Psychbite], PsychINFO and Scopus. Boolean operators were used to combine search terms relating to each of PICO. Search terms included Stroke, CVA, "cerebrovascular accident", arm, "upper limb", "upper extremity", "arm recovery", "upper limb recovery", "motor recovery", "arm rehab*", "upper limb rehab*", "virtual reality", VR, "serious games for health", "video games", gaming, "gaming technologies", "e-rehab". Reference lists of review articles were searched for additional relevant articles.

The search was limited to studies published after January 2013 as technological advances and increased penetration of technology into society are likely to result in changes to feasibility and attitudes towards technology. Studies published in any language other than English were excluded due to lack of availability of interpreters. While studies employing the use of straps to secure movement sensors or low- technology splints (commonly used in clinical practice) were included, to avoid confounding factors and to reflect clinical practice more accurately, studies employing exoskeletons (such as the SaeboFlex) and robots were excluded. Additionally, (and again to avoid confounding factors), studies were excluded if VR gaming technologies were combined with another modality (e.g. electrical stimulation techniques, mirror-box therapy), if they included children, non-stroke participants or did not involve upper-limb motor recovery (unless results pertaining to adult, stroke upper-limb,

using VR gaming technologies alone were identifiable). Furthermore, study protocols, editorials, commentary papers, narrative reviews without synthesis, papers providing technical details of VR systems only, those involving telemonitoring or use of VR for assessment purposes, those comparing VR gaming technologies with interventions not commonly used in clinical practice (e.g. Transcranial Magnetic Stimulation and brain-machine interfaces) were excluded.

Titles and abstracts were screened for eligibility. Where reports met the eligibility criteria or where there was uncertainty as to whether the report met the eligibility criteria, the full text was obtained and screened for eligibility.

Primary research papers evaluating efficacy were cross-referenced against the list of studies included in SRs. Where duplication was found, the primary research study was excluded from analysis of efficacy to avoid 'double-counting' of papers. However, where such primary research papers had also provided evidence of acceptability and feasibility, papers were retained and included in the analysis of these constructs only.

3.5 Data Extraction, Data Analysis and Quality Assessment

Data on participants, interventions, comparators, outcomes measures, results and indicators of acceptability and feasibility (as described in Section 3.3) were extracted using a standardised data extraction form (Appendix 3).

The Critical Appraisal Skills Programme (CASP) checklists (for RCTs, SRs, Qualitative studies, case control studies) were chosen to appraise methodological quality of included articles in this review. Questions within the CASP checklists were used as appraisal criteria operationalised in the evidence tables (Appendices 3.1-3.4). However, checklist criteria were not used as a means of study exclusion. While numerous critical appraisal tools exist, there is a lack of consensus regarding the most appropriate for evaluation of health research, (Katrak et al., 2004; Munthe-Kaas et al., 2019; Quigley et al., 2019). CASP tools were chosen due to their emphasis on contextual detail, thereby mapping onto study aims regarding feasibility and acceptability and enhancing the clinical relevance of review findings (Harrison et al., 2017). Additionally, the succinct nature of CASP tools and similarity in format between appraisal tools facilitated extraction of data into evidence tables (Appendices 3.1-3.4).

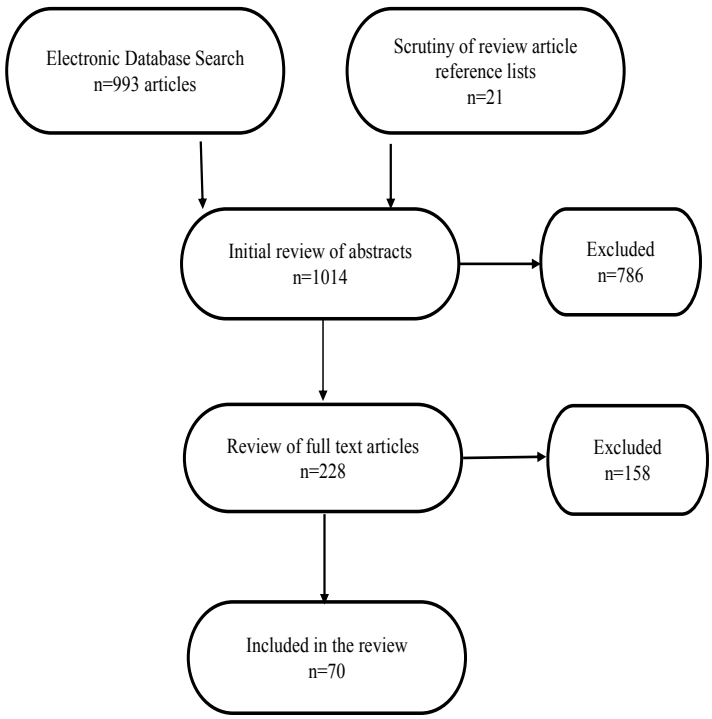
3.5.1 Assessment of Stroke Severity

While studies frequently discuss impairment in terms of whether it can be considered mild, moderate, or severe, the use of different measures between studies and a lack of description or consensus about cut-off values between categories make evaluation by the effect of severity of upper-limb impairment, hard to ascertain. Articles were therefore reviewed and where possible, a judgement drawn, based on a combination of baseline measures, stated inclusion criteria and description of ability to interact with a device (for example when an article stated that the participant had to hold the movement sensor in their affected arm, the categories of moderately-severe and severe were ruled out). The cut-off values suggested by Woodbury et al. (2013) were used where baseline Action Research Arm Test (ARAT) or Fugl–Meyer Assessment-Upper Extremity (FMA-UE) scores (when scored using 30 items) were apparent. Where the full FMA-UE scores were provided, the cut-off score of 22 or below (suggested by Hoornhorst et al., 2015) was used to define severe impairment. Discussion and, where possible, description of upper-limb impairment of participants is discussed under each subheading.

3.6 Search Results

The search results are presented in Figure 3.1.

Figure 3.1 Flow Chart of Literature Search



A total of 993 papers were identified through electronic database searches and an additional 21 papers were identified through searching reference lists of identified articles (n=1,014). Following screening of titles and abstracts 786 papers were excluded (as duplicates, non-VR, non-English, use of VR plus exoskeletons or robotics, study protocols, narrative reviews without synthesis, technical reports without evaluation by stroke survivors). Full texts of the remaining 228 articles were obtained. Of these, 154 papers were excluded on the basis of being unable to ascertain results relating to adult, stroke, upper-limb recovery using VR gaming technologies in isolation, non-use of measures of impairment, activity or participation to evaluate efficacy (e.g. use of improvement in game scores, or change in brain imagery measures), use of author judgements without quantitative or qualitative evaluation by stroke participants or clinicians regarding system feasibility and/or acceptability. Additionally, four review articles were excluded. One (Laver et al., 2015) had been superseded by an updated version (Laver et al., 2017) and three contained no additional relevant studies to Laver et al. (2017) (Dos Santos et al., 2015; Farmer et al., 2014; Pollock et al., 2014). Seven studies were reported in two articles each (Adie et al., 2017 & Wingham et al., 2015; Brunner et al., 2017 & Pallesen et al., 2018; Demers et al., 2017 & 2018; House et al., 2015 & 2016; Paquin et al., 2015 & 2016; Rand et al., 2015 & 2017; Standen et al., 2015 & 2017). Seventy reports of 63 studies were included in this review.

3.7 Characteristics of Included Studies

Of the 70 articles included in the final review, six were systematic reviews (SRs) and 64 were original research articles (of 57 studies). A synopsis of study characteristics of original research articles is provided in Appendix 3.5. Of the 42 articles examining efficacy, six were systematic reviews and 36 were original research papers not already evaluated in the SRs. Thirty-seven articles evaluated system acceptability. Twenty-six provided details of study exclusion rates. Thirty-five provided indications of feasibility for independent use. Thirty-one papers recorded occurrence of adverse effects and four provided system costs. No study provided integrated mixed-methods evaluation of efficacy, feasibility and acceptability.

3.7.1 Characteristics of Systematic Reviews

Of the six SR's, three evaluated commercially available, non-immersive, off-the-shelf VR gaming systems (Casserly and Baer, 2014; Pietrzak et al., 2014; Thomson et al., 2014) and the remaining three reviews evaluated purpose-built systems in addition to off the-shelf VR gaming systems (Hatem et al., 2016; Laver et al., 2017; Veerbeek et al., 2014). The level of immersion of included papers in reviews by Hatem et al., (2016) and Veerbeek et al., (2014) was not clear. Reviews by Laver et al. (2017) included evaluation of immersive systems.

Five reviews excluded studies of non-commercial systems and therefore did not evaluate the efficacy of modified versions of off-the-shelf VR gaming systems (Casserly and Baer, 2014; Hatem et al., 2016; Laver et al., 2017; Pietrzak et al., 2014, Thomson et al., 2014). Details of individual reviews are presented in Appendix 3.1.

3.7.2 Characteristics of Off-the-Shelf VR Gaming System Studies

Study characteristics of the 22 research articles of 19 studies exploring the use of commercially available, off-the-shelf VR gaming systems for upper-limb rehabilitation after stroke are presented in Table 3.1.

Table 3.1 Characteristics of Off-the-Shelf VR Gaming System Studies

Study	Device Type	Setting	Level of immersion	Activity type	Area of training	Personalisation
Adie et al. (2017) & Wingham et al., (2015;)	Nintendo Wii	Home based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Carregosa et al. (2018)	Nintendo Wii	Not stated	Non-immersive	Game	Shoulder, elbow, forearm	None
Chen et al. (2015a)	Nintendo Wii and XaviX	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Choi et al. (2014)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Da Silva Ribeiro et al. (2015)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Fan et al. (2014)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Givon et al. (2016)	Microsoft Kinect, Sony Playstation 2 Eyetoy, Sony Playstation 3 MOVE, See MEe, Nintendo Wii	Not stated	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Kong et al. (2016)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Lee (2013)	Microsoft Kinect	Not stated	Non-immersive	Game	Shoulder, elbow, forearm	None

Study	Device Type	Setting	Level of immersion	Activity type	Area of training	Personalisation
Matsuo et al. (2013)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
McNulty et al. (2013)	Nintendo Wii	Home based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
McNulty et al. (2015)	Nintendo Wii	Home based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Paquin et al. (2015 & 2016)	Nintendo Wii and uDraw	Clinically based	Non-immersive	Game, sport	Wrist & hand	None
Rand et al. (2015 & 2017)	Microsoft Kinect, Sony Playstation 2 Eyetoy,	Home based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Rinne et al. (2016)	Not stated	Not stated	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Saposnik et al. (2016)	Nintendo Wii	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Sin and Lee (2013)	Microsoft Kinect	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Türkbey et al. (2017)	Microsoft Kinect	Clinically based	Non-immersive	Game or sport	Shoulder, elbow, forearm	None
Vanbellingen et al. (2017)	Leap Motion	Clinically based	Non-immersive	Game	Wrist & hand	None

Of these, 11 studies evaluated the Nintendo Wii, three used the Microsoft Kinect, one used the Leap Motion and one used an unstated commercial game. Eleven studies were clinically based, four were home-based and the setting for the remaining four was unclear. All systems were non-immersive, employed game or sports activities. Seventeen trained shoulder, elbow or forearm movements and two targeted the wrist and hand. No system was personalised. Details of individual studies are presented in Appendix 3.2.

3.7.3 Characteristics of Purpose-Built System Studies

Study characteristics of the 24 original research articles of 22 studies exploring the use of purpose-built VR systems for upper-limb rehabilitation after stroke are presented in Table 3.2.

Table 3.2 Characteristics of Purpose-Built Gaming System Studies

Study	Device Type	Setting	Level of immersion	Activity type	Area of training	Personalisation
Brunner et al. (2017) & Pallesen et al. (2018)	YouGrabber	Clinically based	Non-immersive	Games	Entire upper limb	Yes
Choi et al. (2016)	Non-commercial, Protoype	Clinically based	Non-immersive	Games	Shoulder, elbow, forearm	Yes
Finley and Combs (2013)	HandDance Pro	Not stated	Non-immersive	Dance moves	Hand	Yes
House et al. (2015 & 2016)	Non-commercial, Protoype	Clinically based	Non-immersive	Traditional exercise	Entire upper limb	Yes
Hung et al. (2016)	Rehaslide	Not stated	Non-immersive	Games	Shoulder, elbow, forearm	None specified
Jordan et al. (2014)	Non-commercial, Protoype	Home based	Non-immersive	Games	Shoulder, elbow, forearm	Yes
Lee (2015)	IREX	Clinically based	Non-immersive	Games	Entire upper limb	Yes
Lee et al. (2016b)	Non-commercial, Protoype	Clinically based	Non-immersive	Not stated	Not stated	None specified
Mace et al. (2017)	Non-commercial, Protoype	Not stated	Non-immersive	Games	Hand	Yes
Orihuela-Espina et al. (2013)	Non-commercial, Protoype	Not stated	Non-immersive	Games	Entire upper limb	None specified
Perez Marcos et al. (2017)	Non-commercial, Protoype	Not stated	Non-immersive	Games	Shoulder, elbow, forearm	Yes
Rand et al. (2013)	Non-commercial, Protoype	Not stated	Non-immersive	Games & exercise	Hand	None specified
Schuster-Amft et al. (2015)	YouGrabber	Not stated	Non-immersive	Games	Entire upper limb	Yes
Shin et al. (2014)	Non-commercial, Protoype	Clinically based	Non-immersive	Games	Hand	Yes
Shin et al. (2016)	Non-commercial, Protoype	Clinically based	Non-immersive	Games	Hand	Yes
Slijper et al. (2014)	Non-commercial, Protoype	Home based	Non-immersive	Games	Entire upper limb	Yes
Stockley et al. (2017)	YouGrabber	Clinically based	Non-immersive	Games	Hand	None specified
Subramanian et al. (2013)	CAREN	Not stated	Immersive	ADL activity	Shoulder, elbow, forearm	Yes
Tanaka et al. (2013)	Non-commercial, Protoype	Not stated	Non-immersive	Traditional exercise	Shoulder, elbow, forearm	Yes

Study	Device Type	Setting	Level of immersion	Activity type	Area of training	Personalisation
Turolla et al. (2013)	Non-commercial, Protoype	Not stated	Non-immersive	ADL activity	Shoulder, elbow, forearm	Yes
Wittman et al. (2015)	ArmeoSenso	Home based	Non-immersive	Games	Shoulder, elbow, forearm	Yes
Yin et al. (2014)	Non-commercial, Protoype	Not stated	Non-immersive	ADL activity	Shoulder, elbow, forearm	Yes

Eight studies evaluated commercially available systems including the YouGrabber, HandDance Pro, Rehaslide, IREX, CAREN and ArmeoSenso. The remaining 14 studies used prototype VR systems which were not commercially available at the time of publication. Ten studies were clinically based, three were set in participant homes and the setting for the remaining nine was unclear. Subramanian et al., (2013) was the only study to use immersive VR technology.

Six studies targeted the entire upper-limb including the wrist and hand, nine targeted the shoulder, elbow and forearm, while six targeted the hand. The target for one study was not apparent. One study used dance moves, two used traditional exercises in a VR setting, one used a combination of games and exercise and three used activities of daily living (ADL). Lee et al. (2016b) did not state the type of activity. All other studies employed games. Some degree of personalisation (most commonly with regard to speed, and range of movement) was possible in all but five of the systems. Details of individual studies are presented in Appendix 3.3.

3.7.4 Characteristics of Studies Using Modified Versions of VR Commercial Gaming Devices

Study characteristics of 18 original research articles of 16 studies exploring the use of modified versions of commercial gaming systems for upper-limb rehabilitation after stroke are presented in Table 3.3.

Table 3.3 Characteristics of Studies Using Modified Commercial Gaming Systems

Study	Movement detection System	Setting	Level of immersion	Activity type	Area of training	Personalisation
Adams et al., 2018	Microsoft Kinect camera	Clinically based	Non-immersive	Games	Shoulder, elbow, forearm,	Yes
Aşkin et al., 2018;	Microsoft Kinect camera	Clinically based	Non-immersive	Games	Shoulder, elbow, forearm, wrist	None specified
Ballester et al., 2017	Microsoft Kinect camera	Home	Non-immersive	Games	Entire upper limb	Yes
Cameirão et al. (2017)	Sony Eyetoy camers	Clinically based	Non-immersive	Games	Shoulder, elbow, forearm,	Yes
Chen et al. (2015b)	Microsoft Kinect camera	Clinically based	Non-immersive	Games	Shoulder, elbow, forearm,	Yes
Chiu et al. (2017)	Novint Falcon	Not stated	Non-immersive	Games	Hand	None specified
Demers et al. (2017 & 2018)	Microsoft Kinect camera	Clinically based	Non-immersive	Games	Hand	None specified
Ellington et al. (2015)	Microsoft Kinect camera	Clinically based	Non-immersive	ADL tasks	Entire upper limb	None specified
Kato et al. (2015)	Microsoft Kinect camera	Hospital and home	Semi-immersive	Traditional exercises	Shoulder, elbow, forearm,	Yes
Kizony et al. (2013)	Microsoft Kinect camera	Home set-up within hospital	Non-immersive	Games	Shoulder, elbow, forearm,	Yes
Lee et al. (2016a)	Microsoft Kinect camera	Clinically based	Non-immersive	Traditional exercises	Entire upper limb	None specified
Moldovan et al. (2017)	Microsoft Kinect camera & Leap Motion	Clinically based	Non-immersive	Games	Entire upper limb	Yes
Seo et al. (2016)	Microsoft Kinect camera & Essential Reality gaming glove	Clinically based	Non-immersive	Games	Entire upper limb	None specified
Standen et al. (2015 & 2017)	Nintendo Wii	Home	Non-immersive	Games	Hand	Yes
Tsekleves et al. (2016)	Nintendo Wii	Laboratory based	Non-immersive	Games	Shoulder, elbow, forearm,	Yes
Yeh et al. (2017)	Novint Falcon	Not stated	Non-immersive	ADL tasks	Hand	None specified

Nine studies used the Kinect camera to track motion, one used the Kinect camera in combination with the Leap Motion (hand tracking technology), another used the Kinect camera in combination with the Essential Reality P5 gaming glove (which detects finger and thumb movements). Two studies used two Nintendo Wii movement sensors, two used the Novint Falcon haptic feedback devices (designed to provide a sense of touch of VR objects) and one study used the Sony Eyetoy camera to detect motion. Ten studies were clinically or laboratory based, three evaluated VR technologies in a home setting and one used a combination of hospital and home settings. The setting for two studies was unclear. Kato et al. (2015) was the only study to use semi-immersive technology, the rest were non-immersive systems. The SaeboVR system using the Kinect camera was the only commercially available device (Adams et al., 2018).

Five devices targeted the whole upper-limb including the hand, one targeted the shoulder to the wrist, six targeted the shoulder elbow and forearm, while four studies targeted the hand in isolation. Two studies employed ADL tasks, two used traditional style exercises and the other 12 used purpose-built games. Some degree of personalisation (most commonly with regard to range of movement and speed) was possible in nine of the VR systems. Details of individual studies are presented in Appendix 3.4.

3.8 Efficacy of VR Gaming Technologies for Upper-Limb Rehabilitation

Efficacy of VR gaming technologies for upper-limb stroke rehabilitation is presented in this section, starting with evidence from SRs. Evidence from original research papers not included in the SRs is then presented by the type of VR system used.

3.8.1 Evidence from Systematic reviews

A summary of evidence from SRs is included in Appendix 3.1. The three reviews evaluating commercially available, off-the-shelf VR gaming systems (Casserly and Baer, 2014, Pietrzak et al., 2014, Thomson et al., 2014) identified an additional 24 studies to Laver et al (2017) through the inclusion of quasi and non-experimental study designs. All reviews reported positive effects on upper-limb recovery however no meta-analysis or sub-group analysis by stroke severity or chronicity was performed therefore the effectiveness for participants with differing levels of impairment was not apparent. Methodological limitations may have limited review conclusions, as no engineering databases were searched and 50% of studies included in the review by Pietrzak et al., (2014) were reviewed by abstract alone.

A SR and meta-analysis of randomised controlled studies (RCTs) published between 2001 and 2011 (Veerbeek et al., 2014) without limits to the type of VR system used, identified 15 relevant studies, of which seven were not included in the review by Laver et al. (2017). The authors report a significant improvement in ADLs with VR interventions (although they do not provide effect estimates and confidence intervals [CI]). While studies included participants with differing length of time since stroke onset, results are not considered by chronicity. Moreover, as severity of stroke is not stated, the relevance of these results to all stroke participants is unclear. However, results regarding the positive effect of VR are in agreement with Casserly and Baer (2014), Pietrzak et al. (2014) and Thomson et al. (2014). While the other reviews excluded non-commercial devices, criteria stated by Veerbeek et al. (2014) allowed for inclusion of studies using modified versions of commercial systems. However, it was unclear whether any such studies were actually included. In addition, if studies using these systems were included, they would be unlikely to have used components of the Microsoft Kinect system, due to the proximity of the Kinect launch date (November 2010) and the date of the final literature search (June 2011).

A more recent systematic review by Hatem et al. (2016) included 14 studies conducted between 1971 and 2015, of both purpose-built and commercial off-the-shelf VR devices. Although only two databases (neither engineering) were employed, an additional ten studies not included in the review by Laver et al. (2017) were identified. Hatem et al. (2016) concluded that there is moderate level evidence that VR is as effective as conventional therapy. Additionally, they concluded that there is moderate level evidence that systems using serious games (i.e. purpose-built) and more immersive systems are superior to conventional therapy. While papers included by Hatem et al. (2016) were either systematic reviews, randomised controlled trials, or controlled trials and with PEDro ratings above or equal to 4, there was no meta-analysis or subgroup analysis by severity or chronicity. Moreover, studies using VR in addition to brain stimulation and use of an exoskeleton restricts the conclusions which can be drawn about the effectiveness of VR alone.

An updated Cochrane review by Laver et al. (2017) included 35 relevant studies (involving 1,243 participants) published before May 2017. Like Hatem et al. (2016) the review by Laver et al. (2017) included studies that employed both commercially available gaming-based and commercially available purpose-built systems and also allowed studies which had used robotics in conjunction with VR. Laver et al. (2017) performed a dual analysis, firstly comparing VR gaming technologies with the same dose of conventional therapy and in the

second, the effectiveness of VR gaming technologies was examined as a means of providing additional therapy.

Laver et al. (2017) found there was no significant difference in upper-limb function, activity, grip strength or self-reported amount of use when comparing VR gaming technologies with the same dose of conventional therapy. In agreement with findings by Hatem et al. (2016) Laver et al. (2017) therefore conclude that there is low grade evidence that VR gaming technologies are as effective as, but not superior to, conventional therapy. When considering results by the type of VR system used (i.e. whether off-the-shelf or purpose-developed) in keeping with the conclusions of reviews by Casserly and Baer, (2014), Pietrzak et al. (2014) and Thomson et al. (2014), Laver et al. (2017) again found that when the dose is matched, off-the-shelf VR technologies are as good as, but not better than conventional therapy. Conversely, and in line with reviews which had included purpose-built systems (Hatem et al., 2016; Veerbeek et al., 2014), Laver et al. (2017) found significant benefit for purpose-built VR programmes when compared to a matched dose of conventional therapy (standardised mean difference [SMD] 0.17; 95% CI, 0.00-0.35). This suggests the need for systems designed specifically for stroke survivors.

When VR was used as a means of providing additional therapy, a significant improvement in upper-limb function was found (SMD 0.49; 95% CI, 0.21-0.77). Moreover, when VR was used as a means of providing additional therapy, studies providing more than 15 hours in total of VR intervention, showed a significant benefit (SMD 0.54; 95% CI, 0.14-0.80) compared to those providing less than 15 hours. Together findings, suggest that the effectiveness of VR is underpinned by the ability to provide additional practice as opposed to the effects of the VR intervention itself. As few studies in any of the reviews included immersive VR, no analysis by level of immersion could be undertaken. It is therefore possible that different effects and mechanisms may underlie systems providing a more immersive experience.

Laver et al. (2017) also performed subgroup analysis by baseline severity of upper-limb impairment. When compared with a matched dose of conventional therapy, improvements were apparent in those classified as having mild to moderate upper-limb impairment and in those with moderate to severe upper-limb impairment. However, results were not statistically significant and no cut-off values or other indication of how severity was calculated was provided in the paper (or in a follow-up email to Laver et al., 2017) and therefore the severity of those in the moderate to severe category is uncertain. In addition, although protocols of

some studies included in the review by Laver et al. (2017) *allowed* the inclusion of those with more severe upper-limb deficits, in many cases it is not possible to ascertain the severity of those who *actually* participated, and as such, the effectiveness with those with more severe deficits remains unclear. Furthermore, as studies were included if they used robotics and exoskeletons in addition to VR, the effectiveness of VR in isolation is not apparent. Methodological issues meant no subgroup analysis by stroke severity could be undertaken when considering VR as a means of providing additional therapy. A trend for greater improvement in those with stroke chronicity above six months was noted when comparing VR with conventional therapy (SMD 0.19; 95% CI, 0.02-0.39) and was supported by significant improvement when VR was used as additional therapy (SMD 0.65; 95% CI, 0.19-1.11), suggesting VR may be more appropriate in later stage, community rehabilitation.

Evidence from SRs support the use of VR as an adjunct to, but not as a replacement for, conventional therapy. Additionally, Casserly and Baer (2014), Thomson et al. (2014) and Laver et al. (2017) conclude that the VR systems are safe to use as no serious adverse effects were reported in any of the studies included in their reviews. However, this conclusion should be viewed with caution as few of the included studies provided details of the incidence of minor or moderate adverse events and moreover almost half failed to report on whether any type of adverse event had occurred or not. Limitations in reviews were apparent resulting in uncertainty over the efficacy of VR gaming technologies alone for those with more severe upper-limb impairment. Additionally, no review provided analysis of systems using modified versions of commercially available entertainment-based systems.

In a rapidly developing field, additional literature not available, or not included in the systematic reviews was identified. This is presented in the following sections organised by type of VR system used.

3.8.2 Efficacy of Commercial Off-The-Shelf VR Gaming Systems

A summary of evidence from studies evaluating commercial, off-the-shelf VR gaming devices is included in Appendix 3.2. An additional ten studies not included in SRs discussed in Section 3.7.1 assessed the efficacy of commercially available, off-the-shelf, VR gaming systems (Carregosa et al., 2018; Chen et al., 2015a; Choi et al., 2014; Givon et al., 2016; Lee, 2013; McNulty et al., 2013; Paquin et al., 2015 & 2016; Rand 2015 & 2017; Türkbey et al., 2017; Vanbellingen et al., 2017).

Two hundred and eighty-one participants were included across the ten studies (range 17 to 47; mean [Standard deviation {SD}] 23.4 [11.79]). Five were randomised controlled trials (Choi et al., 2014; Givon et al., 2016; Lee, 2013; Rand et al., 2017; Türkbey et al., 2017) involving 125 participants, one was a non-randomised control trial (Chen 2015a) using 24 participants and four used a single-group, pre-test, post-test design (Carragosa et al., 2018; McNulty et al., 2013; Paquin et al., 2015 & 2016; Vanbellingen et al., 2017) using a combined total of 58 participants. Five studies used participants with a stroke chronicity above six months (Carragosa et al., 2018; Givon et al., 2016; Paquin et al., 2015 & 2016; Rand et al., 2015 & 2017; Türkbey et al., 2017); three included those with chronicity above three months (Chen et al., 2015a; Lee, 2013; McNulty et al., 2013). Two studies recruited participants within three months of stroke (Choi et al., 2014; Vanbellingen et al., 2017). The target dose of intervention varied ranging from a target of 270 minutes up to 1,800 minutes and was provided in schedules between 30-60 minutes at a time, two to six days a week, over two to 12 weeks. Two studies were home based (McNulty et al., 2013, Rand et al., 2015 & 2017); five were hospital based (Chen et al., 2015a; Choi et al., 2014; Paquin et al., 2015 & 2016; Türkbey et al., 2017; Vanbellingen et al., 2017) and the setting for the remaining three was uncertain (Carragosa et al., 2018; Givon et al., 2016; Lee, 2013).

Results from Randomised Controlled Trials

Results from all RCTs found statistically significant improvements in primary outcome measures of upper-limb motor ability following use of commercial off-the-shelf VR gaming-based systems regardless of chronicity, study setting, targeted joints or intervention dose (Choi et al., 2014; Givon et al., 2016; Lee, 2013; Rand et al., 2017; Türkbey et al., 2017). Effect sizes were not provided. Additionally, the minimally clinically important difference (MCID) was reached in the study by Tükbey et al. (2017) indicating that a clinically meaningful, as well as a statistically significant improvement had occurred.

In keeping with findings by Laver et al. (2017) and Hatem et al. (2016), four of the five RCT's found that VR interventions were as effective as, but not better than conventional therapy (Choi et al., 2014; Givon et al., 2016; Lee, 2013; Rand et al., 2017). While the fifth study (Türkbey et al., 2017) concluded that VR was better than conventional therapy, the VR group received both the intervention and conventional therapy, thereby doubling the treatment time compared to the control group. It is therefore likely that the greater improvements seen in the VR group resulted from the increased intervention dose as opposed to the effect of the intervention per se.

Results from Quasi-Experimental Studies

In support of findings from RCT's, results from four quasi-experimental studies found statistically significant improvements in the primary outcome measures of upper-limb motor ability following use of commercial off-the-shelf VR gaming-based systems regardless of chronicity, study setting, targeted joints or intervention dose (Chen et al., 2015a; McNulty et al., 2013; Paquin et al., 2015 & 2016; Vanbellingen et al., 2017). Effect sizes were not provided. Additionally, the minimally clinically important difference (MCID) was reached in studies by Chen et al. (2015a) and Carragosa et al. (2018) indicating that a clinically meaningful improvement had occurred.

Results by Stroke Severity

Most of the studies appeared to employ participants with mild to moderate upper-limb impairment (Carregosa et al., 2018; Chen et al., 2015a; Choi et al., 2014; Paquin et al., 2015 & 2016; Rand et al., 2017, Vanbellingen et al., 2017). All concluded that VR was effective. No indication of severity was provided by Lee (2013). Inclusion criteria in Türkbey et al. (2017) study was stated as having a Brunnstrom stage of equal to or above three indicating that those with severe deficits could be included. However, the severity of those who actually participated is not stated.

Inclusion criteria and baseline scores on outcome measures suggested that two studies included those with more severe deficits. Participants in McNulty et al. (2013) ranged from 2-46 on the FMA-UE suggesting that the participant scoring 2 experienced severe deficits. Moreover, mean (SD) scores on the FMA-UE were 17.2 (4.1) again indicating severe deficits and the authors report that all participants were classified as having low motor function based on their "recently devised scheme" (p116). As participants were beyond three months since stroke, when all spontaneous recovery is believed to have occurred (Kwakkel and Kollen, 2015; Krakauer, 2015) significant improvements in mean group scores on the FMA-UE, ARAT, Wolf Motor Function Test (WMFT) and Motor Activity Log (MAL) suggest that VR can be an effective intervention for those with more severe deficits. However, the use of a quasi-experimental design without randomisation or a control group means results must be interpreted with caution. Additionally, inclusion criteria appear to contradict the stated level of severity as participants had to hold the movement sensor in their affected hand, indicating that their actual ability was substantially higher than the FMA-UE score indicated. Furthermore, some non-Wii based activities were incorporated when required, although details of to what extent this occurred is not stated.

In the RCT by Givon et al. (2016), mean (SD) FMA-UE baseline scores of 32.2 (20.5) in the VR group and 26.5 (19.6) in the control indicated that the mean group severity was in the moderate category. However, at least one participant had a baseline FMA-UE score of 5, indicating severe impairment. Improvements in the primary outcome measure of grip strength were statistically significant in both groups suggesting that VR is as effective as conventional treatment in participants with chronic stroke. However, results for individuals were not presented and therefore effects for those with more severe stroke could be lost in group effects. Moreover, grip strength scores could potentially be confounded by increases in hypertonicity in those with severe impairment (Carr and Shepherd, 1980) making this an unreliable measure of upper-limb improvement. As such, the efficacy of off-the-shelf VR gaming systems for upper-limb stroke recovery in those with more severe levels of impairment remain uncertain.

Small sample sizes and the use of single-group, pre-test, post-test study designs in participants with stroke chronicity less than six months when spontaneous recovery is still possible (Kwakkel and Kollen, 2015), limit conclusions which can be drawn. Nonetheless, the evidence concurs with results from Laver et al. (2017) suggesting that VR using commercial, off-the-shelf VR gaming systems is as effective as conventional therapy for upper-limb rehabilitation following stroke. However, the effectiveness for those with more severe levels of upper-limb impairment is uncertain. As all studies used non-immersive systems and all had used either sports or game scenarios, no conclusions can be drawn regarding the effectiveness of immersion or the type of activity used in VR.

3.8.3 Efficacy of Purpose-Built Systems

A summary of evidence from studies evaluating purpose-built VR gaming systems is included in Appendix 3.3. An additional 13 studies not included in SRs discussed in section 3.7.1 assessed the efficacy of purpose-built VR gaming systems (Brunner et al., 2017 & Pallesen et al., 2018; Choi et al., 2016; House et al., 2015 & 2016; Jordan et al., 2014; Lee, 2015; Orihuela-Espina et al., 2013; Perez Marcos et al., 2017; Schuster-Amft et al., 2015; Shin et al., 2016; Slijper et al., 2014; Stockley et al., 2017; Tanaka et al., 2013; Wittman et al., 2015).

A total of 277 participants were included across the thirteen studies (range 2-120; mean [SD] 21 [31.68]). Four studies were RCTs (Brunner et al., 2017; Choi et al., 2016; Shin et al., 2016; Stockley et al., 2017) involving 202 participants; one was a non-randomised control trial (House et al., 2015 & 2016) using 10 participants; six used a single-group pre-test, post-

test design (Jordan et al., 2014; Lee, 2015; Orihuela-Espina et al., 2013; Perez Marcos et al., 2017; Tanaka et al., 2013; Wittman et al., 2015) involving 51 participants and two employed single-case experimental designs (Schuster-Amft et al., 2015; Slijper et al., 2014) involving 14 participants. Eight studies included participants with stroke chronicity above six months (House et al., 2015 & 2016; Jordan et al., 2014; Orihuela-Espina et al., 2013; Perez Marcos et al., 2017; Schuster-Amft et al., 2015; Slijper et al., 2014; Stockley et al., 2017; Wittman et al., 2015), two used participants with a stroke chronicity below three months (Brunner et al., 2017; Tanaka et al., 2013) and one set no limits on chronicity (Shin et al., 2016). No indication of chronicity was provided by Choi et al., (2016) and Lee (2015).

The target dose of intervention varied between studies ranging from 300 to 1,200 minutes (although one participant in Wittman et al. [2015] achieved 34 hours 18 minutes over a six-week period and another [Slijper et al., 2014] achieved seventy-eight hours and 47 minutes over five weeks). The target time ranged from 30-60 minutes per session, two to five days a week, over two to 12 weeks. Three studies were home based (Jordan et al., 2014; Slijper et al., 2014; Wittman et al., 2015); one was nursing home based (House et al., 2015 & 2016) and five were hospital-based (Brunner et al., 2017; Choi et al., 2016; Lee, 2015; Shin et al., 2016; Stockley et al., 2017). The setting for the remaining four studies was uncertain (Orihuela-Espina et al., 2013; Perez Marcos et al., 2017; Schuster-Amft et al., 2015; Tanaka et al., 2013).

Results from Randomised Controlled Trials

Results from RCTs found statistically significant improvements in primary outcome measures of upper-limb motor ability following use of purpose-built VR systems regardless of chronicity, study setting, targeted joints, intervention dose or whether an ADL, sport or game scenario was used. Although all systems reviewed here were non-immersive, improvements were also seen in an immersive purpose-built system employed by Subramanian et al. (2013) which is included in the review by Laver et al. (2017).

In keeping with findings from off-the-shelf systems reviewed here (Section 3.5.2.), three of four RCT's found that VR interventions were as effective as, but not better than conventional therapy (Brunner et al., 2017; Choi et al., 2016; Stockley et al., 2017). This contrasts with superior effects found in purpose-built systems reported by Laver et al. (2017) and Hatem et al. (2016). Differences may be explained by the use of prototype, non-commercial devices employed in studies included in this review and the inclusion of systems using robotics and exoskeletons in the published reviews. Consistent with findings by Laver et al. (2017) and

Hatem et al. (2016), one RCT (Shin et al., 2016) found improvements in the VR group only and therefore conclude that VR gaming technologies using purpose-built systems are superior to conventional therapy. Differences in outcome between RCT's were unrelated to device type (commercial or prototype) or severity. Due to lack of reporting of chronicity of participants in Choi et al. (2016) and differing chronicity between other studies, any effect of chronicity on results is not apparent.

Results from Quasi-Experimental Designs

Findings of improvements following VR were further supported by results from the eight quasi-experimental studies which all reported significant improvements in the primary outcome measure regardless of commercially availability, chronicity, study setting, targeted joints, intervention dose or whether an ADL, sport or game scenario was used. Improvements reached the MCID in three of six single-group, pre-test, post-test designs (Lee, 2015; Orihuela-Espina et al., 2013; Perez Marcos et al., 2017). While improvements noted by Tanaka et al. (2013) may be a result of spontaneous recovery seen in acute stages, all other studies employed participants with stroke onset of six months and above making recovery as a result of the intervention more likely. Average repetitions using VR were noted to be 650 by House et al. (2015). Similarly, Jordan et al. (2014) report average repetitions between 500 and 800 per session and Perez-Marcos et al. (2017) found median (Inter Quartile Range {IQR}) repetitions per session of 476 (432, 637). Together findings support the theory that effectiveness of VR interventions is underpinned by the ability to provide greater number of repetitions.

Consistent with findings by Laver et al. (2017) and Hatem et al. (2016), the non-randomised controlled trial by House et al. (2015 & 2016) found improvement in the VR group only and therefore conclude that VR gaming technologies using purpose-built systems are superior to conventional therapy. It should be noted that the control group received "normal maintenance" treatment. No further detail is provided however, given the chronicity of participants (mean [SD] of 98 [42] months), such maintenance is unlikely to involve active exercise interventions and therefore these findings may be more of an indication that VR is better than no therapy.

Results by Severity

Assessment by severity was again hampered by underreporting, use of different outcome measures and a lack of definition as to what constitutes mild, moderate or severe stroke. Two studies failed to provide description of severity (Orihuela-Espina et al., 2013; Tanaka et

al., 2013), while inclusion criteria of being able to hold the movement sensor contradicted baseline ARAT scores of 0 for at least one participant in Slijper et al. (2014). Baseline details and inclusion criteria suggested that participants in Schuster-Ampf et al. (2015), Perez Marcos et al. (2017) and Lee (2015) suffered moderate to mild levels of impairment. Although exact baseline FMA-UE scores were hard to ascertain, graphical information indicates efficacy for one participant with more significant impairment in Jordan et al. (2014). This was supported by findings from Wittman et al. (2015) who reported improvements in all participants including those with FMA-UE scores as low as 14, and House et al. (2016) who reported statistically significant improvements in participants with a mean (SD) FMA-UE score of 15.6 (11.1). However, in both cases participant numbers were low (n= 5 and n=7 respectively) and the improvements were not clinically important and moreover the use of a quasi-experimental design further limits conclusions which can be drawn.

While methodological issues were apparent, the evidence concurs with results from previous reviews, suggesting that VR using purpose-built gaming systems is effective for upper-limb stroke rehabilitation. Moreover, there is some evidence that purpose-built systems may be more effective than off-the-shelf systems. Additionally, there was evidence of efficacy for those with more severe levels of upper-limb impairment. However, as numbers were small and improvements below the minimally clinically important difference, efficacy for those with more severe levels of upper-limb impairment is uncertain.

3.8.4 Efficacy of Modified Versions of VR Gaming Systems

A summary of evidence from studies evaluating modified versions of commercial VR gaming devices is included in Appendix 3.4. Thirteen studies assessed the efficacy of modified versions of commercial gaming systems (Adams et al., 2018; Aşkin et al., 2018; Ballester et al., 2017; Cameirão et al., 2017; Chen et al., 2015b; Chiu et al., 2017; Kato et al., 2015; Kizony et al., 2013; Lee et al., 2016a; Moldovan et al., 2017; Standen et al., 2017; Tsekleves et al., 2016; Yeh et al., 2017). None were included in the SR's reviewed in this chapter and therefore all are included in this section of the review.

A total of 219 participants were included across the thirteen studies (range 1-40; mean [SD] 16.84 [13.71]). Five studies were RCTs (Aşkin et al., 2018; Ballester et al., 2017; Kizony et al., 2013; Lee et al., 2016a; Standen et al., 2017) involving 152 participants; one was a non-randomised control trial (Cameirão et al., 2017;) using 13 participants and seven used a pre-test, post-test design (Adams et al., 2018; Chen et al., 2015b; Chiu et al., 2017; Kato et al.,

2015; Moldovan et al., 2017; Tsekleves et al., 2016; Yeh et al., 2017) involving 54 participants.

Two studies used participants with a stroke chronicity below three months (Cameirão et al., 2017; Kato et al., 2015) one used participants with chronicity above three months (Chen et al., 2015b), six studies included participants with stroke chronicity above six months (Adams et al., 2018; Aşkin et al., 2018; Ballester et al., 2017; Kizony et al., 2013; Lee et al., 2016a; Tsekleves et al., 2016) and two set no limits on chronicity (Standen et al., 2017; Yeh et al., 2017). No indication of chronicity was provided by Chiu et al. (2017) and Moldovan et al. (2017).

The target dose of intervention varied between studies ranging from 108-360 minutes (it should be noted of the studies providing information on the actual dose achieved, none achieved the target). The target time for sessions ranged from 30-60 minutes, three to seven days a week, over two to eight weeks.

Results From Randomised Controlled Trials

All RCTs reported significant improvements in primary outcome measures following VR interventions regardless of stroke chronicity, study setting, device type, treatment target, dose or activity type. In keeping with findings from reviews by Laver et al. (2017) and Hatem et al. (2016), one of five RCTs found that VR interventions were as effective as, but not better than conventional therapy (Kizony et al., 2013). Three RCTs (Aşkin et al., 2018; Ballester et al., 2017; Lee et al., 2016a) found significantly greater improvements in VR groups compared to controls and therefore concluded that VR is superior to conventional therapy. However, participants in the VR group in the study by Aşkin et al. (2018) received twice the amount of therapy than those in the control group and therefore the greater improvements noted in this group may be attributed to the extra intervention time. Treatment dose was matched in the other studies and reasons for discrepancies between RCT findings were not apparent. Findings by Standen et al. (2017) only weakly supported the efficacy of VR, as significant improvements were only found in the intervention group in the secondary outcome measure the (MAL amount of use) and for the primary measure (WMFT) at the half way point only.

Results from Quasi-Experimental Designs

Findings of improvements in primary outcome measures following interventions using modified gaming VR systems were supported by findings from eight quasi-experimental

studies. Statistically significant improvements in primary outcome measures in five studies (Adams et al., 2018; Cameirão et al., 2017; Chen et al., 2015b; Tsekleves et al., 2016; Yeh et al., 2017) were supported by clinically important changes (Adams et al., 2018; Chen et al., 2015b; Chiu et al., 2017 [noted in one of two participants]; Moldovan et al., 2017) and by qualitative reports of increased spontaneous use of the upper limb (Tsekleves et al., 2016). However, as Chiu et al. (2017) Kato et al. (2015); Moldovan et al. (2017) and Tsekleves et al. (2016) all employed two or less participants, results must be interpreted with caution. Moreover, the possible inclusion of participants with stroke chronicity below three months means that improvements noted by Chen et al. (2015b), Chiu et al. (2017), Kato et al. (2015), Moldovan et al. (2017) and Yeh et al. (2017), may be a result of spontaneous recovery seen in acute stages.

Results by Severity

Most studies employed participants with moderate to mild stroke severity (based on inclusion criteria and FMA-UE baseline scores). Although Adams et al. (2018) included at least one participant each with more severe upper-limb deficits, no report of change by severity was provided and therefore effectiveness of modified versions of commercial VR gaming systems with those with more severe levels of upper-limb impairment is unclear.

There was disagreement in the literature as to whether modified versions of commercial VR gaming devices were more effective than conventional treatment for upper-limb rehabilitation following stroke. Nevertheless, findings provide support for the use of modified versions of VR gaming technologies as an adjunct to traditional therapy in those with mild to moderate upper-limb impairment. A lack of studies examining efficacy in those with more severe deficits meant no conclusions could be drawn about system efficacy in those with more severe levels of impairment.

3.8.5 Summary of Findings from Efficacy Studies

Findings from this review agree with previous review papers concluding that the use of VR gaming technologies positively influences upper-limb recovery following stroke. Improvements were seen regardless of the level of immersion, the device type used to deliver the VR intervention, the study setting or the activity type (whether game, exercise or ADL activity). Evidence indicates when the dose is matched, off-the-shelf VR gaming technologies are as effective as, but not superior to, conventional therapy. Findings from studies using purpose-built VR gaming technologies suggest superior effects of VR compared with conventional treatment. However, methodological issues (such as small

numbers of participants and a lack of control groups in studies using participants in acute and subacute stages of stroke where spontaneous recovery is likely) limit the conclusions which can be drawn.

A lack of reporting of baseline measures of upper-limb impairment meant assessment of effectiveness was difficult to gauge in those with more severe upper-limb impairment. While inclusion criteria stated in some studies *allowed* recruitment of those with more severe levels of impairment, the level of those who *actually participated* was often not apparent. Some studies described a range of baseline scores indicating that those with more severe deficits were included, though mean group scores suggested participants suffered mild to moderate levels of impairment and reporting of group results meant changes in those with more severe deficits were lost in group effects. Moreover, the use of different measures between studies and a lack of agreement about what is meant by the terms mild, moderate and severe further hampered analysis and as such, conclusions about effectiveness of VR gaming technologies in those with more severe upper-limb deficits are less certain.

As treatment effectiveness is ultimately dependent on treatment adherence which in turn is determined by the acceptability of an intervention, acceptability of VR gaming technologies for upper-limb rehabilitation are explored next.

3.9 Acceptability of VR Gaming Technologies for Upper-Limb Stroke Rehabilitation

Evidence of acceptability of VR gaming technologies for upper-limb stroke rehabilitation is presented by type of VR system used.

3.9.1 Evidence of Acceptability of Off-The-Shelf VR Gaming Technologies

A summary of evidence from studies evaluating commercial, off-the-shelf VR gaming systems is included in Appendix 3.2. Twelve studies and three systematic reviews provided information about the acceptability of using off-the-shelf systems for upper-limb stroke rehabilitation. Of these, two used qualitative methods (Paquin et al., 2016; Wingham et al., 2015), eight used Likert-scale questionnaires (Chen et al., 2015a; Fan et al., 2014; Givon et al., 2016; McNulty et al., 2013; McNulty et al., 2015; Rand et al., 2015 & 2017; Türkbey et al., 2017; Vanbellingen et al., 2017), and some suggested acceptability through use of subjective statements regarding enjoyment and engagement (Casserly and Baer, 2014; Da Silva Ribeiro et al., 2015; Pietrzak et al., 2014; Thomson et al., 2014). Additionally, low drop-out rates, strong adherence to attendance requirements (Adie 2017; Fan et al., 2014; Givon et al., 2016; Türkbey et al., 2017; Vanbellingen et al., 2017) and continued wish to exercise

using VR following the end of the trial (Rand et al., 2017; Vanbellingen et al., 2017) suggested acceptability.

Overall ratings of levels of enjoyment (Chen et al., 2015a; Rand et al., 2015; Türkbey et al., 2017), device satisfaction (McNulty et al., 2013; McNulty et al., 2015; Rand et al., 2015; Vanbellingen et al., 2017) and motivation (Chen et al., 2015a; Fan et al., 2014; Vanbellingen et al., 2017) were high across all studies, regardless of device used and stroke chronicity. Enjoyment in one study could be related to increased socialisation as games were played as a pair (Givon et al., 2016). However, while participants in Vanbellingen et al. (2017) wanted to use VR gaming technologies at home, they remarked on the need for technological improvements (specifics not stated), increased sensitivity and affordable technology to enable home-use.

Two studies included some participants with more severe levels of upper-limb impairment as indicated by the stated ranges of FMA-UE scores (Givon et al., 2016; McNulty et al., 2013). As most participants in McNulty et al. (2013) appeared to be suffering from more severe stroke, findings indicate acceptability of VR gaming systems in those with severe deficits. However, mean FMA-UE scores show most participants in the study by Givon et al. (2016) suffered mild to moderate impairment and as findings were not presented by severity, evidence of acceptability of off-the-shelf VR gaming technologies for those with more severe deficits is lacking.

Themes from qualitative analysis of semi-structured interviews with participants who had used the Wii, provided possible explanation for high ratings of factors related to acceptability. These included themes of enjoyment and motivation to exercise (for example, VR gaming technologies not being like ‘boring traditional exercise’ and a feeling of ‘time flying’ while using VR systems), the opportunity to receive extra therapy and feedback, belief in the effectiveness of the VR system, flexibility of when to exercise and the ability to exercise in private (Paquin et al., 2016; Wingham et al., 2015). However, challenges to using the Wii were apparent. These included a preference for different types of exercise (including more ADL based exercises) and the necessity of having the right level of challenge, with participants experiencing boredom with exercises perceived as too easy and frustration with those felt to be too difficult thereby supporting the need for personalisation of VR activities. Both qualitative studies used the Wii and employed participants with moderate to mild stroke only and neither was in-patient based. Additionally, although rehabilitation exercises are

usually prescribed by therapists, no study explored the acceptability of these devices from the therapist's viewpoint.

From the perspective of stroke participants with mild to moderate levels of upper-limb impairment, off-the-shelf VR gaming systems were acceptable for use in upper-limb stroke rehabilitation although the need for personalisation was apparent. Although only two studies employed any participants with more severe levels of upper-limb impairment some evidence of acceptability in this patient group was evident.

3.9.2 Evidence of Acceptability of Purpose-Built VR Gaming Technologies

A summary of evidence from studies evaluating purpose-built VR gaming systems is included in Appendix 3.3. Fifteen studies provided information about the acceptability of using purpose-built systems. Of these, seven used quantitative methods (Choi et al., 2016; House et al., 2015 & 2016; Jordan et al., 2014; Mace et al., 2017; Pallesen et al., 2018; Perez-Marcos et al., 2017; Rand et al., 2013), four used qualitative methods (Pallesen et al., 2018; Finley and Combs, 2013; Hung et al., 2016; Stockley et al., 2017) and some suggested acceptability through the use of subjective statements regarding enjoyment and engagement (Schuster-Amft et al., 2015; Shin et al., 2014; Slijper et al., 2014; Stockley et al., 2017; Subramanian et al., 2013; Yin et al., 2014).

High ratings of levels of enjoyment (Jordan et al., 2014; Mace et al., 2017; Perez-Marcos et al., 2017; Rand et al., 2013), device satisfaction (Choi et al., 2016; House et al., 2015 and 2016 Pallesen et al., 2018; Jordan et al., 2014) and motivation (Pallesen et al., 2018; Stockley et al., 2017) by stroke participants were supported by recommendation of VR-systems to other stroke survivors (House et al., 2015; Perez-Marcos et al., 2017). These results were corroborated by findings from qualitative studies with themes of increased motivation, rewarding feedback, enjoyment (not being like boring traditional exercise), being expressed (Finley and Combs, 2013; Hung et al., 2016; Pallesen et al., 2018). Positive attitudes towards the use of purpose-built systems were apparent regardless of commercial availability or stroke chronicity. While most systems employed the use of games, Perez-Marcos et al. (2017) practiced traditional style exercises reaching and grasping virtual objects. High ratings of enjoyment suggested acceptability of the use of traditional style exercises within a VR environment.

Based on the reported range of baseline FMA-UE scores, participants in two studies (Choi et al., 2016; House et al., 2015 & 2016) employed participants with more severe levels of

upper-limb impairment. Although mean FMA-UE baseline scores indicate a moderate mean level of impairment for participants in Choi et al. (2016), mean (SD) FMA-UE scores (15.6 [11.1]) in House et al. (2015 & 2016) demonstrate system acceptability for those with more severe levels of upper-limb impairment. While most studies reported acceptability from the view of stroke participants, Pallesen et al. (2018) additionally collected views from clinicians. Although lower than those reported by stroke survivors, high rating of device satisfaction, and clinician belief that VR system was an effective method to achieve intensive practice, suggested acceptability.

While high levels of acceptability for purpose-built VR systems was apparent, the use of comments such as “life deleted” and “system failure” was noted to be demoralising for those with more severe disability (Hung et al., 2016). In addition, participants in this study found feedback during the game distracting. Furthermore, findings by Pallesen et al. (2018) and Hung et al. (2016) support the need for diversity of games and increased ability to customise devices to enable delivery of the correct level of challenge.

Evidence of high levels of acceptability for purpose-built VR gaming systems for use in upper-limb stroke rehabilitation was apparent. While most evidence of acceptability was from stroke survivors with moderate to mild levels of upper-limb impairment, evidence of acceptability with those with more severe levels of impairment and also from clinicians was found, suggesting acceptability in these groups also. However, issues with feedback were expressed and the need for more diverse games with greater degrees of personalisation was noted.

3.9.3 Evidence of Acceptability of Systems Using Modified Versions of VR Gaming Devices

A summary of evidence from studies evaluating modified versions of commercially available VR gaming devices is included in Appendix 3.4. Ten studies provided information about the acceptability of using modified versions of commercial VR gaming technologies for upper-limb stroke rehabilitation. Of these, six used quantitative methods (Chen et al., 2015b; Chiu et al., 2017; Ellington et al., 2015; Lee et al., 2016a; Seo et al., 2016; Yeh et al., 2017) one used qualitative methods (Standen et al., 2015), one used a mix of quantitative and qualitative methods (Demers et al., 2017) and two suggested acceptability through the use of subjective statements regarding enjoyment and engagement (Moldovan et al., 2017; Tsekleves et al., 2016).

High ratings of and themes related to enjoyment (Chen et al., 2015b; Chiu et al., 2017; Demers et al., 2017; Ellington et al., 2015; Seo et al., 2016; Standen et al., 2015; Tsekeleves et al., 2016; Yeh et al., 2017), system satisfaction (Demers et al., 2017; Ellington et al., 2015; Lee et al., 2016a; Yeh et al., 2017) and motivation (Chen et al., 2015b; Demers et al., 2017; Standen et al., 2015; Tsekeleves et al., 2016) were reported by stroke participants regardless of stroke chronicity and system used. Themes of "flow", flexibility of when to play and increased interaction with grandchildren (Standen et al., 2015) helped explain high quantitative ratings of enjoyment. While games were found to be more motivating and were rated higher than ADL activities by participants in the study by Seo et al. (2016), ratings of a system using ADL activities were high in the study by Ellington et al. (2015). This may be linked to a belief in the usefulness of the VR system as Ellington et al. (2015) found a significant relationship between perceived usefulness and attitude to technology. Additionally, these authors found significant relationships between perceived usefulness and intention to use technology and also attitude to technology and intention to use it. This was supported by a high proportion of studies reporting participants wanted to continue using the technology (Chen et al., 2015b; Lee at al 2016a; Seo et al., 2016; Tsekleves et al., 2016; Yeh et al., 2017). However, boredom with games was expressed by one participant in Demers et al. (2017). This may be related to experience of VR gaming, as boredom was noted by participants with greater VR gaming experience by participants in Standen et al. (2015). Additionally, boredom may be linked to lack of challenge, as boredom was associated with games that were too easy by participants in Tsekleves et al. (2016) thereby emphasising the need for personalisation of activities to maintain interest.

Acceptability from those with more severe upper-limb deficits was hard to ascertain as only one study included such participants (Seo et al., 2016). However, as the number of those with more severe deficits was not reported, nor the group mean score stated, the acceptability to those with differing levels of stroke severity is not clear. Most studies reported acceptability from the view of stroke participants. However, themes of perceived usefulness and device satisfaction noted in data analysis from clinician focus groups suggested acceptability in clinicians as well as participants (Demers et al., 2017 & 2018). While some studies reported satisfaction with feedback (Chen et al., 2015b; Tsekeleves et al., 2016), participants in Seo et al. (2016) and Demers et al. (2017) reported lower levels of satisfaction with feedback. Whether this was linked to demoralising feedback as reported by Hung et al. (2016) or other reasons, was not apparent.

Evidence of high levels of acceptability for modified versions of VR gaming devices for

upper-limb stroke rehabilitation in those with mild to moderate levels of upper-limb impairment was apparent, although issues with feedback and the need for greater personalisation to maintain level of challenge was noted. While most evidence of acceptability was from the viewpoint of stroke participant's, evidence of clinician acceptability was also found. Acceptability for those with more severe levels of impairment was not evident.

3.9.4 Summary of Findings from Acceptability Studies

While critical to exercise adherence (Taylor, 2015), few studies explored the acceptability of VR gaming technologies for upper-limb stroke rehabilitation and when such evaluation has been performed, there has often been a lack of analytical rigour. Of those reporting acceptability, most used quantitative methods, and demonstrated high levels of acceptability but not reasons for this. Qualitative studies suggested increased enjoyment, motivation, device satisfaction, perceived effectiveness, feedback, increased socialisation and flexibility in when to exercise accounted for high ratings seen in quantitative studies. While use of the study researcher during data collection could result in higher evaluations, with participants more likely to express socially desirable responses, nevertheless, there was considerable evidence of acceptability of VR gaming technologies for upper-limb stroke rehabilitation regardless of stroke chronicity, study setting or device type. Few studies assessed acceptability from the clinician's viewpoint. Of those which did, acceptability was apparent although less fervent than that expressed by stroke participants. The input of stroke clinicians in the development of purpose-built VR gaming systems was not explored but is likely to result in higher rating of acceptability (Taylor, 2015).

While acceptability of VR gaming technologies was high, the need for more motivational feedback and increased personalisation to enable the maintenance of the correct level of challenge was apparent. Evaluation by those with more severe deficits was limited but acceptability for a purpose-built system developed for those with more severe deficits was apparent. Lack of evaluation of efficacy and acceptability by those with more severe deficits may be linked to a lack of feasibility of use as is explored next.

3.10. Feasibility of VR Gaming Technologies for Upper-Limb Rehabilitation

Evidence of feasibility of VR gaming technologies for upper-limb stroke rehabilitation is presented by type of VR system used.

3.10.1 Evidence of Feasibility of Off-The-Shelf VR Gaming Systems

A summary of evidence from studies evaluating commercial, off-the-shelf VR gaming devices is included in Appendix 3.2.

3.10.1.1 Occurrence of Adverse Events

Of 19 identified studies examining the use of commercially available, off-the-shelf VR gaming technologies, thirteen provided details of adverse events. In agreement with findings from SRs (Casserly and Baer, 2014; Laver et al., 2017, Pietrazak et al., 2014; Thomson et al., 2014) there was no occurrence of any serious adverse events including falls, suggesting system safety. Four stated that no adverse events occurred (Givon et al., 2016; McNulty et al., 2015; Paquin et al., 2015; Rand et al., 2015 & 2017). Lee (2013) note no increase in spasticity while using the Kinect but provide no further detail. Two studies stated that no serious adverse events occurred but provide no detail as to whether minor adverse effects were experienced (Adie et al., 2017; Vanbellingen et al., 2017). However, a qualitative study nested in Adie et al.'s (2017) RCT, note incidences of hitting the hand against the side of the wheelchair while playing the Wii bowling game and incidences of shoulder pain. The severity and possible mechanisms of pain are not explored. Additionally, pain was experienced by participants in three studies (Kong et al., 2016, Saposnik et al., 2016; Türkbey et al., 2017). In Kong et al.'s (2016) study, pain increased over time with 28.5% of participants in the VR group experiencing upper-limb pain at 15 weeks compared with 20% in the control group. This is similar to Türkbey et al. (2017) who reported pain in 30% of participants in their VR group. However, Türkbey et al. (2017) do not discuss whether adverse events occurred in their control group and Saposnik et al. (2016) noted similar incidence of pain between VR and conventional therapy groups, together suggesting that pain may be related to exercise, regardless of how it is delivered. Moreover, as pain severity and mechanism were not explored in any study, it is possible that some incidences of pain may be due to delayed onset muscle soreness, a condition associated with unaccustomed exercise, and may therefore be a sign of exercise intensity.

Fatigue was noted by participants in two studies (Saposnik et al., 2016; Türkbey et al., 2017). As different devices were used in the studies, this appeared unrelated to device type and furthermore may be considered a sign of intensity of work as opposed to a harmful effect. Other adverse effects reported included mild nausea, headache and light headedness (Saposnik et al., 2016; Türkbey et al., 2017). As Türkbey et al. (2017) do not report the incidence of adverse effects in the control group and findings from Saposnik et al. (2016)

report similar incidence between VR and conventional therapy groups, these effects may be unrelated to VR interventions.

Adverse effects did not appear to be related to chronicity of stroke or severity as participants with different stroke chronicity and different levels of upper-limb impairment experienced such events. However, as these only arose in studies using over 45 minutes of intervention, occurrences may be linked to the overall time spent exercising.

3.10.1.2 Rates of Study Exclusion

Twelve studies provided information about the number of people screened and the number recruited (Adie et al., 2017; Da Silva Ribeiro et al., 2015; Fan et al., 2014; Givon et al., 2016; Kong et al., 2016; McNulty et al., 2015; Rand 2015 & 2017; Rinne et al., 2016; Saposnik et al., 2016; Sin and Lee, 2013; Türkbey et al., 2017; Vanbellingen et al., 2017). One study reported that no participants were excluded following screening (Sin and Lee, 2013). However, as inclusion criteria included active movement in all upper-limb joints, it is likely that screening had occurred before referral to the study. Other studies reported much higher exclusions ranging from 58% (reported by Da Silva Ribeiro et al., (2015) to 96% (reported by Adie et al., 2017). Exclusions were mainly due to physical impairments including lack of movement and inability to hold the Wiimote movement sensor and suggested limited feasibility of use for off-the-shelf systems for upper limb rehabilitation.

3.10.1.3 Feasibility of Independent Use

Seven studies reported that the therapist or research assistant was present throughout the VR intervention (Da Silva Ribeiro et al., 2015; Fan et al., 2014; Givon et al., 2016; Kong et al., 2016; Paquin et al., 2015; Saposnik et al., 2016). No indication of therapist presence was provided in other studies. Assistance was required for system set-up, calibration, the provision of additional feedback to avoid compensatory strategies and to prevent falls while using the Eyetoy, Wii and Kinect (Givon et al., 2016; Kong et al., 2016; Saposnik et al., 2016). Participants in studies by Vanbellingen et al. (2017) and Paquin et al. (2015) also reported the need for reassurance and psychological support, particularly in the initial stages of system-use. Together findings suggest limited feasibility for independent use, nonetheless, Adie et al. (2017), McNulty et al. (2015) and Rand et al. (2017) successfully deployed VR gaming systems for home use suggesting independent use is possible. However, all participants in these studies had milder strokes and in addition, inclusion criteria in the study by Adie et al. (2017) stated the need to have a live-in carer or family member to help set-up the system. This was noted to be a barrier to use when stroke

survivors were reluctant to accept help or when the care-giver lacked confidence or interest in technology (Wingham et al. 2015). Feasibility of independent use therefore remains limited particularly for those with more severe deficits.

3.10.1.4 VR System Feasibility

Further feasibility issues were apparent when considering the movement detection systems employed. The Wii and Playstation Move systems use hand-held movement sensors with various buttons to enable full game-play, thereby limiting use by the majority of stroke survivors in whom a loss of the necessary strength and dexterity to hold and manipulate the device is common. Adie et al. (2017), Wingham et al. (2015) and Carragosa et al. (2018) stipulated the ability to hold and manipulate the movement sensor as inclusion criteria thereby excluding those with more severe deficits. Even so, a theme of difficulty using the movement sensor by those with mild to moderate levels of impairment was apparent in qualitative data (Wingham et al., 2015) and in SR findings by Thomson et al. (2014) suggesting lack of feasibility even in those with milder deficits. Other studies used straps, bandages or orthoses to attach movement sensors (Choi et al., 2014; Fan et al., 2014; Kong et al., 2016; McNulty et al., 2015) again suggesting a lack of feasibility for independent use. Although the numbers who required such assistance was not stated, findings of a lack of feasibility for those with more severe deficits are supported by Rinne et al. (2016) who found that only 36% of moderately impaired and no participants with severe deficits were able to use conventional controllers to play commercial games.

Other systems (such as the Kinect and Eyetoy) employ camera-based movement sensors thereby removing the need to use hand-held controllers. However, occlusion errors in sitting or by body parts held in abnormal postures limit accuracy of these systems and resulted in the Kinect only being used for participants who were able to exercise in standing (Rand et al., 2015 & 17). Additionally, “frequent” recalibration was required due to occlusion errors (Sin and Lee, 2013). Furthermore, the need for the shoulder to be held at 90^0 flexion for calibration purposes limited use in those with more severe deficits (Türkbey et al., 2017)

In addition to issues with movement detection systems, problems using off-the-shelf games were noted in the SR by Thomson et al. (2014) and in three studies (Choi et al., 2014; Givon et al., 2016: Kong et al., 2016), two of which (Givon et al., 2016: Kong et al., 2016), had employed participants with more severe deficits. In all three studies, assistance from a therapist or the less affected side was necessary to move the affected upper-limb sufficiently to enable game play. This lack of feasibility in those with higher levels of disability was

supported by findings by McNulty et al. (2013) who noted that only one of 13 stroke survivors was able to use the Wii bowling activity, and none were able to play Wii tennis.

3.10.1.5 System Costs

One study (Adie et al., 2017) provided a comparison of costs between VR using the Wii and conventional therapy. Based on one Wii system being used for 24 patients over three years, costs of the Wii intervention were £1,106 per participant compared with £730 for conventional therapy. While more expensive than conventional therapy in this study, the costs of off the shelf systems (for example the Wii cost at £179 when launched in 2006; the Kinect camera at £129.99) compare favourably against systems developed specifically for stroke rehabilitation as discussed below in 3.7.2.

3.10.1.6 Summary

While relatively inexpensive and safe to use, high levels of participant exclusion on the basis of physical impairment was apparent in studies using off-the-shelf VR gaming technologies for upper-limb stroke rehabilitation. While feasible to use by those with milder impairment, in those with moderate to severe levels of upper-limb impairment, a lack of the necessary range of movement to interact with games, limited independent use. Moreover, camera-based movement detection systems struggled to detect movements from those with abnormal body postures or who needed to sit while using the device. Equally, systems using hand-held movement sensors were not viable for those without the ability to hold, coordinate and manipulate the controller. As such, there was limited evidence of feasibility for off-the-shelf VR gaming systems by those with more severe upper-limb impairment.

3.10.2. Evidence of Feasibility of Purpose-Built VR Gaming Systems

A summary of evidence from studies evaluating purpose-built VR gaming systems is included in Appendix 3.3.

3.10.2.1 Occurrence of Adverse Effects

Of 22 identified studies examining the use of purpose-built VR systems, 13 provided details of adverse events. There was no occurrence of any serious adverse events, including falls, suggesting the safety of purpose-built systems for upper-limb stroke rehabilitation. Five stated that no adverse events occurred (Brunner et al., 2017 & Pallesen et al., 2018; Choi et al., 2016; Shin et al., 2014; Subramanian et al., 2013; Turolla et al., 2013). Results from Turolla et al. (2013) are particularly convincing as they included 376 participants over ten years, although it should be noted that a therapist was present throughout each session.

Two studies commented that the systems were safe but provide no detail as to whether minor adverse effects were experienced (Lee et al., 2016b; Schuster-Amft et al., 2015). Lower-limb and or back pain was experienced by two of 23 participants who used VR technology in standing (Yin et al., 2014), and upper-limb pain and or discomfort was experienced by three of 12 participants in Jordan et al., (2014) and two of ten participants in Perez -Marcos et al. (2017). Severity of pain and discomfort and was rated as 2.7 out of 5 (with higher numbers indicating a greater degree of pain) in House et al. (2015 & 2016). However, as the mechanism of pain was not explored in any study, it is possible that some incidences of pain may be unrelated to device use or due to delayed onset muscle soreness, a normal condition associated with unaccustomed exercise.

Fatigue was noted by participants in two studies (Perez-Marcos et al., 2017; Stockley et al., 2017) with planned dosage between 30 and 60 minutes. As fatigue is a normal phenomenon associated with exercise it may be considered a sign of intensity of work as opposed to a harmful effect. Levels of fatigue were not specified and therefore whether fatigue was debilitating or not was not apparent. As dosage of treatment ranged from 30-60 minutes in studies reporting pain and fatigue and in those which did not, such incidences appeared unrelated to intensity of the regime. Moreover, as pain occurred in studies with differing levels of FMA-UE scores, incidences of pain appeared unrelated to stroke severity. Interestingly, although cyber sickness has been associated with more immersive devices (Prashun et al., 2010), no incidences occurred in the study using the immersive CAREN system (Subramanian et al., 2013).

3.10.2.2 Rates of Study Exclusion

Nine studies provided information about the number of people screened and recruited. One study reported that just one participant was excluded following screening (Stockley et al., 2017). Participants in this study presented with moderate to mild stroke severity only therefore it is likely that they had undergone some additional screening prior to recruitment. Other studies reported much higher rates of exclusion ranging from 33% (as reported by Lee et al., 2016b) to 88% (reported by Brunner et al., 2017). Main reasons for exclusions were due to severity of physical impairments, cognitive problems, early discharge and participant declination.

3.10.2.3 Feasibility of Independent Use

Three studies reported that the therapist or research assistant was present throughout the VR intervention to assist with set up and instruction (Perez-Marcos et al., 2017; Shin et al.,

2014; Turolla et al., 2013). No indication of the clinician presence was provided in other studies, however the need for clinician support was noted by Stockley et al. (2017), Brunner et al. (2017) and Pallesen et al. (2018) suggesting that such systems cannot replace clinicians. Conversely, three studies successfully deployed purpose-built VR systems for home use suggesting feasibility of independent use (Jordan et al., 2014; Slijper et al., 2014, Wittman et al., 2015). As some participants in each study suffered more severe levels of impairment (scoring below 22 on the FMA-UE) findings indicate home-use is feasible when using purpose-built systems. None of these systems were commercially available however.

3.10.2.4 VR System Feasibility

Systems using inertial movement sensors frequently employed straps to attach the sensor, although the number of people required to use systems in this manner were not reported (Choi et al., 2016; Lee, 2015; Orihuela-Espina et al., 2013; Yin et al., 2014). In addition, friction reducing systems (Perez-Marcos et al., 2017; Yin et al., 2014) and simple movement sensors without buttons were employed to enable use by those with more severe deficits. Unlike commercial systems using camera-based systems, no reports of occlusion errors were reported, even in those with more severe levels of impairment (House et al., 2015 & 2016) again supporting feasibility of these systems. Although only participants with mild stroke severity were able to fully use a dexterity training game on a computing tablet (Rand et al., 2013), the use of purpose -built games which could be personalised in various features (such as speed and range of motion) enabled participants with different levels of severity to successfully interact with the VR systems in other studies. Moreover, unlike some of the studies examining off-the-shelf, VR gaming systems, no purpose-built system reviewed here, required external support from a therapist or the less-affected upper-limb.

While purpose-built systems appeared more feasible for use than off-the-shelf versions, limitations were apparent. Frustration with system ‘freezing” was noted in two of the studies using the YouGrabber (Pallesen et al., 2018 and Stockley et al., 2017) and distracting background visual effects were noted by Finley and Combs (2013) using the commercially available Hand Dance Pro. Moreover, issues with size and complicated set-up were apparent limiting feasibility in both home and clinical environments. For example, the Caren system used by Subramanian et al. (2017) requires considerable space and immersive VR equipment. The BrightArm Duo system used by House et al. (2015 & 2016) incorporated overhead cameras mounted on a trestle and a table measuring 80” by 25” requiring on-site construction.

3.10.2.5 System Costs

Only one study provided an estimate of cost. Orihuela -Espina et al. (2013) estimated their system would cost $1,000 Dollars (US). As participants in Hung et al. (2016) were willing to spend between $300- $1,500 dollars on a home-based system, the system proposed by Orihuela-Espina et al. (2013) appears to be feasible in terms of cost for some individuals. Website searches, email requests and telephone calls to manufacturers of other commercial systems failed to reveal actual costs of their systems however, a recent survey by the author of similar devices at a UK neurological convention revealed prices to be between £30,000 and £100,000 putting such systems beyond the remit of most NHS physiotherapy departments and making feasibility for home use extremely limited.

3.10.2.6 Summary

Purpose-built VR gaming technologies were safe to use and moreover, evidence of home-use and suggested system feasibility of independent use for some systems. The personalisation of activities (typically with regards to range of movement and speed), use of hand-free systems and overhead movement tracking sensors (reducing camera occlusion errors) resulted in feasibility of use in those with more severe levels of impairment. However, high levels of participant exclusion on the basis of physical impairment was apparent, limiting generalisability of findings. Moreover, system costs and complicated set-up and large space requirements limit feasibility of these systems in both NHS and home environments.

3.10.3 Evidence of Feasibility of Systems Using Modified Versions of VR Gaming Devices

A summary of evidence from studies evaluating modified versions of commercially available, VR gaming systems is included in Appendix 3.4.

3.10.3.1 Occurrence of Adverse Effects

Of 16 identified studies using modified versions of commercial VR gaming devices, only eight provided details of adverse events (Adams et al., 2018; Aşkin et al., 2018; Demers et al., 2017; Kato et al., 2015; Kizony et al., 2013; Moldovan et al., 2017; Standen et al., 2015 & 2017; Tsekleves et al., 2016). While there was no occurrence of any serious adverse events including falls, suggesting system safety, few provided details regarding the occurrence of less serious events. Four stated that no adverse events occurred (Adams et al., 2018; Aşkin et al., 2018; Kizony et al., 2013; Moldovan et al., 2017) but do not list which parameters were assessed and how this data was captured. Tsekeleves et al. (2016) noted no increase in spasticity while using a modified version of the Wii but provide no further detail. Similarly, Kato et al. (2015) note no occurrence of cyber sickness but provide no details about the occurrence or not of other possible side effects. Adverse events were noted

in two studies. Eye fatigue was noted in 57.1% of participants in Demers et al. (2017), while upper-limb pain was reported as a reason for study drop out in two participants in Standen et al. (2017). No further detail as to the cause or severity of pain is provided nor details of any other occurrence of adverse effects. As upper-limb discomfort has been noted as a common occurrence in upper-limb exercise following stroke (including those using VR) it is possible that the lack of discomfort reported in modified systems examined here, is a result of lack of reporting as opposed to improved levels of discomfort with modified devices. No relationship between adverse events and treatment intensity, device type, chronicity or severity was apparent due to limited reporting of adverse events.

3.10.3.2 Rates of Study Exclusion

Five studies provided information about the number of people screened and the number recruited (Aşkin et al., 2018; Cameirão et al., 2017; Kizony et al., 2013; Lee et al., 2016a; Standen et al., 2017). Exclusion rates ranged from 7% (Aşkin et al., 2018) to 80% (Kizony et al., 2013). As no system required movement sensors to be held, inability to hold the movement sensor (an exclusion criterion for many studies using off-the-shelf gaming systems), was not an exclusion criterion in studies using modified versions of commercial VR gaming systems, suggesting greater feasibility.

3.10.3.3 Feasibility of Independent Use

Three studies reported that the therapist was present during the VR intervention (Kato et al., 2015; Kizony et al., 2013; Lee et al., 2016a). The therapist was required to teach and provide instruction when new games were introduced in Kizony et al. (2013) but was absent at other times. Reasons for therapist presence was unclear in Lee et al. (2016a). A therapist was present throughout to help with system set up and to operate the computer in the study by Kato et al. (2015). This study employed a semi-immersive VR system and the inability to use independently may reflect the greater system complexity associated with more immersive environments which may limit feasibility of use in the community.

Some systems were successfully deployed in community settings (Ballester et al., 2017; Kato et al., 2015; Standen et al., 2015 & 2017) all of which employed participants with mild to moderate stroke severity. However, help was needed to put on gloves (Ballester et al., 2017). Although possible to use the modified VR system proposed by Standen et al. (2015 & 2017) for home use, significant therapist support was required. On top of set-up visits, data collection visits, phone support, scheduled weekly or fortnightly visits, an additional 78 home visits were required for the 17 participants in the VR group (range from three to 14). This

amounted to an additional 92 hours and 45 minutes of therapist contact time (ranging from one hour 20 to 18 hours and 10 minutes per participant, exclusive of therapist travel time). Training took an average of 230 minutes per participant in the VR group (ranging from 50 to 540 minutes) plus an additional median time of 45 minutes (range from 0 to 430 minutes) sorting technical issues. Additional issues included participant problems changing batteries. This study highlights the need for careful implementation and ongoing support to enable feasibility of use of VR devices in community settings. Moreover, as technical difficulties were attributed to the device being a prototype, it is important that future studies eliminate as many such issues as possible before trialling devices in the more expensive, community setting.

3.10.3.4 VR System Feasibility

There were no reports of inability to use any of the modified systems. Some degree of personalisation (most commonly with regard to range of movement and speed) was apparent in nine of the VR systems included in the review (Adams et al., 2018; Ballester et al., 2017; Cameirão et al., 2017; Chen et al., 2015b; Kato et al., 2015; Kizony et al., 2013; Moldovan et al., 2017; Standen et al., 2017; Tsekleves et al., 2016) and although other systems failed to report on the degree of personalisation possible, high ratings of system feasibility were reported (Chen et al., 2015b; Demers et al., 2017; Ellington et al., 2015; Seo et al., 2016; Yeh et al., 2017). However, system limitations were apparent. Clinicians in Demers et al. (2017) reported concerns that their system using the Kinect would be too difficult for those with more severe upper-limb deficits (although inclusion criteria meant this was not assessed). Additionally, frustration with a lack of accuracy was noted by stroke participants in studies by Demers et al. (2017), Ellington et al. (2015) and Seo et al. (2016), all of which used the Kinect camera. Problems with accuracy of movement tracking were also apparent in the system using the Wii in combination with a motion glove (Standen et al., 2015 & 2017) although it is unclear whether the problem was with the motion glove or the Wii component. In addition, difficulties donning and doffing the glove were noticed in both systems using gloves to track finger movements (Seo et al., 2016; Standen et al., 2015 & 2017). Only one study employed any participants with more severe levels of upper-limb impairment (Seo et al., 2016). While this study included at least one participant with FMA-UE of 2 (as ascertained by the stated range of impairment), the mean score was 42 suggesting few participants were in the severe category. However, as the system was feasible to use with this participant, findings provide weak evidence of feasibility

3.10.3.5 System Costs

Costs of the commercially available system using modified gaming technology using the Kinect camera, developed by Saebo were quoted as £10,000 (June 2017, personal communication from Saebo representative). While this may be within the financial reach of some therapy departments, it limits feasibility for home use. However, systems not developed for profit, which use relatively cheap VR gaming devices are likely to be cheaper and therefore more feasible for home and clinical use. Only one study (Seo et al., 2016) estimated the cost of their system. This was estimated to be $160 and in line with the price of the Novint Falcon at $249 (anarkik3d.co.uk accessed 28/05/2018); Nintendo Wii at £179 (at launch. Wikipedia accessed 29/05/2018), the Kinect camera at £129.99 (Wikipedia accessed 29/05/2018) and the Essential Reality P5 gaming glove at $40 (Seo et al., 2016). These compare favourably with purpose-built commercial systems. However, development costs and the technical expertise to develop such systems requires consideration.

3.10.3.6 Summary

Modified versions of commercially available, VR gaming devices for upper-limb stroke rehabilitation were safe to use and system-costs compared favourably with purpose-built systems. While the use of hands-free systems and personalisation enabled use by participants with moderate and mild stroke severity, evidence of feasibility in those with more severe levels of impairment was lacking. Moreover, accuracy of systems using the Kinect camera were apparent. The use of prototype systems proved particularly problematic when introducing such a system into the community and highlighted the need to detect and resolve technical issues prior to implementation in the home.

3.10.4 Summary of Findings from Feasibility Studies

VR gaming technologies were safe to use for upper-limb stroke rehabilitation with no study reporting any significant adverse effects. While mild adverse effects were noted (mainly pain and fatigue), underreporting of mechanisms and severity limited analysis. Evidence that similar side effects were experienced in those undertaking conventional therapy suggested incidences of adverse effects were associated with exercise and not a consequence of VR gaming. High rates of exclusion on the basis of physical limitations were apparent in most studies reporting exclusion rates and suggests limited feasibility in those with more severe upper-limb impairment. Additionally, as most studies excluded participants with cognitive issues, pre-existing upper-limb pain, shoulder subluxation, epilepsy, communication disorders and medical instability, validity among the general stroke population was limited.

The lower costs and smaller size of off-the-shelf gaming and modified systems suggested greater likelihood of home and hospital use. However, the lack of personalisation in off-the-shelf VR gaming technologies was a barrier to use amongst those with more severe levels of impairment suggesting that such systems are only feasible to use in those with less severe deficits. Personalisation and use of modified movement detection systems resulted in greater ability to use purpose-built and modified gaming systems and in the case of purpose-built systems, evidence of system feasibility was apparent in those with severe upper-limb deficits. Conversely, the substantial costs, larger size and complicated set up associated with purpose-built systems would make clinical and home use unviable. While issues of accuracy were apparent in some systems using modified systems, the cheaper costs, and ability to personalise makes this a credible option for upper limb stroke rehabilitation. However, feasibility with those with more severe levels of upper-limb impairment has not been established.

3.11 Summary of Key Findings

A summary of review findings by device type is presented in Table 3.4.

Table 3.4 A Summary of Key Findings Presented by Device Type

	VR Gaming Technology Type		
Key Feature	**Off-the-shelf**	**Purpose-built**	**Modified Commercial system**
Efficacy	• As effective as, but not superior to, conventional treatment (Sections 3.7.1 & 3.7.2) • Efficacy in those with severe upper-limb deficits is uncertain (Sections 3.7.1 & 3.7.2)	• Indication of superior effects compared with off-the-shelf systems (Sections 3.7.1 & 3.7.3) • Efficacy in those with severe upper-limb deficits is uncertain • (Sections 3.7.1 & 3.7.3)	• As effective as conventional treatment (Section 3.7.4) • Efficacy in those with severe upper-limb deficits uncertain (Section 3.7.4)
Acceptability	• Acceptable for upper-limb rehabilitation for those with moderate and mild upper-limb stroke severity (Section 3.8.1) • Indications of acceptability for those with more severe upper-limb deficits (Section 3.8.1) • Personalisation required (Section 3.8.1)	• Acceptable for upper-limb rehabilitation (Section 3.8.2) • Motivating feedback and personalisation required (Section 3.8.2)	• Acceptable for upper-limb rehabilitation (Section 3.8.3) • Acceptability for those with more severe upper-limb deficits is uncertain (Section 3.8.3) • Different feedback and personalisation required (Section 3.8.3)
Safety	• Minor adverse events only (Section 3.9.1.1)	• Minor adverse effects only (Section 3.9.2.1)	• Minor adverse effects only (Section 3.9.3.1)
Feasibility	• High study exclusion rates on basis of	• Lower study exclusion rates compared with off-	• Lower study exclusion rates compared with

	VR Gaming Technology Type		
Key Feature	**Off-the-shelf**	**Purpose-built**	**Modified Commercial system**
	physical impairment (Section 3.9.1.2) • Limited feasibility of independent use (Section 3.9.1.3 & 3.9.1.4) • Physical assistance required to play games (Section 3.9.1.4) • Hand-held movement sensors difficult or impossible to use (Section 3.9.1.4) • Lack of accuracy with camera-based systems (Section 3.9.1.4) • Cost: relatively inexpensive (Section 3.9.1.5)	the-shelf systems on basis of physical impairment (Section 3.9.2.2) • Size and complicated set-up limits feasibility of some systems in home environments (Section 3.9.2.4) • Feasibility of independent game-play (Section 3.9.2.3 & 3.9.2.4) • Costly compared with off-the-shelf systems (Section 3.9.2.5)	off the shelf systems (Section 3.9.3.2) • Limited feasibility for independent set-up (Section 3.9.3. & 3.9.3.4) • Feasibility of independent game - play (Section 3.9.3.4) • Costly commercial system; non-commercial system compares favourably with purpose-built systems (Section 3.9.3.5)

3.12 Discussion

The use of a mixed-methods review enabled the exploration of several different questions within a single review. It has been recommended as a means of establishing efficacy and appropriateness of an intervention (Harden, 2010) and was therefore felt to be the most suitable method to address current review questions regarding efficacy, acceptability and feasibility of VR interventions for upper-limb stroke rehabilitation. However, mixed-methods reviews have been criticised for a lack of consensus as to how to undertake the review, the resource intensive nature of the process and for the large volume of citations generated (Grant and Booth, 2009; Petticrew et al., 2013).

A substantial number of SRs exploring the effectiveness of VR systems for upper-limb rehabilitation have been published. As these are said to be the “most reliable and comprehensive statement about what works” (Mallet et al., 2012. P445) the decision to include SRs was taken. Synthesising systematic reviews allowed the inclusion of a large volume of primary studies while reducing the large number of citations associated with the use of a mixed-methods review. However, there is the risk of inflating effects when a primary study is reported in more than one review. To reduce this risk, SRs which contained no additional studies to the key review by Laver et al. (2017) were excluded. However, it is acknowledged that some duplication of studies between SRs occurred nonetheless. In order to capture studies published since the completion of the SRs and those using modified systems (which were excluded from the identified SRs), original research studies, not included in the SR’s were also included, adding to the comprehensiveness of the review.

Due to the ability to reduce bias, it is generally accepted that RCTs provide the highest level of evidence to assess the effectiveness of an intervention. However, RCTs have been criticised for failing to address contextual factors which may influence outcome and explain why an intervention may work in one case and not in another (Carey and Stiles, 2015). Other issues with RCTs investigating the use of VR interventions for upper-limb recovery after stroke include the impossibility of blinding study participants as to whether they have received an intervention or not, volunteer bias and the tendency for underpowered studies (the median [IQR] number of participants in all original RCTs reviewed here was just 27.5 [20, 44]). The use of a cut-off score of quality (such as the PEDro score for evaluation of RCTs) would have reduced bias and resulted in the inclusion of more methodologically sound studies in the analysis of efficacy. However, this would have further reduced the already limited number of studies assessing the efficacy of purpose-built and modified VR systems and therefore an inclusive approach was taken with regards to the quality and the type of study included in this review. It is acknowledged that this approach increased the risk of bias and limits the conclusions which can be drawn.

Overall, evaluation of studies in this review was hampered by a lack of description of both the VR intervention and study methods. Use of established reporting guidelines (such as those recommended by the EQUATOR network [www.equator-network.org]) and the TIDieR check-list for describing an intervention (Hoffman et al., 2014) would have increased transparency, aided evaluation of VR systems and evaluation of the quality and findings from included studies.

In spite of these methodological issues, findings from this review evaluating studies published since 2013, indicate that the use of commercially available, off-the-shelf, VR gaming technologies (developed and calibrated for the neurologically intact) can be as effective as conventional treatment in the rehabilitation of the upper-limb post stroke. However, support for use with those with more severe upper-limb impairment is lacking. While largely acceptable and safe to use, high levels of participant exclusion and the presence of a therapist to calibrate, set up systems and provide feedback suggested limited possibility for independent use. In addition, the degree of coordination and dexterity necessary to use hand-held movement sensors and camera occlusion errors caused by the presence of chairs, mobility aids and abnormal body postures (typically seen in stroke) further limited feasibility. Moreover, and the need for assistance (from a therapist or the less affected upper-limb) to obtain the range of movement, coordination and speed necessary to play games, further limited use, particularly for those with more severe deficits and

suggested the need for personalisation of VR gaming technologies. As a result, purpose-built systems and systems using modified versions of commercially available VR gaming devices have been developed.

Findings from studies using purpose-built and modified versions of commercial VR gaming technologies suggest that unlike off-the-shelf VR gaming technology, purpose-built systems may be more effective than conventional therapy. However, again few systems had evaluated devices for use by those with more severe upper-limb deficits. Purpose-built technologies appeared to suffer from fewer movement detection issues than technologies using modified VR gaming devices, implying greater feasibility. However, high costs and the complicated set-up of such systems suggests that use at home and in many clinical settings is not possible. Similar to results from studies using off-the-shelf VR gaming technologies, high levels of acceptance for purpose-built and modified VR gaming technologies was apparent. However, in both systems, issues with feedback and the need for greater personalisation to allow maintenance of an appropriate level of challenge for participants with different levels of impairment were noted.

Findings from this review confirmed the need for VR gaming technologies to provide motivating feedback, to be hands-free and personalised to enable use by participants with different levels of impairment, including those with more severe upper-limb deficits, and to ensure the level of challenge to drive change and maintain motivation is maintained. As price is critical to uptake, the use of movement detection systems developed for VR gaming systems is an attractive alternative to more expensive purpose-built systems. To address this identified need, a personalised, hands-free, VR gaming system for upper-limb stroke rehabilitation using low-cost technology (originally developed for the VR gaming market) was created, the development and preliminary evaluation of which is detailed in the next chapter.

Chapter 4. Phase 1: Development and Preliminary Evaluation of Personalised Stroke Therapy Rehabilitation System

4.1 Introduction

Findings from the literature (Chapter 3) and a scoping study (Warland et al., 2012; Appendices 1.3 and 2) identified the need for low-cost, purpose-built, VR gaming technologies, suitable for upper-limb rehabilitation with stroke survivors including those with more severe levels of impairment. This chapter details the co-design and iterative development of such a system, the Personalised Stroke Therapy (PST) system, using a customised version of the Nintendo Wii. This aligns with the MRC Framework (Craig et al., 2008) modelling processes and outcomes within the development phase (Section 2.2). Details have been previously published (Paraskevopoulos et al., 2016; Tsekleves et al., 2012 & 2016; Warland et al., 2012).

The chapter begins with an overview of the development process, followed by a description of the system architecture and activities. Finally, preliminary evaluation of the system is reported.

4.2 Aims

The aims of this study phase were to co-design, develop and evaluate a low-cost VR gaming system for upper-limb stroke rehabilitation.

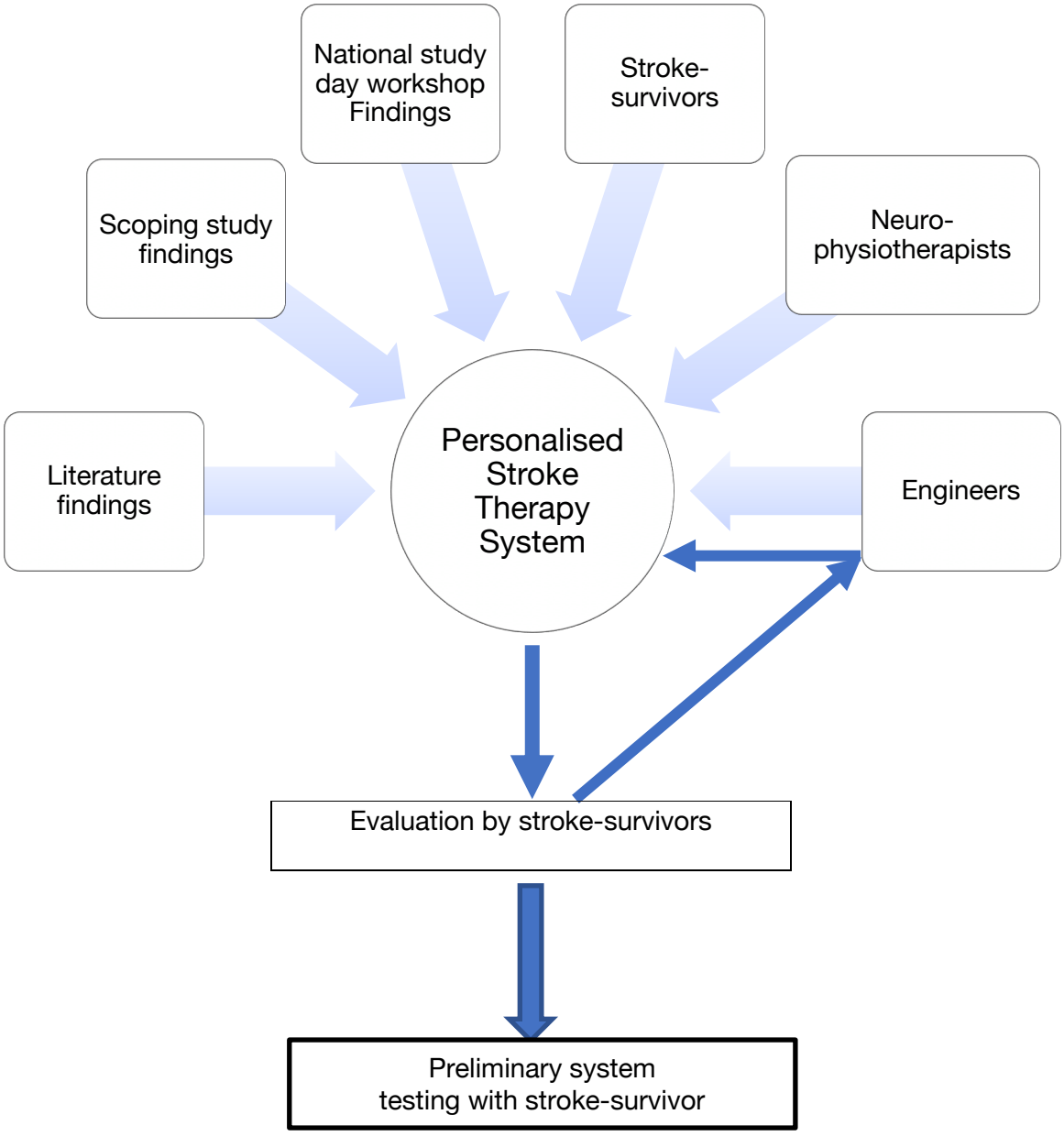
4.3 The Personalised Stroke Therapy System Co-Design Development Process

The co-design and iterative development of the PST system was informed by:

- The literature (Chapter 3)
- Findings from a scoping study (Appendix 2)
- A national study day workshop for therapists exploring the use of VR gaming technologies for rehabilitation.
- A ‘product design team’ of stroke survivors, engineers and neuro-physiotherapists.

The contribution of each is summarised in turn below and illustrated in Figure 4.1.

Figure 4.1 Flowchart of the Personalised Stroke Therapy System Development Process



4.3.1 A Summary of Literature Findings

Key findings from the literature (Chapter 3) implied that VR gaming technologies employed for rehabilitation purposes need to be affordable, provide accurate tracking of movements, use hands-free movement detection systems, provide positive feedback and employ activities which can be tailored dependent on an individual's specific ability. The provision of VR gaming technologies through telerehabilitation has also been advocated to help promote exercise adherence with service-users at home (Reinkensmeyer et al., 2012). While evaluation of this aspect was beyond the scope of this study (as initial assessment of the

system feasibility, acceptability and efficacy are required prior to evaluation as home therapy), the PST system was developed with this capability.

4.3.2 A Summary of Scoping Study Findings

Results from a scoping study (Appendix 2) confirmed literature findings that VR gaming technologies for stroke rehabilitation needed to be affordable, easy to set-up, simplified and personalised with regard to level of challenge, dependent on individual need. In addition, findings suggested the need for encouraging feedback and more therapy-like activities to increase therapist acceptance, and therefore use of VR technologies in rehabilitation. Finally, the need for a hands-free movement detection system was identified as being critical for use by stroke-survivors with impaired upper-limb strength, movement, dexterity and coordination.

4.3.3 A Summary of National Study Day Workshop Findings

As part of the iterative co-design of the PST system, the Brunel University London PST system development team hosted a national study day for therapists interested in VR gaming technologies for rehabilitation. The World Cafè approach (World Cafè Community Foundation, 2015) was used for workshops, where the 41 participants from across the UK were randomly divided into three groups and each “table” of participants discussed a different topic related to use of gaming technologies in rehabilitation. After approximately 20 minutes, participants moved onto another table and another topic. Broad topics for discussion were; barriers and facilitators to use of VR gaming technologies in clinical practice and consideration of the way forward for such technologies. Opinions were written onto a ‘table-cloth’ by group members and analysed for themes and shared ideas by the lead researcher (AW)

Three main topics were identified. Firstly, positive effects of VR gaming technologies in rehabilitation. These included adding variety and interest to treatment, increasing motivation and exercise adherence, the provision of feedback, while adding fun, “healthy” competition and promoting socialisation between service-users. The second topic related to how gaming technology was used in rehabilitation. Few participants had access to purpose-built systems and the Wii was the most commonly used device where it was primarily employed in group settings where it was used mainly for balance rehabilitation. Participants described using gaming devices in orthopaedic, neurological and musculoskeletal conditions, across all age groups.

However, while VR gaming devices were acceptable for use in principle, a third main theme of barriers to their actual use was apparent. A lack of knowledge about how often and how long to use devices, which activities were used suitable for which conditions and uncertainty about the evidence-base, were frequently voiced barriers to use. A recommendation for evidence-based guidelines was made (detailing dosage, which conditions are appropriate for VR gaming interventions and which games and activities to use for different treatment effects). Safety was identified as a positive feature, however there was uncertainty regarding the safety of VR gaming technologies with patients who had pacemakers or epilepsy, again, suggesting the need for more explicit guidance about participant suitability. Concerns when using commercial VR gaming technologies included inappropriate pace, intensity and level of difficulty and consequently, the need to tailor activities to an individual's ability and condition was a prevalent theme. Noise was also identified as a barrier to use in clinical environments and feedback was sometimes considered as being "offensive" and needed to be more encouraging. Further suggestions included the development of functionally-based, age-related activities and activities suitable for upper-limb stroke rehabilitation. Other challenges voiced included finding suitable space to safely store VR gaming devices, difficulty in using hand held movement sensors and reduced patient contact time due to the prolonged time to set-up a gaming session caused by the necessity of having to navigate through several screens before being able to play activities.

Findings from the study day were in keeping with the literature and supported the need for the development of hands-free, personalised systems for rehabilitation purposes. Interestingly while all participants had used VR gaming technologies in rehabilitation, a lack of knowledge about the effectiveness, suitability and dosage was apparent. This discrepancy suggests that despite an awareness of the importance of evidence-based practice, that many therapists are prescribing treatments without due consideration to the evidence.

4.3.4 A Summary of System Development Team Membership and Iterative Co-Design

The PST system development team comprised three engineers with technical expertise in the use of VR game development, two physiotherapists experienced in neurorehabilitation and four stroke-survivors (working at a partnership/co-production level as discussed in Section 2.4). Combining perspectives from different development team members has been advocated as a powerful way to generate ideas, to ensure the development of a higher quality, more satisfactory product (Steen et al., 2011). As "experts by experience" (Steen et al., 2011), inclusion of stroke survivors maximised the utility of relevance of the PST system from the service-user perspective. Demographic details for each stroke-survivor team member is provided in Table 4.1.

Table 4.1 Demographic Details of Stroke Survivor Team Members

Pseudonym	Gender	Age	Hemiplegic side	Time since stroke	Modified Rankin Score	Upper-limb movement
Paul	Male	33	Right	18 months	3	Moderate shoulder and elbow movement, flickers in the hand and wrist (no grasp)
Florence	Female	52	Left	16 months	2	Slight weakness and reduced coordination
Rose	Female	57	Left	14 months	4	Minimal movement in upper limb
Lucy	Female	32	Right	11 years	2	Moderate shoulder, elbow and hand movement

Three stroke-survivors (Paul, Florence and Rose), who, following the completion of an unrelated study, had given permission to be contacted about opportunities to be involved in future stroke projects, volunteered to join the development team. A fourth team-member, (Lucy), asked to join the project team after reading about the study on the University website.

Findings from the literature, scoping study and the national study day workshops, together with input from the neuro-physiotherapy and stroke survivor members of the research team, were used to co-design the prototype system. The prototype was trialled by three of the stroke-survivor team members (Paul, Florence and Rose) and iterative feedback was provided to the team engineers to further improve the system. The cyclical process of evaluation and adjustment of successive versions continued until the system was felt to be at a stage for more formal evaluation, whereon more comprehensive system testing was undertaken by one stroke-survivor team-member (Section 4.5).

4.4 Architecture of the Personalised Stroke Therapy System

A detailed explanation of the technical development of the PST device has been published (Paraskevopoulos et al., 2016; Tsekeleves et al., 2012 and 2016). A summary of the system architecture is provided next for context.

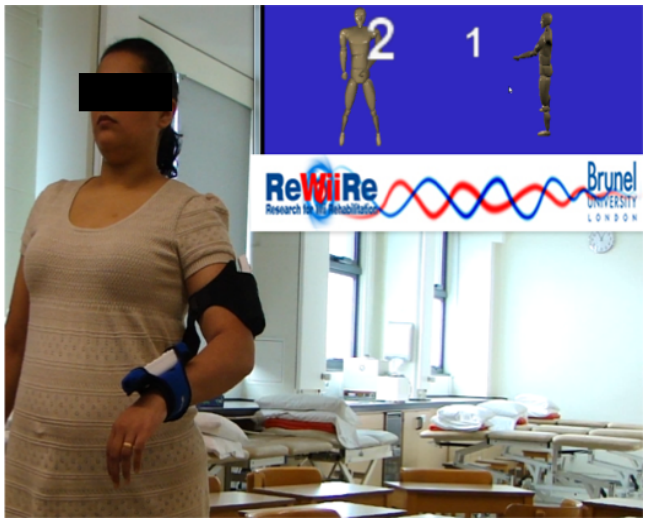
4.4.1 Movement Sensors

Two Nintendo Wiimote MotionPlus wireless movement sensors, developed for use with the off-the-shelf Wii gaming console, were incorporated into the PST system to enable interaction between the system-user and the PST system. The sensor uses a combination of gyroscopes and accelerometers to measure velocity, orientation and gravitational forces and

by this means, provides information about position and movement in three-dimensional space. At launch the cost of the Wiimote Motion Plus was $60 (Arstechnica.com). As cost has been identified as a barrier to uptake of technology (Scherer, 2017), the rationale for the use of a commercially available existing movement sensor was to reduce costs involved in the system development.

While the adaptation of other relatively low-cost commercially available systems was considered, at the time of the study the Wii was the most commonly-used system in rehabilitation (and therefore as a “normal” activity, may be considered to be more acceptable for use in rehabilitation) (Langan et al 2018). In addition, the Wiimote was available to purchase independently of the whole gaming console (thereby further reducing cost) and was readily customisable (allowing use with systems other than Wii). Some low-cost commercially available systems (such as the Microsoft Kinect) operate through use of depth-sensors, and by doing so negate the need to hold or attach movement sensors to the user. However, these suffer from occlusion errors and in doing so reduce accuracy, particularly when unusual movement patterns (such as those typically seen post stroke) are employed (Hondori and Khademi, 2014). However, as fast-moving technological advances can result in obsolescence of technological devices, the PST system was designed with cross platform transferability enabling use with other technologies.

Figure 4.2 Photo of Stroke Survivor Team Member Showing Position of the Movement Sensors



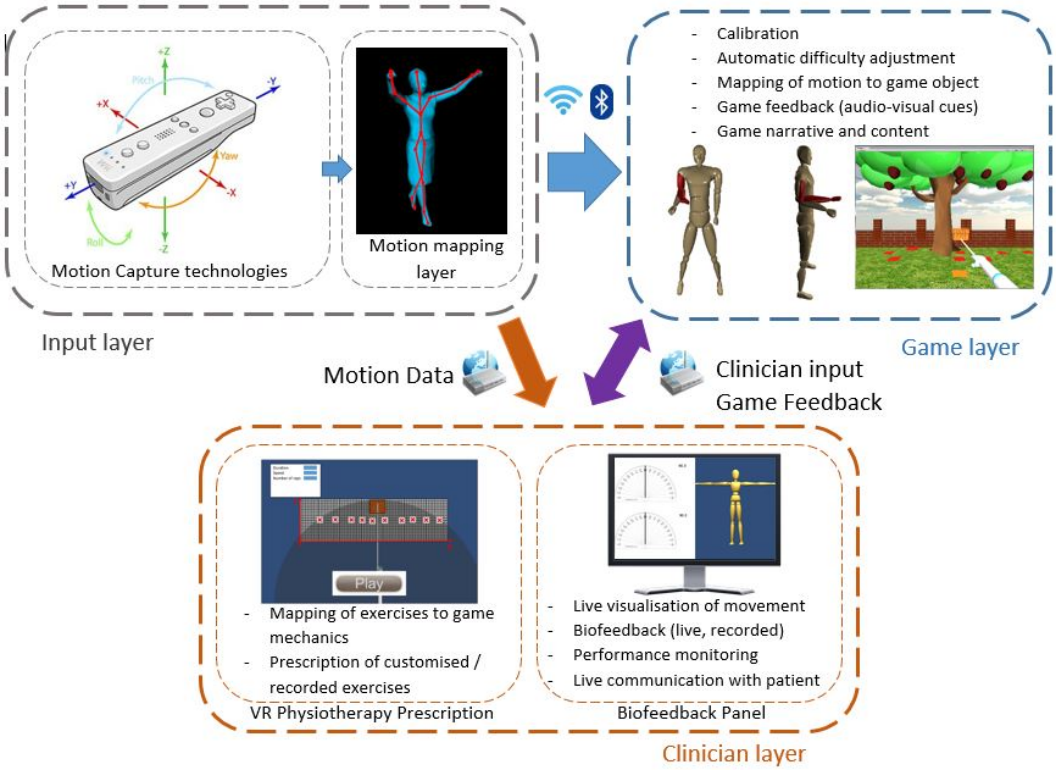
As the need for hand dexterity and strength has been identified as a barrier to use of gaming technologies for stroke rehabilitation (Appendix 2) the PST system used Lycra pockets with Velcro straps to secure movement sensors thereby allowing use by service-users who were unable to hold and operate the Wiimote. One sensor was secured on the lateral aspect of

the upper-arm midway between the shoulder and elbow and the second was secured to the dorsal aspect of the forearm midway between the elbow and wrist (Figure 4.2).

4.4.2 Software Architecture

Movement data from the Wiimote sensors was sent to a computer using Bluetooth (wireless) technology and a data fusion algorithm was used to combine and smooth data to achieve greater accuracy in movement tracking. This information was then mapped onto a three-dimensional body model (Figure 4.3).

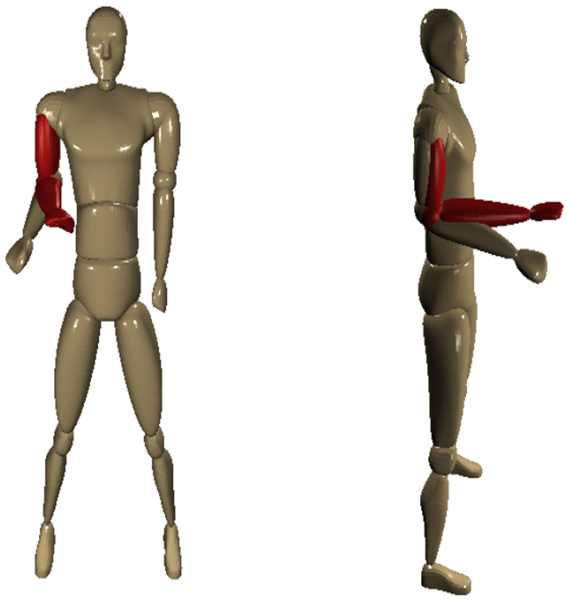
Figure 4.3 PST System Architecture



In order to provide useful feedback when using the PST system, accurate and responsive tracking of the arm is required. A study to evaluate the accuracy of the motion capture system was therefore undertaken by study engineers (reported in Tsekleves et al. 2016), in which movements detected by the state of the art, Vicon MoCap studio (capable of achieving accuracy to within a few millimetres) were compared with those from the low-cost PST system developed for this study. There was high correlation between both systems with accuracy in the PST system being between 5.5 and 10.7% for each of the three planes of movement.

As feedback from stroke-survivor design team members and results from the scoping study (Appendix 2) indicated that avatar appearance was not considered an important feature by service-users, a generic, non-gender specific avatar was used (Figure 4.4).

Figure 4.4 A Screenshot of the Avatar



4.4.3 VR Rehabilitation Activities

A library of rehabilitation activities and games were developed targeting shoulder, elbow and forearm movements. Activities were developed in-line with motor learning principles (discussed in Sections 1.3.1 and 1.4.1) and specifically aimed to encourage intensive repetitious practice of a functional movement and discourage learnt-non-use of the hemiplegic upper-limb through the provision of feedback and exercise using an enjoyable and motivational activity, While mirror-neurone activation through action observation has been postulated as a mechanism behind VR rehabilitation (Adamovich, 2009; Celnik et al.,2006; Ertelt et al., 2007; Franceschini et al., 2012; Pekna et al., 2012), the use of a non-immersive system in this study made this mechanism less-likely.

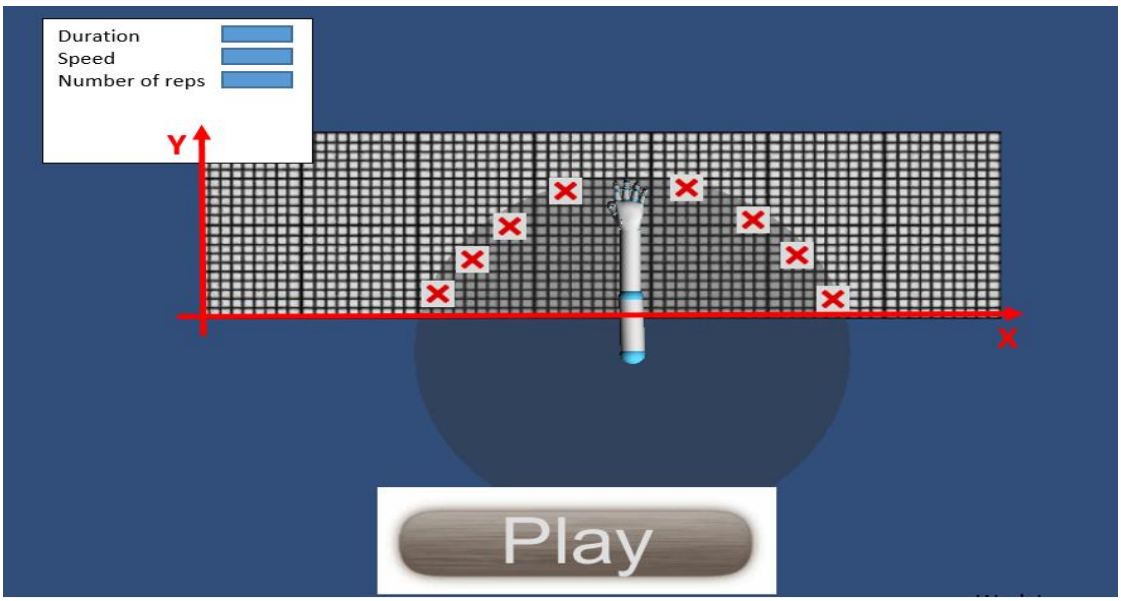
Details regarding game characteristics and targeted movements for activities and games used in the single-case preliminary study (Section 4.5) and feasibility study (used for study phase 2; Chapters 5-8) are provided in Table 4.2. While most functional upper-limb activities involve the arm, wrist and hand (Shumway-Cook and Wollacott, 2017), as with any system using the Wiimote movement sensors (Sections 3.6.2 and 3.6.4) it was not possible to track wrist and hand movements with the PST system. The exclusion of the wrist and hand was a limitation of the PST system and the impact of this is discussed in Section 9.8.2.

Table 4.2 Characteristics of VR Rehabilitation Activities

Activity name	Virtual Therapist	Apple-catching	Air hockey	Ball-hitting
Activity type	Traditional rehabilitation exercise	Game	Game	Game
Activity aim	Blend movements between virtual therapist (recorded movement) and own arm	Catch as many apples falling from a tree in the given time	Move the on-screen paddle to move puck and score goals in the computer-controlled opponent's goal while defending own goal	Hitting randomly placed on-screen balls to score points
Targeted joints and movements	**Shoulder** • Flexion / extension, • Horizontal flexion / extension, • Abduction / adduction, • Internal / external rotation **Elbow** • Flexion / extension **Forearm** • pro/supination	**Shoulder** • Flexion / extension, • Horizontal flexion / extension, • Internal / external rotation **Elbow** • Flexion / extension **Forearm** • pro/supination	**Shoulder** • Flexion / extension, • Internal / external rotation **Elbow** • Flexion / extension	**Shoulder** • Flexion / extension, • Horizontal flexion / extension, • Abduction / adduction • Internal / external rotation **Elbow** • Flexion / extension
Personalisation	• Side of hemiplegia • Speed • Range of movement • Plane of movement • Targeted joints • Duration • Number of repetitions • Type of simulated activity	• Side of hemiplegia • Range of movement • Plane of movement • Duration	• Side of hemiplegia • Speed • Range of movement • Duration	• Side of hemiplegia • Speed • Range of movement • Plane of movement • Duration • Time balls remain on screen
Feedback	• On-screen blending of arms in real time	• Score during activity • Final score • Motivational message	• Score during activity • Final score • Motivational message	• Score during activity • Final score • Motivational message

As the need for personalisation was recognised (Appendix 2; Section 4.3.3), activities were designed so that through the use of a therapist interface (Figure 4.5) features such as player handedness, game duration, number of repetitions, range of movement and game speed can be altered by the therapist dependent on individual ability. Moreover, at the end of each game participants are able to see their score and an encouraging message such as, “well done”, “keep going”, “good effort”.

Figure 4.5 An Example of The Therapist Interface for the Apple-Catching Game.



In addition to the games, a ‘virtual therapist’ application was developed (Figure 4.6) in which functional movement patterns involving the shoulder, elbow and forearm are captured by recording the system-user performing a series of functionally-based movements (with facilitation from a therapist to ensure recorded movements slightly exceed ability, resulting in a greater degree of challenge). The range, speed and targeted movements are customised for each individual dependent on ability and individual interest (for example one participant requested practicing movement patterns based on an unloading a dishwasher, in which they practiced movements involved in reaching down to pick up plates before placing them on shelves of different heights; another activity simulated movements involved in personal grooming such as reaching for a hairbrush and brushing their hair, reaching for a toothbrush and brushing their teeth, reaching for tee-shirts on shelves of various heights and donning the tee-shirt; another practiced an upper-limb dance routine). Each routine was designed to last approximately one minute with movements starting within the participant’s existing range of movement at their preferred speed before progressing the range followed by the speed of movement. The recorded movement is mapped onto the arm of the ‘virtual therapist’

(depicted in red in Figure 4.6) and then played back on a loop (the duration of which is set by the therapist) at the same speed and range as the recording. System-users are instructed to follow the recorded virtual therapist arm (depicted in red in Figure 4.6) with their own arm (depicted in white in Figure 4.6). When system-user's movements match those of the virtual therapist, the onscreen arms are seen to blend together thereby providing instantaneous feedback.

Feedback from the three stroke-survivor team-members, revealed a strong preference for a mirror image view when using applications. In addition, field-notes made by the therapists noted higher scores and more fluid movement by participants when using a mirror-view. Therefore, a mirror-view was used for third-person activities used with the prototype PST system.

Figure 4.6 Photograph of Stroke-Survivor Team Member Using the Virtual Teacher Application with Screenshot

4.5 Preliminary Evaluation of the PST System

More comprehensive system evaluation was undertaken by a stroke-survivor member of the PST Development team. A TIDieR checklist (Hoffman et al., 2014) describing the intervention is provided in Appendix 4.

4.5.1 Methods

4.5.1.1 Design:

Field-testing of the PST system was undertaken using a pre-test, post-test design with one stroke survivor team-member. While not possible to generalise findings, this design allowed more in-depth exploration of the PST system and has been advocated as a relatively inexpensive and useful method for early-stage exploratory work (Bowling, 2014).

4.5.1.2 Setting and Resources:

The setting was a quiet university therapy room. Equipment for the intervention consisted of the PST system (including two Wiimote movement sensors, two Velcro pockets to secure the sensors), a laptop computer loaded with the PST software, a standard 46” television screen and an HDMI cable to enable visualisation of the activities on the television screen. In addition, equipment for outcome measures and data collection paperwork was required.

4.5.1.3 Participant:

A 31-year-old, right-handed female stroke-survivor member of the development team (Lucy) participated in the preliminary evaluation of the PST system. Lucy had suffered a right-sided stroke aged 19 resulting in a left hemiplegia, scoring 2 on the modified Rankin Scale (mRS) equating to a descriptor of a mild stroke. While exhibiting shoulder, elbow, wrist and hand movement against gravity, movement was neither full range, nor against resistance. Moreover, she reported being strongly right-handed and stated that she rarely attempted to use her left upper-limb in functional activities. She had finished all formal rehabilitation at the time of joining the development team. Verbal communication from the Chair of the Brunel University School of Health Sciences and Social Care Ethics Committee, confirmed that ethical approval was not required as Lucy was considered an autonomous team member with the specific role of system evaluation.

4.5.1.4 Protocol:

Assessments were taken at baseline and one day post intervention. To allow recovery from possible fatigue, assessments were completed one-day either side of the intervention. The planned intervention consisted of three times weekly exercise sessions for two weeks using three activities (two games [ball-hitting and air hockey] and the virtual therapist application). Each session was planned to last 45-minutes maximum with each activity being played for five minutes at a time with a two-minute minimum rest period, between each game. Exercises were tailored for side of hemiplegia, speed, range of movement, duration required and, in the ball-hitting game, the time the target remained on screen. Exercises could be completed in sitting or standing dependent on user preference. Lucy chose to exercise in standing.

4.5.1.5 Data Collection: All assessments were undertaken by the study researcher (AW). The Nine Hole Peg Test (NHPT) (Mathiowetz et al., 1985), FMA-UE (Fugl-Meyer et al., 1975) (Deakin et al., 2003) and the Modified Ashworth Scale (mAS) (Bohannon and Smith, 1987) were used to assess for impairment, while the Motor Activity Log (MAL) 14 Amount of Use scale (Uswatte et al., 2006) was used to assess for functional change. Measures were selected on the ability to assess impairment and activity levels of the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001), brevity of assessment to reduce overall study burden, combined with high levels of validity and reliability (NHPT, Chen et al., 2009; Heller et al, 1987; Parker et al. 1986) (FMA-UE, Duncan et al., 1983; Hseih et al., 2009; Malouin et al., 1994; See et al., 2013; Woodbury et al., 2008) (mAS, Li et al., 2014; Katz et al., 1992), (MAL-14, Uswatte et al., 2006; van der Lee et al 2004). In addition, each activity was rated for enjoyment and level of challenge. The use of contemporaneous field-notes written by the lead researcher provided additional data.

4.5.2 Results

Six sessions of intervention were completed with time spent using the PST system ranging from 15 to 25 minutes per session (average of 18.3 minutes per session, total of 110 minutes). Reasons for reduced intervention time related to technical issues. No adverse effects occurred. Change in outcome measures between baseline and post-intervention are presented in Table 4.3.

Table 4.3 Change in Score by Time Point

		Pre-intervention	Post-intervention
Nine Hole Peg Test (Average time in seconds to place each peg)		29 seconds	7.8 seconds
Fugl-Meyer Assessment- upper extremity (Score 0-66 with high score indicating less impairment)		39	47
Modified Ashworth Scale (Score 0—6 with 0 demonstrating no increase in muscle tone and 6 the affected part is held in rigid flexion or extension)	Shoulder adduction	0	0
	Elbow flexors	1+	1+
	Wrist extensors	3	1
	Finger flexors	3	1
Motor Activity Log 14 (score 0-70 with higher score indicating better use of the limb in functional activities)		7	10

4.5.3 Discussion of Preliminary System Evaluation

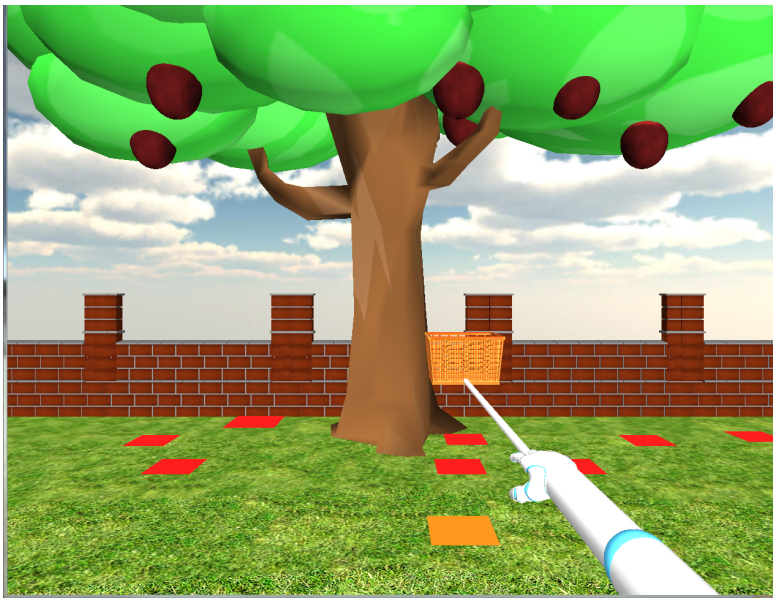
The stroke survivor was able to use the PST system, indicating feasibility. However, initial issues storing the recording of the virtual therapist recorded movements resulted in the need to rerecord movements each time the game was played, resulting in reduced game-playing time. Study engineers were able to rectify this, adding a recording storage element by intervention four. Although the stroke-survivor initially classified the application as being only "moderately fun" (rating it as 6 out of 10 on a Likert scale) her comments about it being "enjoyable because it's a good work out" suggests acceptability of the application. No problems were apparent with the ball-hitting exercise indicating feasibility of use. However, rating of game acceptability decreased over time as her score improved suggesting the need for further adaptations to maintain challenge for higher level participants. Field-notes revealed great difficulty using the air hockey game initially. This was associated with poor performance scores and low ratings of enjoyment. Following technical adjustments by the engineering team (to reduce the game speed and range of movement necessary to move the puck across the entire field of play) much higher ratings of enjoyment were stated and Lucy reported "the word air hockey causes a Pavlovian response with regard to motivation".

Improvements in NHPT, FMA-UE and the MAL-14 scores were apparent post intervention. Due to the nature of the study design, it was unlikely that improvements were as a result of the intervention. While at 11-years following stroke, it is likely that all spontaneous recovery had occurred, the intervention intensity was unlikely to facilitate plastic change. Moreover, the non-immersive nature of the PST system meant that activation of mirror neurones was less likely. As the participant commented on the spontaneous use of the hand and arm in functional activities, it is more likely that the improvements seen post intervention were as a result of the PST system addressing learnt non-use.

4.6 Further PST System Developments

Following the preliminary testing, further evaluation of games by more impaired stroke-survivor team members indicated continued feasibility issues with the air hockey game, indicating a lack of suitability for those with more severe upper-limb deficits. While study findings indicated the feasibility of using the ball-hitting game, stroke survivor team members expressed a preference for a newly developed apple-catching game (Figure 4.7 described in Table 4.2) which had been developed based on feedback from the case study. This together with the Virtual Teacher were therefore selected for further system evaluation in a feasibility study (Chapters 5-8).

Figure 4.7 Screenshot of the Apple-Tree Game



Additionally, floor effects with the NHPT were apparent in those with more severe upper-limb deficits and this measure was therefore omitted from the feasibility study.

4.7 Summary

In summary, this chapter reported on the development of the personalised stroke therapy system for upper-limb stroke rehabilitation using an iterative co-design process. System evaluation by stroke survivor team members provided proof of concept.

Further evaluation of the system is presented in Chapters 5-8.

Chapter 5. Phase 2: Method

5.1 Introduction

This chapter describes methods used to examine the feasibility, acceptability and preliminary efficacy of using the Personalised Stroke Therapy (PST) system for upper-limb stroke rehabilitation. This aligns with the feasibility / piloting stage of the MRC Complex Interventions Framework (Craig et al., 2008; Section 2.2). Details of this study have been published (Warland et al., 2018). A TIDieR checklist (Hoffman et al., 2014) describing the intervention is provided in Appendix 5.

5.2 Research Aims and Objectives

The primary aims of this study phase were to determine the feasibility (including safety) and acceptability of using the PST system for upper-limb rehabilitation with community dwelling stroke survivors. Feasibility and acceptability of both the intervention and study protocol were operationalised in accordance with the classifications described in Section 2.3 (Table 2.2). Although designed as a feasibility study, a secondary aim was to examine preliminary efficacy of the PST system. Specific study objectives are outlined below.

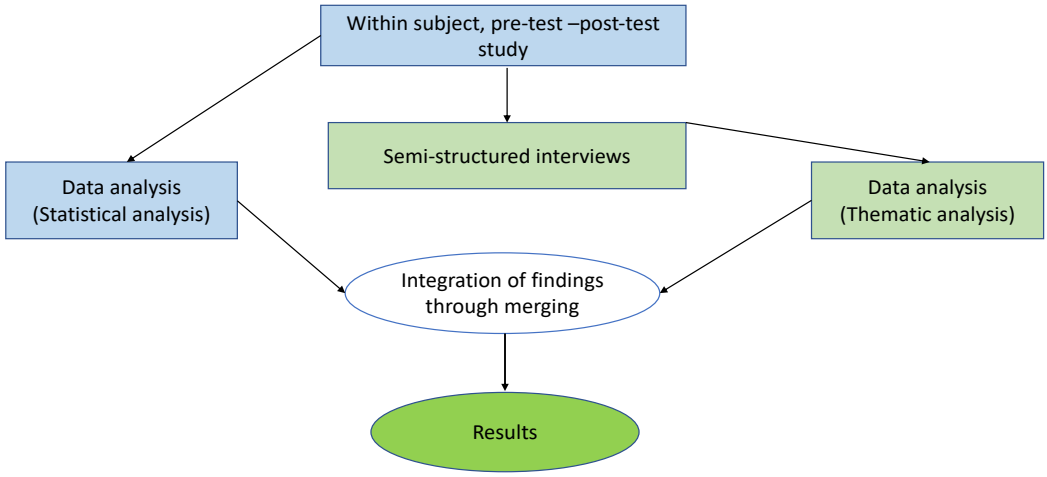
1. To evaluate the feasibility (including safety) of using the PST system for upper-limb rehabilitation for stroke survivors.
2. To explore the acceptability of using the PST system as an intervention for upper-limb rehabilitation with stroke survivors.
3. To examine preliminary estimates of efficacy of the PST system in stroke survivors.
4. To determine feasibility and acceptability of the methodology and key parameters for any future randomised controlled trial (RCT).
5. To ascertain to what extent quantitative results confirm qualitative findings regarding acceptability, feasibility and efficacy of the PST system for upper-limb rehabilitation and acceptability and feasibility of the study protocol.

5.3 Study Design

To address study aims and objectives a mixed-methods convergent design was used (Figure 5.1), with a within-subject (single group), pre-test- post-test (quantitative) phase being followed by qualitative data collection using semi-structured interviews. Each phase was analysed separately, prior to integration of the findings.

The within subject (single group), pre-test- post-test, study design was felt suitable for a time and cost-bound study where primary aims were exploratory. Semi-structured interviews enabled detailed exploration and focus on contextual detail as well as the collection of potentially sensitive data that would not be possible, or ethically sound, in a group situation (Lewis, 2003). Moreover, emerging topics identified from earlier interviews were explored in subsequent interviews, thereby checking validity of insights with other participants (Miles et al., 2014).

Figure 5.1 Mixed-Methods Convergent Design



5.4 Participants

Study eligibility was ascertained through assessment against inclusion and exclusion criteria as detailed below.

5.4.1 Inclusion and Exclusion Criteria

Inclusion criteria were:

- Adult participants with mild to moderately-severe loss of upper-limb function (score between 14-25 for both elbow and shoulder movement on the Motricity Index)
- Unilateral stroke
- Minimum of 12 weeks following stroke
- Finished all formal upper-limb rehabilitation
- Able to sit independently for a minimum of five minutes
- Residing within one hours travel from the study site

- Ability to understand and communicate in English and to follow instructions
- Capacity to consent

Exclusion criteria were:

- Pre-existing upper-limb pain at rest or on movement
- Fixed contracture, active disease or orthopaedic conditions affecting the movement in the arm affected by stroke
- Photosensitive epilepsy in adulthood
- Medical instability
- Acquired brain injury from other causes and cerebellar lesions
- Pacemakers
- Visual neglect/hemianopia or uncorrected visual field deficits (score of 44 or below on the Star Cancellation Test)

5.5 Recruitment, Screening and Consent

This study aimed to recruit 12 participants. This was in keeping with previous feasibility studies of VR gaming technology in stroke rehabilitation which recruited between eight and ten people into their treatment arms (Celinder and Peoples, 2012; Levin et al., 2012; Saposnik et al., 2010). Twelve was considered a realistic number in keeping with a resource limited, student project while also allowing for drop outs. In accordance with this type of study no power calculation was undertaken.

Participants were recruited via the **Re**seachin in **Wii Re**habilitation (ReWiiRe) scoping study website, the Brunel University website, through use of advertising flyers (Appendix 6) and four study awareness raising events at four local stroke support groups (involving a short presentation by the lead researcher detailing the study purpose and participant requirements). Volunteers were provided with a participant information sheet (Appendix 7) detailing study requirements. As travel burden has been identified as a barrier to research participation (Martin, 2013), pre-paid, wheelchair accessible taxis were offered to all participants to maximise recruitment.

To ensure inclusion and exclusion criteria were met, all volunteers underwent initial screening including collection of demographic data (by telephone or in person at study awareness events) followed by physical assessment at the first appointment where procedures and risks were explained to participants and written informed consent was obtained (Appendices 8-9).

5.6 Study Setting and Resources.

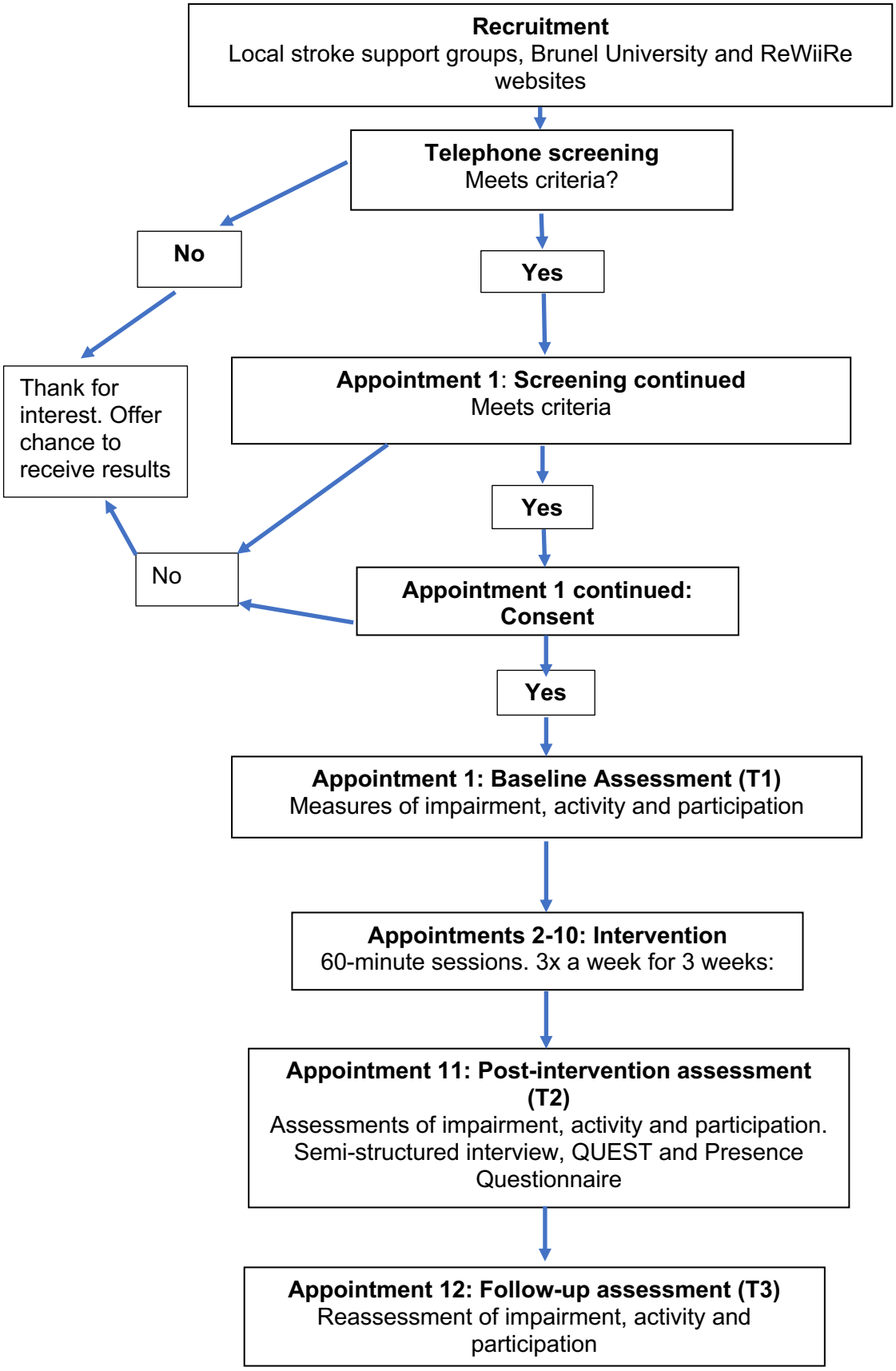
All appointments were carried out on an individual basis in a university laboratory. The laboratory set up was standardised (with the use of floor markers) as illustrated in Figure 5.2. Equipment for the intervention consisted of the PST system as described in Section 4.4., a laptop computer loaded with the PST software, a standard 46" television screen and an HDMI cable to enable visualisation of the activities on the television screen. In addition, equipment for outcome measures (Section 5.9.2), a tape recorder for recording the interviews and study paperwork including a data collection form (Appendix 10) and a Specific Operations Protocol (Appendix 11) were required.

Figure 5.2 Laboratory Set-Up

5.7 Intervention Protocol

The study procedure, including intervention protocol, is outlined in Figure 5.3. Assessments were taken at baseline (T1), one day to one-week post-intervention (T2) and at follow-up (one-month post-intervention) (T3).

Figure 5.3 Flowchart of Study Procedure



To allow for recovery from fatigue, the intervention began a minimum of one-day post baseline assessment (T1). The planned intervention consisted of 40 minutes exercise, three days a week over three weeks. While mirroring a more realistic clinical picture, the requirement to attend only three days a week was chosen to aid recruitment, as more demanding protocols have been identified as a barrier to recruitment for trials involving physical activity (Rogers et al., 2014). Moreover, this is similar to protocols used in other feasibility trials which have employed eight sessions over two weeks (Saposnik et al., 2010) and nine sessions over three weeks (Celinder and Peoples, 2012; Levin et al., 2012).

Two activities (one game and one exercise) were used in this study phase. The apple-tree game (where arm movements operate an on-screen basket which is moved to catch apples falling from an on-screen tree) requires the system-user to practice shoulder, elbow and forearm movements in order to catch apples randomly falling from a tree (Figure 4.7). In the virtual therapist application, participants move their upper-limb in functional movement patterns (Section 4.4.2) to try and match movements of an on-screen 'therapist'. Activities were tailored for individual needs with regard to player handedness, game duration and range of movement for the apple-tree game and time played, range of movement and speed for the virtual therapist application. Both activities were performed for a maximum of 10 minutes and were then repeated. A minimum of two minutes rest was incorporated between each of the four 10-minute exercise blocks. Deviations from the protocol were recorded to inform any future studies (e.g. where participants required more or longer rest periods, were unable to exercise for the full 40 minutes or were unable to attend the prescribed number of visits). Participants exercised in standing or sitting dependent on personal preference. Participants were required to exercise their hemiplegic upper-limb under the direct supervision of a member of the research team.

All interventions were completed on an individual basis. Three researchers delivered the intervention, all of whom were qualified physiotherapists, experienced in stroke rehabilitation and had received appropriate training.

5.8 Data Collection

Data collection was conducted between January and May 2015. Assessments were undertaken on an individual basis by one of three researchers**.** The lead researcher completed all post-intervention interviews. Where possible, each of the three assessments was undertaken by a different assessor who was blind to previous scores.

5.8.1 Standardisation of Assessment

To ensure standardisation of assessment, all researchers involved in assessment received training on the outcome measures being used, including training on the FMA-UE as detailed by See et al. (2013) and training on the Action Research arm Test (ARAT). In addition, a Specific Operations Protocol (Appendix 11) was developed to ensure standardisation of assessment. While outcome measures detailed in the Specific Operations Procedure largely followed the published versions (referenced in Appendix 11), minor changes were made to the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) to ensure only relevant sections were included. Additionally, minor changes to improve clarity of scoring was made to the FMA. Changes to the published protocol are highlighted in Appendix 11.

5.8.2 Outcome Assessments

Details of the assessments carried out at each time-point in the study are presented in Table 5.1.

Table 5.1: Outcome Measures at Each Time Point

Measures	Baseline (T1)	During intervention	Post intervention (T2)	Follow- up (T3)
ABILHAND	Yes	No	Yes	Yes
ARAT	Yes	No	Yes	Yes
FMA UE	Yes	No	Yes	Yes
MAL-28	Yes	No	Yes	Yes
SIPSO	Yes	No	Yes	Yes
BORG scale of perceived exertion	No	Yes	No	No
Pain VAS	No	Yes	No	No
FAST motion sick scale	No	Yes	No	No
Falls incidence	No	Yes	No	No
Level of enjoyment	No	Yes	No	No
QUEST	No	No	Yes	No
iGroup Presence Questionnaire	No	No	Yes	No
Semi-structured Interview	No	No	Yes	No

5.8.2.1 Assessment of Acceptability and Feasibility of PST Device and Study Experience

Information regarding acceptability and feasibility of the PST device and study protocol were established through use of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) questionnaire, semi-structured interviews and use of field-notes. As

presence has been identified as a key issue affecting the effectiveness of virtual reality devices (Witmer and Singer, 1998), sense of presence in the virtual environment was examined using the iGroup Presence Questionnaire (IPQ).

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)

The QUEST (Demers et al., 1996) is a 12-item questionnaire that assesses user satisfaction with an assisted device. Four questions assessing satisfaction with service issues (such as delivery and repairs) were irrelevant to the present study and were therefore omitted from the assessment. Items are scored on a 5-point ordinal scale (minimal score of 5 and maximum of 40), with a higher score indicating greater levels of satisfaction. Reliability and validity have been established (Demers et al., 1999, Demers et al., 2000).

Semi-Structured Interview Topic Guide

A semi-structured interview topic guide (Appendix 12) was developed using an adapted version of an interview topic guide used in the scoping study with additional input from stroke survivors who participated in the development of the PST system, study engineers and feedback from a pilot study.

Field-Notes

Researcher observations and reflections and ad hoc comments made by participants during the study were recorded on the data collection form.

IGroup Presence Questionnaire (IPQ)

The IPQ (Schubert et al., 2001) is a 14-item self-report questionnaire with subscales looking at spatial presence, sense of involvement and sense of realness. Items are scored on a 7-point Likert rating scale ranging from -3 to 3. A maximal score of 84 is possible with a higher score indicating greater sense of presence and immersion in the activities. The IPQ has been shown to have good reliability and validity (Schubert et al., 2001).

5.8.2.2 Measures of Adverse effects and Intervention Experience

During intervention sessions, subjects rated their level of exertion and level of enjoyment for each activity using respectively, the 15-point Borg Scale of Perceived Exertion (rated from 6 to 20, with a higher score indicating a higher level of perceived exertion) and an 11-point visual analogue scale (VAS) (rated from 0 to 10, with a higher score indicating a higher level of enjoyment). In addition, participants were monitored for adverse effects throughout the intervention. Incidences of pain were recorded using an 11-point VAS (from 0 to 10, with a

high score indicating greater perception of pain); motion sickness on the 21-point FAST Motion Sickness Scale (from 0 to 20, with a higher score indicating greater experience of motion sickness) (Appendices 13-16). Incidences of falls, near falls or other adverse effects were recorded on the intervention data collection form (Appendix 10).

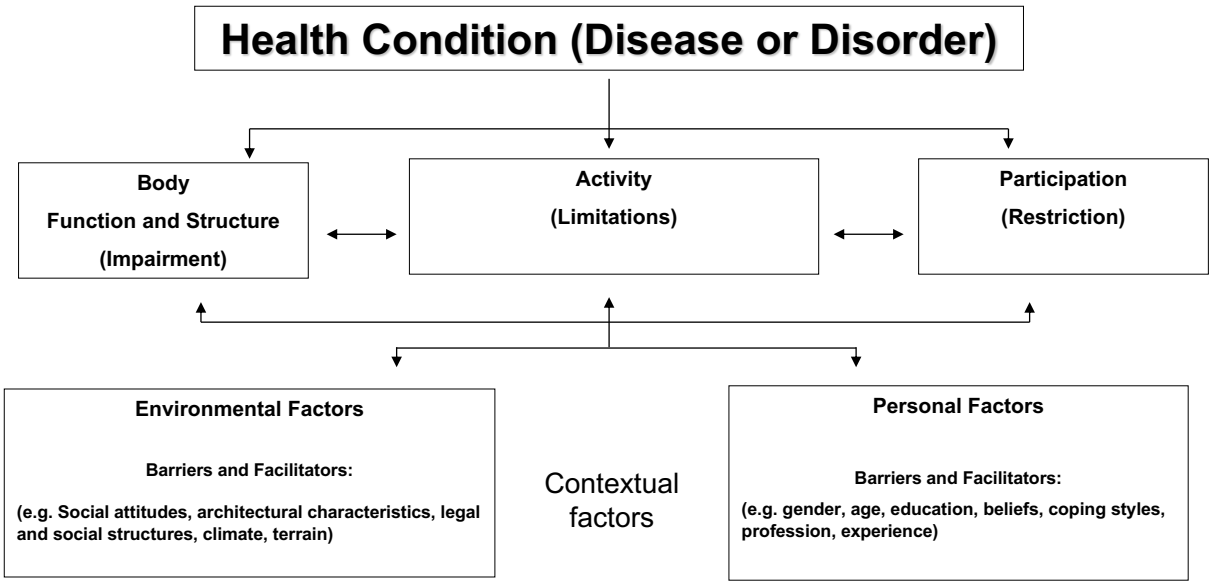
5.8.2.3 Measures of Efficacy

The International Classification of Functioning, Disability and Health (ICF) (World Health Organisation [WHO] 2001) illustrated in Figure 5.4, is a framework for describing, measuring and classifying health, function and disability. It has been recommended to evaluate the effectiveness of interventions (Alt Murphy et al., 2015) through measuring outcome in different domains:

- Firstly, at the level of body structure and functions (that is impairments suffered at the body level as a result of the health condition);
- Secondly at the activity level (that is limitations in the ability to perform functional tasks) and
- Thirdly at the level of participation (that is the effect on the health condition of the ability to participate in society).

As no one measure is able to capture the differing effects of stroke (Ashford et al., 2008; Baker et al., 2011), different measures were employed to assess preliminary efficacy of the PST system at all levels of the ICF. When selecting specific outcome measures, Wade's (1992) recommendations were employed to ensure selected measures were valid, reliable, sensitive, simple and communicable. Details of specific measures used are discussed in turn below.

Figure 5.4 The International Classification of Functioning, Disability and Health (WHO 2001)



Measures of Impairment

Fugl-Meyer Assessment of Motor Recovery After Stroke –Upper Extremity (FMA-UE)

The upper extremity (motor, coordination and speed) sections of the FMA (Deakin et al., 2003; Fugl-Meyer et al., 1975) were used to assess impairment. To aid clarity in instruction and scoring, minor changes to the published version by Deakin et al. (2003) were made as highlighted in Appendix 11.

Participants were assessed on motor ability, coordination and speed and scored on a 3-point ordinal scale from 0 (cannot perform) to 2 (able to perform fully). Scoring is between 0 and 66 with a higher number indicating a better performance. The FMA-UE is reliable (interrater reliability, r = 0.995-0.996 [Duncan et al., 1983]); intrarater reliability, r = 0.99 [See et al., 2013]) valid (criterion validity, r = 0.96 [Malouin et al., 1994]; construct validity: correlated with ARAT, r = 0.73, 95% CI, 0.58-0.83 [Hsieh et al., 2009] and content validity Woodbury et al., 2008] measure of impairment. The minimal clinically important difference (MCID) is 10 (Shelton et al., 2001) and the minimal detectable change (MDC) is 5.2 (Wagner et al., 2008).

Measures of Activity

ABILHAND

The ABILHAND (Penta et al., 2001) therapist-administered questionnaire, assesses perceived difficulty in performing functional unilateral and bilateral activities of daily living without the use of external aids or assistance, regardless of compensation strategies or limb

employed to complete the tasks. Participants rate 23 activities as 'impossible', 'difficult', 'easy' or '?' if the action has not been tried before and is scored between 0 and 69 with the higher score indicating better performance. The ABILHAND is reliable (test/ retest reliability, intraclass correlation coefficient [ICC] = 0.85 [Ekstrand et al. 2014]) valid (criterion validity, r=0.66 p<0.01 [Wang, 2011]; construct validity: correlated with Brunnstrom motor assessment r = 0.73; p<0.001 [Penta et al., 2001]; with high content and face validity [Penta et al., 2001]) and responsive (Penta et al., 2001). The MCID has not been established.

Action Research Arm Test (ARAT)

The ARAT (Lyle, 1981) is a measure of upper-limb activity consisting of 19 items divided into subscales of grasp, grip, pinch and gross movement. Participants have 60 seconds to complete each activity and tasks are scored between 0 (can perform no part of the task) and 3 (task is performed normally) and is scored between 0 and 57, with a higher score indicating a better performance. The ARAT is reliable (interrater reliability, ICC=0.995 [van der Lee et al., 2001], intrarater reliability, ICC=0.989 [van der Lee et al., 2001] internal consistency, Cronbach's alpha =0.985 [Nijland et al., 2010]), highly valid (criterion validity, r=0.94, p=<0.001 [Yozbatiran et al., 2008], construct validity correlated with FMA, r = 0.73, p=<0.01 [Hseih et al., 2009] and responsive measure (van der Lee et al., 2002) in chronic stroke survivors. The MCID is 5.7 (van der Lee et al., 2001).

Motor Activity Log -28 (MAL-28)

The MAL-28 (Uswatte et al., 2006) is a semi-structured interview during which participants rate the amount they use the hemiplegic upper-limb when performing 28 activities (including object manipulation and gross motor activities). Items are scored on a 6-point ordinal scale rating from 0 (the weaker arm is never used for that activity) to 5 (the ability to use the arm is the same as before the stroke). When no attempt has been made to use the arm, reasons for this are recorded. When the reason for not using the affected arm is because it would never be possible (e.g. combing hair when a person is bald) or if in the case of written task, the non- dominant hand is affected, the item is not included when calculating the final score. The total score is divided by the number of items completed to give the final score. Scoring is between 0 and 5 with a higher score indicating better ability. The MAL-28 has good reliability (test/retest reliability, r =0.70 [van der Lee et al., 2004], internal consistency, alpha = 0.88 [van der Lee et al., 2004]) and validity (criterion validity, correlation with ARAT r =0.70 [Uswatte et al., 2006]) and responsiveness (Lin et al., 2010). An MCID of 0.5 has been suggested by van der Lee et al. (2004).

Measures of Participation

Subjective Index of Physical and Social Outcome (SIPSO)

The SIPSO (Trigg and Wood, 2003) is a 10 item, self-report questionnaire that assesses physical function and social and emotional integration following stroke. Items are scored on a 5-point ordinal scale. Scoring is between 0 and 50 with a high score indicating a better level of integration. The SIPSO has good reliability (internal reliability, ICC=0.91, 95% CI, 0.90-0.92 [Kersten et al., 2004], test/retest reliability ICC=0.96 [Trigg and Wood, 2003] and construct validity (r =0.94 [Trigg and Wood, 2003]). The MCID has not been established.

5.9 Data Management

Immediately following assessment, all paperwork was placed in opaque, sealed envelopes which were stored unopened, in a locked cabinet on university premises accessible only by the lead researcher. Envelopes remained sealed until the end of the study (T3) for each participant to aid blinding to previous scores. At the end of the study, intervention details and results were entered into a spreadsheet by the lead researcher and double checked by a research assistant.

5.10 Data Analysis

5.10.1 Quantitative Analysis

Frequencies were reported for gender, side of weakness, mRS, Motricity Index (MI) score, hand dominance, presence of a communication disorder, incidence of deviance from the protocol and incidence of adverse events. Mean and standard deviation were reported for age, rating of level of enjoyment, rating of perceived exertion, number of sessions attended, sense of presence while using the PST system and user satisfaction with the PST system.

As preliminary results from feasibility studies provide an indication of readiness to proceed to a full study (Bowen et al., 2009), inferential statistics were therefore used in this study. Additionally, use of inferential statistics enabled the calculation of a power statistic to determine the sample size for a future trial. Wilcoxon Signed Ranks were conducted to determine changes in efficacy outcome measures (FMA-UE, ABILHAND, ARAT, MAL-29 and SIPSO) between baseline and post-intervention (T1 to T2), post-intervention and follow-up (T2 to T3) and baseline and follow-up (T1 to T3). Friedman's tests were not performed as one participant did not complete the final follow up session (T3) and therefore their results could not be included were Friedman's test applied. Statistical significance was assumed when $p \leq 0.05$. Non-parametric tests were used due to concerns about the small sample

size, concerns regarding normal distribution of data and the level of data being at ordinal and nominal levels.

Bonferroni adjustments were not employed as assessment of efficacy was not a primary aim of this thesis and in addition, their use has been criticised for increasing the risk of type II errors (Armstrong, 2014; Nakagawa, 2004; Perneger, 1998). All analyses were performed using IBM Statistical Package for the Social Sciences (SPSS) version 20.

In addition, preliminary efficacy was examined through comparison of changes in individual scores between time-points. The change in individual scores was compared to the MCID where this has been established (FMA-UE, ARAT and MAL-28). As preliminary analyses, all results should be interpreted with caution

5.10.2 Qualitative Analysis

Interviews were transcribed verbatim and checked for authenticity against original recordings by the lead researcher. Verbatim transcriptions of interview data and fieldwork notes were analysed by the lead researcher using the six step Thematic Analysis phases recommended by Braun and Clarke (2006) as outlined in Table 5.2. A theme was identified when more than one person identified a particular topic (prevalence) using a semantic approach (i.e. where surface meanings were accepted and no attempt to explore underlying assumptions were made). Data was analysed inductively (with themes being driven by the data and not developed a-priori).

Thematic Analysis was selected, as the systematic approach provided by Braun and Clarke (2006) provided a useful “recipe” to ensure methodological rigour in the analysis. This was particularly important due to the relative inexperience of the researcher in qualitative data analysis. In addition, as the skills involved in thematic analysis are frequently required when performing other types of qualitative analyses, it has been suggested as a particularly suitable method for novice qualitative researchers (Braun and Clarke, 2006). Moreover, as Thematic Analysis is not tied to a particular epistemological approach (Braun and Clarke, 2006), its use was not in conflict with the philosophical approach of the thesis.

The NVivo10 qualitative data software package (QSR International Pty Ltd. Version 10, 2012) was used to manage initial data and identify candidate themes (Appendix 18). Paper cards were subsequently used to help identification of final themes and generate thematic maps (Appendix 19).

Table 5.2 Stages of Thematic Analysis (Braun and Clarke [2006] p87)

Phase		Description of the Process
1	Familiarising yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas
2	Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code
3	Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential themes
4	Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic "map" of the analysis
5	Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme
6	Producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis

In recognition of the influence of the researcher on qualitative data collection and interpretation, techniques recommended by Lincoln and Guba (1985) and Teddie and Tashakkori (2009) were undertaken to increase the trustworthiness of qualitative research elements. These included techniques to increase credibility such as *prolonged engagement* to build trust between the researcher and research participant and to increase the researcher awareness of contextual factors influencing findings; *thick descriptions* of contextual information to aid transferability of interpretations and the use and *triangulation* through use of integrated mixed-methods. While full-scale *response validation* (member checking) was not undertaken due to the additional study burden, during interviews participants were asked to clarify meaning in instances where the meaning was unclear or ambiguous to the researcher. Additionally, a *reflexive diary* was kept in which the details and rationale for methodological changes (such as a new area of questioning, developed in response to previous interviews) and personal reflections were recorded. Finally, regular discussion with the supervisory team was undertaken at all stages of analysis to challenge assumptions and improve credibility of findings. However, while these steps were undertaken to increase research rigour, it is acknowledged that personal and professional experiences, gender, culture and roles as a physiotherapist and researcher and the relationship with the research participants will have influenced the development of research questions and influenced study design, data collection, analysis and interpretation of study findings.

5.10.3 Integration of Quantitative and Qualitative Findings

Side by side joint displays as recommended by Creswell (2015), were used to integrate findings from quantitative and qualitative arms of the study (as discussed in Sections 2.5 and 2.6). Initial integration was undertaken by the lead researcher (AW), with validation of findings through discussion and review of themes with a second member of the research team (CK).

5.11 Ethics and Governance

Ethical approval for this study was granted by the University Research Ethics Committee REC reference number 14/06/PHD/02 (Appendix 17). The principles of the Data Protection Act (1998) were adhered to throughout the study. The study sponsor was Brunel University London.

5.12 Summary

This chapter outlined the recruitment, procedure and analytical methods employed in a mixed-methods study examining preliminary efficacy, acceptability and feasibility of the PST system for arm recovery following stroke.

Quantitative results will be presented in the next chapter.

Chapter 6. Phase 2: Quantitative Results

6.1 Introduction

This is the first of three chapters presenting results from phase two of the study examining the feasibility (including safety) and acceptability of the PST system for upper-limb rehabilitation following stroke and the feasibility and acceptability of the study protocol. In addition, results from a secondary aim, to examine the efficacy of the PST system are presented.

Descriptive statistics related to participant demographics, attrition and adherence to the study protocol, safety, user satisfaction, level of perceived exertion and immersion while using the PST system are presented. In addition, preliminary efficacy of the PST system is examined by detailing group changes in performance in outcome measures between time points. Individual changes in performance are also presented and compared to meaningful change values, where established.

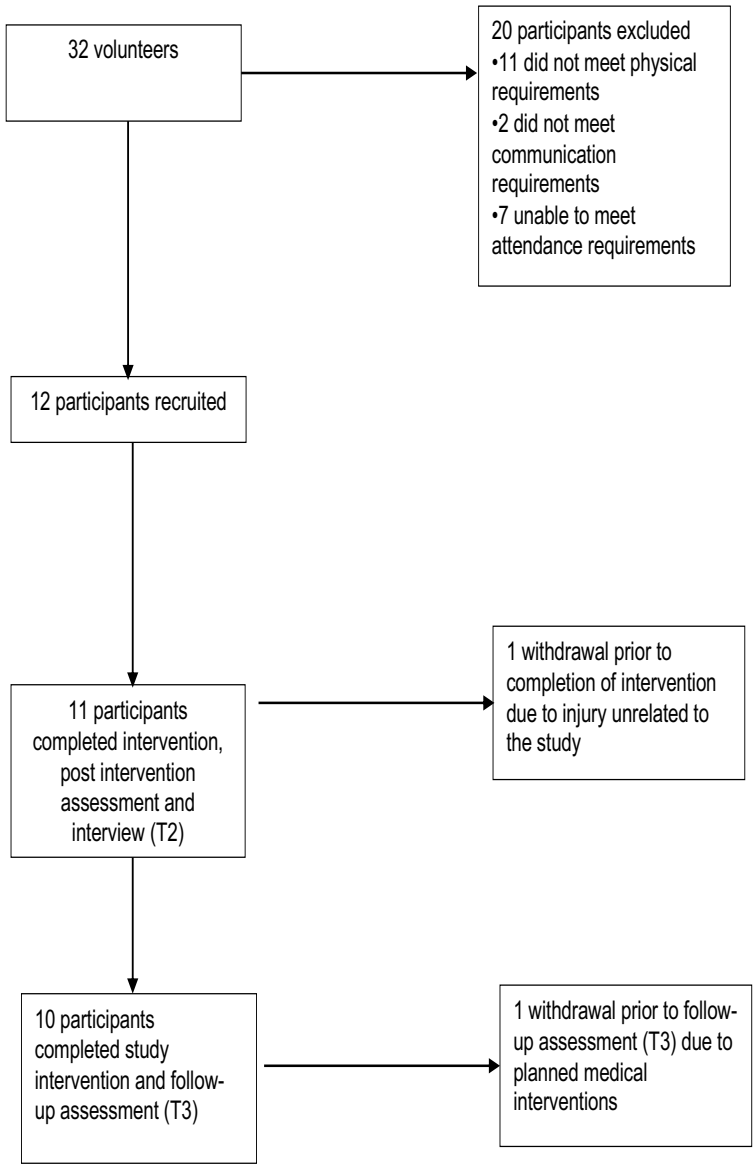
6.2 Study Recruitment

A flowchart detailing recruitment and retention of participants is presented in Figure 6.1. Thirty-two people volunteered for the study. Of the 32 volunteers, 20 were excluded. Three were excluded due to pre-existing upper-limb pain, three had no discernible upper limb impairment (scored above 25 on the MI), three had no discernible upper-limb movement (score of 9 or below on the MI), two had photosensitive epilepsy, two were unable to meet communication requirements, five were away during the study time frame and two were unable to commit to the study attendance requirements.

6.3 Participant Details

Participant details are presented in Table 6.1. Twelve participants (nine female, 11 right hand dominant prior to stroke), aged between 48 and 67 years (mean [SD] 58 [7.1] year), with a mix of left and right hemiplegia (seven and five respectively) with stroke onset between 12 and 304 months (median [IQR] 41 [34.75] months) were recruited to the study. Seven participants scored 14 for both elbow and shoulder function on the MI indicating observable movement that was not full range or against gravity. One participant scored 19 for both elbow and shoulder indicating full range movement against gravity but not resistance.

Figure 6.1 Recruitment and Retention of Participants



One participant scored a combination of 19 and 25 for the elbow and shoulder respectively indicating full range movement against gravity but not resistance at the elbow, and full range movement against resistance but weakness compared to the less affected limb at the shoulder. Three participants scored 25 at both the elbow and shoulder indicating full range movement against resistance but weakness compared with the less affected side. Four participants were classified as having moderately-severe disability on the mRS (score of four); four as having moderate disability (score of three) and a further four participants were classified as having slight disability (score of 2). Three participants had communication problems related to stroke.

Table 6.1 Participant Details

Participant number and pseudonym	Age (years)	Gender	Time since stroke (months)	Side of weakness	Modified Rankin Score	Motricity Index score: summed (elbow/ shoulder)	Hand dominance	Communication disorder
1: Joe	64	Male	29	Left	2	50 (25/25)	Right	No
2: Lizzie	53	Female	54	Right	3	38 (19/19)	Right	Yes
3: Nancy	65	Female	31	Left	4	28 (14/14)	Right	No
4:*George	48	Male	17	Right	3	28 (14/14)	Right	Yes
5: Ada	66	Female	46	Right	4	28 (14/14)	Right	No
6: Esther	49	Female	41	Left	2	50 (25/25)	Left	No
7: Betty	67	Female	17	Left	4	28 (14/14)	Right	No
8:** Nell	58	Female	304	Right	2	44 (19/25)	Right	No
9: Jenny	49	Female	12	Left	3	28 (14/14)	Right	No
10: Dora	60	Female	41	Left	3	28 (14/14)	Right	No
11: Clara	54	Female	114	Right	4	28 (14/14)	Right	Yes
12: David	63	Male	55	Left	2	50 (25/25)	Right	No

* Dropped out prior to follow-up (T3), therefore not included in statistical analysis at follow-up but included at other assessment points (T1 and T2)

** Dropped out prior to completion of intervention, post-intervention and follow-up therefore not included in statistical analysis of intervention and post-intervention (T2 and T2) but included in baseline analysis (T1).

6.4 Attrition

Details of study attrition are presented in Table 6.2. Of the 12 study participants recruited to the trial, ten completed the intervention and all assessments. One participant (participant eight) dropped out after two intervention sessions secondary to an injury unrelated to the study. Results from this participant are included in baseline calculations but have not been included in post-intervention or follow-up calculations as she was an outlier. A further participant (participant four) completed baseline assessment, intervention and post-intervention assessment (T2) but was lost to follow-up (T3) due to medical intervention unrelated to the study. Results from this participant are included at all calculations except follow-up (T3).

6.5 Adherence to Study Protocol

Details of adherence to the study protocol are presented in Table 6.2. The study protocol aimed for a treatment dose of nine intervention sessions lasting 40 minutes each (360 minutes in total). Participants attended a mean (Standard deviation [SD]) 8.4 (1) intervention sessions (range six to nine sessions). Of the 11 participants who completed the intervention, seven (64%) attended all nine sessions, while two participants attended eight sessions, one attended seven sessions, and one attended six sessions. Reasons for non-attendance included illness, fatigue, the need for further medical intervention and flooding closing the laboratory.

Table 6.2 Adherence to Study Protocol

Participant number and pseudonym	Number of sessions attended n (% of target)	Total time completed in minutes (% of target)	Reason for non-adherence to target number of sessions	Reason for non-adherence to target intervention time
1: Joe	7 (78%)	204 (57%)	Illness	Missed sessions; fatigue; transport delay; required longer time to process information secondary to cognitive problems
2: Lizzie	9 (100%)	332 (92%)	N/A	Unclear
3: Nancy	9 (100%)	302 (84%)	N/A	Transport delay
4: George	8 (89%)	284 (79%)	Hospital admission	Missed sessions; unclear
5: Ada	9 (100%)	295 (82%)	N/A	Transport delay
6: Esther	9 (100%)	334 (93%)	N/A	Unclear
7: Betty	6 (67%)	175 (49%)	Fatigue	Missed sessions; fatigue
8: Nell*	2 (22%)*	66 (18%)*	Dropped out due to injury	Dropped out due to injury unrelated to intervention
9: Jenny	9 (100%)	312 (87%)	N/A	Fatigue; upper limb pain
10: Dora	8 (89%)	162 (45%)	Flood closed laboratory	Missed sessions; fatigue
11: Clara	9 (100%)	298 (83%)	N/A	Transport delay
12: David	9 (100%)	336 (93%)	N/A	Transport delay; upper limb pain

* Dropped out prior to completion of intervention, post intervention and follow up therefore not included in statistical analysis of intervention and reassessments but included in baseline analysis.

The mean (SD) time using the PST system during the intervention phase was 276 (64.3) minutes (range 175 to 336 minutes). While seven participants (64%) achieved over 80% of the planned intervention time, no participant achieved the target intervention time of 360 minutes. Main reasons for non-adherence to the intervention time included fatigue with participants requiring prolonged rest between sessions or reduced intervention time (experienced by four participants over 22 sessions), transport delays (experienced by five participants on 18 sessions) and reduced attendance (affecting four participants over seven sessions). In addition, two participants had treatments curtailed due to upper-limb pain experienced during the activities (on five occasions) and one participant experienced mild cognitive problems which necessitated longer time to process information resulting in reduced intervention time during all seven intervention sessions. In two cases it was unclear why the target intervention time was not achieved.

6.6 Safety of the Personalised Stroke Therapy System

The incidence, severity and type of adverse events experienced during the study are presented in Table 6.3. Five participants experienced 13 incidents of adverse effects related to PST system use. Adverse effects were classified as non-serious in all cases. Two participants noted mild headaches (pain rated 2 to 3/10 on the visual analogue scale) on one occasion each. Both participants felt headaches were due to high levels of concentration while using the PST system and both reported that headaches had abated within two hours, with one participant taking off-the-shelf analgesics. Four participants noted shoulder and/or neck pain (with pain rated between 2 to 5.5/10 on the VAS) on 11 occasions while using the PST device, necessitating curtailment of the intervention on five occasions with two participants. Eight of the incidences were consistent with muscular work (and were therefore considered evidence of intensity of the activity as opposed to a true adverse effect) and three occurrences (in two participants) were consistent with shoulder soft tissue impingement related to arm movements while using the PST system. In all incidences, pain stopped with cessation of the activity and the range of movement required to perform activities were adjusted to avoid pain with subsequent interventions. No participant reported motion sickness, chest pain, cardiovascular or respiratory distress, epilepsy, falls or near falls during the study.

Table 6.3. Incidence, Severity and Type of Adverse Effect Experienced During the Intervention

Adverse effect	Number of participants	Incidence	Severity
Headache	2	2	Non-serious
Neck and/or shoulder pain unrelated to delayed onset muscle soreness	2	3	Non-serious
Motion sickness	0	0	N/A
Chest pain	0	0	N/A
Epileptic seizure	0	0	N/A
Cardiovascular distress	0	0	N/A
Respiratory distress	0	0	N/A
Falls or near falls	0	0	N/A

6.7 User Satisfaction with the PST System

Overall level of enjoyment with PST system activities was high, with a mean (SD) of 7.5 (1.8) out of 10 (range 5 to 10), with higher scores indicating greater levels of enjoyment. Level of enjoyment for the apple-tree game was high with a mean (SD) of 8.1 (1.5) out of 10 (range 5.5 to 10). The virtual therapist activity was rated as being less enjoyable with a mean of 6.8 (SD 2.3) out of 10 (range 3.4 to 10).

Rates of satisfaction with the PST system, as measured by the QUEST, ranged from 20 to 34 out of 35 (with a higher mark indicating a greater level of satisfaction) (mean 30.3; SD 5.1).

6.8 Perceived Rate of Exertion during Activities

Participants rated their level of exertion while using the PST system as being between 6 (‘no exertion at all’) and 16 (‘hard’) on the BORG scale of perceived exertion. The apple-tree game was rated as being the easier activity, with rates of perceived exertion ranging from 6 (‘no exertion at all’) to 15 (‘somewhat hard’) with a mean of 11.6 (SD 1.3) equating to a descriptor of ‘fairly light’. The virtual therapist activity was perceived as requiring a higher rate of exertion with scores ranging from 7.5 (‘extremely light’) to 16 (‘hard’) with a mean of 12.9 (SD 1.5) equating to a descriptor of ‘somewhat hard’.

6.9 Sense of Presence in the Virtual World

Details of participant’s sense of immersion (i.e. the perception of being physically present in the virtual world) while using the PST system are presented in Table 6.4.

Table 6.4 Sense of Presence in the Virtual World Using the IPQ

Participant	Total IPQ score (out of 84)	Spatial presence (out of 30)	Involvement (out of 24)	Realism (out of 24)	Presence (out of 6)
1: Joe	5	0	4	1	0
2: Lizzie	14	5	5	1	3
3: Nancy	44	17	12	11	4
4: George	13	2	7	4	0
5: Ada	18	4	8	2	4
6: Esther	43	19	9	10	5
7: Betty	56	20	21	10	5
9: Jenny	28	3	22	3	0
10: Dora	14	2	11	0	1
11: Clara	69	26	18	20	5
12: David	54	22	17	11	4
Mean (SD)	32.5 (21.5)	10.9 (9.8)	12.2 (6.4)	6.6 (6.2)	2.8 (2.1)

Sense of immersion was low with participants rating their overall sense of immersion between 5 and 69 out of 84 with a mean of 32.5 (SD 21.5) on the IPQ (with a higher score indicating a greater sense of immersion). Further break down of results by subscale revealed that while participants rated their sense of involvement as moderate, sense of spatial presence, sense of realism and sense of presence were all rated as low.

6.10 Efficacy of Personalised Stroke Therapy System

Preliminary efficacy of the PST system was evaluated through examination of group and individual changes in outcome measures between time-points.

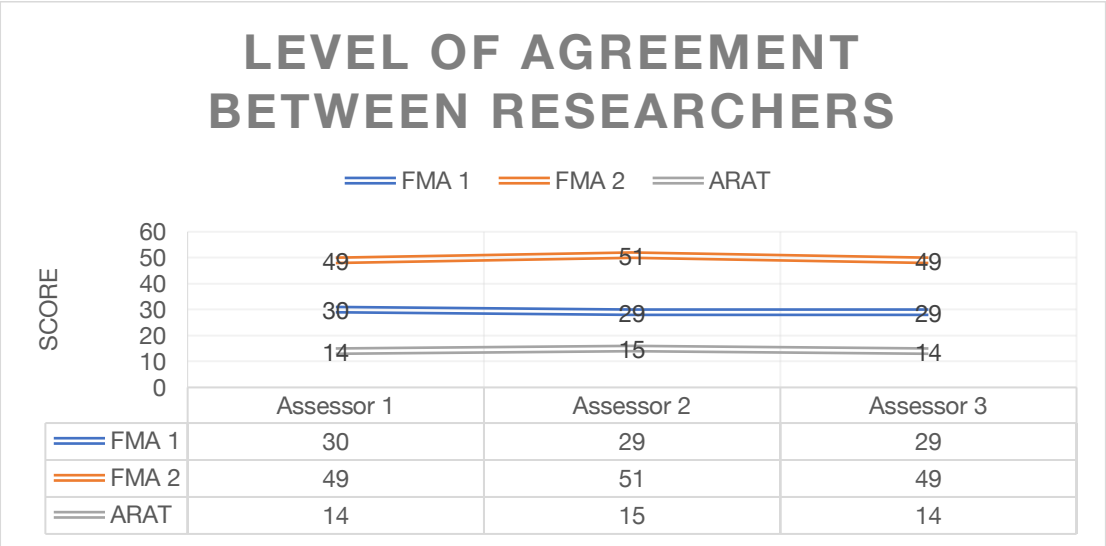
For ten participants, each assessment (T1, T2 and T3) was undertaken by a different researcher who was blind to previous assessment scores. Due to staffing issues, one participant (participant two) was assessed by the same researcher at baseline and at post-intervention (T1 and T2).

6.10.1 Level of Agreement Between Researchers

Level of agreement between researchers for the observer assessed outcome measures (the ARAT and FMA-UE) is presented in Figure 6.2. Researchers independently scored participants on three training videos (2 of the FMA and 1 of the ARAT) and level of agreement was ascertained through visual comparison of scores obtained. While it is acknowledged that only a limited number of videos were evaluated, the level of agreement was very high with assessors being within 2 points difference on the first FMA video and 1-point difference between assessors for both the second FMA and the ARAT videos. This was less than the MCID (for both measures), the minimal detectable change (established for

the FMA-UE only) and the responsiveness level in the case of the ARAT. While intrarater reliability was not assessed, previous studies have demonstrated high ICC for both the ARAT (van der Lee et al., 2001) and FMA-UE (See et al., 2013) as discussed in Section 5.8.2.3).

Figure 6.2 Level of Agreement Between Researchers



6.10.2 Group Changes in Outcome Measures Between Time-points

Group changes in score in impairment, activity and participation between baseline (T1) and post-intervention (T2), post-intervention (T2) and follow-up (T3), and baseline (T1) and follow-up (T3) are presented in Table 6.5.

Between baseline and post-intervention (T1 to T2), statistically significant improvements were demonstrated in all measures of impairment, activity and participation (FMA-UE p= 0.05; ABILHAND p=0.05; ARAT p=0.028; MAL-28 p=006; SIPSO p=0.004). This was a clinically significant improvement in the measure of impairment level (FMA-UE) (median 6; IQR 8).

Between post-intervention and follow-up (T2 to T3) there was a statistically significant deterioration in two measures of activity (ABILHAND p=0.04; ARAT p=0.02). However changes were not clinically significant.

Between baseline and follow-up (T1 to T3) there was a statistically significant improvement in impairment (FMA-UE p=0.033). However, this was not clinically significant. There was no statistically or clinically significant change between baseline and follow-up (T1 to T3) in measures of activity and participation.

Table 6.5 Median (IQR) Change in Impairment, Activity and Participation Between Baseline (T1), Post-Intervention (T2) and Follow-Up (T3)

Domain	Outcome Measure	Baseline	Post-intervention	Follow-up	Difference between baseline and post-intervention		Difference between post- intervention and follow-up		Difference between baseline and follow-up	
		T1	T2	T3	T1 to T2		T2 to T3		T1 to T3	
n		**12**	**11**	**10**	**11**		**10**		**10**	
					Z	P	Z	P	Z	P
Impairment	FMA-UE	25.5 (22.5)	30 (33)	30.5 (30)	-2.807[a]	0.005*[b]	-1.130	0.258	-2.138[a]	0.033*
Activity	ABILHAND	24 (16)	28 (17)	27 (14)	-2.812[a]	0.005*[b]	-2.094	0.036*	-1.611[a]	0.107
	ARAT	5.5 (24)	12 (32)	7 (32)	-2.201[a]	0.028*[b]	-2.252	0.024*	-0.940[a]	0.347
	MAL-28	1.11 (2.7)	1.7 (3.14)	1.9 (3.35)	-2.758[a]	0.006*[b]	-1.126	0.260	-1.262[a]	0.207
Participation	SIPSO	25.5 (11)	30 (11)	28.5 (16)	-2.849[a]	0.004*[b]	-1.588	0.112	-1.634[a]	0.102

*significant change. [a] based on negative rank. [b] based on positive rank

6.10.3 Individual Changes in Outcome Measures between Time Points

Individual changes in outcome measure scores between baseline (T1), post-intervention (T2), and follow-up (T3) are presented in Tables 6.6 to 6.10. Where the MCID has been established, changes in score were compared with the MCID to ascertain whether clinically significant changes had occurred.

6.10.3.1. Changes in Impairment

Individual changes in FMA-UE score between time-points are presented in Table 6.6. An improvement in score in the FMA-UE was demonstrated from baseline to post-intervention (T1 to T2) for 10 out of 11 participants (91%) with one participant demonstrating no change from baseline (9%). These changes were clinically significant (MCID ≥ 10) in three out of 11 cases (27%). Minimal detectable changes were demonstrated in six of 11 (55%) participants.

Five participants (50%) demonstrated a deterioration in score between post-intervention and follow-up (T2 to T3) while four participants (40%) demonstrated a slight improvement. These changes reached the level of clinical significance for one (10%) participant only who demonstrated a clinically important deterioration between post-intervention and follow-up (T2 to T3).

Table 6.6 Change in Individual FMA-UE Score by Time Point

Participant number and pseudonym	Baseline score	Post-intervention score	Follow up score	Change in score from baseline to post-intervention	Change in score from post-intervention to follow up	Change in score from baseline to follow up
	T1	T2	T3	T1 to T2	T2 to T3	T1 to T3
1: Joe	64	64	66	0	2	2
2: Lizzie	19	30	25	11*	-5	6
3: Nancy	9	17	18	8	1	9
4: George	12	24	-	12*	-	-
5: Ada	25	29	33	4	4	8
6: Esther	65	66	66	1	0	1
7: Betty	23	25	23	2	-2	0
8:* Nell	35	-	-	-	-	-
9: Jenny	29	40	37	11*	-3	8
10: Dora	24	26	28	2	2	4
11: Clara	26	33	22	7	-11*	-4
12: David	52	58	53	6	-5	1

* Clinically important change based on MCID of 10

Eight out of 10 participants (80%) demonstrated an improvement in score between baseline (T1) and follow-up (T3). However, these improvements did not reach the level of clinical significance in any participant.

6.10.3.2. Changes in Activity

ABILHAND

Individual changes in ABILHAND score between time-points are presented in Table 6.7. No MCID is available for the ABILHAND and therefore it was not determined if changes were clinically significant.

Ten out of 11 participants (91%) exhibited an improvement in score on the ABILHAND from baseline to post-intervention (T1 to T2) with one participant (9%) demonstrating no change. Seven out of 10 participants (70%) exhibited a deterioration in score from post-intervention to follow-up (T2 to T3), with one participant (10%) demonstrating no change and a further two participants (20%) demonstrating a small improvement in score. Six out of 10 participants (60%) demonstrated an improvement from baseline to follow-up (T1 to T3), while three participants (30%) demonstrated a deterioration in score and one (10%) showed no change.

Table 6.7 Change in Individual ABILHAND Score by Time Point

Participant number and pseudonym	Baseline score	Post-intervention score	Follow-up score	Change in score from baseline to post-intervention	Change in score from post-intervention to follow-up	Change in score from baseline to follow-up
	T1	T2	T3	T1 to T2	T2 to T3	T1 to T3
1: Joe	38	41	32	3	-9	-6
2: Lizzie	34	34	32	0	-2	-2
3: Nancy	13	23	21	10	-2	8
4: George	23	28	-	5	-	-
5: Ada	17	18	17	1	-1	0
6: Esther	36	41	42	5	1	6
7: Betty	21	28	27	7	-1	6
8:* Nell	31	-	-	-	-	-
9: Jenny	12	23	24	11	1	12
10: Dora	21	23	19	2	-4	-2
11: Clara	25	30	27	5	-3	2
12: David	33	40	40	7	0	7

ARAT

Individual changes in ARAT score between time-points are presented in Table 6.8. Seven out of 11 participants (64%) demonstrated an improvement in score from baseline to post-intervention (T1 to T2) on the ARAT. This was a clinically important improvement (MCID ≥ 5.7) in three participants (27%). Two participants (18%) demonstrated no change from baseline and a further two (18%) demonstrated a small deterioration in score.

Seven out of 10 participants (70%) demonstrated deterioration in score between post-intervention and follow-up (T2 to T3). This was a clinically important deterioration in two participants (20%). One participant (10%) demonstrated a small improvement in score (that was not clinically significant) and a further two (20%) demonstrated no change in score.

While four out of 10 participants (40%) demonstrated an improvement in ARAT scores between baseline and follow-up (T1 to T3), three participants (30%) showed no change and a further three (30%) demonstrated a deterioration in score. No change reached the level of clinical significance.

Table 6.8 Change in Individual ARAT Score by Time Point

Participant number and pseudonym	Baseline score	Post-intervention score	Follow-up score	Change in score from baseline to post-intervention	Change in score from post-intervention to follow-up	Change in score from baseline to follow-up
	T1	T2	T3	T1 to T2	T2 to T3	T1 to T3
1: Joe	57	56	57	-1	1	0
2: Lizzie	7	13	6	6*	-7*	-1
3: Nancy	0	3	0	3	-3	0
4: George	3	3	-	0	-	-
5: Ada	3	8	7	5	-1	4
6: Esther	57	57	57	0	0	0
7: Betty	3	4	0	1	-4	-3
8:* Nell	8	-	-	-	-	-
9: Jenny	20	19	19	-1	0	-1
10: Dora	3	8	7	5	-1	4
11: Clara	4	12	7	8*	-5	3
12: David	29	36	30	7*	-6*	1

* Clinically important change based on MCID of 5.7

MAL-28

Individual changes in MAL-28 score between time-points are presented in Table 6.9.

Ten out of 11 participants (91%) demonstrated an improvement in MAL-28 score between baseline and post-intervention (T1 to T2). This reached the level of clinical significance (MCID ≥ 0.5) in three participants (27%). One participant (9%) demonstrated deterioration however this did not reach the level of clinical importance.

Six out of 10 participants (60%) demonstrated deterioration and three (30%) an improvement in score between post-intervention and follow-up (T2 to T3). This was a clinically significant improvement in score for one subject (10%) and a clinically important deterioration in score for two participants (20%).

Five out of 10 participants (50%) demonstrated an improvement in score between baseline and follow-up (T1 to T3). This was clinically significant for two participants (20%). Three

participants (30%) demonstrated a non-significant deterioration and two participants (20%) demonstrated no change in score.

Table 6.9 Change in Individual MAL-28 Score by Time Point

Participant number and pseudonym	Baseline score	Post-intervention score	Follow-up score	Change in score from baseline to post-intervention	Change in score from post-intervention to follow-up	Change in score from baseline to follow-up
	T1	T2	T3	T1 to T2	T2 to T3	T1 to T3
1: Joe	3.04	4.5	3.4	1.46*	-1.1*	0.36
2: Lizzie	0.37	0.66	0.1	0.29	-0.56	-0.27
3: Nancy	0.92	1.2	1.3	0.28	0.1	0.38
4: George	0.07	0	-	-0.07	-	-
5: Ada	0	0.04	0	0.04	-0.04	0
6: Esther	2.6	3.8	4.6	1.2*	0.8*	2*
7: Betty	1.3	2	2.1	0.7*	0.1	0.8*
8:* Nell	0	-	-	-	-	-
9: Jenny	2.9	3.1	2.9	0.2	-0.2	0
10: Dora	1.6	1.7	1.7	0.1	0	0.1
11:Clara	0.3	0.7	0.1	0.4	-0.6*	-0.2
12: David	3.8	4	3.6	0.2	- 0.4	-0.2

* Clinically significant change based on MCID of 0.5

6.10.3.3 Changes in Participation

SIPSO

Individual changes in SIPSO score between time-points are presented in Table 6.10.

Ten out of 11 participants (91%) demonstrated an improvement in score from baseline to post-intervention (T1 to T2). One participant (9%) demonstrated a small deterioration. Seven out of 10 participants (70%) demonstrated a deterioration in score between post-intervention and follow-up (T2 to T3) and three participants (30%) demonstrated an improvement. From baseline to follow-up (T1 to T3), eight participants (80%) demonstrated an improvement in score while two participants (20%) demonstrated a deterioration. No MCID is available for the SIPSO.

Table 6.10 Change in Individual SIPSO Score by Time Point

Participant number and pseudonym	Baseline score	Post-intervention score	Follow-up score	Change in score from baseline to post-intervention	Change in score from post-intervention to follow-up	Change in score from baseline to follow-up
	T1	T2	T3	T1 to T2	T2 toT3	T1 to T3
1: Joe	27	33	29	6	-4	2
2: Lizzie	33	32	37	-1	5	4
3: Nancy	24	29	30	5	1	6
4: George	20	22	-	2	-	-
5: Ada	20	29	28	9	-1	8
6: Esther	32	38	39	6	1	7
7: Betty	18	21	15	3	-6	-3
8:* Nell	34	-	-	-	-	-
9: Jenny	10	18	14	8	-4	4
10: Dora	23	30	28	7	-2	5
11: Clara	27	32	19	5	-13	-8
12: David	28	37	33	9	-4	5

6.11 Sample Size Calculation

A sample size calculation using the FMA-UE as the primary outcome measure (using G*Power, version 3.1) established that a future randomised controlled trial would require 64 participants in each group. Power of 80%, alpha level of 0.05 and effect size of Cohen's D of 0.5 were assumed.

6.12 Summary of Results

In summary, results from this exploratory study found high levels of acceptability and feasibility of use of the PST system for upper-limb rehabilitation in a small group of community dwelling stroke survivors, including those with moderately-severe impairment following stroke. No serious adverse effects were experienced; however, 13 incidents of non-serious adverse effects were reported (in five participants). Preliminary results suggested that bespoke VR gaming technologies may be effective at improving upper-limb impairment, activity and participation following stroke. Lack of fidelity to the intended study dose indicated limited feasibility of the study protocol.

Qualitative findings will be presented in the next chapter.

Chapter 7. Phase 2: Qualitative Findings

7.1. Introduction

In the second of three results chapters, qualitative findings are presented related to study aims exploring the acceptability and feasibility of using the PST system for upper-limb stroke rehabilitation, and stroke survivors' experience of study participation. In order to provide context to responses, stroke survivors' previous experience of rehabilitation is also explored. The chapter presents findings from the data analysis of interviews with 11 stroke survivors, (participant eight had previously withdrawn from the study due to an unrelated injury) and from field-notes made during the intervention phase. Participants are identified by study pseudonym, age and descriptor of stroke severity according to the mRS score.

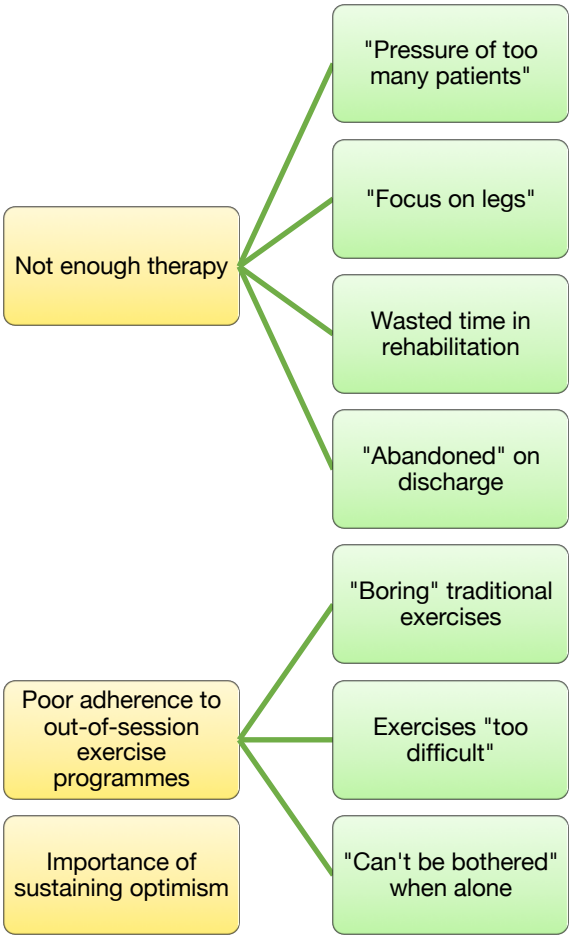
7.2 Study Recruitment and Participant Details

Details of study recruitment and participant details are provided in sections 6.2 and 6.3 respectively.

7.3 Contextual Information: Previous Experiences of Rehabilitation

While experience of using the PST system and experience of study participation were the main topics for discussion, participants were also asked about the amount and type of rehabilitation they received following their stroke. This data provided useful background information against which responses related to main study aims should be evaluated. Although positive elements to rehabilitation (such as the expertise of therapists, their ability to motivate) were described, the three main themes generated from the data analysis represented **barriers experienced in rehabilitation**. These were: 1) **Not enough therapy**; 2) **Poor adherence to home exercise programmes;** and 3) the **Importance of sustaining optimism** (Figure 7.1). Each theme will now be addressed in turn.

Figure 7.1 Thematic Map of Barriers Experienced in Previous Rehabilitation



7.3.1 Not Enough Therapy

The first key finding identified from the analysis was **not enough therapy**. This was supported by subthemes of "**pressure of too many patients"**, a "**focus on legs"**, having "**wasted time in rehabilitation"** and being **"abandoned" on discharge**, which are discussed in-turn below.

"Pressure of too many patients"

Nearly half of participants described receiving less than the recommended minimal input of five, 45-minute therapy sessions per week when in hospital (NICE, 2013). Where this recommendation had not been achieved, participants perceived the **"pressure of too many patients"** to be the main cause.

> *"They did try to do it every day for about 15 minutes, but it didn't always work out that way because they got very busy. They did try their hardest, but no, I was very disappointed with the amount of physio I was able to have in hospital…It's very frustrating because there is nothing out there for stroke patents, whether it be the arm or the leg" (*Jenny, 49, moderate disability)

> *"Well I think the aim was to always have therapy every day. But I didn't get physio every day and I think that was because of the pressure of too many patients…The physios had to fit people into just a brief window during the day. Initially I was seen twice a day briefly, OT and Physio, but that dwindled to just once a day and then, quite often, well it was just no physio and they would apologise and say I'm afraid your session has been cancelled because the physio had to go and deal with somebody else."* (Dora, 60, moderate disability)

A lack of therapy was discussed across participants with chronicity of stroke between 12 months and nine years, supporting findings in the literature that challenges persist across the stroke pathway in delivering the recommended intensity of rehabilitation (McHugh and Swain, 2013; Royal College of Physicians, 2017).

"Focus on legs"

Although therapy for some participants met, or in some cases exceeded, the NICE (2013) recommendations, it was nonetheless evident that the focus of physiotherapy was on walking, with participants, at times, having to choose between rehabilitation of the upper or the lower-limb. A subtheme of a "**focus on legs"**, was recognised in the data supporting the suggestion that lack of upper-limb recovery is at least in part, a result of a lack of therapy (Kong et al., 2011).

> "*He asked me when I went into rehab, he said 'what is more important to you? Do you want to focus on your legs or your arm?' And at that time I wanted to focus on my legs because I thought, well I don't want somebody to push me to the toilet in a wheelchair for the rest of my life. So, I said 'my legs' but then afterwards I thought 'well there's no point getting somewhere if you can't do nothing when you get there!' But I told them to focus on my legs which they did. I did do little bits with my arm but not much…probably about an hour in total, the whole time I was in. Very little."* (Nancy, 65 moderately-severe disability)

> *"No, (upper-limb therapy), they didn't even try. It was just walking. For nine months (as an inpatient) it was just walking, walking, walking" (*Ada, 66, moderately-severe disability)

Interestingly, of the two participants who received active upper-limb exercises (Esther and Joe), both were categorised as having slight disability (mRS of 2), supporting the concept that lack of upper-limb recovery post stroke is partially linked to a self-fulfilling prophecy whereby lack of exercise results in lack of recovery (Teasell et al., 2012). Even when exercises were prescribed, participants spoke of being advised to perform five to ten repetitions of each exercise, once or twice a day. While the exact number of repetitions to

promote neuroplastic change and prevent learnt non-use is uncertain, this intensity would be insufficient to promote recovery (Teixeira-Salmela et al., 2014; Veerbeek et al., 2014).

> *"I think I was meant to do them once a day. Probably four or five exercises and about 5-10 times for each exercise."* (Esther, 49, slight disability)

Wasted Time in Rehabilitation

There was a prominent subtheme of **wasted time in rehabilitation**, with stroke survivors experiencing boredom while sitting by their beds while wanting, and having time, to do more therapy.

> *"I had more time to spare. There was nothing else to do, there was nothing. Every morning you had physio and in the afternoon you had nothing. You either sat down in your bed or slept all day. I used to be watching TV all day." (*Ada, 66, moderately-severe disability)

This issue of wasted time was more apparent at the weekend when no therapy sessions were scheduled.

> "*Weekends especially were boring at the hospital. Nothing to do, nobody about.*" (Jenny, 49, moderate disability)

> *"I just sat by the side of my bed, because I spent all day there." (*Clara, 54, moderately-severe disability)

While the provision of out-of-session exercise programmes may have helped address this issue of wasted time, a lack of knowledge about *how* to exercise, was apparent.

> *"I wasn't doing anything for my arm … at that time I didn't understand what I should be doing for my arm."* (Betty, 67, moderately-severe disability)

> *"I couldn't get anyone to teach me, I had to make it up as I went along."* (George, 48, moderate disability)

"Abandoned" on discharge

On discharge home, **not enough therapy** was again a prominent theme with most participants receiving a limited number of sessions. While participants were aware of resource pressures limiting the amount of therapy available, a theme of being "**abandoned**" at the end of therapy was recognised in the data.

> *"When you go home, locally you just get six weeks and that's it. You are left to your own devices. Abandoned!"* (David, 63, slight disability)

> "*I had (therapy at home) but only for a few weeks. It's not a long time at all and before I knew it, it was over and then you're alone."* (Clara, 54, moderately-severe disability)

While the majority of participants were provided with a "paper tome" of exercises to perform out of therapy time, a substantial theme of **poor adherence to out-of-session exercise programmes** was evident.

7.3.2 Poor Adherence to Out-of-Session Exercise Programmes

Only two of the eight participants who were provided with an out-of-session exercise programme, completed it as prescribed. The "**boring"** nature of traditional exercises, the prescription of exercises which were **"too difficult"** and the need for external motivation with participants not being **"bothered" to exercise when alone** were identified as subthemes affecting adherence to with such programmes.

"Boring" traditional exercises

The **"boring"** nature of traditional physiotherapy exercises was a prevalent and strongly voiced subtheme in participants with all levels of impairment and was highly associated with poor adherence.

> *"I've got reams of sheets at home which I bought home from hospital which have remained closed you know because I haven't done anything with my arm. It was a paper tome!... I was shown (what to do) but they weren't very interesting so…I'm not one of those people that can do the same thing, no matter if it is a good thing for me to do, over and over and over. It's just too dull you know so I wasn't interested."* (Dora, 60, moderate disability)

> "*Because when you come out of hospital you are given a few sheets of paper which isn't really fun and you do them at first but it doesn't take long for those bits of paper to be put in a drawer and forgotten about. Because you were just given a pamphlet, loads of exercises on it. And you took it home and you looked at it and there was no enthusiasm or anything to actually make you want to do it. I could have done more if I hadn't died of boredom doing them! They were VERY boring!"* (Esther, 49, slight disability)

Exercises "too difficult"

A further subtheme affecting adherence to home exercise programmes was the prescription of exercises that were "**too difficult**". This was a particular issue for those with moderate and moderately-severe stroke and highlighted the need for individualisation of exercise programmes.

> *"I did have some (exercises) but they didn't do much for me. I had exercises but at first my arm was so weak I couldn't do any of them."* (George, 48, moderate disability)

> "*At first, yes. I did it (complied with the out-of-session exercise programme), one, two, three times but then I thought 'oh no, fuck off!' Oops sorry! I was going nowhere. Too difficult for me and not fun." (pulls a bored face and mimes an exaggerated yawn)* (Clara, 54, moderately-severe disability)

"Can't be bothered to exercise" when alone

In addition, a subtheme of participants not being "**bothered" to exercise when alone** was recognised and suggested the need for external motivation to aid exercise adherence.

> *I probably stuck with the programme for maybe a month and that's when my daughter stopped phoning me every day to make sure I had done them!* (Esther, 49, slight disability)

> *"I never try and use my right (hemiplegic) arm when I'm at home. I would exercise it more if someone was there with me. I can't be bothered when I'm on my own."* (Nancy, 65, moderately-severe disability)

Interestingly while these participants identified external input as being core to adherence to exercise, others felt motivation came from within, with a view that this was down to luck and that external forces had limited ability to motivate.

> *"Motivation is a toughie. You either have it or you don't"* (Joe, 64, slight disability)

> *"It would depend on the person, whether they want to do it or not*." (Betty, 67, moderate disability)

The issue of poor adherence was not seen in all participants, with two reporting excellent adherence to prescribed out-of-session exercise programmes. However, in both cases, the programme consisted of stretches for the upper limb, not active exercises.

> *"Yes, I've still got them (home exercise sheets). There were a lot of arm exercises and like, well more the arm exercises to, like nothing really to build my muscles up, just stretching to stop my hand and arm from being bent. I've done them all, all the exercises that they taught me how to do, for the past three years I've done them...I do it every morning and every night."* (Ada, 66, moderately-severe disability)

Reasons for better adherence in these participants may be due to ease of exercise (as neither participant mentioned any difficulty in performing these exercises) and a belief in exercise effectiveness (expressed by one participant [Ada] as a perceived ability of the exercise to "stop (her) hand and arm from becoming "bent").

7.3.3 The Importance of Sustaining Optimism

A striking theme identified when participants spoke of their previous rehabilitation experience, was the **importance of sustaining optimism**. Participants spoke emotively of the negative and potentially devastating psychological repercussions of removing optimism through insensitive comments made by therapists.

> *"On my arm? To be honest? They said to me, 'we can't do anything about your arm so concentrate on the leg'. I know now this is rubbish. You shouldn't tell ANYONE that. The way they treated me was good and bad. On the good side they got me walking again, and then you're out (of hospital). I'm happy with that. But to say to someone you're never going to get your arm working, mentally, that's no good. It's really bad, because now I can look back and say they are wrong, but at the time it's like the world was coming over me. It's a mental side. You can really fuck someone up in their head and there's no way back from that."* (George, 48, moderate disability)

> *"They said, 'it won't get better. Don't waste time trying. That arm will never work'. That is a very bad thing to say. Very wrong. It made me very sad, like I wanted to give up."* (Betty, 67, moderately-severe disability)

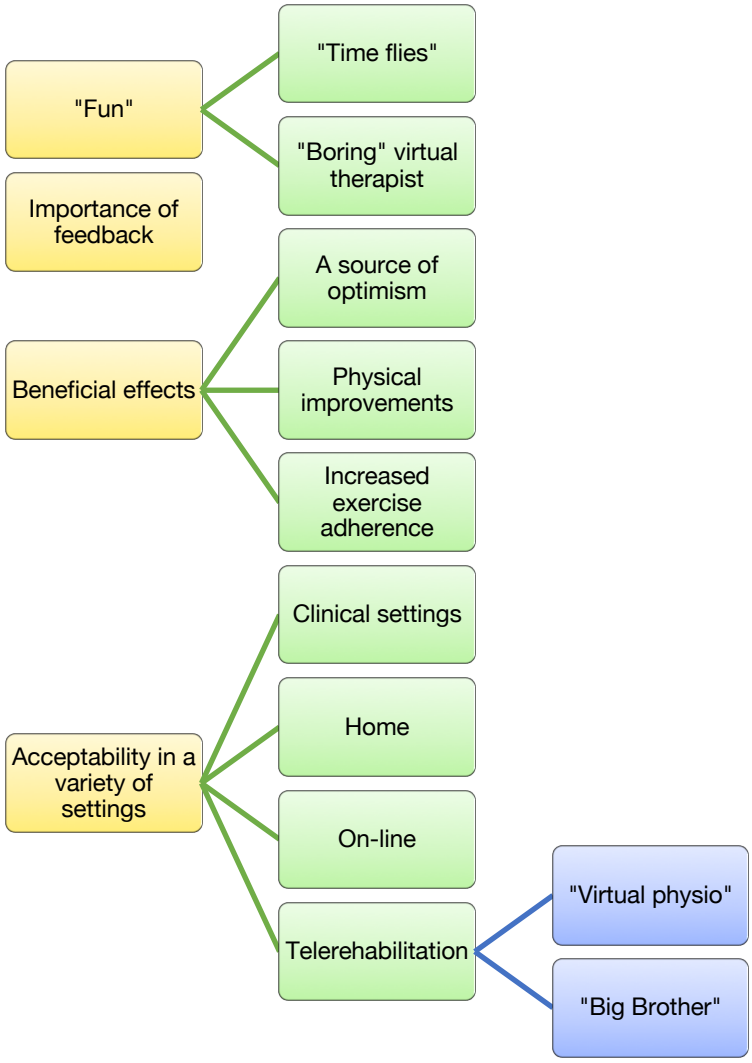
In summary, resource pressures, a lack of rehabilitation for the upper-limb, having time to spare during rehabilitation, and a sense of abandonment on discharge were recognised and together led to the identification of a main theme of **not enough therapy**. This was apparent in clinical and home settings and was a particular issue for upper-limb rehabilitation. It was apparent that therapists were attempting to address this issue through provision of out-of-session exercise programmes, however a strong theme of **poor adherence** with such programmes was identified. This was related to the boring nature and level of difficulty of prescribed exercises and for some, the need for external help to maintain motivation to exercise. In addition, **the importance of optimism** in maintaining motivation was powerfully voiced.

These barriers to rehabilitation suggest the need for more therapy in both clinical and home settings and provision of exercises that are interesting, tailored for an individual's capabilities and focused on the upper-limb, suggesting VR gaming technologies would, in theory, be acceptable for use in rehabilitation following stroke. Findings addressing the acceptability of the PST system are presented next.

7.4 Acceptability of the PST System

Main themes of "**fun", "the importance of feedback", beneficial effects, and the acceptability of use in a variety of settings** were noted when participants discussed their experience of using the PST system (Figure 7.2).

Figure 7.2 Thematic Map of PST System Acceptability



7.4.1 "Fun"

A highly prevalent theme of "**fun**" was recognised when participants spoke of their experience of using the PST system and was particularly strong when discussing the apple-tree game.

> *"I loved the one with the apples! That is so funny. The apple would drop and I'd think 'Oh God, I must get that'. It was really nice, really motivated me. I think it's really good.... It's like the apples coming out of the tree you don't know where they are, so it's like 'oh!' (sounds surprised). I liked the whole package. It was fun, really good fun."* (Lizzie, 53, moderate disability)

> *"That was really good, it was interesting and fun to play...It's just fun, it's getting, you know, catching the apples. It doesn't matter if you miss them, how many you get what score you get. It was really good. Really interesting, it was fun to use and play and I enjoyed every minute."* (Ada, 66, moderate-severe disability)

The theme of "fun" was underpinned by a concept that "**time flies"** while having fun.

"Time flies"

The perception of time distortion, i.e. that "time flies", as a result of enjoyment when using the PST system was a prevalent subtheme recognised in the data.

> *"(*Time*) went very quickly. I was always amazed when it was time for my husband to come and pick me up because it seemed to go so quickly. Because I was enjoying it. I think when you enjoy something it always ends too quickly doesn't it?... When you enjoy exercising you don't know you're exercising."* (Nancy, 65, moderately-severe disability)

> *"It didn't seem like 40 minutes. It seemed like ten… the psychology behind it, I don't know what it is, but when you've got a game and you're so involved in it, time flies. It takes you out of the physical world so it was fun."* (George, 48, moderate disability)

However, the theme of "fun" was less apparent when discussing the virtual therapist application.

"Boring" virtual therapist

The virtual therapist application was less well received by some participants with a view that it was like a "boring" "lesson" similar to traditional physiotherapy.

> *"I'd much rather have been in the room playing with the apples and then you'd say 'you've got to do the virtual one and I'd be like 'oh no!' It's like a game with the apples or 'you, must, get, on, with, your, lessons' (*taps out the phrase on desk*) that's what it feels like to me…It was a lesson while the apple-tree was a game. I didn't mind the lesson but it wasn't fun in the way that lessons tend not to be."* (Lizzie, 53, moderate disability)

> *Well (the apple-tree game) is a bit more interesting and less like physio basically even though I know it is physio, but less like physio, less like being in hospital and having to do repetitive physio. I'd give it (the virtual therapist) two out of ten because it was a bit boring."* (Dora, 60, moderate disability)

However, all participants agreed that the virtual therapist application was the more demanding activity and as such, was perceived as being more physically effective.

> *"The apple tree is fun but the other one is like exercise… the robot (*the virtual therapist*) is more effective. Better exercise with the robot. More effective because I do more things like this and this (demonstrates different arm movements), so it's better exercise with the robot."* (Betty 67, moderately-severe disability)

> *"I enjoyed (the virtual therapist) because I felt that I was doing physiotherapy. I felt it was really doing something for me because at home on your normal tasks you wouldn't often reach up so high or out so far so I did think I was getting more back exercise wise."* (Esther, 49 slight disability)

Interestingly, while being acknowledged as the more effective activity, most participants with moderate to moderately-severe disability stated they would opt for the apple-tree game if given a choice between the two activities.

> *"If I had to pick between them, I'd pick the apple game".*" (Dora, 60, moderate disability)

> *"I would want the apple game. That was a little bit easier and the apple game is fun but the other one is hard, like exercise."* (Betty, 67, moderately-severe disability)

However, in participants with milder stroke, a preference for the more difficult virtual therapist application was apparent due to perceived increased effectiveness compared to the apple-tree game.

> "*You know, if I had the choice of the two I would definitely err in favour of the virtual teacher. Purely because it is a little more intensive."* (David, 63, slight disability)

> *"With the virtual teacher, I felt I probably used more muscles and more concentration than the apple game. Fun wise, I suppose the apple tree game had it. The virtual teacher I felt was probably doing me more good."* (Esther, 49, slight disability)

The greater amount of feedback received while playing the apple-tree game may have contributed to it being acknowledged as being the more enjoyable activity.

7.4.2 Importance of Feedback

The activities used with the PST system provided different levels of feedback. The apple-tree game provided knowledge of results through provision of a score of the number of apples caught, a rating (out of five stars) of their overall achievement and an encouraging comment regarding performance. Performance on the virtual therapist application was less overt, with on-screen blending of the recorded and actual upper-limb movements occurring when physical movements in real time coordinated with the recorded movement. The **importance of feedback** was a prevalent theme identified when participants discussed their experience of playing the apple-tree game and was recognised as being critical for motivation.

> *"I like that part of it. I like to be able to sort of get better each time…To go from 3 stars to 5 and be super-duper at it. I wanted my gold stars!"* (Esther, 49, slight disability)

> *"With four stars it was ok, but with 5 it was whhhheeeeeyyy!"* (Clara, 54, moderately-severe disability)

While feedback with the apple-tree game was linked to greater motivation, participants voiced concerns regarding the lack of feedback and encouragement with the virtual therapist application which was felt to have a negative effect on motivation.

> *"(It) didn't give me encouragement in the way the apple one did... When it called you 'world class' or 'legend' you thought 'oh yes, I've cracked this!' ...(*The score*) was important. Very important…I could have done with a hint or two. You know 'lift this, move that', what you needed to do to be 'world class'…I liked being 'world class!"* (Nancy, 65, moderately-severe disability)

> *"If you had more of an indication that yes, what you are doing is correct, it would make you want to carry on more…You know, just something that pops up on the screen. If they were able to do that, that would improve the game because now you've got no feedback. Because if you are doing it right, it makes you want to do more…I'm not competitive but when I see a score of 54 I think yeah I want to carry on"* (Jenny, 49, moderate disability)

The importance of feedback was further emphasised when participants were asked about improvements they would like, with suggestions of different types of feedback such as haptic (sensory) feedback and noises to indicate when they had had been successful or not.

> *"I would like a sound like a plop when the apple falls and a splat if you miss it, or a comment like 'really good job' or a score when my arm lines up."* (Ada, 66, moderately-severe disability)

> *"On the PS3 you have haptic feedback. That would be good. You get a buzz when you got it, or a cheer, or you got a boo if not."* (George, 48, moderate disability)

In addition to themes of "**fun"** and **the importance of feedback**, subthemes relating to perceived **beneficial effects of the PST system** were recognised.

7.4.3 Beneficial Effects the PST System

A strong theme of the **beneficial effects** of the PST system was underpinned by subthemes of the PST system as a **source of** "**optimism**"**, physical improvements** experienced at both impairment and functional levels and **increased exercise adherence**.

Source of "Optimism"

A subtheme of the PST system as a **source of "optimism"** was identified and was associated with noticing unexpected physical improvements during the slow recovery process.

> *"I impressed myself how much I could move my arm when I was concentrating. I thought I had virtually no movement in it at all but I was surprised how much I did have…my arm was actually moving which impressed me, so it made me feel very optimistic that my arm had improved."* (Nancy, 65, moderately-severe disability)

Jenny became noticeably emotional as she described the PST system as a source of optimism.

> *"This is the first thing I've done since the stroke that I've actually noticed improvement. Because everything with a stroke is long winded. Everything takes time and you don't notice how well you have done. Because I've tried everything but this is the first thing that has given me hope, sort of like the light at the end of the tunnel"* (Jenny, 49, moderate disability)

In addition to psychological benefits, a prevalent subtheme of **physical improvements** following PST system use was recognised.

Physical improvements

Participants noted improvements in impairments of strength, range of movement, perception, coordination and stamina after using the PST system.

> *"I can actually lift my arm up higher and hold it more than I did before"* (Ada, 66, moderately-severe disability)

> *"What I think what it's done for me, is sort of improve the position. I'm way more confident to pick things up with my left hand, put it down without spilling it. What I think the games have done for me, sharpened my perception of where the hand is and for that I say thank you… The bigger picture, it has helped me with stamina"* (Joe, 64, slight disability)

In addition, a strand of increased functional use of the upper-limb was discussed by participants with differing levels of ability.

> *"...I did manage to get my cardigan on the other day which I haven't done in years. I've never managed to get it on on my own and I did it and thought it's getting better. …But this week I thought I'm going to do it by myself, I'm not going to ask anybody. I'm going to sit there and I got my left arm in and then I managed to get my right arm in as well so I was most impressed."* (Nancy, 65, moderately-severe disability)

> *"I've managed to zip up my jacket for the first time since the stroke! I can't believe it but I can do this (demonstrates forearm pro and supination). I can actually do things now that I couldn't do before I used (the PST device). Because I can actually do my jacket up on my coat…It does take me a while, but eventually I do get the zip up and today I actually was able to do my shoelaces up on my trainers for the first time. I was never able to do that either so I'm really chuffed!"* (Jenny, 49, moderate disability)

Psychological and physical improvements were noted by all participants and were associated with increased adherence with exercise programmes.

Increased exercise adherence

A subtheme of the PST system improving adherence to exercise programmes suggested the system could help motivate individuals to achieve intensity of practice.

"*Well because normally you couldn't sit there and move it like that for hours at a time, or even 15 minutes at a time because it gets boring. But when you have got something to interest you, challenge you, it's much better. So it did help me to exercise my arm, yes...I don't really give it much exercise at home. I wouldn't have been exercising my arm if I'd been at home, I'd have been sitting watching Jeremy Kyle or some such rubbish like that!*" (Nancy, 65, moderately-severe disability)

"I walk a lot but (the PST system) made me use my arms a lot. I mean A LOT!" (Lizzie, 53, moderate disability).

The ability to be monitored by the therapist while using the PST device was considered key to aid motivation and therefore exercise adherence.

"Because you're not sitting at home with your pamphlets of paper. You are actually participating in something…It would give you more reason to actually do it, especially knowing the physio is watching or could check up on you…they are there to help you get better and you are there to help yourself get better so (being watched) wouldn't bother me. But yes, you wouldn't have that morning off, you would actually get on and do it." (Esther, 49, slight disability)

"I can't think of anything bad about it. Nothing really because if they were checking that you were using it, you wouldn't be able to cheat would you? You wouldn't be able to say 'oh yes, I've been on it every day for three hours if they could check and say "no you haven't'. I think that would be one of the pros that they could check you were using it… It's for your own good isn't it? Because it's all too easy for them to give you a list of exercises and say I want you to do them twice a day and then they say have you done them? and you say yes, that's easy to say isn't it? But if they can actually physically check, you are going to HAVE to do them." (Nancy, 65, moderately-severe disability)

Possible mechanisms of recovery were identified as further strands in the narratives with recovery being linked to the ability of the PST system to motivate participants to 'push themselves further' and by doing so, helping to provide greater intensity and repetition of movements.

"(the virtual therapist) is more movement than what I do usually. It felt arrrgghhh! Hard work." (Clara, 54, moderately severe-disability)

*"I wouldn't have attempted to do a chicken wing movement (*shoulder abduction*) or bring my arm across the body without it."* (Nancy, 65, moderate-severe disability)

In addition, a perceived ability of the PST system to address the issue of learnt non-use was recognised in participants with moderate and mild disability following stroke.

"Again, it gets the muscles moving and working a lot more which is, you know, where I've sort of thought, well blow it, I'll just use my right hand sort of thing. You are (with the PST system) actually physically moving the left hand and arm which is what is needed. I was going to say that you probably recall that I mentioned a couple of times that I feel there is a little bit of muscle wastage, well I felt those muscles being used again. You've heard the old expression 'God, I've got muscles where I never

thought I did have, well I've got muscles where I REMEMBER having them!" (David, 63, slight disability)

*"(*The PST system*) was making me use it and reminding me it was still there for use. As I say, when I got home I did tend to use my left (hemiplegic) arm more. It kind of triggered something in my brain, that my left arm was still there and I could use it more. It was the fact that I was using it (*in the study*), so I found that when I went out the door, normally I would have used my right arm, but I didn't, I held the handle in my left arm. Even when I went home I seemed to be using my left arm a lot more… My partner has noticed me using my arm more spontaneously, opening doors unwrapping things. Things like that... I feel this has awakened my brain to the hand.*" (Esther, 49, slight disability)

It has been postulated that provision of visual feedback via an avatar can activate 'mirror neurones' (brain cells involved in performing a movement which also "fire" when observing a movement) which may aid recovery from stroke (Celnik et al., 2006; Francheshini et al., 2012). This phenomenon is more frequently associated with more immersive VR activities (Henderson et al., 2007). While not a prevalent theme, one participant discussed phenomena associated with mirror neurone activation, raising the possibility that this was a mechanism at play while using the PST system with this participant.

*"(The virtual therapist application) made me feel my arm but not the shoulder blade as I could see my arm, but not the shoulder blade." (*Lizzie, 53, moderate disability)

Subthemes related to **fun** and **beneficial effects** while using the PST system suggested general acceptability of the device. This was explored further through asking of questions related to use in different settings.

7.4.4 Acceptability of PST Devise Use in a Variety of Settings

Participants were asked about the acceptability of use of the PST system in a variety of settings.

Clinical and home settings

A theme of acceptability of using the PST system in clinical and home settings was noted.

*"I would have used it in hospital without a doubt. (*The PST system*) would make me (*exercise*) because I'd be worried in case I stopped doing it that my improvement wouldn't stay. So yes, just for the pure fact that I want to improve, I'd do it… Oh yes, I would use it at home too because I'm seeing improvements."* (Jenny, 49, moderate disability)

"Would I have used it? Oh God- yes, yes, yes! …If I had a stroke now, I would really like that." (Lizzie, 53, moderate disability)

There was no consensus about where participants would like the VR system set-up while in hospital, with some preferring the day room, others by the bedside and others still in the therapy department. In addition, participants were not concerned about exercising in front of other service-users, feeling that they were all in a similar situation and a belief that the device may facilitate social interaction.

> *"It wouldn't bother me exercising in front of peers because you would all be in the same boat."* (Dora, 60, moderate disability)

> *"I think it probably would be better in the day room because there was more room there and you could have had, there are always people in the day room, so you could have said 'well I'll do it and see if you can beat me'. In physio there are too many distractions because I'm pretty nosy. I would have been looking to see what everyone was doing."* (Nancy, 65, moderately-severe disability)

The PST system was also perceived as a way of promoting social interaction once discharged from hospital including providing a way on interacting with children and grandchildren.

> *"We would play it as a family competition. I'd play it every day when the (Grandchildren) come back from playschool."* (Joe, 64, slight disability)

> *"Now I can play with my children".* (George, 48, moderate disability)

Conversely, others expressed concern about the level of competition this might bring and noted the need to be able to play someone with similar level of disability to ensure that the level of challenge was appropriate.

> *"I think it would be quite fun to do it with somebody but it depends if the person you were playing against is going to be too good or too competitive, because that might sort of take away from what you are actually doing."* (Ada, 66, moderately-severe disability)

> *"This is a question that comes down to the individual. It wouldn't bother me particularly because I'm quite competition orientated but other people may think 'oh God, you know I'm going to get a whopping again', and it could actually be a little bit of a regressive thing. It could actually make you think I'm going to get a caning off this guy again I'm not really up for that. It might put them off."* (David, 63, slight disability)

On-line

The concept of playing against someone on-line was raised as an option and acceptance was a particularly strong strand in those with communication difficulties.

> *"Yes (playing against someone) would really interest me. Because I can't speak a lot and so yes doing this on line. It's good, I could play with other people."* (Clara, 54, moderately-severe disability)

> *"It would be good for someone like me, as speaking to someone new in person is difficult."* (Lizzie, 53, moderate disability)

Telerehabilitation: virtual therapist or "Big Brother"?

In addition, a very high level of acceptability of using the PST system as a means of delivering telerehabilitation was expressed, with all participants stating they would like to use the device in this way.

> *"I think (*telerehabilitation using VR gaming technologies*) will be so, SO useful. You HAVE to do it. You have to continue to make it."* (George, 48, moderate stroke)

The ability to have feedback from a "**virtual physio"** was identified as an important source of motivation.

> *"(*Teletherapy using the PST system*) wouldn't bother me, because I feel like the therapist and me, the therapist would feel really close. Because now, I do this and that (*shows arm moving*) and now the therapist doesn't know."* (Clara, 54, moderately-severe disability)

> *"For me it would be a big, big plus. You can market it as something like a virtual video physio teacher. You can market it anyway you want but what you're doing is saying to someone 'I'm a physio, you've got better this week'. That would be a big, big lift for me."* (George, 48, moderate disability)

While overall the concept of using VR gaming technologies as a means of delivering telerehabilitation was well received, two participants raised concerns regarding intrusive monitoring, by "Big Brother" (a term used in George Orwell's dystopian novel, 1984 [Orwell, 2018] where aggressive government surveillance is used to monitor and control the population).

> *"Some people might look on it with a sort of 'Big Brother' attitude, like I'm being watched. But on the other hand, some people might sort of go, they are obviously taking an interest in what I'm doing and they are just sort of encouraging me, geeing me up a bit, you know, so there are pros and cons in both directions. Personally, I would say, yes, bring it on! It wouldn't bother me at all. It just shows they are taking an interest in my welfare."* (David, 63, slight disability)

> *"I wouldn't want it sophisticated to the level of a webcam. It would bother me because I don't use that at home. You know, the tiny camera can actually see the whole room. Quite frightening!"* (Dora, 60, moderate disability)

In summary, themes recognised suggested acceptability of use of VR gaming technologies. The device was felt to aid motivation to exercise the upper-limb following stroke in participants with differing levels of stroke severity, including those with moderately-severe disability. Moreover, the device was felt acceptable to use in clinical and home settings

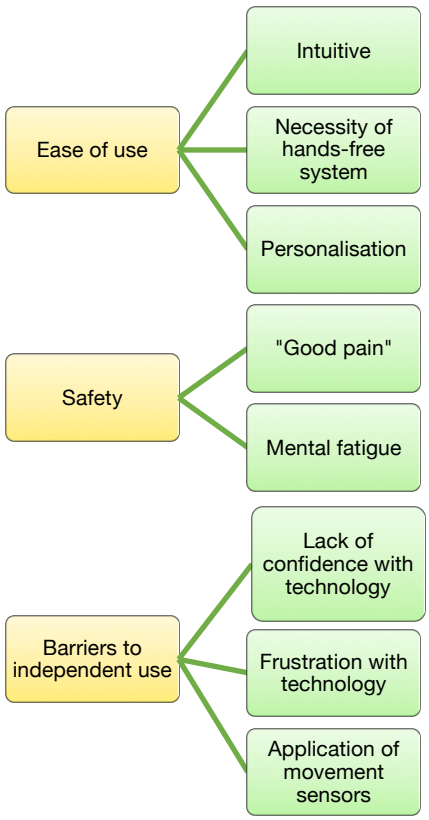
including use as telerehabilitation. The fun nature of activities and the provision of augmented extrinsic feedback were recognised as motivating factors and were more strongly associated with use of the apple-tree game. However, the virtual therapist application was felt to be the more difficult and therefore the more physically effective activity. Activity preference was associated with level of disability. In addition, several beneficial effects were associated with use of the PST system such as psychological and physical improvements in upper-limb impairment and function and increased adherence to exercise programmes.

In keeping with the MRC recommendations (Craig et al., 2008) issues of feasibility of use were also explored.

7.5 Feasibility Findings

This section explores matters related to PST system feasibility. Themes of **ease of use**, **safety** and **barriers to independent use** are presented in Figure 7.3.

Figure 7.3 Thematic Map of Feasibility of PST System Use



7.5.1 Ease of Use

A theme of **ease of use** of the PST system was recognised and was underpinned by a subtheme of it being **intuitive** to use.

Intuitive to use

The majority of participants felt the system was easy and intuitive to use without the need for detailed explanations.

> *"I automatically get what to do with this to play the game."* (Lizzie, 53, moderate disability)
> *"It was pretty self-explanatory".* (David, 63, slight disability)

Necessity of a hands-free system

In addition, the use of the **hands-free system** (with the motion sensors being strapped to participant's arms) was recognised as a key feature enabling feasibility of use for those with hand impairments following stroke.

> "*…because I've got the hand (*indicates that has minimal movement*) at first I thought 'No! Not possible'. But then you strapped it to my arm and I said, 'oh (*sounds surprised*), okay'."* (Clara, 54, moderately-severe disability)

> "*Because (*in hospital*) I couldn't hold the remote. They did think about it but they dismissed it when they saw I couldn't use my hands.*" (Dora, 60, moderate disability)

However, field-notes made during the study noted that while use of hands-free movement sensors enabled all participants to use the system, only two participants were able to attach the movement sensors without help, suggesting that difficulty attaching the sensors is a barrier for independent use.

Personalisation

The ability to **personalise** PST system settings ensured the correct level of challenge for study participants, including those with moderately-severe disability who had previously struggled to perform upper-limb exercises.

> *"Usually I can't do (exercise). No point, for me it's too hard… I feel that the treatment has really helped my arm, as it's exercise, exercise even I could do!"* (Clara, 54, moderately-severe disability)

> *"I don't think you need loads (of movement) to play with it. I think, you know, with minimal arm movement you could give this a go because I did."* (Nancy, 65, moderately-severe disability)

While enabling participants with more severe strokes to interact with the system, **personalisation** meant it was still possible to maintain the level of challenge for those with milder stroke severity.

> *"I had to really move (*to catch some of the apples*). It depends how they were set out. You were particularly cheeky one day last week and you put one almost behind*

*the tree trunk sort of thing and I was going (*makes effortful noise*), trying to get to it. I thought that was a good one! But yes it makes you work."* (David, 63, slight disability)

"You still had to strain to do this. It's not easy. But I suppose that's good. It feels like you are really doing something." (Jenny 49, moderate disability)

However, the need for further personalisation to maintain the level of challenge was apparent, with a strong strand of wanting the apples to fall at a faster speed being identified in participants with mild stroke severity.

"The apples fell like they were filled with helium, very slowly. If you could alter the speed a bit so that people who progress with it would find it a little more challenging catching apples that are moving a bit quicker." (Joe, 63, slight disability)

"I felt I would like it so I could make them fall faster maybe. So I wasn't waiting for them to fall." (Esther, 49, slight disability)

This strand did not appear in those with moderately-severe strokes, with all suggesting the speed was appropriate for this participant group.

"No, I think the way it is it's okay because it gives you time to move and steady your basket." (Ada, 66, moderately-severe disability)

"I thought the speed was just right." (Nancy, 65, moderately-severe disability)

7.5.2 Safety

When asked directly about adverse effects experienced while using the PST system, all participants indicated it was **safe** to use and that activities were well tolerated with minimal adverse effects.

"Good pain"

Pain was experienced by a small number of participants. However, it was felt to be at an acceptable level and was recognised as a "**good pain"** in keeping with stretching, effort or delayed onset muscle soreness (normal phenomena following unaccustomed exercise and doing a strenuous work out).

"It's an 'I've been using it' type pain. Muscle soreness, but not agonising you know…like when you do something different. It was a good old fashioned muscle ache as if you have been working the muscle pretty hard." (David, 63, slight disability)

"I do feel pain but it's a stretching pain but that doesn't bother me because I can actually do things now that I couldn't for before, so it's a good pain." (Jenny, 49, moderate disability)

Mental fatigue

Using the PST system was associated with inducing **mental fatigue**. This was considered by some participants as a sign of concentration and could therefore be an indication of intensity of practice.

> *"Tired mentally not physically."* (Joe, 64, slight disability)

> *"It's a little bit hard, that's why I'm tired. When I finished the robot game I am feeling tired. Not tired, with my arm, you know, in my brain, because I am focused, full of focus."* (Betty, 67, moderately-severe disability)

While no safety issues were encountered during the study, other barriers to use were apparent.

7.5.3 Barriers to Independent PST System Use

Barriers to PST system use included a **lack of confidence** and **frustration with technology** and difficulty in the **application of the movement sensors.**

A subtheme of a **lack of confidence with technology** was identified as a major barrier to independent use of VR gaming technologies.

> *"I think I would err on the safe side and I would like somebody there with me the first few times to make sure I have really got it and for them to say' yes, that's fine', then I'd have got the confidence because I'd hate to go in and break something …If you leave it to someone who doesn't know what they are doing, that could cause all sorts of problems."* (Jenny, 49, moderate disability)

> *"Technology doesn't worry me but it has to be fairly simple or I'll lose interest if it's too difficult."* (Dora, 60, moderate disability)

This was a theme in those who had limited experience with technology and was not related to age, with participants in their 40's reporting this as an issue while some older participants reported feeling more confident.

> *"I was nervous before the stroke. I mean I didn't have a computer before the stroke. A friend of mine said get yourself a computer, get online, email friends. I sort of bit the bullet and went for it! I bought one and haven't looked back since. Yes, now it doesn't faze me at all."* (David, 63, slight disability)

In addition, **frustration with technology** was recognised, demonstrating the need for technology to be easy to use without extensive technological experience or knowledge.

> *"I understand that technology has a place in the modern world…But technology that doesn't work for me annoys me! My TV has an intelligence I don't understand. It's just so annoying."* (Joe, 64, slight disability)

> *"It's frustrating because I know that I sometimes, with problems (*with technology*) at home, I give up because I just get so frustrated and I think, oh it's not worth it and that's probably why I don't play computer games normally...You want something you can just plug in and play"* (Jenny, 49, moderate disability)

Overall the PST system was felt to be easy and safe to use, supporting a theme of feasibility of use in clinical settings. However, a lack of confidence with technology posed a barrier to PST system use at home for some, suggesting the need for initial support and in addition, the need for technology to be simple to set up and use. Moreover, while it was feasible for all participants to use the device, field-notes showed that most participants required **assistance to apply the movement sensors**, suggesting issues with feasibility for independent use. Furthermore, as a member of the research team set up the activities, feasibility of independent system use was not explored, but may be a potential barrier.

7.6 Exploring Participant Experience of Study Participation

In order to address research aims related to the acceptability of the study design, participants were purposively asked about their experience of participation in the study. Findings of **enjoyment** in study participation and the **acceptability of the study burden** were identified.

7.6.1. Enjoyment in Study Participation

Overwhelmingly, people described taking part in the study was an enjoyable process.

> *"The sessions have gone really quickly. I have really enjoyed myself."* (Clara, 54, moderately-severe disability)

> *"I enjoyed it-coming here, the games, the whole thing, I really did*." (Joe, 64, slight disability)

Reasons for enjoyment related to the fun nature of the activities and a belief in the effectiveness of the device (Section 7.4). In addition, in some participants, enjoyment may have been due to a reduction in social isolation experienced through involvement in the study as discussed below.

7.6.2 Acceptability of the Study Burden

When participants were asked about the acceptability of study attendance requirements (of three, 40-minute sessions a week for three weeks), a strong theme of acceptability was recognised.

> "*I think it was about the right time ... No, three times wasn't too much."* (Lizzie, 53, moderate disability)

> *"Three times, I think that's okay because I like my other activities, so it's fitting it around those."* (Dora, 60, moderate disability)

However, when asked about the acceptability of attending five times a week, opinion was divided with a strand of this being too much for those with slight and moderate disability and a strand of acceptability being noted in those with moderately-severe disability.

> *"Five times, might have been stretching it a little bit yes."* (David, 63, slight disability)

> "*I can be here every day. Well it depends on hospital appointments, but apart from that I can be here every day for three hours, four hours…It doesn't matter. I would do anytime, all day and every day!"* (Ada, 66, moderately-severe disability).

The greater acceptance of a more intensive protocol in those with more severe strokes may be related to the phenomenon of an 'open diary' with those with moderately-severe disability experiencing greater social isolation and less occupation than those with milder disability.

> *"You (the researchers) made it fun and it was nice talking to people otherwise you are just stuck at home by yourself. I haven't got a life. I've got a totally open diary. I don't go anywhere or see anyone really."* (Jenny, 49, moderate disability).

> "*As I say, I've got nothing else to do all day anyway.*" (Nancy, 65, moderately-severe disability)

A further burden on participants related to travel commitments, with the need for pre-paid taxis to avoid additional inconvenience on relatives and the additional time burden of travel being noted.

> *"I felt guilty because it was tying (my husband) up all the time with bringing me here and that.*" (Nancy, 65, moderately severe disability)

> "*I think the actual session was fine, but because I was travelling in from (*another borough*) that meant altogether that was two hours and for me, even though it sounds quite easy, that I just get out and get in a taxi, it was quite tiring because the taxi drivers had a captive audience so they would chat to me and for me talking is quite tiring…I don't think I would have (participated in the study) if I'd had to pay for the taxis. It's a lot of money and it always takes forever to get any money back."* (Dora, 60, moderate disability)

In summary, the study design was acceptable for participants with different levels of stroke severity. However, more intensive protocols may prove too onerous for those with less severe stroke.

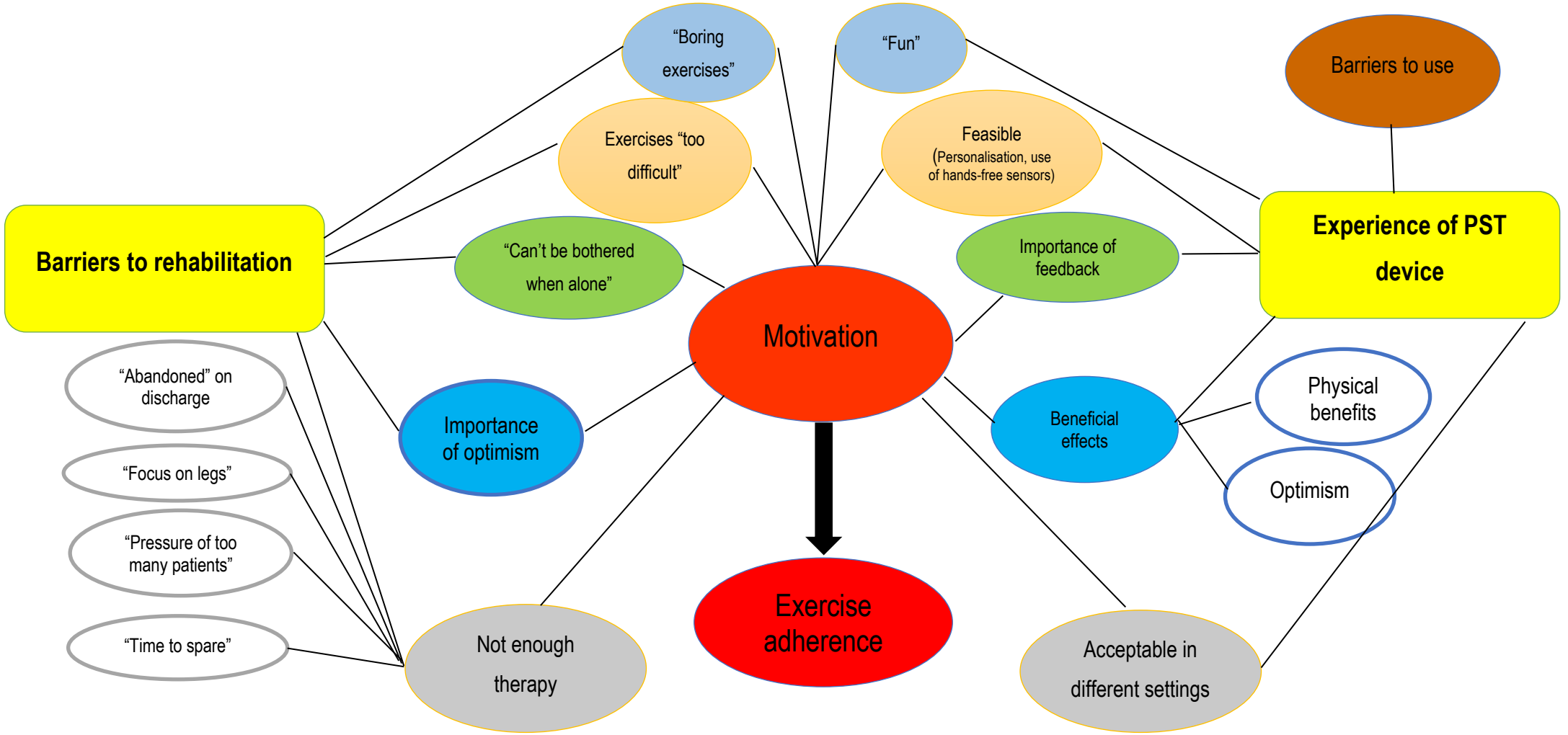
7.7 Summary

Thematic analysis of intervention field notes and interview transcripts from 11 participants who had used the PST system for upper-limb rehabilitation resulted in the identification of themes related to barriers experienced in rehabilitation and those related to motivation and

effectiveness of the PST system (Figure 7.4). While a lack of confidence with technology and suggestions for further personalisation were identified, overall findings suggest a high degree of acceptability of the PST system for use in clinical and home settings including the concept of use in telerehabilitation. Acceptability was linked to enjoyment, physical and psychological benefits experienced while using the device and a perceived ability to address several barriers to rehabilitation including lack of therapy, reduced motivation and poor adherence to out of session exercise programmes. In addition, the use of a hands-free system and ability to personalise the PST system activities ensured system feasibility and was key to enable participants with differing levels of disability to interact with the device and maintain level of challenge. Finally, themes of enjoyment in study participation and satisfaction with the study burden suggested acceptability of the study protocol.

To gain a more complete and robust understanding of study findings, integrated findings from quantitative and qualitative arms of the study will be presented in the next chapter.

Figure 7.4 Thematic Map Showing Cross-Over Between Barriers to Rehabilitation and Experience of Using the PST System



Chapter 8: Integration and Discussion of Study Phase 2 Findings

8.1 Introduction

In keeping with a mixed-methods design, integration of key findings from quantitative and qualitative arms of study phase two are presented in this chapter. Ascertaining to what extent (if any) survey results confirm interview findings enables a more complete and robust understanding of the study aims as discussed in Section 2.2.

This chapter begins with presentation and discussion of key integrated findings related to study aims of feasibility (Table 8.1), acceptability (Table 8.2) and provisional estimates of efficacy (Table 8.3) of the Personalised Stroke Therapy (PST) system for upper-limb stroke rehabilitation. This is followed by findings as related to the feasibility and acceptability of the study protocol (Table 8.4). Findings are presented in side by side display tables as recommended by Creswell (2015) and discussed in Sections 2.5 and 2.6 with results from statistical analysis providing quantitative evidence, while themes identified through qualitative analysis of interviews and field notes are presented (in bold type) and supported through use of illustrative quotes. The term "**QN**" indicates a quantitative finding, "**QL**" refers to a qualitative finding and the number refers to where findings are located in the results tables. Although a theme was identified when two or more participants discussed an issue, for brevity, one exemplar quote is used for each point raised and readers are invited to refer to Chapter 7 for further quotes.

8.2 Integrated Findings of Feasibility

Integrated findings related to the feasibility are presented in Table 8.1.

8.2.1 The PST System was Safe to Use

There was agreement between data sets that the PST system was safe to use with adverse effects being infrequent and when occurring, mild in nature (**QN1, QL1- 2,** Table 8.1). While upper-limb pain was experienced by five participants (**QN1**, Table 8.1) it was mainly associated with unaccustomed muscular activity and was described as a "good pain" (**QL1,** Table 8.1) and evidence of intensity of practice, as opposed to a true adverse effect. Two participants experienced pain consistent with shoulder soft tissue impingement on three occasions (combined total) (**QN1**, Table 8.1) possibly because of a disparity between task demands and participant's actual motor ability. Pain stopped on cessation of movement and

did not reoccur once the range of movement required was adjusted (again supporting the need for personalisation of activities). Mental fatigue (**QL2,** Table 8.1) was noted but was again considered by participants as an indication of exercise intensity and effort. Silence in both data sets regarding other side-effects, again supports the finding of safety of the PST system.

8.2.2 The PST System was Feasible to Use

The PST system was felt to be intuitive to operate without the need for extensive instructions (**QL3**, Table 8.1), and all participants were able to use the system regardless of stroke severity (**QN2**, Table 8.1). Critically, the ability to personalise activities depending on individual need and the use of a hands-free system (**QL4**, Table 8.1) also enabled use by participants with severe upper-limb impairment without the need for orthoses or additional help (**QL5**, Table 8.1). However, while an average rating of perceived effort for the apple-tree game was “fairly light” (**QN6**, Table 8.2), a theme of considerable effort was apparent in the qualitative data (**QL12**, Table 8.2). This apparent discrepancy may be a result of differences in the selection of the movement range required to play the apple-tree game as several participants spoke of one researcher (the lead researcher) setting parameters that made game play much harder in comparison to the second researcher (**QL14,** Table 8.2). The findings of effort associated with the virtual therapist application and the apple-tree game suggest that through personalisation of the range of movement, speed, and duration of activities, the PST system was able to maintain the level of challenge for those with a wide range of impairments following stroke. There was strong agreement between data sets that the apple-tree game was the easier task (**QN6, QL12,** Table 8.2) and in line with this, participants with milder stroke severity identified a need for a faster speed of the falling apples (**QL13,** Table 8.3) suggesting the need for further personalisation. This was not a theme in those with more severe disability indicating the slower speed was appropriate for those participants.

The use of the hands-free system was essential for the majority of participants in the present study, several of whom had been unable to use the hand-held movement sensors when they had tried to use VR gaming technologies in the past (**QL4,** Table 8.1). However, field notes showed that only two participants were able to attach the movement sensors themselves, thereby limiting feasibility of independent set-up (**QL8,** Table 8.1).

Table 8.1: Integrated Feasibility Findings

Topic	Quantitative Findings	Qualitative Findings	Level of agreement
Safety	**(QN1)** Thirteen incidents (in 5 participants) of adverse effects (all non-serious): • mild headache (2 to 3 on VAS) in two participants, one occasion each. • shoulder/neck pain (2 to 5.5 on VAS) in four participants on 11 occasions. Eight incidences consistent with effort and three occurrences of shoulder impingement No incidence of motion sickness, cardio-respiratory distress, epilepsy, falls or near-falls	A theme of **safety** of the PST system was supported by subthemes of: **(QL1)** A **"good pain**" *"There can be an ache afterwards, but, yeah, a good ache"* (Clara, 54, moderately -severe disability) **(QL2) Mental fatigue** "Focusing for that amount of time could be quite draining" (Dora, 60, moderate disability)	Agreement
Ability to use the PST device	**(QN2)** Twelve participants aged between 48-68 years (mean [SD] 58 [7.1] years) with stroke chronicity between 12 and 304 months (median [IQR] 42 [34.75] months) were able to use both activities on the PST system after personalisation. Mean (SD) time using the PST system = 276 (64.3) minutes, range 175 to 336 minutes (target 360 minutes).	A theme of **ease of use** was supported by subthemes of: **(QL3)** The PST system was **intuitive to use** *"I got what I needed to do straight away."* (Ada, 66, moderately severe disability) **(QL4)** The **necessity of a hands-free system** "*With this hand? (indicates hemiplegic hand). No, not possible to hold."* (Betty, 67, moderately-severe disability) **(QL5) Personalisation** of activities *"I think it's a good design that could cover all people as you could crank it up and down depending on how bad the stroke is."* (David, 63, slight disability)	Agreement
Barriers to use		A theme of **barriers** to use was supported by subthemes of: **(QL6)** A **lack of confidence with technology**	Silence in quantitative data

		"I think I would err on the safe side and I would like somebody there with me the first few times to make sure I have really got it and for them to say yes, that's fine, then I'd have got the confidence because I'd hate to go in and break something …If you leave it to someone who doesn't know what they are doing, that could cause all sorts of problems…You want something you can just plug in and play". (Jenny, 49, moderate disability) **(QL7) Frustration with technology** *"It can be bloody frustrating when it (computer) suddenly decides to stop working and you've no idea why."* (Nancy, 65, moderately-severe disability) **(QL8) Difficulty attaching the movement sensors** Only two of 12 participants were able to attach and remove the movement sensors independently. (Fieldnote)	

8.2.3 Lack of Confidence with Technology is a Barrier to Use

Confidence with technology was not assessed quantitatively, however, themes of a lack of confidence and frustration with technology were recognised as potential barriers to use in the qualitative data (**QL6 & 7**, Table 8.1). These findings suggested the need for initial support and the need for technology which is simple to set up and use, to enable independent use.

8.3 Integrated Findings of Acceptability

Integrated findings of acceptability are presented in Table 8.2.

8.3.1 The PST System was Acceptable to Use

Overall, high levels of enjoyment when using the PST system were apparent in both quantitative and qualitative data, suggesting a high degree of acceptability of use (**QN4 & 5, QL9, 10 & 20** Table 8.2). A theme of the virtual therapist being like a "boring, repetitive lesson" was expressed by participants with more severe levels of disability (**QL11,** Table 8.2) and was supported by lower ratings of enjoyment in the quantitative data (**QN5** table 8.2). However, a highly prevalent theme of fun was associated with the apple-tree game by all participants (**QN4, QL10,** Table 8.2), and was related to a feeling of "time flying" (**QL9** Table 8.2). The concept of time flying is said to be positively correlated with enjoyment (Sackett et al., 2010), with time seeming to pass more rapidly with enjoyable activities (Iwamoto and Hoshiyama, 2011) and slower with less enjoyable ones (O'Brien et al., 2011). This distortion in the perception of time is associated with the concept of "flow", that is the "optimal experience" and high level of enjoyment that is said to occur when immersed in a goal directed task, which is both challenging yet perceived to be within an individual's ability (Csikszentmihalyi, 2002; Mao et al., 2016). High ratings of level of enjoyment (**QN4,** Table 8.2) and the theme of time flying (**QL9,** Table 8.2) suggests that participants achieved a state of flow when using the PST system, thereby helping address the issue of boredom experienced with traditional therapy (**QL11** Table 8.2, **QL33** Table 8.3) and suggesting the PST system has the ability to motivate and help deliver the intensity of practice necessary to drive change. While not assessed quantitatively, themes of the motivational effects of feedback (**QL16-17**, Table 8.2), acceptability of use in different settings (**QL18-20**, Table 8.2) provided further support to findings of acceptability of the PST system.

There was strong agreement between data sets that the virtual therapist was the more strenuous activity (**QN6 & 7, QL12 & 15,** Table 8.2). As flow is said to be greatest when level of effort and challenge matches ability (Abuhamdeh and Csikszentmihalyi, 2012; Pageau

and Surgan, 2015), the preference for the apple-tree game in those with more severe stroke and preference for the virtual therapist application with those with milder strokes (**QN4 & 5, QL15** Table 8.2) may therefore be related to the level of challenge experienced. This again highlights the necessity of personalisation of rehabilitation activities.

8.3.2 Feedback is Important for Motivation

In addition to the level of challenge (**QN6, QL12,** Table 8.2), the higher rating of enjoyment with the apple-tree game (**QN4,** Table 8.2) may relate to the game-like characteristics inherent in its design, as all participants discussed the motivational effects from having a score to beat and a star reward system to improve upon (**QL16,** Table 8.2). Moreover, a need for increased feedback to maintain motivation was identified (**QL17,** Table 8.2) and this may have contributed to the lower rating of enjoyment for the virtual teacher application. The need for increased feedback with regard to how to improve (so called knowledge of performance) was also noted (**QL16,** Table 8.2). As intrinsic (internal) feedback mechanisms may be damaged following stroke, there is a greater reliance on feedback from an external source (so called, extrinsic feedback) (Van Vilet and Wolf, 2006). The preference for the apple-tree game observed in participants with more severe strokes may therefore be linked to the greater amount of extrinsic feedback provided by the apple-catching game, while those with milder strokes were potentially more capable of using intrinsic feedback to identify and correct their own mistakes (Cirstea and Levin, 2007; Winstein, 1991).

8.3.3 Telerehabilitation: Additional Support or Big Brother?

When asked directly about the concept of using VR gaming technologies as part of telerehabilitation, a strong theme of acceptance was apparent in the qualitative data with all participants stating they would want to use such a device (**QL22,** Table 8.2). The ability of the therapist to monitor exercise was strongly associated with increased exercise adherence (**QL32,** Table 8.3) and was viewed as an opportunity to receive feedback on performance and a feeling of support, which have been identified as critical in rehabilitation (Barker and Brauer, 2005). However, as well as a lack of confidence with technology (**QL6,** Table 8.1) two participants expressed a mild concern that others may be worried by the intrusive, “Big Brother” nature of telerehabilitation, suggesting issues of acceptability with some (**QL22,** Table 8.2).

Table 8.2. Integrated Acceptability Findings

Topic	Quantitative Findings	Qualitative Findings	Level of agreement
Enjoyment	Mean (SD) ratings of enjoyment when using the PST system: **(QN4)** Apple tree game: 8.1 (1.5) **(QN5)** Virtual therapist application: 6.8 (2.3),	A theme of **fun** while using the PST system was underpinned by subthemes of: **(QL9) Time flying** "*I thought the whole hour was like 'oh God no, I have to go home now'. It flew by, it really did."* (Lizzie, 53, moderate disability) **(QL10) Apple tree game: fun** *"I really enjoyed scrumping again."* (Joe, 64, mild disability) **(QL11) Virtual therapist: boring** *"The difference between the two are the game was fun the other one wasn't!"* (George, 48, moderate disability)	Agreement
Level of effort	Mean (SD) rating of exertion on the BORG Scale of Perceived Exertion. **(QN6)** Apple tree game: 11.6 (1.3) equating to a descriptor of "fairly light". **(QN7)** Virtual therapist application: 12.9 (1.5), equating to a descriptor of "somewhat hard".	**(QL12)** Both activities were associated with **effort** *"Neither was easy to be honest."* (Jenny, 49, moderate disability) *"(The apple-tree game) was easier than the teacher one, but you still had to work at it, especially if YOU (the lead researcher) were placing the apples"* (Dora, 60, moderate disability) **(QL13)** The need for further **personalisation.** Suggestions for increased speed of falling apples was as subtheme in those with mild stroke but speed was felt to be at right level for those with moderately severe stroke "*They needed a stiff breeze to liven them up!*" (David, 63, slight disability) "*For me it was good"* (Betty, 67, moderately-severe disability) **(QL14) Difference in level of difficulty** prescribed between researchers "*No offence but you (the lead researcher) were queen of the mean! You always made sure that at least one apple was placed just beyond my reach*	Partial agreement

		while (the research assistance) was much kinder! Then I managed to be the top scrumper!" (Esther, 49, slight disability).	
Preference for activity type		**(QL15)** A **preference** for the virtual therapist application in those with milder strokes and the apple tree game in those with moderate and moderately severe stroke. *"I would give it (the virtual teacher) eight out of ten. The fun bit was getting your arm exactly like their arm was."* (Esther, 49, slight disability) *"I'd go for the apple one, no question!"* (Ada, 66, moderately severe disability)	Silence in quantitative data
Feedback		A theme of **motivation through feedback** was supported by subthemes of: **(QL16)** The **apple-tree game as a good source of feedback** *"I felt the apple one was giving me lots of encouragement. When it called you 'world class' or 'legend' you thought oh yes, I've cracked this! (The score) was important. Very important…I could have done with a hint or two. You know 'lift this, move that' what you needed to do to be world class!"* (Nancy, 65, moderately-severe disability) **(QL17)** The **need for increased feedback with the virtual therapist** application *"You'd be more involved in the game if you could see how much you were getting better"* (George, 48, moderate disability)	Silence in quantitative data
Acceptance of PST system in different settings		A theme of **acceptability of use in different settings** was underpinned by subthemes of: **(QL18)** promoting socialisation **on-line** "*It would be good for someone like me, as speaking to someone new in person is difficult."* (Lizzie, 53, moderate disability) **(QL19)** promoting socialisation with family at **home** *"Maybe I could do it with my Grandchildren, show them I'm not a complete fossil!"* (Nancy, 65, moderately severe disability)	Silence in quantitative data

		(QL20) Wanting to use in **home and clinical settings** *"I would have used it every day, maybe more."* (Ada, 66, moderately severe disability) **(QL21)** However**, concerns about the level of competition** were voiced *"Of course for that to work you'd have to be able to handicap the other person, level the field."* (Dora, 60, moderate disability) **(QL22) Telerehabilitation:** A source of **Virtual physio or Big Brother**? *"Some people might look on it with a sort of 'Big Brother' attitude, like I'm being watched. But on the other hand, some people might sort of go, they are obviously taking an interest in what I'm doing and they are just sort of encouraging me, geeing me up a bit, you know, so there are pros and cons in both directions. Personally, I would say, yes, bring it on!"* (David, 63, slight disability)	
Need for increased therapy		A theme of **not enough therapy,** was supported by subthemes of**:** **(QL23)** "**the pressure of too many patients**". *"I felt sorry for (the therapists). They worked so hard but some days it was too many of us, not enough of them".* (Lizzie, 53, moderate disability) **(QL24)** "**A focus on legs**" *"I said 'look' and showed them my arm. And they said 'leg not arm'. I had no arm therapy".* (Clara, 54, moderately-severe disability) **(QL25) Wasted time in rehabilitation** *"On the plus side, I read a lot of books!" (*Esther, 49, slight disability) **(QL26)** Being **"abandoned" on discharge** home. *"Unfortunately there's not much once you get home. A couple of visits and then you're kicked out to get on with it".* (Jenny, 49, moderate disability)	Silence in quantitative data

8.4 Integrated Findings of Efficacy

Integrated findings related to efficacy are presented in Table 8.3.

8.4.1 Efficacy Findings

No participant achieved the targeted intervention time (**QN2,** Table 8.1). Nonetheless, there were indications of PST system efficacy for upper-limb rehabilitation in this cohort of stroke survivors (**QN8-10, QL27, 28 & 30,** Table 8.3). There was evidence of improvement in all measures of impairment, activity and participation between T1 to T2 (**QN8-10,** Table 8.3) (p value < 0.05 for all) and clinically important changes in impairment and activity between T1 and T2 (**QN8-9,** Table 8.3). These findings were supported by prevalent subthemes of improvements in (physical and psychological) impairment and activity generated from qualitative data (**QL27, 28 & 30,** Table 8.3).

Interestingly, while there was evidence from quantitative data that improvements were maintained at the impairment level between T1 to T3 (p=0.033) (**QN8,** Table 8.3), there was no evidence that improvements were maintained in measures of activity and participation (**QN9 & 10,** Table 8.3). These findings suggest that the dosage of therapy may be insufficient to sustain changes in activity and participation and support findings by Teixeira-Salmela et al. (2014) who noted improvements in activity and participation required higher doses of intervention compared to improvements at an impairment level.

Increased participation in society following PST system use was not a theme in the qualitative data. However, the ability to play against someone on-line (expressed by participants with impaired communication) (**QL18,** Table 8.2) and the motivational aspects of playing against family members (**QL19,** Table 8.2**)**, suggested VR gaming technologies could potentially promote socialisation. However, as concerns about the level of competition were raised (**QL21,** Table 8.2**)**, such programmes would potentially need to incorporate an equalizing feature system to ensure equity between players.

8.4.2 Possible Mechanisms in Recovery

Qualitative data suggested possible mechanisms of recovery namely the ability of the PST system to deliver intensity of practice **(QN4- 5, QL9, 12 & 19,** Table 8.2**)**, to address learnt non-use (**QL28,** Table 8.3) and activate mirror-neurones (**QL31,** Table 8.3).
Themes of enjoyment (**QN4-5, QL9-10,** Table 8.2) and motivation to exercise (**QL16,** Table 8.2 & **QL30,** Table 8.3) associated with the PST system, suggested the potential of such gaming technologies to be used as instruments to address barriers to rehabilitation identified

when participants discussed their previous experience of rehabilitation. These barriers included resource issues of “too many patients” (**QL23,** Table 8.2), a “focus on legs” and walking at the expense of the upper limb (**QL24,** Table 8.2), “wasted time in rehabilitation” (**QL25,** Table 8.2) boredom and therefore poor adherence with traditional exercise (**QL32-33 & 35,** Table 8.3), the prescription of exercises that were too difficult (**QL34** Table 8.3) and a feeling of being abandoned on discharge (**QL26,** Table 8.2). Neuroplastic change is unlikely to have occurred with the intervention dose provided in the present study (Veerbeek et al., 2014; Teixera-Salmela et al., 2014). Although the system was non-immersive in nature (confirmed by low ratings of immersion on the IPQ and relative silence in the qualitative data) (**QN11, QL31,** Table 8.3**)**, nonetheless, the possibility of mirror neurone activation cannot be ruled out as observation of movements combined with physical practice has been associated with improved physical performance (Ertelt et al., 2007; Jang et al., 2005; Parker et al., 2011). It is probable that physical improvements noted in both sets of data (**QN8-10, QL27-30,** Table 8.3), were due to increased motivation to try and use the affected limb and spontaneous functional use (**QL28,** Table 8.3). In addition, the psychological effects of renewed optimism in upper-limb recovery as a result of the study intervention (**QL30,** Table 8.3) suggested increased motivation to try and use the arm in functional tasks. Finally, although not a theme in the data, improvements seen may be related to greater use of compensatory strategies.

Integrated findings related to the efficacy of PST system use for upper-limb rehabilitation post stroke are presented in Table 8.3.

Table 8.3: Integrated Efficacy Findings

Topic	Quantitative Findings	Qualitative Findings	Level of agreement
Change in upper limb impairment	**(QN8)** Group change in FMA-UE T1-T2: Statistically significant improvement in impairment (p=0.005) Clinically significant improvement (median 6, IQR 8) T1 to T3: statistically significant improvement (p= 0.033)	**(QL27) Improvements in impairments** "You know it's (the arm) been a bit jerky before but now it's smoothed out quite a bit." (David, 63, slight disability)	Agreement
Change in upper limb activity	**(QN9)** Group changes in ABILHAND, ARAT and MAL-28 scores T1-T2: Statistically significant improvement on the ABILHAND (p= 0.005) ARAT (p=0.028) and the MAL-28 (p=0.006) T1 to T3: Non–significant improvement on the ABILHAND (p=0.107) the ARAT (p=0.347) and MAL-28 (p=0.207)	**(QL28) Increased UL functional use** *"My partner has noticed me using my arm more spontaneously, opening doors, unwrapping things. Things like that…I feel this has awakened my brain to the hand."* (Esther, 49, slight disability).	Agreement
Change in participation	**(QN10)** Group changes SIPSO score T1-T2: Statistically significant improvements in participation on and SIPSO (p= 0.004) T1-T3: non-significant improvement in score on the SIPSO (p=0.102).		Silence in qualitative data

Effectiveness of the activities		**(QL29)** Virtual therapist application was considered the most effective activity *"The robot (the virtual therapist) is more effective. Better exercise with the robot. More effective because I do more things like this and this (demonstrates different arm movements), so it's better exercise with the robot."* (Betty 67, moderately-severe disability)	Silence in quantitative data
Psychological effects		**(QL30)** The PST system as a **source of optimism** *"Because everything with a stroke is long winded…this is the first thing that has given me hope, sort of like the light at the end of the tunnel"* (Jenny, 49, moderate disability)	Silence in quantitative data
Sense of immersion while using the PST device.	**(QN11)** Mean (SD) score on iGroup Presence Questionnaire 32.5 (21.5) out of 85 (with a higher score indicating greater sense of immersion).	**(QL31)** Sense of immersion was low *"The (virtual physio) made me feel my arm but not my shoulder blade as I could see my arm but not my shoulder blade"* (Lizzie, 53, moderate disability)	Agreement
Adherence to out of session exercise programmes		A theme of **poor adherence** with traditional out of session exercises was underpinned by subthemes of: **(QL32)** I**ncreased exercise adherence with telerehabilitation** *"But if they can actually physically check, you are going to HAVE to do them."* (Nancy, 65, moderately-severe disability) **(QL33) "Boredom"** with traditional exercises "*I was quite a motivated kind of chap, give most things a good go, but it was all quite repetitive and boring to be honest so it doesn't take long before you start shirking off*". (Joe, 64, mild disability) **(QL34)** The prescription of exercises that were "**too difficult**". *"Some of (the exercises) were useful, but some were just impossible, so I never did them at home"* (Dora, 60, moderate disability) **(QL35)** Not being "**bothered" to exercise when alone** *"When I was in hospital, after I did a work-out I felt like I had achieved something and wanted to continue. To be honest with you, once I was on my own, I didn't do them"* (Jenny, 49, moderate disability)	Silence in quantitative data

8.5 Integrated Findings of the Feasibility and Acceptability of the Study Protocol

Integrated findings related to the feasibility and acceptability of the study protocol are presented in Table 8.4.

8.5.1 Lack of Fidelity to the Study Protocol

Recruitment techniques appeared adequate (**QN15,** Table 8.4) and use of pre-paid taxis facilitated inclusion (**QL41**, Table 8.4). However, the failure for any participant to achieve the targeted intervention time (**QN13 & 14,** Table 8.4) caused predominantly by transport delays and fatigue (**QL39 & 40,** Table 8.4**)**, suggests limited feasibility of the study protocol.

8.5.2 The Study Burden was Acceptable

The study burden was considered acceptable (**QL37**, Table 8.4) and was supported by a theme of enjoyment in study participation (**QL36,** Table 8.4) and low attrition levels (**QN12,** Table 8.4). Theoretical acceptability of study protocols with greater time commitments was apparent in those with more severe strokes and appeared to be related to greater social isolation and lack of occupation in those with greater stroke severity (**QL38,** Table 8.4).

Table 8.4: Integrated Findings of the Feasibility and Acceptability of the Research Protocol

Topic	Quantitative Findings	Qualitative Findings	Level of agreement
Study attrition	**(QN12)** Eleven of 12 participants completed baseline assessment (T1), intervention and reassessment and semi-structured interview at (T2) Ten of 12 participants completed all assessment phases at T1, T2 and T3 One participant withdrew during the intervention stage due to injury unrelated to study. One participant withdrew after reassessment (T2) due to medical intervention unrelated to the study.	**(QL36)** Theme of **enjoyment in study participation** *"I'm going to miss coming here."* (Nancy, 65, moderately-severe disability)	Agreement
Study attendance requirements	**(QN13)** Seven of 11 participants (64%) who completed the intervention phase attended all 9 intervention sessions. (mean (SD) of 8.4 (1), range 6-9)	**(QL37)** Theme of **acceptability of study burden**. "I think it was about the right time ... No, three times wasn't too much." (Lizzie, 53, moderate disability) **(QL38) Acceptance of studies with more intensive protocols was dependent on stroke severity** *"I can be here every day. Well it depends on hospital appointments, but apart from that I can be here every day for three hours, four hours…it doesn't matter. I would do it anytime, all day and every day!"* (Ada, 66, moderately-severe disability) *"Five times, might have been stretching it a little bit yes."* (David, 63, slight disability) **(QL39) Reasons for non-attendance**: Illness (one participant on two occasions), fatigue (one participant on three occasions) the need for further medical intervention (one participant on one occasion) and closure of	Partial agreement

		the laboratory due to flooding (one participant on one occasion) limited attendance for four participants (Fieldnotes)	
Intervention time	**(QN14)** Mean (SD) intervention time was 276 minutes (64.3), range 175-336 minutes.	**(QL40) Reasons for decreased intervention time** included: Transport delays, fatigue, mild shoulder/neck pain, missed sessions, mild cognitive issues resulting in increased processing time and decreased intervention and in two participant's reasons were unclear (Field notes).	Agreement
Recruitment	**(QN15)** Thirty-two stroke survivors volunteered to participate in study. Twenty volunteers were excluded (11 did not meet physical requirements, two did not meet communication requirements (and seven were unable to meet attendance requirements)	**(QL41) Provision of transport is necessary for study participation**. *"Well because you supply taxis I'm ok with (attendance requirements). I would be concerned if I had to rely on my Dad, having to ask him to take me and that would be a bit much for him."* (Jenny, 49, moderate disability) **(QL42)** All participants travelled to the university site by car. Nine participants required taxis, one was driven by their spouse and two drove themselves (Fieldnotes)	Agreement

8.6 Summary

In summary, results from a mixed-methods study found high levels of acceptability and feasibility of use of a novel VR gaming system, using adapted commercial gaming technology as a method to deliver upper-limb rehabilitation in a group of community dwelling stroke survivors including those with severe upper-limb impairment. In addition, findings suggested efficacy of the system with participants with different levels of impairment, including those with more severe deficits as a result of stroke. Finally, the study protocol was shown to be acceptable, however, issues in delivering the targeted intervention-time were apparent.

A discussion of key findings, study strengths, limitations and suggestions for future research are presented in the next chapter.

Chapter 9: Discussion

9.1 Introduction

This thesis detailed the design, development and mixed-methods evaluation of a VR gaming technology for upper-limb stroke rehabilitation, and in doing so, addressed primary research aims regarding the feasibility and service-user acceptability of such a system. The MRC Framework for Complex Interventions (Craig et al., 2008) provided the theoretical structure for this thesis. The development stage of the framework was addressed by the literature review and study phase one. Together findings demonstrated the need for a low-cost, hands-free, VR gaming technology for upper-limb stroke rehabilitation with the ability to be personalised to allow use by those with a wide range of impairment. The personalised stroke therapy (PST) system was subsequently co-designed and developed with iterative input from stroke survivors, neurotherapists and engineers. The feasibility / piloting phase of the MRC framework was addressed using a mixed-methods study (study phase two) and examined the feasibility and acceptability of the PST system, alongside preliminary system efficacy. Overall, results demonstrated the feasibility and acceptability of the PST system for upper-limb stroke rehabilitation in a group of community dwelling stroke survivors with mild to severe levels of upper-limb impairment. Furthermore, while not designed to assess effectiveness, study findings provided an indication of possible system efficacy.

In this chapter, key findings are discussed within the context of the published literature. Strengths and limitations of the overall study are then considered, and followed by recommendations for future practice, education and research.

9.2 Consensus for Descriptors of Stroke Severity Needed

Determining the efficacy of stroke interventions is complicated by a lack of consensus in the classification of upper-limb stroke severity. Terms such as mild, moderate and severe stroke are frequently employed in the literature to describe study participants. While ostensibly useful descriptors, few studies define what these terms mean or clarify the cut-off scores for these categories, leading to difficulty evaluating findings. For example, the systematic review by Laver et al. (2017) provides analysis of outcome by stroke severity, dividing participants into mild to moderate, or moderate to severe categories but provide no indication as to how this was established (in the paper or in a follow-up direct request). Subramanian et al. (2013) using two categories, classify mild stroke as a score above 49 out of 66 on the FMA-UE and anything below this figure as moderate to severe. Hoornhorst et al. (2015) describe five

FMA-UE categories where a score of 53 or above equates to a descriptor of full capacity, 52 - 48 as notable capacity, 47 - 32 as limited capacity, 31 - 23 as poor capacity and a score below this as no capacity. While Woodbury et al. (2013) employ three categories with the moderate category from 19 - 47 (+/-2). However, as Woodbury et al. (2013) excluded reflex components of the assessment, the total available score of only 60 points results in difficulty using these cut-off scores when interpreting studies which employ the full (66-point) version of the FMA-UE. Others have used descriptors at odds with the apparent ability of participants. For example, Slijper et al. (2014) describe severe upper-limb impairment in participants who all had to be able to hold the movement sensor, suggesting that the degree of severity was in fact mild.

This lack of agreement makes interpreting findings from studies based on descriptors of stroke severity problematic. To address this, Kwakkel et al. (2017) recommend the use of the National Institute of Health Stroke Scale (NIHSS) to determine baseline stroke severity. However, this is not upper-limb specific, and it is therefore recommended that along-side the NIHSS, authors report upper-limb stroke severity using a recognised measure of impairment, clearly state the baseline characteristics of their cohorts and define on what basis they categorise participants.

9.3 Stroke Survivors with Severe Levels of Upper-Limb Impairment Can Successfully Engage with VR Gaming Technologies

Findings from this study (Section 8.2.2) established that stroke survivors with severe upper-limb deficits were able to use the PST system without external support (with upper-limb severity being defined in line with Hoornhorst et al. [2015] as those scoring 22 or less on the FMA-UE). This is important because while those with mild to moderate upper-limb deficits have other rehabilitation options available to them, such as simple recreational activities and traditional therapy exercises, the options for those with more severe levels of impairment are considerably more limited.

The evaluation of VR gaming technologies in the present study added to the limited evidence-base for those with more severe levels of upper-limb impairment. While the systematic review by Laver et al. (2017) provided analysis of outcome by stroke severity, the cut off values for judging severity was not stated and therefore the effectiveness of VR gaming technologies in those with severe levels of upper-limb impairment was hard to ascertain. Additionally, inclusion criteria meant that studies using additional support (from a therapist, robot or an exoskeleton) were included in the review, thereby limiting clinical

feasibility and comparison to the present study which employed a VR gaming technology alone. Furthermore, as the aim of the review by Laver et al. (2017) was evaluation of device efficacy, issues of feasibility were not considered.

Of the 57 research studies included in the literature review within this thesis, only eleven included any participants with severe upper-limb deficits, as defined by FMA-UE scores of 22 or less suggested by Hoornhorst et al. (2015) (Adams et al., 2018; Choi et al., 2016; Givon et al., 2016; House et al., 2015 & 2016; Jordan et al., 2014; Kong et al., 2016; McNulty et al., 2013; Rinne et al., 2016; Seo et al., 2016; Slijper et al., 2014; Wittman et al., 2015). Although precise numbers of those with severe deficits were not reported, central tendency descriptors of upper-limb deficits in five of these studies (Choi et al., 2016; Givon et al., 2016; Seo et al., 2016; Slijper et al., 2014; Wittman et al., 2015) and graphical information in a sixth, (Jordan et al., 2014), indicated that few participants exhibited severe levels of upper-limb impairment. Evaluation by those with more severe deficits may therefore have been lost in group effects.

Participants in a study using a modified version of commercial VR gaming technologies by Adams et al (2018) and in a study using purpose-built technology by House et al (2015 & 2016) presented with more severe upper-limb deficits (with respective mean [SD] FMA-UE scores of 22 [6.3] and 15.6 [11.1]). While participants appeared able to use the hands-free system employed by Adams et al (2018), no indication of study exclusion rates, occurrence of adverse effects or formal assessment of feasibility was provided. Moreover, at a cost of around £10,000 pounds (personal communication from company representative February 2018) the feasibility for home use is questionable. Ratings of feasibility provided by House et al. (2015 & 2016) suggested participants with more severe upper-limb impairments were able to successfully use this system. However, this system required the use of a large table requiring on-site construction, thereby limiting feasibility of use in the community and many clinical environments.

In the present study, Velcro straps to secure movement sensors enabled game play by those unable to hold the controllers (Section 8.2.2). However, these sensors were relatively large, and few participants were able to secure them independently suggesting the need for further technological development to enable independent use. Study findings of the necessity of hands-free movement detection systems were supported by Rinne et al. (2016) who found that stroke survivors exhibiting severe levels of upper-limb impairment were unable to use any conventional hands-free movement detection system employed in their study. Moreover, Wingham et al. (2015) noted that even those with mild deficits experience

difficulty holding, moving and manipulating hand-held movement sensors again endorsing the need for hands-free systems.

The use of low-cost camera-based systems to track movements (such as the Microsoft Kinect) have become more common in the literature and negate the difficulties associated with the attachment of movement sensors. However, the cameras suffer from occlusion errors and are unable to accurately track movement if the body area being tracked is effectively hidden by proximity to nearby objects (such as furniture or a walking aid) or a superimposed body part (Demers et al., 2017; Ellington et al., 2015; Rand et al., 2015 & 2017; Sin and Lee, 2013). For example, if the exercise involves shoulder flexion with an extended elbow, and while attempting the movement the participant internally rotates the arm and / or flexes the elbow (typical movement synergies following stroke), the Kinect camera will be unable to differentiate between the trunk, upper and lower arms. As the Kinect has been developed with movement patterns derived from the neurologically intact, it presents an image of the participant performing the movement in a 'normal' manner. Such feedback may hinder recovery through the provision of incorrect knowledge of results. Therefore uptake of such systems into clinical practice for those with abnormal movement patterns and postures, or for those reliant on physical assistance (such as a walking aid or chair), is likely to be limited.

Interestingly, Microsoft launched the Xbox Adaptive Controller in September 2018, which has been designed to enable game play for those with a variety of neurological conditions including those with stroke, through the ability to connect external devices such as buttons, switches and joysticks. The price of around £75 makes this an attractive proposition. However, as it is designed for use with games developed for the able-bodied it is unlikely that such games have the ability to provide the necessary feedback as to how to improve. Additionally, it is unclear whether the controller and games promote therapeutic arm and hand movements, or simply enable game play through use of compensatory strategies.

In the present study, the ability to use VR gaming technologies by participants with severe upper-limb deficits may be explained by the ability to personalise activities to the level of the individual. In contrast with these findings of feasibility, McNulty et al. (2013) noted an inability to use several off-the-shelf Wii games by the majority of participants in their study. As participants in the study by McNulty et al. (2013) exhibited mean (SD) FMA-UE score of 17.2 (4.1) (although inclusion criteria of being able to hold the Wii movement sensors contradicted the stated severity) results suggest the need for purpose-built activities for upper-limb stroke rehabilitation for those with severe deficits. Similarly, Kong et al. (2016)

included participants with severe upper-limb impairment (mean [SD] FMA-UE score of 14.6 [12.6]) in their study using off-the-shelf technology. However, therapists assisted limb movements in cases where participants lacked the ability to interact with the games independently and therefore the feasibility of off-the-shelf VR gaming technologies for those with severe upper-limb deficits is questionable.

9.4 Personalisation of VR Gaming Technologies is Necessary for Upper-Limb Stroke Rehabilitation

The ability to individually calibrate activities ensured that those with minimal active movement were able to use the system (Sections 7.5.1 and 8.2.2). As a result, just 19% of study volunteers (six of thirty-two) were excluded on the basis of upper-limb impairment. This compares favourably with studies examining non-personalised VR gaming technologies for the shoulder, elbow and forearm, where study exclusion rates (in studies not allowing external assistance to move the limbs) ranged from 56% (Da Silva Ribeiro et al., 2015) to 96% (Adie et al., 2017).

Shoulder pain as a result of soft tissue impingement was noted by two participants while using the PST system (Section 8.2.1). As shoulder pain post-stroke hinders rehabilitation, negatively impacts performance of ADLs and quality of life (Lindgren et al., 2007), the occurrence of shoulder pain was an important concern. The ability to adjust the range of movement resulted in pain-free game-play and continued ability to exercise using the PST system, confirming the need for personalisation of VR systems for rehabilitation purposes.

The use of researchers to subjectively set game-play features (such as the range of movement required to complete activities), and the inability to adjust speed of the falling apples in the apple-tree game, resulted in a disparity in the level of challenge experienced by some participants (Section 8.2.2). This suggests that greater personalisation is necessary. This is in keeping with findings by Hung et al. (2016), Pallensen et al. (2018), Vanbellingen et al. (2017) and Wingham et al. (2015) who identified the need for greater levels of challenge in participants with mild and moderate stroke severity and noted frustration when activities were felt to be too difficult. To ensure optimal practice conditions and use by stroke survivors with differing levels of ability, it is recommended that future studies should employ gaming technologies with the ability to adjust speed, duration of play, range of movement, task complexity and task type, dependent on individual need. Additionally, the ability to personalise feedback is recommended.

The PST system provided greater and more appropriate feedback than off-the-shelf VR gaming systems, and in doing so addressed reported issues of insufficient, inaccurate and demoralising feedback noted in the literature (Demers et al., 2017; Hung et al., 2016; Seo et al., 2016) and in preliminary stages of the PST system development (Sections 1.4.3; 4.3.2 and 4.3.3). However, study findings suggest that while the provision of a score and affirming message were highly rated and considered a source of motivation, further feedback regarding how to improve was required (Section 7.4.2). This is in keeping with findings by Wang et al. (2017) who noted a lack of feedback regarding provision of knowledge of performance in most VR gaming systems. Moreover, when such feedback was provided, it was often in the form of kinematic measures such as position, time and velocity patterns, with questionable value to the stroke survivor (Simpson and Eng, 2013). Technological advances are likely to result in more accurate assessment of movement and provision of more detailed and personalised feedback which will help address these issues and decrease reliance on therapists. While gradually reducing the amount of feedback (so called 'faded feedback') has been advocated to avoid over-dependence on external sources (Winstein,1999), findings by Subramanian et al. (2010) suggest that lesion location may inhibit the ability to use internal feedback mechanisms. Therefore, the ability to adjust the amount, timing and type of feedback is recommended in future systems, with therapist input to ensure the development of more pertinent feedback dependent on service-user's individual needs.

Additionally, Demain et al. (2013) suggest incorporating haptic feedback to provide information regarding physical properties of VR objects (such as weight, size, shape, temperature and texture) and information regarding the physical properties of movement within a VR environment (such as forces resisting or perturbing movement). Such tactile and kinaesthetic feedback is thought to provide greater integration of sensorimotor information and in doing so, optimise function and enhance motor recovery (Bolognini et al., 2016). However, the requirement for accurate feedback to avoid 'sensory conflict' (Demain et al., 2013. P 415) needs to be balanced with the need for lightweight and discreet movement detection systems to avoid alteration in movement strategies employed to achieve a task (Demain et al., 2013; Levin et al., 2015). Moreover, such technological advances need to be low-cost to facilitate uptake into clinical practice (Demain et al., 2013).

9.5. The Potential Role of VR Gaming Technologies in Self-Management

Study findings confirmed reports (Royal College of Physicians, 2016; Stroke Association, 2015) of a lack of upper-limb therapy both in hospital and on discharge (Section 7.3.1). This

suggests the need for greater self-management, the importance of which has become increasingly recognised and prioritised for research (James Lind Alliance, 2011; NICE, 2007; Rankin et al., 2012). However, in keeping with the published literature (Jurkiewicz et al., 2011; Peek et al., 2016; WHO, 2003), poor adherence to out-of-session therapy programmes was noted in this study when participants discussed their previous experience of rehabilitation (Section 7.3.2). Five factors have been identified as affecting adherence including socioeconomic, health-care system, condition, intervention and personal factors (WHO, 2003). In recognition of the multiple components affecting adherence, it follows that no single behaviour change method can be applied universally (NICE, 2007). In spite of this, features potentially offered by VR gaming technologies, including the provision of positive feedback (Peek et al., 2016), ongoing monitoring (Peek et al., 2016; WHO 2003) and the ability to play with others (Jurkiewicz et al., 2011; Poltawski et al., 2015) have been associated with increased adherence and thereby, in agreement with findings by Demain et al., (2013), indicate a role for VR gaming technologies in self-management. However, the occurrence of shoulder pain and increased fatigue associated with PST system use (Section 8.2.1) suggests that careful monitoring and education of system users is required in order to avoid such adverse effects, particularly when such systems are used independently.

Findings from this study confirm that overall, VR gaming technologies are considered an acceptable activity for upper-limb stroke rehabilitation by service-users (Sections 4.3.1 and 8.3.1). This is in agreement with the published literature (Demers et al., 2017 & 2018; Pallenson et al., 2018; Paquin et al., 2015 & 2016; Wingham et al., 2015). Acceptability was linked to enjoyment experienced while exercising with the PST system (Sections 6.7 and 7.4.1), a belief in the effectiveness of the system (Section 7.4.3) and the ability to address issues of boredom frequently experienced with traditional exercises (Sections 7.3.2 and 7.4.3). As Langan et al. (2018) argue that the uptake and maintenance of a behaviour is reliant on perceived value and / or enjoyment, findings of enjoyment while using the PST system and a belief in its effectiveness suggest the ability to improve exercise adherence and promote self-management. Furthermore, as service-user and clinician involvement in system development has been recommended as way of improving acceptability of VR gaming technologies (Langan et al., 2018; Tatla et al., 2015) the use of service-users and therapists in the co-design of the VR gaming technologies in the present study (Chapter 4) may therefore aid exercise adherence.

While findings from acceptability studies suggest high levels of enjoyment while exercising using VR gaming technologies, participants in a study by Wingham et al. (2015) wanted to move on from using the Wii after a six-week trial. Long term adherence and enjoyment were

not explored in the present study. However, a decreased rating of enjoyment occurred alongside increased rating of ease of use in the development study (Section 4.5.1.7), indicating the lower scores over time noted by Wingham et al. (2015) may relate to a reduced challenge experienced over time. This again suggests the need for personalisation to ensure the level of challenge remains sufficient to facilitate 'flow' (that is high levels of enjoyment and perception of time flying, associated with an activity which is both challenging but perceived to be within one's ability) (Csikszentmihalyi, 2002). However, Hamilton et al. (2018) also note the possibility of the novelty of VR gaming technologies 'wearing off' suggesting the need for a library of activities and the need for studies exploring acceptability and adherence to VR gaming technologies in the long-term.

9.6 Training and Support is Required to Enable Uptake of Novel Treatments in to Clinical Practice

While familiarity and therefore confidence with technology is increasing (Taylor, 2015), findings from all study phases indicated that a lack of familiarity remained a barrier to uptake of VR gaming technologies by service-users and clinicians (Sections 4.3.3 and 7.5.3). These findings suggest that support is critical to enable independent use by service-users, particularly in the community where Standen et al. (2015 and 2017) noted a training time of between 50 to 540 minutes per participant and a median of 45 minutes (range 0-430 minutes) of additional technical support was required to support home-use of a VR gaming technology. Hamilton et al. (2018) note that level of engagement and therefore adherence is dependent on both the perceived benefit and the level of support offered. Taken together, literature and study findings indicate the necessity of careful training and on-going support to ensure successful implementation and uptake, particularly in home-based settings.

In addition to service-user concerns, a 'cultural resistance' to uptake of technology has been identified in healthcare workers (Taylor, 2015; Tatla et al., 2015). This has been related to a professional 'inertia', a lack of confidence, lack of training and lack of health care professional knowledge about suitable technologies (Demain et al., 2013; Hamilton et al., 2018; Hughes et al., 2014; Langan et al., 2018; Taylor, 2015; Tatla et al., 2015). This is confounded by a recognised lack of time, money and expertise to identify, obtain and appraise appropriate evidence (Oliver et al., 2014; Wolf et al., 2016).

While a lack of evidence has also been suggested as a barrier to uptake of novel treatments by therapists (Dannapfel et al., 2013), study findings (Section 4.3.3) provide evidence that VR gaming technologies are being incorporated into clinical practice regardless of the

evidence-base. In agreement with Hughes et al. (2014) this suggests that the evidence-base is not the primary factor influencing therapist practice. While the evidence-base regarding VR gaming technologies is not strong enough to support definitive recommendations, evidence of effectiveness as an adjunct to treatment is increasing (Laver et al., 2017). In agreement with Taylor (2015) and Wolf et al. (2016), study findings (Section 4.3.3) indicate the need for best practice clinical guidelines to inform the prescription of VR technologies in rehabilitation (including details of appropriate devices, activities and dose with regard to the condition, chronicity and severity of deficit). However, a recognised gap exists between research findings and uptake into clinical practice, suggesting the need for specific strategies and plans to aid implementation (Lynch et al., 2018). This has led some authors to advocate the use of knowledge transfer strategies to ensure uptake of appropriate interventions (Connell et al., 2016; Stander et al., 2018).

9.7 Efficacy of VR Gaming Technologies for Upper-Limb Recovery Post Stroke

While phase two was not designed as an efficacy study, improvements in measures of upper-limb impairment and activity were observed (Section 6.10), suggesting possible effectiveness of the PST system for participants with various levels of impairment including those with severe deficits. It was not possible for two out of the 11 participants to demonstrate clinically significant changes on objective outcome measures (FMA and ARAT) due to ceiling effects (where baseline measures were too close to the maximum possible score to show significant change). However, of the remaining nine, five demonstrated clinically significant changes on either or both objective measures and can therefore be considered as responders. Of the four who did not demonstrate clinically significant improvements on the FMA or ARAT, three were classified as having moderately severe disability on the mRS, and all four scored poorly on the MI (scoring 14/14 for shoulder and elbow). While this finding suggests that those with more severe deficits may not respond as well to the intervention, it should be noted that two of the responders also presented with MI scores of 14/14 for the shoulder and elbow, one of whom was also classified as having moderately severe disability on the mRS. The utility of VR gaming technologies for those with more severe levels of disability therefore cannot be ruled out and in agreement with recommendations by Levin et al. (2015), findings from this study support the need for further research involving those with more severe levels of impairment.

Activation of mirror neurones through action observation, neuroplastic change due to intensity of practice and increased use /reduction in learnt non-use have been suggested as possible mechanisms underpinning recovery when using VR (Adamovich et al., 2009; Demain et al., 2013; Ertelt et al., Jang et al., 2005; 2007; Veerbeek et al., 2014). The use of

a non-immersive system and low ratings of presence (Sections 6.9 and 8.4.2) meant that mirror neurone activation was less likely to be a factor underpinning improvements in the current study. Participants classified as responders received a higher intervention dose (mean [SD] of 312 [22.1] mins) compared to the non-responders (mean [SD] 233 [75.2] mins) (Section 6.5), thereby supporting the principle that greater gains occur with increased dose (Veerbeek et al., 2014). However, the intensity of intervention provided in this study is below the intensity likely to induce neuroplastic, restorative change (Veerbeek et al., 2014). It is therefore likely that improvements seen in measures of efficacy are a result of a change in behavioural strategies (specifically, reversal of learnt non-use phenomena) as participants in the present study were beyond the stage where spontaneous recovery is likely to occur (Kwakkel and Kollen, 2013). This theory that improvements seen were as a result of reversal of learnt non-use, is supported by qualitative findings (Sections 4.? and 7.4.3) of increased spontaneous use of the hemiplegic limb and reports of the PST system "reminding" participants to use their hemiplegic limbs in functional activities. However, in agreement with other authors (Bernhardt et al.,2017; Levin et al., 2009), further work examining the relative contributions of these factors is warranted.

Levin et al. (2009) argue for a clarity in terminology used to describe recovery and together with Alt Murphy et al. (2015) and Bernhardt et al. (2017) recommend the use of study designs and outcome measures (such as kinematic measures or brain imaging) capable of differentiating between mechanisms of recovery in order to ascertain at which level(s) VR gaming technologies may work. However, Cirstea and Levin (2007) note that for service-users, functional improvement is the main concern, regardless of mechanism.

The proportional recovery rule (discussed in Section 1.2.2.2), suggests that recovery is poor for most people with more severe levels of initial impairment (Rondina et al., 2017). Kwakkel and Kollen (2013) therefore argue that as the degree of recovery can be predicted within the first few days following stroke that patients should be selected for therapy on the basis of such a prognosis. While this approach would undoubtedly reduce rehabilitation costs and benefit those with milder stroke severity, it should be noted that Kwakkel and Kollen (2013) in agreement with Rondina et al. (2017) also acknowledge that not all patients will follow this pattern and furthermore, that some patients with severe initial deficits will go on to make a good recovery. Moreover, studies by Rondina et al. (2017) and Kwakkel and Kollen (2013) did not consider the effect of ICF domains of personal and contextual factors (such as motivation or pre-morbid activity levels) in their analysis. Rondina et al. (2017) argue that in future it may be possible to better predict outcome based on biomarkers. However, in the

absence of such evidence, and in light of indications of upper-limb recovery even in those with severe deficits, this author argues that rationing of therapy based on initial presentation, runs the risk of being a self-fulfilling prophecy whereby those with poorer prognosis fail to receive rehabilitation and therefore fail to improve.

9.8 Study Strengths and Limitations

9.8.1 Study Strengths

The multi-disciplinary nature of the development team (including stroke survivors with differing degrees of upper-limb impairment, engineers and neuro physiotherapists) was a key study strength. Some authors have voiced concerns regarding tensions caused by the potential mismatch between service-user expectation and realistic possibilities and the additional time and budgetary requirements necessary to involve service-users (Cossar and Neil, 2015). However, the inclusion of service-users at a partnership level in the development stage of this study ensured PST system feasibility and the inclusion of features likely to result in greater engagement.

A further study strength was the inclusion of stroke survivors with communication and mild cognitive impairments. While this increased the study burden (with more time being required to communicate) and resulted in greater participant fatigue and therefore a reduced presence in the qualitative data, recruitment of such participants is recommended as being more representative of the stroke population. Moreover, their inclusion provided additional insights into the way technology can be useful. While separation of post intervention assessments and interviews may have reduced fatigue and facilitated data collection, this option must be weighed up against the additional costs and study burden associated with the requirement for an extra study visit.

The use of a mixed-methods study design in study phase two provided greater insight than the use of single methods or the use of multiple methods without integration. For example, agreement between qualitative and quantitative data sets increased the credibility of findings of enjoyment and acceptability of VR gaming technologies for rehabilitation (Section 8.3.1). Qualitative findings of intensity of exercise, the ability to address learnt non-use and possible mirror-neurone activation through PST system use, suggested possible mechanisms behind improvements noted in quantitative results (Section 8.4). Quantitative findings of PST system feasibility were explained by qualitative findings of the need for a hands-free, personalisable system (Section 8.2.2). High retention rates of study participants were explained by qualitative findings of an “empty diary” and the provision of pre-paid transport

(Section 8.5.2). In addition, qualitative findings of a “good pain” while exercising suggested that pain (noted in quantitative findings) can be related to an effortful work-out and should therefore not always be viewed as an adverse effect (Section 8.2.1). While not a feature in this study, disparity between datasets can suggest areas for further study.

Moreover, the use of a mixed-methods design in study phase two adds to the evidence base which is dominated by quantitative approaches to acceptability, feasibility and efficacy. Five studies included in the literature review employed both quantitative and qualitative analysis of VR gaming technologies for upper-limb stroke rehabilitation (Adie et al., [2017] & Wingham et al., [2015]; Brunner et al., [2017] & Pallensen et al., [2018]; Demers et al., 2017 & 2018; Paquin et al., [2015 & 2016]; Standen et al., [2015 & 2017]). However, none of these studies integrated findings. Separate analysis and dissemination of findings from different types of data may facilitate publication (with some journals favouring a particular methodology) and can result in a greater number of publications (an important consideration for academic staff where publication may be used as a basis for allocation of public funds). Additionally, it should be noted that integrating studies can be a time consuming and challenging process. In spite of these difficulties, publication of mixed-methods studies are nonetheless recommended due to the greater insight provided.

The use of the TIDieR checklist to describe interventions (Hoffman et al., 2014) ensured completeness of intervention description. Additionally, a specific operations protocol improved study reliability and in addition the systematic recording and reporting of adverse effects including assessment of pain severity and mechanism (recommended by Kwakkel et al. [2017]) were further strengths. As no one outcome measure can capture the differing aspects of stroke (Ashford et al., 2008), the use of outcome measures evaluating change at different ICF levels provided a more rounded evaluation of the efficacy of the PST system. The use of the FMA-UE, ARAT and ABILHAND have been recommended for use as having the strongest level of utility (Alt Murphy et al., 2015; Kwakkel et al., 2017). However, Kwakkel et al. (2017) note the inability to differentiate between restitution and compensation and therefore also advocate for the use of kinematic measures (such as measures of velocity, acceleration and joint positions). While collection of kinematic information from the PST system was initially considered, loss of engineering support resulted in an inability to capture this data. As technological advances may result in the ability to record kinematic measures more readily, it is therefore recommended that future systems capitalise on any such ability.

9.8.2 Study Limitations

As with all studies, limitations were apparent and findings must therefore be interpreted within this context.

Use of an interviewer unknown to the participants was not possible within the confines of a time and funding-limited study and therefore the lead researcher (AW) undertook all interviews. The use of the lead researcher as interviewer may have precipitated more positive responses from study participants, all of whom were aware of the study purpose and role of the lead researcher. However, participants were reminded at the start of the interview of the importance of giving responses that truly reflected their experiences, (i.e. the good and the bad) to mitigate against this. While follow-up telephone conversations to clarify meaning were undertaken on two occasions during phase two, and additional questions asked to confirm meaning were made during interviews, widespread response validation was not undertaken due to resource issues and additional burden for study participants. The use of the lead researcher in coding of qualitative data and development of themes was a further methodological limitation and may be associated with inadvertent bias in development of themes. To help address possible biases, level of agreement with coding categories was ascertained through use of reflective field-notes and regular engagement with the supervisory team to enhance criticality and challenge assumptions was undertaken.

While those with severe levels of upper-limb impairment were able to successfully use the PST system, it was not feasible to use with all stroke-survivors. Eight study volunteers were excluded on physical grounds likely to preclude use of the system (three on the basis of pre-existing upper-limb pain, two because of photo sensitive epilepsy and three due to a lack of discernable movement against gravity in the shoulder and or elbow). While feasibility of using VR gaming technologies for rehabilitation is likely to be limited in those with upper-limb pain and photosensitive epilepsy, the exclusion of those with very severe upper-limb weakness suggests the need for VR gaming technologies incorporating additional assistance such as electrical stimulation and / or robotics to enable use by stroke survivors who lack discernable active movement.

While used in gross motor tasks (such as balance and walking), the most important functions of the upper limb (such as personal and domestic activities of daily living) involve a combination of gross movements (reaching) and fine movements (to grasp and manipulate objects) (Shumway-Cook and Woollacott, 2017). While reaching towards an object is predominantly a function of the arm (i.e. shoulder, elbow and forearm), grasping and

manipulation are functions of the hand. However, a high degree of interdependency between the arm and hand exists and both elements are required to successfully and efficiently achieve most activities of daily living. Additionally, it has been demonstrated that spatiotemporal movement characteristics of the arm are altered by the functional goal of the movement (for example the trajectory, velocity and relative time in acceleration and deceleration phases involved in a pointing task are different to those seen when reaching for an object [Marteniuk et al., 1987]). However, technical challenges and costs involved in developing a system to simultaneously rehabilitate the arm and hand resulted in the absence of the hand in the PST system. This reduced the functional relevance of the movement patterns practiced and was recognised as an important limitation of the system. Nonetheless, improvements in hand impairment and function were apparent (Section 8.4.1), suggesting that some degree of carry-over to the hand occurred even though the hand was not targeted by the PST system. However, in recognition of the importance of the hand in upper-limb function, it is recommended that future systems exploit technical advances (enabling accurate measurement of the hand using inconspicuous movement sensors) to develop rehabilitation systems capable of addressing the entire upper-limb including the hand.

The Wii was chosen to explore the concept of using VR gaming technologies for upper-limb stroke rehabilitation in this study as it was the most widely available and commonly used VR gaming device employed in rehabilitation settings at the time of this study (Langan et al., 2018). However, a limitation inherent in all studies using gaming technology is the risk of redundancy with devices rapidly being superseded. It is therefore critical that devices and activities can quickly and easily be adapted for continued use in rehabilitation on different operating platforms and that such developments remain attractively priced. As immersion has been linked with improved efficacy (Hatem et al., 2016), future VR gaming technologies should consider using more immersive technologies. Additionally, the use of more discreet, user-friendly movement sensor technologies should be considered. However, these developments must be balanced with financial considerations and ease of use, as high costs and complicated set-up are likely to make use of such systems prohibitive (Scherer, 2017). Moreover, exploration of safety aspects of more immersive technologies is required due to potential increased risk of side effects such as motion sickness and falls. Future studies should also consider exploration of the effectiveness, acceptability and feasibility of such devices in different clinical specialities.

As the primary aim of this study was to explore issues of feasibility and acceptability, not efficacy, the study was not powered and did not utilise a control group. It is therefore not

possible to determine if changes in impairment, activity and participation were due to the intervention or other factors such as familiarity with tests over time. Other methodological weaknesses included a lack of blinding of study participants, small sample size and use of a convenience sample which may have resulted in a biased estimate of the effect of the intervention. The use of mixed-methods helped ameliorated some areas of weakness with the provision of extra data from qualitative findings augmenting quantitative results.

9.9 Contributions to Knowledge

This thesis has added to the body of knowledge in a number of areas. To the author's knowledge, this is the first review of the literature to combine findings of efficacy of different types of VR systems with findings of feasibility and acceptability. The literature review added to recently published systematic reviews (Hatem et al., 2016; Laver et al., 2017) through the inclusion of up-dated literature and through the inclusion of, and separate analysis of systems using modified versions of commercial VR gaming technologies. Moreover, in contrast to other reviews, the exclusion of studies using robotics and exoskeletons in the present review, enhanced the clinical utility of the findings.

Phase two findings added to the limited body of evidence regarding the feasibility and acceptability of VR gaming technologies and specifically with systems using modified versions of commercially available, off-the-shelf systems. Significantly, this study helps address the gap in the literature regarding the feasibility and acceptability of such systems for those with more severe levels of upper-limb impairment. Finally, while a limited number of studies have also examined efficacy, feasibility and acceptability of VR gaming devices, to the author's knowledge, this is the only study to provide integration of quantitative and qualitative findings and to do so with stroke survivors with severe upper-limb deficits.

9.10 Recommendations

Inherent methodological flaws in this study impact on the level of recommendations that can be made. Nonetheless it is argued that important issues have been raised by this study which are worthy of consideration. Key recommendations from this study and implications for clinical practice, education and future research and recommendations are therefore presented next.

9.10.1 Implications and Recommendations for Future Practice

- Findings of a lack of upper-limb therapy combined with findings of feasibility, acceptability and preliminary estimates of efficacy of a novel, low-cost,

personaliseable VR gaming technology for upper-limb rehabilitation, suggest that therapists should consider the use of such technologies as an adjunct to traditional upper-limb stroke rehabilitation, and as a means of delivering extra therapy or when traditional rehabilitation is no longer available.

- This study has shown that hands-free and personalisable VR gaming technologies developed specifically for upper-limb stroke rehabilitation, are feasible and acceptable for use by those with severe levels of upper-limb impairment following stroke. As stroke survivors with severe levels of impairment have fewer rehabilitation options open to them, it is therefore recommended that clinicians consider using such technologies in clinical practice.

9.10.2 Implications and Recommendations for Education

- While evidence of acceptability, feasibility and efficacy of technology as an adjunct to therapy is increasing, a lack of knowledge and a lack of confidence in using assistive technologies has been identified as a barrier to uptake of technologies into clinical practice (Demain et al., 2013; Hughes et al., 2014). This suggests the need for information about such technologies to be included in undergraduate and postgraduate curricula. However, as evidence of uptake of therapies regardless of awareness of the evidence base was apparent in study phase one findings, further emphasis on the evidence behind its use should also be provided.
- This study has highlighted the benefits of using a mixed-methods approach when evaluating a complex intervention. However, an absence of education regarding mixed-methods has been recognised (O'Cathain et al., 2010). It is therefore recommended that mixed-methods is taught alongside quantitative and qualitative approaches at postgraduate level to equip practitioners with the tools to evaluate the evidence and to increase use of mixed-methods in research. While undertaking a mixed-methods research study at undergraduate level is rarely feasible, in light of an increased prevalence of published mixed-methods studies, it is recommended that mixed-methods approaches are taught at undergraduate level to enable students to better evaluate evidence.

9.10.3 Implications and Recommendations for Future Research

- This study has shown the importance of hands-free and personalisable VR gaming technologies to ensure feasibility of use for upper-limb stroke rehabilitation. This is particularly pertinent for those suffering more severe upper-limb deficits for whom off-the-shelf, entertainment-based technologies are of limited use. In keeping with the

MRC recommendations (Craig et al., 2008), further evaluation of the costs and effectiveness of VR gaming technologies, particularly in those with more severe levels of upper-limb impairment, is warranted.

- Additionally, the move towards home-based rehabilitation suggests that future studies should address acceptability (including exploration of barriers to uptake of new technology), feasibility (including incidence and severity of adverse effects, set up and costs) of VR gaming technologies in home environments and effectiveness of such systems on long term exercise adherence. However, due to potentially higher costs of implementing a home-based system, it is important that VR gaming systems are technically advanced with known anomalies corrected prior to home assessment. Moreover, careful patient- education is required to minimize the occurrence of adverse effects such as shoulder impingement and fatigue.
- Advances in technology are enabling the development of smaller, more discrete movement detection sensors. At present accurate movement tracking is problematic, and costs relatively high compared to sensors used in VR gaming technologies. Technical advances are likely to result in greater accuracy and costs are likely to decrease over time, making clinical use more feasible. It is therefore recommended that those involved in developing VR based systems for rehabilitation purposes capitalise on such advances and consider incorporating these technologies into future developments.
- This study has shown the importance of collaborative design with service-users, therapists and engineers working in partnership to ensure interventions are acceptable and feasible for rehabilitation purposes. Although difficulties were noted, in agreement with NHS England (2015) and Moore et al. (2015) the inclusion of service-users in the research process is nonetheless recommended due to the additional insights provided.
- Research indicates that while neuroplasticity is greatest (and therefore rehabilitation most effective) in the weeks following stroke, demand for therapy outstrips available resources, resulting in a failure to deliver the intensive repetitious practice to drive neuroplastic recovery. As VR gaming technologies have the potential to help deliver an increased dose of exercise without the need for significant extra therapist contact time, future studies should assess the effectiveness, feasibility and acceptability of using VR gaming technologies as an adjunct to traditional therapy in the acute rehabilitation phase.
- A lack of consensus about cut-off scores for the terms ‘mild’, ‘moderate’ and ‘severe’ upper-limb stroke resulted in difficulty interpreting literature findings. To facilitate

interpretation and communication of findings, future research should attempt to establish consensus agreement regarding cut-off scores for different levels of stroke severity for the most frequently employed outcome measures used at baseline (e.g. FMA-UE and ARAT). Additionally, studies should clearly state the severity of upper-limb impairment for participants who actually participated in studies (not just those who could have been included) to enable the evaluation of interventions by stroke severity.

- As a lack of description about pertinent features of VR systems and study characteristics hampers both evaluation and replication, it is recommended that future studies use the TIDieR template (Hoffman et al., 2014) to ensure completeness of the intervention.
- Finally, this study has demonstrated the additional insights provided through the use of mixed-methods. The use of mixed-methods research is therefore recommended in future studies evaluating complex interventions.

9.11 Conclusion

In summary, findings from a scoping study and a review of the literature demonstrated the need for VR gaming technologies for upper-limb stroke rehabilitation to be personalised to improve acceptability and enable feasibility of use, particularly among those with more severe levels of upper-limb impairment. The PST system was developed in collaboration with stroke-survivors, engineers and therapists. It used adapted commercial VR gaming technology (the Nintendo Wii) and purpose-built activities to deliver upper-limb rehabilitation to a group of community dwelling stroke survivors. High levels of acceptability and feasibility of the PST system were found. Feasibility of use was associated with the use of a hands-free system and the ability to personalise activities dependant on individual needs. Critically, this enabled use by participants with severe upper-limb deficits, in whom there is a recognised difficulty in provision of suitable exercise. Acceptability was linked to enjoyment, feedback, perceived physical and psychological benefits and the ability to address several barriers to rehabilitation, including a lack of therapy, reduced motivation and poor adherence to out of session exercise programmes. The results of the study also indicated that VR gaming technologies may improve impairment, activity and participation among stroke survivors in the short-term.

Findings from this study were used to help in the collaborative design and the ongoing evaluation of a VR gaming technology (the Neurofenix platform. www.neurofenix.com) for home-based upper-limb stroke rehabilitation. Specifically, therapist and service-user

participant feedback from all study phases were used to supplement findings from the product design team, to ensure salient features were included to maximise acceptability, user-engagement and feasibility of use. Additionally, study findings were used to inform the study protocol and methodology for a multiphase, mixed-methods study design evaluating the Neurofenix VR gaming technology (Kilbride et al., 2018). A feasibility study has been completed and a funded evaluation of the system in the home setting has been undertaken.

While fast-moving technological advances can result in redundancy of VR gaming systems, results from the present study demonstrate the feasibility and acceptability of the concept of using bespoke VR gaming activities as a means to deliver stroke rehabilitation. In addition, findings can be used to develop future VR gaming technologies suitable for use in stroke rehabilitation.

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Appendices

1: Select Publications

1.1 Warland et al. (2018)

DISABILITY AND REHABILITATION, 2018
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ORIGINAL ARTICLE

Check for updates

The feasibility, acceptability and preliminary efficacy of a low-cost, virtual-reality based, upper-limb stroke rehabilitation device: a mixed methods study

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ABSTRACT

Purpose: To establish feasibility, acceptability, and preliminary efficacy of an adapted version of a commercially available, virtual-reality gaming system (the Personalised Stroke Therapy system) for upper-limb rehabilitation with community dwelling stroke-survivors.

Method: Twelve stroke-survivors (nine females, mean age 58 years, [standard deviation 7.1], median stroke chronicity 42 months [interquartile range 34.7], Motricity index 14–25 for shoulder and elbow) were asked to complete nine, 40-min intervention sessions using two activities on the system over 3 weeks. Feasibility and acceptability were assessed through a semi-structured interview, recording of adverse effects, adherence, enjoyment (using an 11-point Likert scale), and perceived exertion (using the BORG scale). Assessments of impairment (Fugl–Meyer Assessment Upper extremity), activity (ABILHAND, Action Research Arm Test, Motor Activity Log-28), and participation (Subjective Index of Physical and Social Outcome) were completed at baseline, following intervention, and at 4-week follow-up. Data were analysed using Thematic Analysis of interview and intervention field-notes and Wilcoxon Signed Ranks. Side-by-side displays were used to integrate findings.

Results: Participants received between 175 and 336 min of intervention. Thirteen non-serious adverse effects were reported by five participants. Participants reported a high level of enjoyment (8.1 and 6.8 out of 10) and rated exertion between 11.6 and 12.9 out of 20. Themes of improvements in impairments and increased spontaneous use in functional activities were identified and supported by improvements in all outcome measures between baseline and post-intervention ($p < 0.05$ for all measures).

Conclusions: Integrated findings suggested that the system is feasible and acceptable for use with a group of community-dwelling stroke-survivors including those with moderately-severe disability.

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Gaming technologies; stroke rehabilitation; technology; game-based rehabilitation; hemiplegia; virtual reality

➤ IMPLICATIONS FOR REHABILITATION

- To ensure feasibility of use and maintenance of an appropriate level of challenge, gaming technologies for use in upper-limb stroke rehabilitation should be personalised, dependent on individual need.
- Through the use of hands-free systems and personalisation, stroke survivors with moderate and moderately-severe levels of upper-limb impairment following stroke are able to use gaming technologies as a means of delivering upper-limb rehabilitation.
- Future studies should address issues of acceptability, feasibility, and efficacy of personalised gaming technologies for delivery of upper-limb stroke rehabilitation in the home environment.
- Findings from this study can be used to develop future games and activities suitable for use in stroke rehabilitation.

Introduction

Stroke is the leading cause of disability worldwide including the UK where over 100,000 strokes occur annually, resulting in an economic burden of £9 billion per year [1]. With improving survival rates and longer life expectancy in general, the burden of caring for stroke survivors is likely to increase [2,3]. Eighty-five per cent of stroke survivors will initially experience upper-limb (UL) deficits [1] and of those with minimal movement on admission, only 11.6–14% regain full function [4,5]. As a lack of UL recovery results in significant dependence and a reduced quality of life, it has been found to be one of the strongest predictors of reduced psychological well-being following stroke [6,7]. Effective UL treatment interventions have therefore been identified as a priority for stroke research [8].

Effective treatment interventions post-stroke is characterised by high intensity and repetitive practice of a meaningful task [9]. In keeping with this, current guidelines recommend therapy sessions should be carried out for a minimum of 45 min daily for a minimum of 5 days a week [10]. However, changes in infrastructure, resource pressures [11], an emphasis on mobility during rehabilitation [12], a reduction in hospital length of stay [13], and a lack of therapy on discharge home have resulted in challenges delivering the amount of rehabilitation necessary to optimise recovery [1,14]. With demand for therapy outstripping available resources,

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there is a greater emphasis on stroke survivors exercising independently. However, adherence to such programmes is notoriously poor [15–17]. Lack of support, lack of feedback, and boredom with exercises are the most frequently cited factors associated with poor adherence [12,18,19].

It has been suggested that the use of virtual-reality (VR) based activities can improve UL recovery following stroke through provision of a motivating treatment that is not reliant on increased therapist contact time [20–23]. The enjoyable and challenging nature of such activities may help address issues of boredom [12] and in addition, the ability to provide feedback may enhance motor learning [24,25] and exercise adherence [26] and therefore help provide the high intensity, repetitious practice necessary to drive recovery [27]. Moreover, it has been postulated that the provision of visual feedback via an on-screen character (avatar) can activate "mirror neurones" (brain cells involved in performing a movement which also "fire" when observing a movement) which has been suggested may aid recovery from stroke [28–31].

While some bespoke and commercially available VR systems (such as GestureTek, IREX, CAREN, ARMEO) have been developed specifically for rehabilitation purposes, most are complex and beyond the financial scope of therapy departments. These costs and complicated set-up, are likely to limit feasibility and acceptability of use in the community [32]. Commercially available VR gaming technologies (such as the Nintendo Wii, Microsoft Kinect, Razer Hydra and Leap Motion) have become increasingly popular as motivating and relatively cheap alternatives [33,34]. However, issues of acceptability and feasibility have been noted, particularly in those with more severe disability due to the large range of movement, coordination, and speed required to play the games, the degree of coordination and dexterity necessary to use movement sensors and the demoralising effect of "negative" feedback [35–40]. As a result, some teams have adapted low-cost, commercially available VR gaming devices for use in rehabilitation [39–42]. However, new therapies require thorough evaluation of efficacy, acceptability, and feasibility of use prior to introduction into clinical practice [32,38,43].

Several systematic reviews have concluded that both commercially available and bespoke versions of VR systems are feasible to use and have positive effects on UL recovery following stroke, for those with moderate and mild UL deficits [38,44–48]. Evidence in support of use in those with more severe disability is less convincing, with studies aiming to include those with moderate to severe UL impairments showing non-significant levels of improvement [48]. However, although protocols of some studies included in the review by Laver et al. [48] *allowed* the inclusion of those with more severe UL deficits, in many cases it is not possible to ascertain the severity of those who *actually* participated and as such, the effectiveness with those with more severe deficits is unclear. Moreover, many studies inclusive of participants with moderate to severe UL impairments have also employed the use of robotics or physical assistance from therapists in addition to VR, suggesting issues of feasibility of the systems when used alone and limited feasibility in the community [49–52]. While critical to exercise-adherence, few studies have considered patient evaluation of VR devices and when such evaluation has been performed, there has often been a lack of analytical rigour [38].

This paper builds on previous work [35,39,53] outlining service-user, engineer, and neuro-therapist involvement in the development of a low-cost, personalised stroke therapy (PST) system for UL rehabilitation following stroke, using an adapted version of a non-immersive commercially available VR gaming device. The PST system addresses several barriers identified in a previous stage of the study [35] including the use of a hands-free system, easier setup, greater accuracy, and crucially, the ability to personalise activities with regard to range of movement, time played, sensitivity, and speed. In this study, the concept of using adapted versions of commercially available VR gaming devices for delivery of UL rehabilitation was explored using the PST system. The primary objectives were to determine the feasibility (including safety) and acceptability of using the PST system for delivery of UL rehabilitation with community-dwelling stroke survivors with differing levels of disability, including those with moderately-severe UL impairment. Although designed as a feasibility and acceptability study, a secondary aim was to examine preliminary estimates of the efficacy of the PST system.

Methods

Design

A mixed methods convergent study design was used, with separate quantitative and qualitative analyses followed by integration of the findings. Ethical approval for this study was granted by the Department of Clinical Sciences Research Ethics Committee, Brunel University (REC reference number 14/06/PHD/02). The principles of the Data Protection Act (1998) were adhered to throughout the study. The study sponsor was Brunel University.

Recruitment

Following recruitment presentations and use of poster advertisements at local stroke support groups, 32 people volunteered to participate in the study of which 12 fulfilled inclusion and exclusion criteria. In order to be more representative of the general stroke population and to address the lack of research focus on stroke survivors with more severe UL deficits, participants with mild to moderately-severe loss of UL function following unilateral stroke were included (score between 14–25 for both elbow and shoulder movement on the Motricity Index). Further inclusion criteria were adults who were a minimum of 12 weeks following stroke, had finished all formal UL rehabilitation, were able to sit independently for a minimum of 5 min, had the capacity to consent, understand and communicate in English and to follow instructions. Volunteers with pre-existing UL pain at rest, fixed contracture, active disease, or orthopaedic conditions affecting the movement in the arm affected by stroke, photosensitive epilepsy, medical instability (such as uncontrolled angina), acquired brain injury from other causes, cerebellar lesions, pacemakers, visual neglect, hemianopias, or uncorrected visual field deficits (score of 44 or below on the Star Cancellation Test) were excluded from the study. As travel burden has been identified as a barrier to research participation [54], pre-paid, wheelchair accessible taxis were offered to all participants to maximise recruitment. A flowchart detailing recruitment and retention of participants and study procedure is presented in Figure 1.

The personalised stroke therapy system

The system adopted the holistic framework and system architecture proposed by Paraskevopoulos et al. [39,55] as depicted in Figure 2.

The use of two Nintendo Wiimote wireless movement sensors, developed for use with the Nintendo Wii gaming console, enabled interaction between the system-user, and the PST system. Movement data from the Wiimote sensors was sent to a computer using Bluetooth (wireless) technology and a data fusion algorithm [56] was used to combine and smooth data in order to achieve greater accuracy in movement tracking. This information was then mapped onto a three-dimensional body model. A game engine (Unity) (which has a free version) was employed to create a

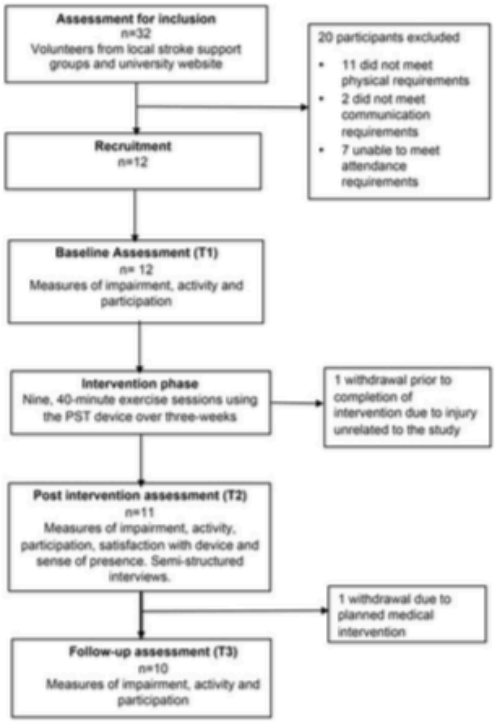

Figure 1. Flowchart of recruitment, retention and study procedure.

physical simulation of the PST system user by means of a 3D avatar which could be viewed on a computer screen.

The PST system used elastane pockets with hook and loop straps to secure movement sensors thereby allowing use by those unable to hold and operate the movement sensors. One sensor was secured on the lateral aspect of the upper-arm midway between the shoulder and elbow and the second was secured to the dorsal aspect of the forearm midway between the elbow and wrist.

Two activities (one game and one exercise), were used in the study. The apple-catching game requires the system-user to practice shoulder, elbow, and forearm movements in order to operate an on-screen arm to catch apples randomly falling from a tree (Figure 3). Through the use of a therapist interface (Figure 2), features such as player handedness, game duration, number of repetitions, and the range of movement required to play the game can be altered by the therapist dependent on the system user's ability. System-users are able to see their score and an encouraging message is provided at the end of each game (e.g., "well done", "keep going", "good effort"). In the virtual therapist application, functional movement patterns involving the shoulder, elbow, and forearm are captured by recording the system-user performing these movements with facilitation from a therapist to ensure movements are challenging and functional. The recorded movement is mapped onto the arm of the virtual therapist and then played back on a loop (the duration of which is set by the therapist) at the same speed and range as the recording. System-users are instructed to follow the recorded virtual therapist arm (depicted in red in Figure 4) with their own arm (depicted in white in Figure 4). When system user's movements match those of the virtual therapist, the onscreen arms are seen to blend together thereby providing instantaneous feedback.

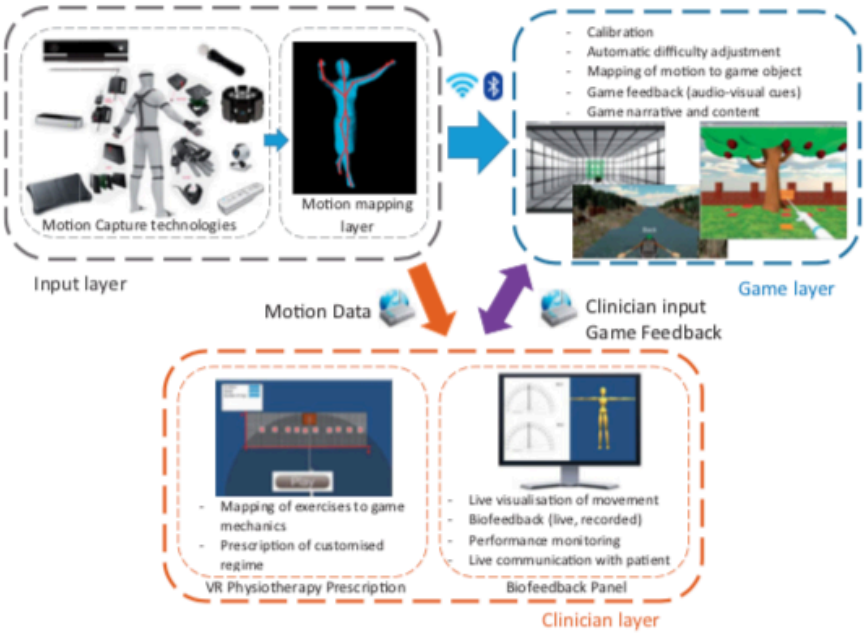

Figure 2. System architecture of the personalised stroke therapy system.

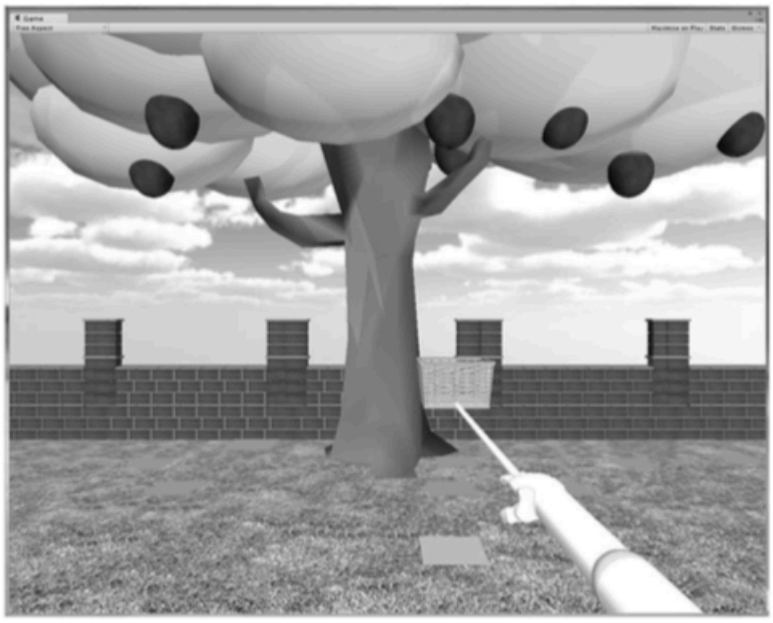

Figure 3. Apple-catching game screenshot.

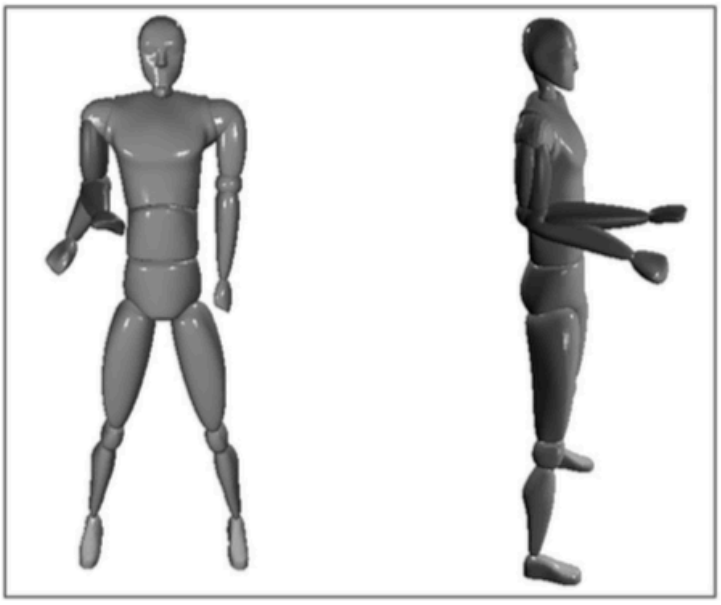

Figure 4. Virtual therapist application screenshot.

Assessment

Assessments of efficacy were conducted at baseline (T1), at 1–5 days post-completion of the intervention phase (T2) and at follow-up (T3) 4 weeks after completion of the intervention.

Information regarding acceptability and feasibility of the PST system was collected at T2 through semi-structured interviews performed by the lead researcher. As presence has been identified as a key issue affecting the effectiveness of VR devices [57], sense of presence in the virtual environment was examined using the iGroup Presence Questionnaire (IPQ) [58] at T2 (maximum score 84, with a higher score indicating a greater sense of immersion in the virtual environment).

During intervention sessions, participants rated their level of exertion and level of enjoyment for each activity immediately after cessation of each activity, using respectively, the 15-point Borg Scale of Perceived Exertion (rated from 6 to 20, with a higher score indicating a higher level of perceived exertion) and an 11-point visual analogue scale (VAS) (rated from 0 to 10, with a higher score indicating a higher level of enjoyment). Participants were monitored for adverse effects throughout the intervention. Incidences of pain were recorded and if incurred, severity was assessed using an 11-point VAS (from 0 to 10, with a high score indicating greater perception of pain). In addition, participants were assessed by the therapist to establish the nature of the pain and when required, the range of movement required for game-play was adjusted to avoid painful movements. Incidences of motion sickness were recorded and if incurred, severity was assessed using the 21-point FAST Motion Sickness Scale (from 0 to 20, with a higher score indicating greater experience of motion sickness). Incidences of falls, near falls, or other adverse effects were recorded on the intervention data collection form.

Efficacy of the PST system was evaluated through examination of group changes in outcome measures between time-points. As no one measure is able to capture the differing effects of stroke [59,60], different measures were employed to assess the efficacy of the PST system at all levels of the International Classification of Functioning, Disability, and Health Framework (ICF) [61]. The upper extremity (motor, sensation, coordination, and speed) sections of the Fugl-Meyer Assessment (FMA-UE) [62,63] were used to assess impairment (scores between 0 and 70 with a higher number indicating a better performance). UL activity was assessed using the ABILHAND questionnaire [64] (scores between 0 and 69 with the higher score indicating better performance), Action Research Arm Test (ARAT) [65] (scores between 0 and 57 with a higher score indicating a better performance) and the Motor Activity Log-28 (MAL-28) [66] (scores between 0 and 5 with a higher number indicating better ability). Participation was measured using the Subjective Index of Physical and Social Outcome (SIPSO) [67] (scoring is between 0 and 50 with a high score indicating a better level of integration).

To ensure standardisation of assessment, all researchers involved in assessment received training on the outcome measures being used, including training on the FMA-UE as detailed by See et al. [68] and in addition, a specific operations protocol was developed to ensure standardisation of assessment.

Intervention

The planned intervention consisted of nine, 40-min exercise sessions using the PST system, delivered 3 days per week over 3 weeks. While mirroring a more realistic clinical picture, the requirement to attend only 3 days per week was chosen in order to aid recruitment, as more demanding protocols have been identified as a barrier to recruitment for trials involving physical activity [69]. To ensure consistency, all appointments were carried out on an individual basis in a university room using a standardised set-up imitating a typical living space.

Participants were required to exercise their hemiplegic arm under the direct supervision of a member of the research team (all of whom were qualified physiotherapists, experienced in stroke rehabilitation) using the apple-catching and virtual therapist applications. The supervising therapist set up and calibrated the system dependent on individual participant need, assisted participants to secure the Wiimote movement sensors and instructed participants regarding game-play and the avoidance of over-compensatory movements. Both activities were performed for a maximum of ten minutes and were then repeated. A minimum of 2 min rest was incorporated into each of the four, 10 min exercise blocks. Deviations from the protocol (e.g., when participants required more frequent or prolonged rests) and occurrences of adverse effects (such as pain) were recorded. Participants exercised in standing or sitting dependent on personal preference.

Data analysis

Descriptive statistics are presented for quantitative data. Scores obtained on the FMA-UE, ABILHAND, ARAT, MAL-28, and SIPSO were compared between T1 and T2, and T1 and T3, respectively, using Wilcoxon Signed Ranks. All analyses were performed using IBM SPSS version 20. In addition, change in individual scores between time-points was compared with the minimally clinically important difference (MCID) where this had been established (FMA-UE, ARAT, and MAL-28). Fieldwork notes and verbatim transcriptions of interview data were analysed using the six-step Thematic Analysis phases recommended by Braun and Clarke [70]. The NVivo10 qualitative data software package (QSR International Pty Ltd. Version 10, 2012) was used to manage the data. While, a theme was identified when two or more participants discussed an issue, for brevity, one exemplary quote is used for each point raised. Side by side joint displays as recommended by Creswell [71] were used to integrate findings from quantitative and qualitative arms of the study. Initial analysis was undertaken by the lead researcher, with validation of qualitative findings through discussion and review of themes with a second member of the research team who is an experienced qualitative researcher (C. K.).

Results

Twelve community-dwelling stroke survivors (9 female) aged between 48 and 68 years (mean (SD) 58 (7.1) years) were recruited to the study. Stroke chronicity was between 12 and 304 months (median (IQR) 42 (34.7) months) and participants were classified as having slight to moderately-severe stroke severity (between 2 and 4 on the Modified Rankin Scale). Participant details (using pseudonyms) are presented in Table 1.

One participant (George) dropped out prior to follow-up (T3), due to medical intervention unrelated to the study and was therefore not included in the statistical analysis at T3 but is included in analysis at other assessment points. A further participant (Nell) dropped out during the intervention phase due to an injury unrelated to the study and was therefore not included in analysis at T2 and T3. For 10 participants, each assessment was undertaken by a different researcher who was blind to previous assessment scores. Due to staffing issues, one participant (George) was assessed by the same researcher at T1 and T2.

Integrated findings regarding feasibility (including safety), acceptability, and efficacy of the PST system are presented in Tables 2–4, respectively. The term "**QN**" indicates a quantitative finding, "**QL**" refers to a qualitative finding and the number corresponds to where the findings (including exemplary quotes) can be found in the results tables.

Thirteen adverse effects were experienced by five participants (**QN1**, Table 2). The mean time using the PST system was 276 min (standard deviation 64.3; range 175–336 min) out of a target of 360 min (**QN2**, Table 2). The discrepancy between target duration and achieved duration was due to late attendance at the sessions because of travel delays and participant fatigue. Participants reported high levels of enjoyment for both activities (**QN4 & 5**, Table 3) and average rating of perceived exertion (RPE) was "fairly light" and "somewhat hard" for the apple-catching game and

Table 1. Participant details.

Participant number and pseudonym	Age (years)	Gender	Time since stroke (months)	Side of weakness	Modified Rankin score[a]	Motricity Index score[b]: summed (elbow/shoulder)	Hand dominance	Communication disorder
1: Joe	64	Male	29	Left	2	50 (25/25)	Right	No
2: Lizzie	53	Female	54	Right	3	38 (19/19)	Right	Yes
3: Nancy	65	Female	31	Left	4	28 (14/14)	Right	No
4: George[c]	48	Male	17	Right	3	28 (14/14)	Right	Yes
5: Ada	66	Female	46	Right	4	28 (14/14)	Right	No
6: Esther	49	Female	41	Left	2	50 (25/25)	Left	No
7: Betty	67	Female	17	Left	4	28 (14/14)	Right	No
8: Nell[d]	58	Female	304	Right	2	44 (19/25)	Right	No
9: Jenny	49	Female	12	Left	3	28 (14/14)	Right	No
10: Dora	60	Female	41	Left	3	28 (14/14)	Right	No
11: Clara	54	Female	114	Right	4	28 (14/14)	Right	Yes
12: David	63	Male	55	Left	2	50 (25/25)	Right	No

[a]Score of 2 = slight disability; 3 = moderate disability; 4 = moderately-severe disability.
[b]Score of 14 = observable movement, not full range, or against gravity. Score of 19 = full range movement against gravity but not resistance. Score of 25 = full range movement against resistance but weakness compared to the less affected limb.
[c]Dropped out prior to follow-up (T3), therefore not included in statistical analysis at follow-up but included at other assessment points (T1 and T2).
[d]Dropped out prior to completion of intervention, post-intervention and follow-up therefore not included in statistical analysis of intervention and post-intervention (T2 and T2) but included in baseline analysis (T1).

virtual therapist application, respectively (**QN6 & 7**, Table 3). Scores on each outcome measure at each time-point are presented in Table 5.

Discussion of integrated findings

The PST system was safe to use

As with other VR gaming studies [48], there was strong agreement between quantitative and qualitative findings that the PST system was safe to use, with adverse effects being infrequent and when occurring, mild in nature (**QN1, QL1 & 2**, Table 2). While UL pain was experienced by five participants (**QN1**, Table 2), it was mainly associated with unaccustomed muscular activity and was described by participants as a "good pain" (**QL1**, Table 2) and evidence of intensity of practice as opposed to a true adverse effect. Two participants experienced pain consistent with shoulder soft tissue impingement **(QN1**, Table 2**)** possibly as a result of disparity between the participant's actual motor ability and the task demands. Pain stopped on cessation of the activity and did not reoccur once the range of movement was adjusted to avoid painful movements (again supporting the need for personalisation of activities with regard to the range of movement required). Similar to findings by Lewis et al. [72] and Thomson et al. [34] fatigue (**QL2**, Table 2) was noted but was again considered by participants as an indication of intensity of use.

The PST system was feasible to use

The PST system was felt to be intuitive to operate without the need for extensive instructions (**QL3**, Table 2), and all participants were able to use the system (**QN2**, Table 2). Critically, the ability to personalise activities depending on individual need and the use of a hands-free system (**QL4**, Table 2) also enabled use by participants with moderately-severe disability without the need for orthoses or additional help (**QL5**, Table 2). The average RPE for the virtual therapist application as "somewhat hard" (**QN7**, Table 3) was echoed in the qualitative data (**QL11**, Table 3). However, while the average RPE for the apple catching game was "fairly light" (**QN6**, Table 3), a theme of considerable effort was apparent in the qualitative data (**QL11**, Table 3). This apparent discrepancy may be a result of differences in the selection of the movement range required to play the apple-catching game as several participants spoke of one researcher (the lead researcher) setting parameters that made gameplay much harder in comparison to the second researcher (**QL13**, Table 3). The findings of effort associated with the virtual therapist application and the apple-catching game (when set up by the lead researcher) suggest that through personalisation of the range of movement, speed, and duration of activities, the PST system was able to maintain the level of challenge for those with a wide range of impairments following stroke. There was strong agreement between data sets that the apple-catching game was the easier task (**QN6, QL11**, Table 3) and in line with this, participants with milder stroke severity identified a need for a faster speed of the falling apples (**QL12**, Table 3) suggesting the need for further personalisation. This was not a theme in those with more severe disability indicating the slower speed was appropriate for those participants.

Similar to other studies [36,40], the use of the hands-free system was essential for the majority of participants in the present study, several of whom had been unable to use the hand-held movement sensors when they had tried to use VR gaming technologies in the past (**QL4**, Table 2). However, field notes showed that only two participants were able to attach the movement sensors themselves, thereby limiting feasibility of independent set-up (**QL7**, Table 2).

Lack of confidence with technology is a barrier to use

Confidence with technology was not assessed quantitatively, however, in support of findings by Wingham et al. [36], a theme of a lack of confidence with technology, was recognised as a potential barrier to use in the qualitative data (**QL6**, Table 2). The lack of confidence suggested the need for initial support and the need for technology which is simple to set up and use to enable independent use.

The PST system was a source of motivation

In support of findings from other VR based rehabilitation studies [36,72,73] overall, high levels of enjoyment when using the PST system were apparent in both quantitative and qualitative data, suggesting a high degree of acceptability of use (**QN4 & 5, QL8, 9 & 19**, Table 3). A theme of the virtual therapist being like "boring, repetitive physio" was expressed by participants with more severe levels of disability (**QL10**, Table 3) and was supported by lower ratings of enjoyment in the quantitative data (**QN5**,

Table 2. Integrated feasibility findings.

Topic	Quantitative findings	Qualitative findings	Level of agreement
Safety	**(QN1)** Thirteen incidents (in 5 participants) of adverse effects (all non-serious): • Mild headache (2–3 on VAS) in two participants, one occasion each. • Shoulder/neck pain (2–5.5 on VAS) in four participants on 11 occasions. Eight incidences consistent with effort and three occurrences of shoulder impingement No incidence of motion sickness, cardio-respiratory distress, epilepsy, falls, or near-falls	A theme of **safety** of the PST device was supported by subthemes of: **(QL1)** A "**good pain**" PST device use. *"It's an 'I've been using it' type pain … like when you do something different. It was a good old fashioned muscle ache as if you have been working the muscle pretty hard"*. (David, 63, slight disability) **(QL2) Mental fatigue** *"It's a little bit hard, that's why I'm tired … Not tired with my arm you know, in my brain, because I'm focused"* (Betty, 67, moderately-severe disability	Agreement
Ability to use the PST system	**(QN2)** All participants were able to use both activities on the PST system after individualised calibration. Mean (SD) time using the PST device 276 (64.3) min, range 175–336 min (target time 360 min).	A theme of **ease of use** was supported by subthemes of: **(QL3)** The PST system being **intuitive** to use *"I automatically get what to do with this to play the game"* (Lizzie, 53, moderate disability) **(QL4) The necessity of a hands-free system** *"Usually I can't do (exercise). No point, for me it's too hard, because I've got the hand (indicates that has minimal arm movement) At first I thought 'no! not possible' But then you strapped it to my arm and I said 'oh (sounds surprised), okay'"* (Clara, 54, moderately-severe disability) **(QL5) Personalisation of activities** *"I don't think you need loads (of movement) to play with it. I think, you know, with minimal arm movement you could give this a go because I did."* (Nancy, 65, moderately severe disability)	Agreement
Barriers to use		A theme of barriers to PST system use was supported by subthemes of: **(QL6)** A **lack of confidence with technology** *"I think I would err on the safe side and I would like somebody there with me the first few times to make sure I have really got it and for them to say yes, that's fine, then I'd have got the confidence because I'd hate to go in and break something … If you leave it to someone who doesn't know what they are doing, that could cause all sorts of problems … You want something you can just plug in and play"*. (Jenny, 49, moderate disability) **(QL7) Difficulty attaching the movement sensors** Only two of 12 participants were able to attach and remove the movement sensors independently (Fieldnote).	Silence in quantitative data

QN: Quantitative finding; QL: qualitative finding; PST: personalised stroke therapy.

Table 3). However, a highly prevalent theme of fun was associated with the apple-catching game by all participants (**QN4, QL9**, Table 3), and was related to a feeling of "time flying" (**QL8**, Table 3). The concept of time flying is said to be positively correlated with enjoyment [74], with time seeming to pass more rapidly with enjoyable activities [75] and slower with less enjoyable ones [76]. This distortion in the perception of time is associated with the concept of "flow", that is the "optimal experience" and high level of enjoyment that is said to occur when immersed in a goal-directed task, which is both challenging yet perceived to be within one's ability [77,78]. High ratings of level of enjoyment (**QN4**, Table 3) and the theme of time flying (**QL8**, Table 3) suggests that participants achieved a state of flow when using the PST system, thereby helping address the issue of boredom experienced with traditional therapy (**QL10**, Table 3; **QL31**, Table 4) and suggesting the PST system has the ability to motivate and help deliver the intensity of practice necessary to drive change.

There was strong agreement between data sets that the virtual therapist was the more strenuous activity (**QN6 & 7, QL11 & 14**, Table 3). As flow is said to be greatest when level of effort and challenge, matches ability [79,80] the preference for the apple-catching game in those with more severe stroke and preference for the virtual therapist application with those with milder strokes (**QL14**, Table 3) (in spite of being rated as less fun) (**QN4 & 5**, Table 3) may therefore be related to the level of challenge experienced. This again highlights the necessity of personalisation of rehabilitation activities.

More feedback is required from the virtual teacher application

In addition to the level of challenge (**QN6, QL11 & 14**, Table 3), the higher rating of enjoyment with the apple-catching game may relate to the game-like characteristics inherent in its design, as all participants discussed the motivational effects of having a score to beat and a star reward system to improve upon (**QL15**, Table 3). Moreover, a need for increased feedback to maintain motivation was identified (**QL16**, Table 3) and this may have contributed to the lower rating of enjoyment for the virtual teacher application. This supports findings from other studies of VR in stroke rehabilitation where the motivational effects of feedback and having a score to beat were

Table 3. Integrated acceptability findings.

Topic	Quantitative findings	Qualitative findings	Level of agreement*
Enjoyment	Mean (SD) ratings of enjoyment out of 10 when using the PST system: **(QN4)** Apple-catching game: 8.1 (1.5) **(QN5)** Virtual therapist application: 6.8 (2.3)	A theme of **fun** while using the PST system was identified and was underpinned by subthemes of: **(QL8) Time flying** *"It didn't seem like 40 minutes. It seemed like ten … - when you've got a game and you're so involved in it, time flies. It takes you out of the physical world so it was fun"* (George, 48, moderate disability) **(QL9) Apple-catching game: fun** *"That was really good, it was interesting and fun to play … It's just fun, it's getting, you know, catching the apples … It was really good. Really interesting, it was fun to use and play and I enjoyed every minute."* (Ada, 66, moderate severe disability) *"I loved the one with the apples! That is so funny. It's like the apples coming out of the tree you don't know where they are, so it's like 'oh!' (sounds surprised). I liked the whole package. It was fun, really good fun."* (Lizzie, 53, moderate disability) **(QL10) Virtual therapist: like boring, repetitive physio** *"Well (the apple-tree game) is a bit more interesting and less like physio basically even though I know it is physio, but less like physio, less like being in hospital and having to do repetitive physio. I'd give it (the virtual therapist) two out of ten because it was a bit boring."* (Dora, 60, moderate disability)	Agreement
Level of effort	Mean (SD) rating of exertion on the BORG Scale of Perceived Exertion. **(QN6)** Apple-catching game: 11.6 (1.3) equating to a descriptor of "fairly light" **(QN7)** Virtual therapist application: 12.9 (1.5), equating to a descriptor of "somewhat hard"	**(QL 11)** The virtual therapist application was felt to be the harder activity but both activities were associated with **effort.** *"(The virtual therapist) felt arrrgghhh. Hard work"* (Clara, 54, moderately-severe disability) *"You still had to strain to do (the apple-catching game). It's not easy"* (Jenny, 49, moderate disability) **(QL12)** Suggestions for increased **speed of falling apples** was a subtheme in those with mild stroke but speed was felt to be at the right level for those with moderately-severe stroke. *"The apples felt like they were filled with helium, very slowly"* (Joe, 63, slight disability) *"I thought the speed was just right"* (Nancy, 65, moderately-severe disability) **(QL13) Difference in level of difficulty** prescribed between researchers *"I had to really move (to catch some of the apples). It depends how (the apples) were set out. You were particularly cheeky one-day last week and you put one almost behind the tree trunk sort of thing and I was going (makes effortful noise), trying to get to it. I thought that was a good one! But yes it makes you work"* (David, 63, slight disability)	Partial agreement
Preference for activity type		**(QL14)** A **preference** for the virtual therapist application in those with milder strokes and the apple-catching game in those with moderate and moderately-severe stroke. *"You know, if I had the choice of the two I would definitely err in favour of the virtual teacher. Purely because it is a little more intensive."* (David, 63, slight disability) *"If I had to pick between them, I'd pick the apple game. Well it's a bit more interesting and less like physio"* (Dora, 60, moderate disability)	Silence in quantitative data
Feedback		A theme of **motivation through feedback** was supported by subthemes of: **(QL15)** The **apple-tree game as a source of motivating feedback** *"I felt the apple one was giving me lots of encouragement. When it called you 'world class' or 'legend' you thought oh yes, I've cracked this! (The score) was important. Very important … I could have done with a hint or two. You know 'lift this, move that' what you needed to do to be world class … I liked being world class!"* (Nancy, 65, moderately-severe disability)	Silence in quantitative data

(*continued*)

Table 3. Continued

Topic	Quantitative findings	Qualitative findings	Level of agreement*
		(QL16) The **need for increased feedback with the virtual therapist** application. *"If it maybe said, like when you do it correctly. If you had more of an indication that yes, what you are doing is correct, it would make you want to carry on more … Yes, more incentive to say 'well done', 'correct', 'you've done that', 'move on'. For me (it would) make me want to do it more. Because if you are doing it right, it makes you want to do more … I'm not competitive but when I see a score of 54 I think yeah I want to carry on"* (Jenny, 49, moderate disability)	
Acceptability of PST system use in different settings		A theme of acceptability of use in different settings was underpinned by subthemes of: **(QL17) Promoting socialisation on-line** *"It would be good for someone like me, as speaking to someone new in person is difficult."* (Lizzie, 53, moderate disability) **(QL18) Promoting socialisation with family.** *"Now I can play with my children"* (George, 48, moderate disability) **(QL19) Wanting to use in home and clinical settings** *"I would have used it in hospital without a doubt … Oh yes, I would use it at home too because I'm seeing improvements"* (Jenny, 49, moderate disability) **(QL20)** Concerns **about the level of competition** were voiced *"People may think 'oh God, you know I'm going to get a whopping again', and it could actually be a little bit of a regressive thing. It could actually make you think I'm going to get a caning off this guy again. I'm not really up for that. It might put them off."* (David, 63, slight disability) **(QL21) Telerehabilitation: a source of motivation or 'Big Brother'?** *"Some people might look on it with a sort of Big Brother attitude, like I'm being watched. But on the other hand, some people might sort of go, they are obviously taking an interest in what I'm doing and they are just sort of encouraging me, geeing me up a bit, you know, so there are pros and cons in both directions. Personally I would say, yes, bring it on! It wouldn't bother me at all. It just shows they are taking an interest in my welfare so it's going to be helpful for them as well."* (David, 63, slight disability)	Silence in quantitative data
Need for increased therapy		A major theme of **not enough therapy,** was supported by subthemes of: **(QL22) "Too many patients"** *"I didn't get physio every day and I think that was because of the pressure of too many patients … Initially I was seen twice a day briefly, OT and Physio, but that dwindled to just once a day and then, quite often, well it was just no physio and they would apologise and say I'm afraid your session has been cancelled because the physio had to go and deal with somebody else."* (Dora, 60, moderate disability) **(QL23) "A focus on legs" (QN18)** *"He asked me when I went into rehab, he said 'what is more important to you? Do you want to focus on your legs or your arm?'"* (Nancy, 65 moderately-severe disability) **(QL24) Wasted time in rehabilitation** *"I had more time to spare. There was nothing else to do, there was nothing. Every morning you had physio and in the afternoon you had nothing. You either sat down in your bed or slept all day."* (Ada, 66, moderately-severe disability) **(QL25)** Being **"Abandoned"** on discharge home. *"When you go home, locally you just get 6 weeks and that's it. You are left to your own devices. Abandoned!"* (David, 63, slight disability)	Silence in quantitative data

QN: Quantitative finding; QL: qualitative finding; PST: personalised stroke therapy.

also noted [69]. In keeping with conclusions drawn by Cristea and Levin [81] the need for increased feedback with regard to how to improve (so-called knowledge of performance) was also noted (**QL15**, Table 3). As intrinsic (internal) feedback mechanisms may be damaged following stroke, there is a greater reliance on feedback from an external source (so-called extrinsic feedback) [82]. The preference for the apple-catching game observed in participants with more severe strokes may therefore be linked to the greater amount of extrinsic feedback provided by the apple-catching game, while those with milder strokes were potentially more capable of using intrinsic feedback to identify and correct their own mistakes [81,83].

Telerehabilitation: an opportunity for additional support and feedback or big brother?

When asked directly about the concept of using VR gaming devices as part of telerehabilitation, a strong theme of acceptance was apparent in the qualitative data with all participants stating they would want to use such a device (**QL21**, Table 3). The ability of the therapist to monitor exercise was strongly associated with increased exercise adherence (**QL31**, Table 4) and was viewed as an opportunity to receive feedback on performance and a feeling of support, which have been identified as critical in rehabilitation [12]. However, as well as a lack of confidence with technology (**QL6**, Table 3) two participants expressed a mild concern that others may be worried by the intrusive, "Big Brother" nature of telerehabilitation, suggesting issues of acceptability with some (**QL21**, Table 3).

Efficacy of the PST system

While no participant achieved the targeted intervention time (**QN2**, Table 2), nonetheless, the PST system appeared to be an efficacious device for UL rehabilitation in this cohort of stroke survivors (**QN8–10, QL26, 27 & 29**, Tables 4 and 5). There was evidence of improvement in all measures of impairment, activity and participation between T1 and T2 (**QN8–10**, Table 4) (p values <0.05 for all) and clinically important changes in impairment and activity between T1 and T2 (**QN8–9**, Table 4). These findings were supported by prevalent subthemes of improvements in (physical and psychological) impairment and activity generated from qualitative data (**QL26, 27 & 29**, Table 4). Interestingly, while there was evidence from quantitative data that improvements were maintained at the impairment level between T1 and T3 ($p = 0.033$) (**QN8**, Table 4), there was no evidence that improvements were maintained in measures of activity and participation (**QN9 & 10**, Table 4). These findings suggest that the dosage of therapy may be insufficient to sustain changes in activity and participation and support findings by Teixeira-Salmela et al. [84] who noted improvements in activity and participation required higher doses of intervention compared to improvements at an impairment level.

While increased participation in society following PST system use was not a theme in the qualitative data, the ability to play against someone online by people with impaired communication (**QL17**, Table 3) and the motivational aspects of playing against family members (**QL18**, Table 3), suggested VR gaming devices could potentially promote socialisation. However, as concerns about the level of competition were raised (**QL20**, Table 3), such programmes would potentially need to incorporate an "equalising" feature system to ensure equity between players.

Possible mechanisms in recovery

Qualitative data suggested possible mechanisms of recovery namely the ability of the PST system to deliver intensity of practice (**QN4 & 5, QL8, 9 & 11**, Table 3), to address learnt non-use (**QL27**, Table 4) and activate mirror-neurones (**QL30**, Table 4).

Themes of enjoyment (**QN4, & 5, QL8 & 9**, Table 3) and motivation to exercise (**QL15**, Table 3 and **QL29**, Table 4) associated with the PST system, suggested the potential of such gaming technologies to be used as instruments to address barriers to rehabilitation identified when participants discussed their previous experience of rehabilitation. These barriers included resource issues of "too many patients" (**QL22**, Table 3), a "focus on legs" and walking at the expense of the upper limb (**QL23**, Table 3), "wasted time in rehabilitation" (**QL24**, Table 3) boredom and therefore poor adherence with traditional exercise (**QL31, 32 & 34**, Table 4), the prescription of exercises that were too difficult (**QL33**, Table 4) and a feeling of being abandoned on discharge (**QL25**, Table 3). Neuroplastic change is unlikely to have occurred with the intervention dose provided in the present study [21,48,84]. Although the system was non-immersive in nature (confirmed by low ratings of immersion on the IPQ and relative silence in the qualitative data) (**QN11, QL30**, Table 4), nonetheless, the possibility of mirror neurone activation cannot be ruled out as observation of movements combined with physical practice has been associated with improved physical performance [31,85,86]. It is probable that physical improvements noted in both sets of data (**QN8–10, QL26–29**, Table 4), were due to increased motivation to try and use the affected limb and spontaneous functional use (**QL27**, Table 4). In addition, the psychological effects of renewed hope in UL recovery as a result of the study intervention (**QL29**, Table 4) suggested increased motivation to try and use the arm in functional tasks. Finally, although not a theme in the data, improvements seen may be related to greater use of compensatory strategies.

Study strengths and limitations

The use of mixed methods, integrating quantitative results, and qualitative findings provided extra data and greater insight into phenomena and have been advocated as a "powerful tool" to explore complex issues in healthcare [87,88] and is a strength of this study. In addition, areas of high agreement between the data sets strengthened the validity of findings and where they differed, qualitative findings provided possible explanations for results found. Moreover, the use of both quantitative and qualitative methods allowed the strengths of both types of study to off-set the methodological weaknesses inherent in the other [68].

The multi-disciplinary nature of the development team (including stroke survivors, engineers, designers, and neuro physiotherapists) ensured the PST system included features known to be important for recovery and those likely to result in greater engagement. In addition, while the inclusion of participants with communication difficulties and mild cognitive problems in this study resulted in less data and therefore a reduced presence in the qualitative analysis, recruitment of such participants is recommended nonetheless as being more representative of the stroke population and moreover provided additional insights into the way technology can be useful (**QL17**, Table 3). Additionally, the ability to personalise the PST system and interventions resulted in the inclusion of those with moderately-severe UL deficits. While those with mild to moderate UL deficits have other effective rehabilitation options available to them, such as simple recreational activities [89] and traditional therapy exercises, the options for those with more

Table 4. Integrated efficacy findings.

Topic	Quantitative findings	Qualitative findings	Level of agreement*
Changes in upper limb impairment	**(QN8)** Score on the FMA-UE increased by median (IQR) 6 (8) between T1 and T2 ($p = 0.005$). Reaching MCID in three of 11 participants (27%) Score on the FMA-UE increased by median (IQR) 3.5 (6.75) from T1 to T3 ($p = 0.033$).	**(QL26) Improvements in impairments** *"I can actually lift my arm up higher and hold it more than I did before"* (Ada, 66, moderately-severe disability) *"What I think the games have done for me, sharpened my perception of where the hand is… the bigger picture, it has helped me with stamina* (Joe, 64, slight disability) *"Well I felt those muscles being used again. You've heard the old expression 'God I've got muscles where I never thought I did have', well I've got muscles where I* ***remember*** *having them!"* (David, 63, slight disability)	Agreement
Changes in upper limb activity	**(QN9)** Score on the ABILHAND increased by median (IQR) 5 (4.5) between T1 and T2 ($p = 0.005$) Score on the ARAT increased by median (IQR) 3 (6) between T1 and T2 ($p = 0.028$). Reaching MCID in three of 11 participants (27%) Score on the MAL-28 increased by median (IQR) 0.28 (0.3) between T1 and T2 ($p = 0.006$) Score on the ABILHAND increased by median (IQR) 4 (9) between T1 and T3 ($p = 0.107$) Score on the ARAT increased by median (IQR) 0 (4) between T1 and T3 ($p = 0.347$). Reaching MCID in three of 11 participants (27%) Score on the MAL-28 increased by median (IQR) 0.075 (0.48) between T1 and T3 ($p = 0.207$)	**(QL27) Increased UL functional use** *"(The PST device) was making me use it and reminding me it was still there for use… when I got home I did tend to use my left (hemiplegic) arm more. It kind of triggered something in my brain… when I went out the door, usually I would have used my right arm, but I didn't, I held the handle in my left arm. … My partner has noticed me using my arm more spontaneously, opening doors, unwrapping things. Things like that… I feel this has awakened my brain to the hand."* (Esther, 49, slight disability).	Agreement
Changes in participation	**(QN10)** Score on the SIPSO increased by median (IQR) 6 (3.5) between T1 and T2 ($p = 0.004$) Score on the SIPSO increased by median (IQR) 4.25 (1.75) between T1 and T3 ($p = 0.102$)		Silence in qualitative data
Effectiveness of the activities		**(QL28)** The **virtual therapist application was considered the more effective** activity *"The apple tree is fun but the other one is like exercise … the robot (the virtual therapist) is more effective. Better exercise with the robot. More effective because I do more things like this and this (demonstrates different arm movements), so it's better exercise with the robot."* (Betty 67, moderately-severe disability)	Silence in quantitative data
Psychological effects		**(QL29)** The PST system as a **source of hope** *"Because everything with a stroke is long winded… this is the first thing that has given me hope, sort of like the light at the end of the tunnel"* Jenny, 49, moderate disability	Silence in quantitative data
Immersive effects	**(QN11)** Mean (SD) score on iGroup Presence Questionnaire 32.5 (21.5) out of 85 (with a higher score indicating greater sense of immersion).	**(QL30) Sense of immersion was low** and apparent in participant only *"The (virtual therapist) made me feel my arm but not my arm but not my shoulder blade as I could see my arm but not my shoulder blade"* (Lizzie, 53, moderate disability)	Agreement
Telerehabilitation: effect on exercise adherence		A theme of **increased exercise adherence with telerehabilitation** was noted and was felt to address reasons for poor adherence with traditional therapy (QL32–34).	Silence in quantitative data

(*continued*)

Table 4. Continued

Topic	Quantitative findings	Qualitative findings	Level of agreement*
		(QL31) Increased exercise adherence with telerehabilitation *"I can't think of anything bad about it. Nothing really because if they were checking that you were using it, you wouldn't be able to cheat would you? You wouldn't be able to say 'oh yes, I've been on it every day for three hours if they could check and say "no you haven't'. I think that would be one of the pros that they could check you were using it … It's for your own good isn't it? Because it's all too easy for them to give you a list of exercises and say I want you to do them twice a day and then they say have you done them? and you say yes, that's easy to say isn't it? But if they can actually physically check, you are going to have to do them."* (Nancy, 65, moderately severe disability)	
		(QL32) Boredom *"Because when you come out of hospital you are given a few sheets of paper which isn't really fun and you do them at first but it doesn't take long for those bits of paper to be put in a drawer and forgotten about … there was no enthusiasm or anything to actually make you want to do it. I could have done more if I hadn't died of boredom doing them! They were VERY boring!"* (Esther, 49, slight disability)	
		(QL33) The prescription of exercises that were **"too difficult"**. *"I had exercises but at first my arm was so weak I couldn't do any of them."* (George, 48, moderate disability)	
		(QL34) Not being **"bothered" to exercise when alone** *"I never try and use my right (hemiplegic) arm when I'm at home. I would exercise it more if someone was there with me. I can't be bothered when I'm on my own."* (Nancy, 65, moderately-severe disability)	

QN: Quantitative finding; QL: qualitative finding; PST: personalised stroke therapy; UL: upper limb; FMA-UE: Fugl–Meyer assessment; ARAT: action research arm test; MAL-28: motor activity log-28; SIPSO: subjective index of physical and social outcome; MCID: minimally clinically important difference.

Table 5. Median (IQR) change in impairment, activity and participation between baseline (T1), post-intervention (T2), and follow-up (T3).

		Baseline	Post-intervention	Follow-up	Difference between baseline and post-intervention		Difference between baseline and follow-up	
		T1	T2	T3	T1–T2		T1–T3	
n		12	11	10	11		10	
Domain (*n*)	Outcome measure (*n*)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	*p* value	Median (IQR)	*p* value
Impairment	FMA-UE	29.5 (28)	34 (33)	34.5 (34)	6 (8)	0.005*	3.5 (6.75)	0.033*
Activity	ABILHAND	24 (16)	28 (17)	27 (14)	5 (4.5)	0.005*	4 (9)	0.107
	ARAT	5.5 (24)	12 (32)	7 (32)	3 (6)	0.028*	0 (4)	0.347
	MAL-28	1.11 (2.7)	1.7 (3.14)	1.9 (3.35)	0.28 (0.3)	0.006*	0.075 (0.48)	0.207
Participation	SIPSO	25.5 (11)	30 (11)	28.5 (16)	6 (3.5)	0.004*	4.25 (1.75)	0.102

FMA-UE: Fugl–Meyer assessment; ARAT: action research arm test; MAL-28: motor activity log-28; SIPSO: subjective index of physical and social outcome.
*Significant change.

severe deficits are limited. Of the few studies which have included participants with more severe deficits, most have required additional support (from a therapist or an orthosis) to enable use thereby limiting feasibility in the community [49]). Although some UL movement to use the PST system was required (thereby limiting use in those with severe disability), the use of a hands-free system and the ability to individually calibrate activities ensured that those with moderately-severe disability were able to use the system. Furthermore, the comparison between a therapy-type activity and a game provided greater insight into factors affecting acceptability and provided greater direction for future developments for VR based rehabilitation.

A number of study limitations were apparent and results must therefore be interpreted with caution. The study was primarily designed to examine issues of feasibility and acceptability and was not specifically designed to look at efficacy. As the study was underpowered without a control group it is impossible to determine if changes in impairment, activity, and participation were due to the intervention or other factors such as familiarity with tests over time. Further, the absence of evidence of changes in some outcomes over time may be due to the small sample. Lack of blinding and use of a convenience sample may have also resulted in a biased estimate of the effect of the intervention.

Although participants were reminded at the start of the interview of the importance of giving responses that truly reflected their experiences (i.e., the good and the bad), the use of the lead researcher as interviewer may have precipitated more positive responses from study participants all of whom were aware of the study purpose and role of the lead researcher. The use of an interviewer unknown to the participants although preferable, was not possible within the confines of a time and funding limited study. The use of the lead researcher in the coding of data and development of themes was a further methodological limitation and may be associated with inadvertent bias in development of themes. To help address biases, reflective field-notes and regular engagement with the supervisory team to enhance criticality and challenge assumptions was undertaken.

The PST system was not feasible to use with all stroke-survivors. Of the 32 study volunteers, 11 were excluded on physical grounds likely to preclude use of the system. While feasibility of using video gaming technologies for rehabilitation is likely to be limited in those with UL pain and photosensitive epilepsy (experienced by 3 and 2 volunteers respectively in the present study), the exclusion of those with very mild and severe impairments (experienced by 6 volunteers), suggests the need for further personalisation to allow use by stroke survivors with different levels of UL impairment. Finally, the use of researchers to subjectively set game-play features (such as the range of movement required to complete activities), and the inability to adjust speed of the falling apples in the apple-catching game, resulted in a disparity in the level of challenge experienced by some participants.

Recommendations for future research

To ensure optimal practice conditions and use by stroke survivors with differing levels of ability, it is recommended that future studies should employ hands-free gaming technologies with automatic calibration and the ability to be personalised with regard to speed, duration of play, range of movement, task complexity and type, and amount of feedback. The efficacy of such systems (including any differences between games versus exercise applications) should be examined through the use of more robust methods such as randomised controlled trials.

The move towards home-based rehabilitation suggests that future studies should address acceptability (including exploration of barriers to uptake of new technology), feasibility (including set up) of VR gaming technology in home environments and effectiveness of such systems on long-term exercise adherence.

As immersion has been linked with improved efficacy [90] future studies using VR gaming technology should consider using more immersive technologies where feasible. However, this must be balanced with the financial considerations and ease of use as high costs and complicated set-up are likely to make use of such systems prohibitive [32]. A limitation of the present study inherent in all studies using gaming technology is the risk of redundancy with tested devices rapidly being superseded by advances in technology. It is therefore critical that devices and activities can quickly and easily be adapted for continued use in rehabilitation on different operating platforms and that such developments remain attractively priced.

Finally, as the study was designed as an acceptability and feasibility study, further research into the efficacy of the PST and similar systems particularly in those with more severe disability is warranted.

Conclusion

In summary, results from this mixed-methods study found high levels of acceptability and feasibility of using a VR based system using adapted commercial gaming technology as a method to deliver UL rehabilitation in a group of community-dwelling stroke survivors. Feasibility of use was associated with the use of a hands-free system and the ability to personalise activities depending on individual needs and enabled use by participants with moderately-severe UL deficits, in whom there is a recognised difficulty in provision of suitable exercise [12]. Acceptability was linked to enjoyment, feedback, physical and psychological benefits experienced, and the perceived ability to address a number of barriers to rehabilitation including a lack of therapy, reduced motivation, and poor adherence to out of session exercise programmes. The results of the study also indicated that such systems may improve impairment, activity, and participation among stroke survivors in the short-term.

Crucially, while fast-moving technological advances can result in redundancy in such systems, results from the present study demonstrate the feasibility and acceptability of the concept of using bespoke VR gaming activities as a means to deliver stroke rehabilitation. In addition, findings can be used to develop future games and activities suitable for use in stroke rehabilitation.

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RESEARCH PAPER

Development and preliminary evaluation of a novel low cost VR-based upper limb stroke rehabilitation platform using Wii technology

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Abstract

Purpose: This paper proposes a novel system (using the Nintendo Wii remote) that offers customised, non-immersive, virtual reality-based, upper-limb stroke rehabilitation and reports on promising preliminary findings with stroke survivors. *Method*: The system novelty lies in the high accuracy of the full kinematic tracking of the upper limb movement in real-time, offering strong personal connection between the stroke survivor and a virtual character when executing therapist prescribed adjustable exercises/games. It allows the therapist to monitor patient performance and to individually calibrate the system in terms of range of movement, speed and duration. *Results*: The system was tested for acceptability with three stroke survivors with differing levels of disability. Participants reported an overwhelming connection with the system and avatar. A two-week, single case study with a long-term stroke survivor showed positive changes in all four outcome measures employed, with the participant reporting better wrist control and greater functional use. Activities, which were deemed too challenging or too easy were associated with lower scores of enjoyment/motivation, highlighting the need for activities to be individually calibrated. *Conclusions*: Given the preliminary findings, it would be beneficial to extend the case study in terms of duration and participants and to conduct an acceptability and feasibility study with community dwelling survivors.

➤ Implications for Rehabilitation

- Low-cost, off-the-shelf game sensors, such as the Nintendo Wii remote, are acceptable by stroke survivors as an add-on to upper limb stroke rehabilitation but have to be bespoked to provide high-fidelity and real-time kinematic tracking of the arm movement.
- Providing therapists with real-time and remote monitoring of the quality of the movement and not just the amount of practice, is imperative and most critical for getting a better understanding of each patient and administering the right amount and type of exercise.
- The ability to translate therapeutic arm movement into individually calibrated exercises and games, allows accommodation of the wide range of movement difficulties seen after stroke and the ability to adjust these activities (in terms of speed, range of movement and duration) will aid motivation and adherence – key issues in rehabilitation.
- With increasing pressures on resources and the move to more community-based rehabilitation, the proposed system has the potential for promoting the intensity of practice necessary for recovery in both community and acute settings.

Keywords

Feedback, games, motion capture, Nintendo Wii, stroke rehabilitation, virtual reality

History

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Introduction

Stroke is a leading cause of long term disability worldwide including in the United Kingdom (UK) where an estimated 110 000 new strokes occur each year, leading to an annual economic burden of more than £2.8 billion [1]. Following stroke, 70% of people experience arm weakness, with only 5–20% regaining full function [2]. Treatment interventions shown to be most effective are characterised by high intensity, repetitive and task specific properties, but there are resource challenges in providing this level of intervention. Stroke rehabilitation can be a long process; as such, much of it takes place in the home setting. However, adherence to home exercise programmes (HEPs) is poor with a recent study finding 79% of patients in the community stopped doing their HEP as prescribed after two days [3]. A perceived lack of support from physiotherapists was the most frequently mentioned factor associated with lack of compliance. Boredom, de-motivation and depression also play a part in patients not engaging with exercise [3].

Several VR-based stroke rehabilitation interventions using robotic systems and custom made inertial measurement units

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(IMUs) have been proposed over the years [4–7]. However, many of the current interventions in rehabilitation are either very expensive (i.e. robot-aided systems) or not suitable for use at home. The innovative use of the Nintendo Wii could present a way to enhance community based stroke rehabilitation of the arm by providing a motivating and cost-effective way of exercising that could be remotely monitored and exercises adjusted as required by a physiotherapist [8]. To this end, a 15-month exploratory research study, known as Research in Wii Rehabilitation (ReWiiRe[1]), was undertaken in London, UK, in five National Health Service (NHS) sites to investigate the patient and therapist experience of using the Wii as an adjunct to physiotherapy [9]. This paper details how data from this study were used to inform the design and development of a customised VR-based prototype platform for rehabilitation of the arm after stroke. The platform employs the Nintendo Wii remote and an open source 3D authoring software with a game engine. Firstly, a comprehensive review of the literature is presented to foreground the development work that is the focus of this paper. This is followed by an overview of the architecture of the proposed developed system. Then, results from a formal evaluation of the system are provided and discussed before concluding comments are made.

Literature review

A number of recent literary reviews have investigated the experimental use of the Nintendo Wii in different clinical settings and collected patient and therapist responses on its use [10–13]. These highlight the importance of promoting better accessibility and more widespread use of affordable home-based systems, which on one hand motivate clinical users and on the other, provide the required motion-sensing fidelity needed to offer VR-based rehabilitation. A number of issues with the commercial Nintendo Wii system as well as currently available Wii-based VR interventions have been reported:

- Accurate tracking of the patient through the provision of full kinematic tracking of arm movement in real-time is one of the primary challenges [14].
- The facility for the therapist to remotely monitor and interact with the patient (and vice versa) in line with activity and progress [11].
- Provision of games and exercises that can be customised and are appropriate to stroke users. Most games and exercises are often inappropriate for the stroke population (in terms of feedback, length, speed, complexity and range of movement). They have to be adjusted for each patient's specific impairments/limitations [3,12,15].
- Patient difficulties in holding the Wii remote due to poor distal limb function [14].

In agreement with these studies, the results from initial stages of the ReWiiRe project found a high level of acceptability for the use of Wii in rehabilitation with 76.4% of patients ($n = 88$) and 72.1% of therapists ($n = 92$) agreeing that it was a useful tool in rehabilitation and 75.5% noting that they would like to use it as part of a HEP using teletherapy. Yet, results also highlighted a number of limitations of use, particularly in the field of neurorehabilitation where the duration, speed and complexity of the exercises, the dexterity required to hold and operate the Wii remote (known colloquially as the Wiimote), the accuracy, sensitivity and ability to pick up small movements (typical of stroke survivors) limited its use clinically.

Several studies have reported customised Wii-based interventions aimed at developing a VR-based system that captures the patient upper limb motion in a more accurate way compared to the conventional Wii remote. These can be categorised into three main groups depending on the technical methodology employed for customising the Wii remote, namely, acceleration data only, Wiimote and light-emitting diodes (LEDs) as an Infra Red (IR) camera and a hybrid of the two.

The majority of customised Wii remote stroke interventions employ one or two Wiimotes with a reverse engineered application programming interface (API) to capture the patient motion by reading the Wiimote accelerometer data.

A number of algorithms have been suggested and implemented by various research groups to filter these data and map them to motion to drive either a set of exercises or custom-built games, such as [16–18]. Since all of these approaches obtain the position of the Wiimote in space using the acceleration data (that is the change in the linear acceleration as the patient moves the Wii remote in space), they suffer from a Degree-of-Freedom (DoF) limitation. More precisely, these solutions offer accuracy only in 2-DoF as the acceleration data can only determine the pitch and roll movement. Such systems are therefore more appropriate for gesture-based interventions rather than one-to-one mapping (kinematic animation) of movement onto the VR environment.

Another common Wiimote customisation involves using a pair of Wiimotes with the LED sensor bar or custom LEDs as an IR camera as a low-cost motion capture system, such as [19–21]. Reflective markers or LEDs are usually placed on patient's arm or hand and as the exercises are executed, the range of motion is captured and mapped onto the system display. The limitation in this approach is that each Wiimote can only detect up to four LEDs in space, thus restricting the range of movement and set of exercises that the patient can execute. Also care must be taken to ensure that the angle of the Wiimote does not cause occlusion of LEDs as the patient moves his/her arm. Moreover, the use of LEDs often requires extra power supply devices to be attached to patients.

Wilson [22] and Martin-Moreno [23] have proposed a hybrid solution that incorporates the two aforementioned approaches in an effort to increase accuracy and the number of DoFs. However, this approach suffers from a limited field of view by employing the Wiimote as an IR camera, making it unsuitable for tracking larger motions that are often required in therapy [18]. Williamson et al. [24] have proposed a Wii-based system that merges acceleration and gyroscope data with the Wiimote's IR. This system is aimed at motion recognition for sport-like games (e.g. American football) and not for kinematic analysis and mapping of user motion on a 3D avatar (virtual character).

The data fusion algorithm developed by Williamson et al. [24] requires the use of the Wiimote's IR camera to compensate for the gyroscope drift and movement corrections. Results indicate improved motion recognition when compared to acceleration data alone but loss of accuracy when IR is out of sight.

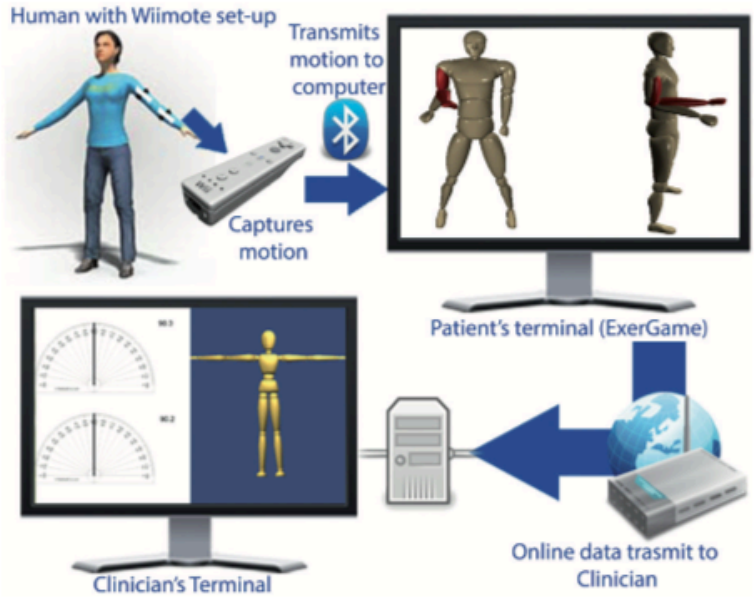
The ReWiiRe system

The system described in this paper was, developed within the ReWiiRe project, following an iterative participatory design and development cycle, where results from qualitative research involving patients and therapists were used to ensure the development is fit for purpose.

The system architecture, as depicted in Figure 1, consists of two front-end interfaces and a back-end database server, namely the patient and the therapist applications and an on-line data-recording platform. It is possible to omit the back-end platform from the infrastructure and maintain a direct connection between the two front-ends, but at the cost of an expandable and reliable system.

[1]For more information, see http://www.rewiire.org.uk.

Figure 1. ReWiiRe's system architecture.



The software is comprised of three bottom-to-top layers, namely the data access and collection, the data fusion and motion tracking algorithm, and the 3D visualisation. The data access operation includes functions that allow the application to acquire sensor data sent from multiple Wiimotes to a personal computer via Bluetooth communication (two Wiimotes are used in our study but more can be added). In the middle layer, the information received from the Wiimote sensors undergoes a process of smoothing and multiplexing using a data fusion algorithm in order to achieve higher accuracy and precision. The end results are mapped into quaternion forms that translate the orientation of a constructed 3D body model and also form the data structure for the top layer. The top layer embraces the dynamic physical simulation of a 3D avatar animation in real-time. For the purpose of the animation, we employ Blender,[2] which is an open source 3D application.

The motion capture information is stored locally and within a predefined time-interval is forwarded to a remote location using secured communication flows (known as network sockets). A database maintains the recorded sessions for each individual patient and is available to the therapist for evaluation and monitoring. It serves as a direct link between the patient and therapist, therefore it can also be used as a communication tool (e.g. the therapist may leave messages for the patient to receive or amend the patient's workout list as (s)he progresses). As the server holds sensitive information, a set of secure protocols is necessary.

The use of network sockets enables interoperability of our data usage in a cross platform environment (bidirectional inter-process communication flow across the host computer and a remote network) and the ability for the therapist to monitor patient progress both off-line (store-and-forward method) but also in real-time (getting a real-time 3D visualisation of the patient's current exercise activities). It should be noted that although the system architecture employs the Nintendo Wii technology for the capture of the motion; it has been designed to be scalable so that other game sensors, such as the Microsoft Kinect, can be employed for the capturing of patient motion.

[2]For Blender's home website, see http://www.blender.org/.

The patient application

Typically VR environments for upper limb rehabilitation are categorised into game-like or teacher-animation [25]. In the former, the patient accomplishes tasks in the context of a game, whereas in the latter, the patient is directly guided throughout the movement. Our system supports both modes, as from the patient application interface, the user can choose a set of exercises from a predefined exercise library set by the therapist, play customised games or check his/her progress. Furthermore we have designed the intervention as a hands free system (the Wiimotes are strapped on the patient's forearm and upper arm). This is an important aspect of the system, which was developed in response to feedback by stroke therapists in the ReWiiRe study, as most stroke survivors cannot grasp and manipulate objects, such as the Wiimote.

To help facilitate the correct execution of the exercises, the design concept of a ''Virtual Teacher'', a term coined by Holden et al. [26], was applied (Figure 2). By superimposing the teacher's arm movement (therapist in this case), on the patient's arm movement and instructing the patient to follow the teacher's arm trajectory, the patient is more likely to perform the action correctly. The provision of real-time 3D representation of the arm that is controlled by the patient is a key component of the ReWiiRe system, as it relates feedback to action by directly representing patient's experience in physical reality.

Furthermore, the system is designed to be expandable so additional applications and games can be integrated into the exercise library. Figure 3 illustrates the ''Hitting the Ball'' game, which has been designed and piloted within this project. In this game the patient moves his/her arm in order to interact with (e.g. move) the avatar's arm and hit the 3D balls within the VR space for a predefined period of time. Game parameters, such as the time that a new ball randomly appears or how far from the avatar's body it moves, as well as the arm range of motion that the avatar supports are fully adaptable dynamically, in order to cater for each

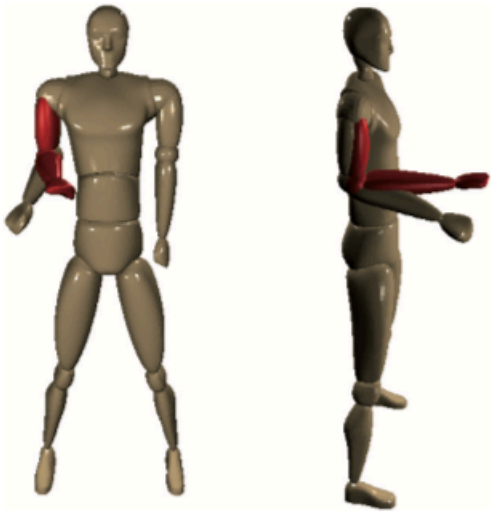


Figure 2. The design of the ''Virtual Teacher'' concept. The patient needs to follow the red arm to perform the prescribed by the therapist exercise.

patient's specific needs. The game records the range of movement and score, to provide the therapist with feedback but also reports back to the patient at the end of each session with simple, yet encouraging and positive feedback messages, such as ''Well done a new record was made'', ''Good effort'', etc.

The therapist application

The therapist application interface comprises a more multifunction application and has direct access to the database of exercises and games. Initially, the therapist is able to retrieve an individual exercise session and with the aid of the 3D application, (s)he can get a visual presentation of the patient carrying out that specific exercise as if (s)he was present during the execution. Through the application, the therapist is able to prescribe a new set of exercises by either selecting them from an existing library or by creating a new one in a perform-capture-record manner similar to the patient's ''Virtual Teacher'' interface. An additional function is the ability to review a range of sessions and monitor the progression of the limb's motor function. The results are displayed in units of arc degrees (i.e. elbow extension = 20°) and percentile improvement from the original assessment (Figure 4). The therapist can also define the range of movement, speed, duration, number of repetitions, scoring and feedback for each set of exercises as well as the prototype games, according to the degree of disability and needs of each stroke patient. Hence the system provides remote progress, assessment and interaction between therapist and patient as well as the ability to customise exercise and game settings to individual patient needs.

Motion capture and VR mapping system

In electronics, the Wiimote coupled with the Wii Motion Plus (or the recently integrated Wiimote Plus) can be considered as a low-cost, IMU since it features both accelerometer and gyroscope sensor devices. Although, these sensors are highly responsive, like any other Micro-Electro-Mechanical System (MEMS) devices, the readings can be prone to noise and errors, such as bias, drift, angular random walk, etc. A sensible approach to the problem is to process concurrently and conjointly both sensors' measurements through a data fusion algorithm so, raw information captured from one sensor can be used to distinguish true readings of the other, and vice versa. Also, the angular rate measurements captured by the gyroscope sensor can be used to distinguish true linear motion from the accelerometer readings and in combination with a matching human body's kinematic analysis, a highly accurate, well responsive one-to-one representation of the control device in 3D space 6-DoF can be achieved. The goal, with regard to the design of the physical simulation, was to mimic the motions seen in the arm close to real-time correspondence. This would, enable users to feel a connection between their actions and that of the 3D avatar, providing them with instant visual feedback to increase motivation to exercise. The full description and discussion of the Motion Capture (MoCap) system is beyond the scope of this paper but more information can be found in Tsekleves et al. [9].

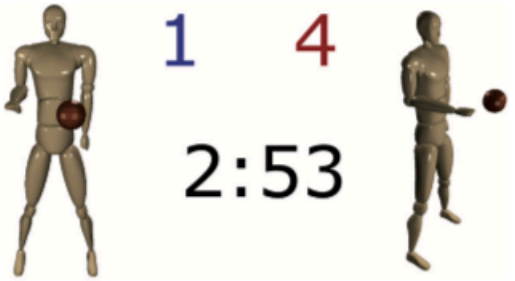


Figure 3. The ''Ball Hitting'' game concept. The patient must hit the balls that appear randomly and within a given time.

Mocap system accuracy validation

Based on the goal, described above, it is clear that the accuracy of the MoCap system was a major challenge and therefore an experiment was conducted to evaluate this, in which the MoCap system was compared with a well-established professional and accurate system, namely the Vicon™ MoCap Studio.[3] The Vicon™ MoCap Studio at the lab of Brunel University, Uxbridge, UK, comprised of 11 infrared cameras and a MoCap software platform, namely Blade 1.7. The software offers a calibration procedure that matches the camera positioning with the cameras in the 3D environment and reconstructs the actual scene into 3D, hence matching the camera frames with the environment frame. The highly sophisticated MoCap studio is capable of achieving accuracy of sub-millimeters. As the ReWiiRe system is markerless, there was no interference when the two systems worked in parallel. A six-rod structure was built to support the Wiimote and provide reference of position into the Vicon platform. For that reason, one reflective marker was attached at the end of each equidistant rod, and two markers were attached to another rod for reference purposes (Figure 5). The structure was wooden as this material does not have any magnetic properties and therefore would not interfere with the measurement units of the Wiimote. The resulting object within the VR environment was an octahedron with the markers acting as vertices. The Wiimote was placed at the centre of the octahedron. As the individual vertices of the octahedron were captured and the motion data was already known, it was possible to calculate the motion data at the centre, which had been designed to be the middle point, as seen in Figure 5. The structure was supported by

[3]http://www.vicon.com/.

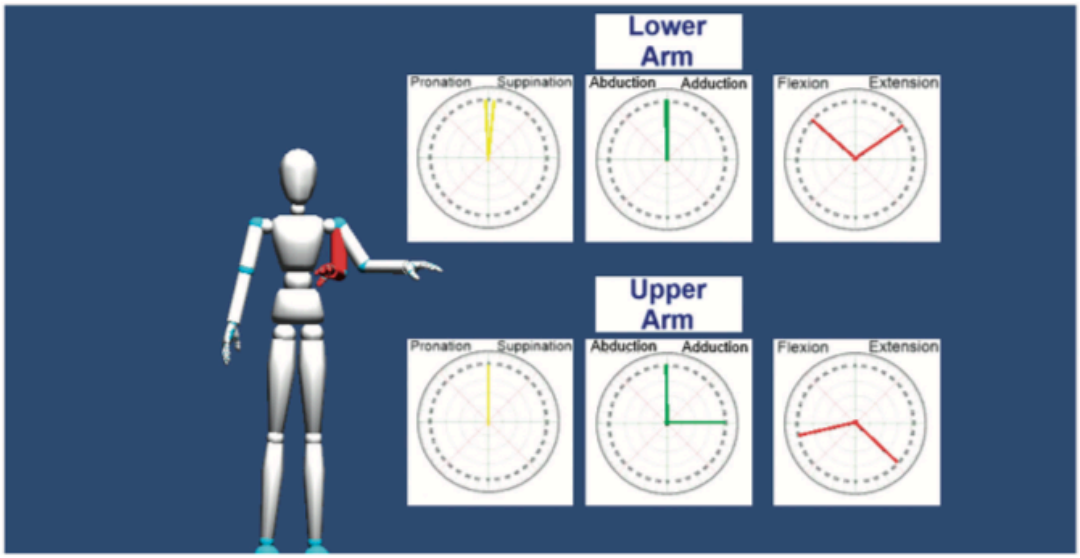


Figure 4. The therapist application.

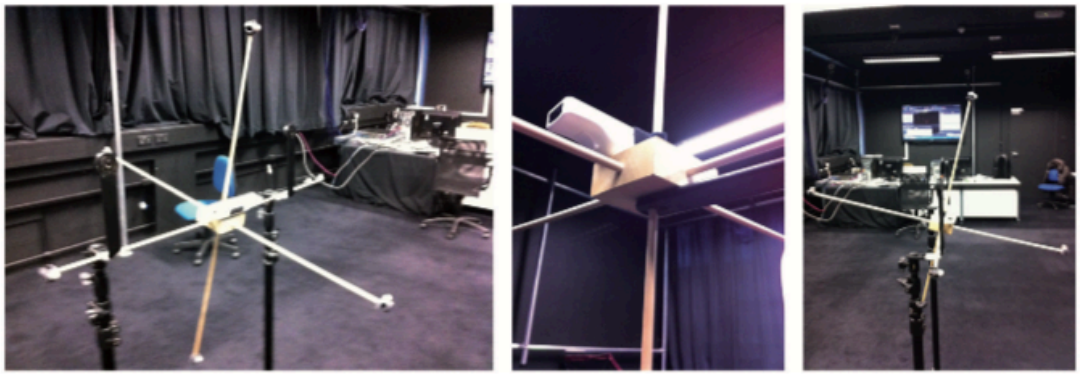


Figure 5. The experimental setup of our mocap system.

two stands so that it could rotate freely along any axis. All axes were tested by a rotational pattern of +90°, −180°, +90° and included three repetitions each time to compile a dataset that could render the system performance. The recordings of both systems were taken simultaneously for time reference purposes.

Mocap validation results

The results presented below are very encouraging as they are very close to the data gathered by the Vicon system, which has an established accuracy level of sub-millimetre.

The movement pattern shows high correlation between the Wiimote and the MoCap systems and quantitative analysis of the Wiimote system data showed a range of accuracy between 5.5% and 10.78% residual value (5.5%, 9.39% and 10.78% correspondingly for each of the axis depicted in Figures 6–8).

This value is the Normalised Root-Mean-Square Deviation (NRMSD), which is commonly used as a formula to calculate deviation for such cases as ours where n = number of samples for each recording

$$\mathrm{NRSMD} = \frac{\mathrm{RMSD}}{x_{\max} - x_{\min}} \tag{1}$$

where

$$\mathrm{RMSD} = \sqrt{\frac{\sum_{i=1}^{n} (y_i - \hat{y}_i)^2}{T_i}} \tag{2}$$

The residual values demonstrated that the ReWiiRe system, as depicted in the figure above, has acceptable levels of accuracy when compared to the commercial and expensive MoCap system. This renders it a valid candidate for the purposes of a biofeedback platform. It should be noted, that the measurement error was due to a broad range of reasons; from magnetic fields that affect the performance of the IMUs, to synchronisation errors during the data capture process. The NRMSD values are an indicator that the proposed system will provide results of acceptable accuracy for a home-based and tele-monitoring system.

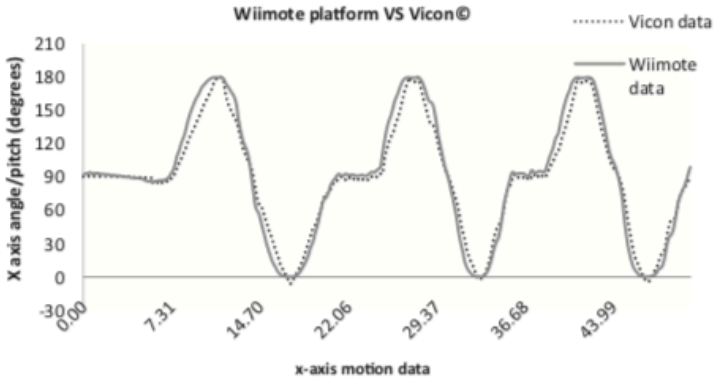


Figure 6. Wiimote mocap system accuracy data in comparison to the Vicon platform– *X*-axis.

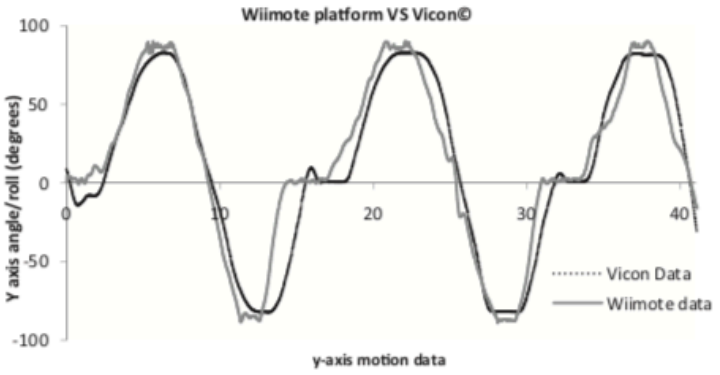


Figure 7. Wiimote mocap system accuracy data in comparison to the Vicon platform – *Y*-axis.

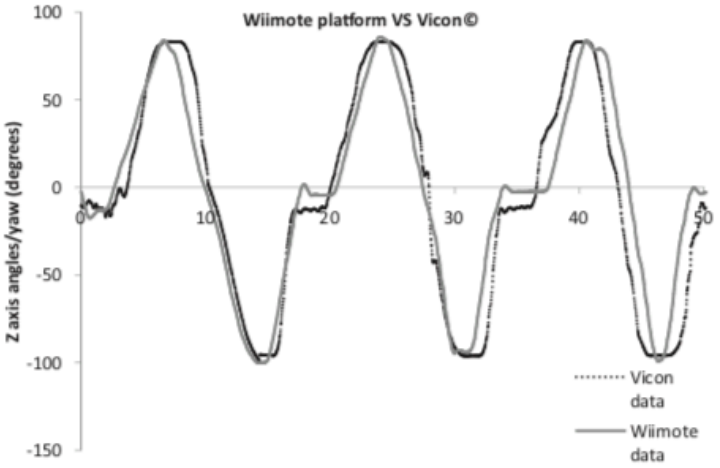


Figure 8. Wiimote mocap system accuracy data in comparison to the Vicon platform – *Z*-axis.

Preliminary evaluation

This section presents the protocol and results of the preliminary evaluation of the final system and findings from a proof-of-concept case study with a stroke survivor who was 11 years post-insult.

System evaluation

Method

Following ethical approval for the study, three stroke survivors were recruited to the ReWiiRe team and assisted with system evaluation and further development:

Figure 9. Study participant pilot testing the three trials.

- Participant 1–33-year-old male with right-sided hemiplegia following a stroke 18 months previously. Scored 3 on the modified Rankin Scale (mRS) indicating moderate disability, with moderate gross movement at the shoulder and elbow, flickers at the wrist and hand (no grasp). Had played with the Nintendo Wii prior to his stroke but had not used it since.
- Participant 2–52-year-old female with right hemiplegia following a stroke 16 months previously. Scored 2 on the mRS indicating slight disability with weak and uncoordinated movement throughout the arm and hand. Had played with the Nintendo Wii prior to her stroke but had not used it since.
- Participant 3–57-year-old female with left hemiplegia following a stroke 14 months previously. Scored 4 on the mRS indicating moderately severe disability with minimal movement at the shoulder and elbow and some non-functional movement in the hand. No previous experience with the Nintendo Wii.

Participants took part in three trials using the Wii-based stroke intervention in a university therapy room (Figure 9). All participants were given time to familiarise themselves with the system. The field test, including familiarisation with the protocol, lasted 50 min. The trials are summarised below:

(1) Teacher animation trial: each participant performed three, pre-recorded upper-limb exercises in which (s)he had to follow a 3D avatar projected on a screen. Three movement patterns, involving the shoulder, elbow and forearm, were selected on the basis of functional utility and subject difficulty in movement performance. The exercises were different for each participant in terms of speed, range of movement and movement performed, dependent on each participant's specific impairments. Each movement pattern was performed by participants for three sets of five repetitions.
(2) Ball hitting game trial: involved the use and display of the 3D avatar on the projector screen where participants tried to ''hit'' randomly appearing balls, (high, middle, low, central, left or right of the screen avatar). Each ball remained on the screen for 5 s, or less if successfully hit. The time taken to hit (or miss) 25 balls was recorded. Two sets of 25 were completed.
(3) Air hockey game trial: centred on playing an air hockey game for 5 min. This involved moving a ''puck'' forward, backward and side-to-side through combined movements of the elbow and shoulder to score goals and defend their own ''net'' against the computer opponent. The range of movement was changed to accommodate the ability of each participant.

All sessions were captured via video and observation notes were made during the trials. After completion of field testing, participants shared their comments, insights and experience about using the customised Wii intervention with the rest of the research team.

Results and discussion

A number of themes emerged from post-intervention debriefs and observation notes, namely: participant connection with the avatar, normal versus mirror view and opinions on the personalisation of the VR environment.

Participant connection with the avatar

Participants reported the importance of being able to see their movement mapped onto a virtual character (avatar), as it helped them in getting a direct visual feedback of the action performed at the time. Participants also reported feeling connected with the avatar:

> I actually like when I am doing it. It (referring to the avatar) feels like that's me. (Participant 1)

This was more evident in the teacher animation and hitting the ball trial. In the former, participants indicated the usefulness in being able to see the physiotherapist's pre-recorded exercise on the screen whilst they were trying to match it. They stressed the importance of feedback and guidance and reported that this would enable the session to take place at home instead of the clinic:

> It [the system] would be like having the physio at home with me, guiding me all the way through what [exercises] I have to do, plus I can see and compare how well I am doing. (Participant 2)

It was observed, particularly in the case of participants 1 and 2, that their ranges of movement improved (i.e. they were able to extend their arms further) when conducting the exercise whilst looking at the avatar compared to exercising without the device. In addition, participants reported that they highly valued the responsiveness of the system, particularly in terms of the visual feedback provided through the depiction of the arm movement on the VR environment:

> It is great! I can see my arm movement appear instantly on screen and can tell how well and far I have gone. (Participant 3)

Participants were asked to perform the exercises in the teacher animation trial while seated and standing up; the avatar was in both cases in a standing posture. Participant 2 did not mind this but participants 1 and 3 found it less helpful:

> It is easier to do exercises when he (referring to the avatar) is standing, it feels more like me. (Participant 1)

Participant responses indicated a direct link between patient motivation and personal connection with the avatar, especially when combined with instant visual representation and feedback of motion on the screen. This was true with regards to the position of the avatar with participants suggesting that if they are seated, so should the avatar. However, this was not the case in terms of the avatar's personal physical characteristics, with all three subjects reporting this as irrelevant.

Default versus mirror view

Another element investigated, in both the teacher animation and hitting the ball game, was the uses of default and mirror views (similar to watching oneself in a mirror). All participants reported preference for the mirror view, as they found it more natural and they were accustomed to using a mirror when conducting exercises either at home or in the gym. It was also observed that participants performed better in terms of response time and scored higher (in the case of the hitting the ball trial) when using the mirror view:

> It feels (referring to the mirror view) a more natural way of seeing things. (Participant 3)

It was not anticipated that viewpoint would have such an impact on participant interaction with the VR environment and performance. It is therefore suggested that any VR stroke rehabilitation environment should support a mirror view, as it is perceived by stroke patients as a more natural way of viewing and understanding their movement. Feedback from this stage resulted in the use of a mirror view being adopted.

VR environment personalisation

According to participants, a key feature of the trialled activities was the ability to personalise various aspects of the VR environment. In particular, exercise duration, range of movement, game-play/activity speed and avatar viewing angle were regarded as the most important personalisation features. Participants commented that when interacting with the teacher animation they found being able to select from a range of prescribed exercises of great benefit. They reported that being able to have control over the range of movement was very important in terms of accessibility.

> I can now play games and do things not possible for me before. (Participant 2)
>
> I used to play Wii bowling and golf before. This is the first time since then I have played games with the Wii again. (Participant 1)

In addition to this, participants indicated that being able to adjust the speed in the hitting the ball and air hockey games made the tasks more manageable and enjoyable:

> I found it (referring to the hitting ball trial) hard at the beginning, as it was too fast for me. After changing the speed it become easier and I could follow it. (Participant 3)

This was found to be a key factor for the adoption of the trialled activities, as different stroke survivors have very different abilities and response times. For instance participant 3 had the slowest reaction time and was slower in completing the tasks when compared to the others.

Single case study

Method

A single-case, before and after study was undertaken to field test the system [27]. The participant was a 31-year-old, right-handed, female (BM), who had suffered a right sided stroke 11 years previously, resulting in a left sided hemiplegia (scoring 2 on the mRS). She had finished all formal rehabilitation.

The study took place in a university therapy room, three times weekly over a two-week period with the subject in standing using the same activities and procedure outlined in the previous section.

Table 1. Pilot single-case study outcome measures.

	Pre-study	Post-study
NHPT		
Average time to place each peg.	29 s	7.8 s
Normal = 2 s		
MAS		
• Shoulder adduction	0	0
• Elbow flexors	1+	1+
• Wrist extensors	3	1
• Finger flexors	3	1
6 point ordinal scale		
0 = no increase in muscle tone		
4 = affected parts rigid in flexion or extension		
FMA: upper limb		
3 point ordinal scale	39	47
0 = unable to perform		
2 = performs fully		
Maximum score = 66		
MAL		
6 point ordinal scale	7	10
0 = never use affected arm for this		
5 = use same as pre-stroke		
Maximum score = 70		

Two-minute rest periods were introduced between each exercise and activity. Six sessions of therapy were completed with an average of 18 min spent exercising (excluding rest periods).

Outcome measures to assess for any change in motor impairment [Fugl-Meyer Assessment (FMA) upper limb section and Nine Hole Peg Test (NHPT)] [28], spontaneous functional use [Motor Activity Log (MAL) – Amount of Use (AOU) sub-scale] or any increase in muscle tone (spasticity) [Modified Ashworth Scale (MAS)], were used to assess baseline ability and outcome (see Table 1). To avoid effects of fatigue, measurements were taken one day prior to the start of the exercise sessions and one day post, by a single assessor. In addition, the subject was asked to subjectively quantify perceived effort and enjoyment of the activities.

Results and discussion

Results from the outcome measures are reported in Table 1. No adverse effects were reported and positive changes were seen in all outcome measures.

A large improvement in score on the NHPT (from 29 to 7.8 s per peg) indicated a significant improvement in upper limb impairment. The NHPT requires the patient to pick up and place 9, 9 mm wooden dowels (known as pegs) in a wooden base with 10 mm holes spaced 15 mm apart in a 3×3 arrangement. The time taken to place all pegs is recorded and reported as seconds to place each peg. The participant completed two trials of the NHPT at each measurement session and the results from the two attempts were averaged to provide the final score. The participant dropped two pegs just as she was about to place them in the board on both of the trials before the study (resulting in the assessor retrieving the peg while the participant continued the test with another peg) and this contributed to the poorer score seen before the study. No pegs were dropped in the post-study assessment.

A clinically significant increase in score was seen on the FMA (an increase of 8 points from 39 to 47 on a 66 point scale) suggesting an improvement in impairment post-study. Moreover, an improvement in score for functional spontaneous use of the arm (MAL score from 7 to 10 on a 70 point scale) indicated that the participant was spontaneously employing her affected arm more following the study.

The MAS is a six-point ordinal scale measuring spasticity or uncontrolled tightening of muscles (where 0 indicates no increase in spasticity and 5 indicates that the limb is held in a rigid posture) and was employed to detect whether use of the technology resulted in an adverse increase in spasticity. The MAS score remained unchanged in the shoulder and elbow and improved slightly (from 3 to 1) in the finger and wrist flexors indicating a non-significant reduction in spasticity and demonstrating that the use of the system did not result in an adverse increase in spasticity with this subject

The participant described her left upper limb as feeling ''warmer'', ''more muscularly defined'' and ''lighter''. Moreover, she reported that she had greater speed and range of movement and that her ''hand wanted to open of its own accord''. She also reported better wrist control, greater functional use and noted that she had automatically used her left arm to lift and drain a cooking pan for the first time since her stroke.

While the results from this study are very encouraging, due to the nature of the study, it is not possible to state with certainty that the improvements seen were as a result of the intervention alone, however, at 12 years post-stroke, it is unlikely that the participant would have spontaneous recovery which typically occurs within the first three months following stroke.

The activities employed, possessed a high level of user-acceptability which is critical in improving compliance with exercise programmes. The stroke survivor in this case study reported that exercise 1 was only moderately fun but nevertheless enjoyable since it felt like a ''good workout'' (Figure 10). She expressed great enjoyment of the ball hitting activity as she scored well and hence found this both fun and motivating. However, as she improved, her enjoyment level began to wane, suggesting the need to progress activities to ensure they remain challenging. Interestingly, the participant was most interested in trialling the air hockey game as this was something that she had played in reality. However, she initially expressed limited enjoyment due to frustration with her, unexpectedly, low score. With repetition and recalibration of the game speed and range of movement required, her score and motivation improved to the extent where she rated the game as 9/10 for fun; expressed the wish to play for longer periods and described how, in her own words, ''the phrase air hockey, caused a Pavlovian response with regard to motivation!'' providing further evidence for the need for individual calibration of activities.

Conclusions

Over a third of stroke survivors have a long-term disability and many experience reduced quality of life. Compliance with traditional rehabilitation techniques and limited resources to provide therapy particularly on discharge from the hospital, mean that the intensity of practice necessary to drive recovery is often not achieved. This paper has presented an innovative system, developed to offer a customised stroke VR-based rehabilitation intervention by using low-cost off-the-shelf game sensors (the Nintendo Wii remote combined with open source 3D software). The presented system offers full kinematic tracking of the user upper limb movement in real-time, thereby making it possible to have a strong personal connection between a stroke survivor and a virtual character to enhance the clinical utility of this innovative technology. This is the first project to fuse the Nintendo Wii remote acceleration and gyroscope data together to track the controller movements and offer a 6-DoF with the use of the Wii remote alone.

System evaluation with stroke survivors (with varying levels of disability), showed positive results. They reported a strong connection with the system and avatar, mainly due to the real-time visual depiction and feedback of their arm movements on the VR environment. They commented positively on the personalisation features of the system, especially in terms of the exercise range, range of movement and game-play/activity speed. These features enabled them to engage in activities and games otherwise unsuitable for them. For some participants, it was the first time they had interacted with VR gaming environment since their stroke. It was also found that use of a mirror view when performing exercises increased stroke patient connection with the VR environment, as well as response times and performance.

Our preliminary clinical trial results also indicated positive changes in the four outcome measures employed in our single-case study. Despite the short study duration, significant improvements were demonstrated, particularly in the NHPT and MAL where significant improvements were observed and greater functional use of the affected arm was reported. It was also noted that activities employed through the customised Wii system were fun and motivating and that customisation of the activities, such as the speed and range of movement required, increased the stroke survivor's score and motivation. It is interesting to note that the case study subject demonstrated improvement in hand function despite the device not actually targeting the hand. This may be due to muscles in the forearm also being involved in hand movement.

Encouraged by the preliminary results, the team plan to extend the study in terms of duration and participant numbers. In addition, exploration of the feasibility and acceptability of the system with community dwelling stroke survivors and studies exploring the use of the system in other neurological conditions are planned.

Figure 10. Stroke survivor pilot testing the ''Teacher Animation'' prototype.

Declaration of interest

The authors report no declarations of interest.

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1.3 Warland et al. (2012)

Good Practice in User Involvement

049
Incorporating patient and carer feedback into service development on an acute stroke unit

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Introduction: The national stroke guidelines propose that the views of stroke patients and their carers should be taken into consideration when evaluating and improving stroke services according to national stroke guidelines. It is recommended that service users should be regularly informed about how their views have influenced services. Limited guidance exists of how to implement service user feedback within the acute stroke service setting.
Method: External interviewer facilitated six focus groups using a semi structured interview to elicit experiences and qualitative data during 2010–2012. Exclusion criteria of patients with severe communication or cognitive impairment. Multi-disciplinary team discussions were held following focus groups regarding feedback and future implementation plans. Newsletter used as a dissemination information tool sent to all participants and staff.
Results: Service improvements that have been implemented have included patient-centered goal setting, an educational stroke DVD, stroke education folders, and a document to enable collaborative discharge planning. Ongoing projects include a 'mini-surgery' to provide advice regarding financial benefits and services and peer stroke survivor support groups.
Conclusion: Patient and carer focus groups have identified areas for improvement and evaluated current services providing practical suggestions of how to improve the patient experience. Feedback has been an important contribution to the stroke service. Increased involvement of aphasic patients is an important consideration for future feedback.

050
Can a hospital based outreach service meet the needs of stroke patients?

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Introduction: The National Stroke Strategy (2007) and RCP guidelines (2008) recommend early discharge from hospital with multi-disciplinary teams providing stroke specific rehabilitation at home. In response to this in April 2011 Nottingham University Hospitals (NUH) established a hospital based outreach team for an area of Nottinghamshire not covered by ESDs to facilitate early discharge and improve patient outcomes.
Method: The Stroke Outreach Service (SOS) is based on the NUH Stroke Unit and is managed within the inpatient therapy structure. Over the past year, the team provided early rehabilitation and support to stroke patients for a period of four weeks. Over nine months from July 2011–March 2012 statistical data has been collected including activity, outcome measures and length of stay, plus patient and carer feedback has been received.
Results: Over nine months from July 2011–March 2012 the Stroke Outreach Service gave input to 109 patients. All received an initial visit within two working days of hospital discharge and 38% did not require any further follow up. Outcome measures demonstrated improvements in patients' balance and ability to carry out ADLs, and feedback from patients and families have included comments on the benefit of meeting the team prior to discharge.
Conclusion: The SOS has demonstrated that an efficient, cost-effective service can be successfully established within the inpatient structure. The benefits of being hospital based include continuity of care, seamless transfer of care and a more responsive team with a strong sense of responsibility for reducing length of stay.

051
ReWiiRe (Research in Wii Rehabilitation): User involvement in the development of a personalised rehabilitation system for arm re-education after stroke

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Introduction: Virtual reality gaming systems, such as Nintendo Wii, are increasingly used in rehabilitation to deliver the intensity and repetition of practice necessary to enhance recovery. This abstract reports service-user (SU) involvement in the ReWiiRe project (www.rewiire.org.uk); which investigated feasibility and acceptability of rehabilitation using Wii and the development of a personalised stroke treatment (PST), using adapted Wii technology, for arm re-education post-stroke. SUs worked collaboratively with therapists and engineers to develop data-collection tools (aphasia-friendly questionnaire, interview schedules); advised on design and testing of equipment prototypes and design and content of bespoke exercises and games, ensuring that PST was relevant and meaningful. A SU participated in a two week case-study testing PST.
Method: Mixed methods: questionnaire, semi-structured interviews and single case-study.
Results: 33 questionnaires and 10 interviews were completed. 87.9% (29/33) questionnaire respondents felt Wii helped with rehabilitation. 57.6% (19/33) reported difficulty using equipment. 33.3% (5/15) of SUs reported difficulties using the hand-held remote controls. Therapists believed use of standard Wii was limited due to the high level of dexterity, movement and coordination necessary to operate the system. A case-study using PST demonstrated a high level of user-acceptability and positive changes on outcome measures.
Conclusion: Use of standard Wii in arm rehabilitation post-stroke is limited. Issues identified from this study, together with input from SUs have been used to iteratively inform the design and development of PST using adapted Wii technology for arm rehabilitation. Proof of concept was confirmed through a case-study. Further study using the PST is planned.

052
Facilitating representative and equitable engagement of stroke survivors and health professionals in setting research priorities

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Introduction: Involvement of patients and clinicians in setting research and funding agendas is ethically desirable and can improve the quality,

2: Scoping Study Abstract

Background: Off-the-shelf virtual reality (VR) gaming technologies, developed primarily for entertainment and general fitness purposes, such as the Nintendo Wii, are increasingly being used in rehabilitation. While the Medical Research Council recommend investigation of efficacy, acceptability and feasibility of interventions prior to clinical implementation, (Craig et al., 2000) there has been little evaluation of the feasibility and acceptability of using these systems for rehabilitation purposes.

Aim: In this mixed-methods study, the concept of using off-the-shelf VR gaming technologies for rehabilitation was explored using the Nintendo Wii in clinical specialities of lower-limb amputee rehabilitation, musculoskeletal outpatient rehabilitation and neurorehabilitation.

Methods: One-hundred and forty-nine service-users and clinicians from five NHS sites, across four NHS trusts completed a questionnaire-based survey. Seventy-one were service-users (31 [44%] aged 18-44; 21 [30%] aged 45-64; 19 [27%] aged 65 and over. Ten [14%] from lower-limb amputee rehabilitation; 43 [61%] from musculoskeletal outpatient rehabilitation and 18 [25%] from neurorehabilitation] and 78 were physiotherapists (ten [13%] from lower-limb amputee rehabilitation; 53 [68%] from musculoskeletal outpatient rehabilitation and 15 [19%] from neurorehabilitation). Sixteen service-users (aged 23 to 77, [mean 48.6 years], five from lower-limb amputee rehabilitation, five from musculoskeletal outpatient rehabilitation and six from neurorehabilitation) and three neurorehabilitation clinicians (aged 28 to 35 [mean 30.3 years]) participated in a one-to-one semi-structured interview regarding their experience of using the Nintendo Wii in clinical practice. Kruskal-Wallace H tests with post hoc Mann-Whitney U tests, and Chi-squared or Fischer's Exact Test (when expected counts per cell were less than 5) were conducted to determine any relationships between key variables. Interview data was analysed using Thematic Analysis. Side by side displays were used to integrate quantitative and qualitative findings.

Integrated Findings: The Nintendo Wii was found to be acceptable and feasible to use in lower-limb amputee and musculoskeletal outpatient rehabilitation. The concept of using virtual gaming technologies as an adjunct to neurorehabilitation and when traditional neurorehabilitation is no longer available, was highly acceptable by service-users and therapy clinicians and was felt to have the potential to address the lack of upper-limb rehabilitation experienced by many stroke survivors. However, feedback was felt to be insulting and demoralising. While safe and feasible to use in balance neurorehabilitation, findings suggested that off-the-shelf VR gaming technologies lacked feasibility for upper-limb stroke rehabilitation due to the high level of dexterity, strength and coordination required to operate the movement sensor, the large range of movement and high level of challenge inherent in games calibrated for the neurologically intact, a lack of instructional feedback, and distracting peripheral features. Additionally, findings from therapists, supported the need for VR gaming technologies to be hands-free, personalised, easy to set-up and affordable.

Conclusions: The concept of using VR gaming technologies as an adjunct to traditional neurorehabilitation is acceptable to service-users and clinicians. However, off-the-shelf systems are unsuitable for upper-limb stroke rehabilitation purposes, suggesting the need for VR gaming technologies to be designed specifically for upper-limb neurorehabilitation purposes.

3: Literature Review Evidence Tables

3.1 Evidence Table for Systematic Reviews

Title Year authors	Search parameters	Study population (stroke unless otherwise stated), stroke chronicity and severity	Description of VR device	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Casserly and Baer (2014)	Databases: n=6 (none engineering) Search dates: 1995-2011. Study designs: RCTs, controlled trials, uncontrolled, single case studies. Any setting	n=8 upper-limb stroke studies (135 participants) Chronicity: any Severity: not stated	Any commercial, off-the-shelf gaming system (only Wii and Eyetoy included). Non-immersive	Effective as an adjunct to conventional therapy. Positive effect on quality of life No meta-analysis	"Appeared to be enjoyable"	Number screened and eligible not apparent No comment regarding time issues or costs made in body of text but state in abstract that feasible in terms of costs, and time (unsubstantiated) No incidence of serious adverse events
Hatem et al. (2016)	Databases: n=2 (none engineering) Search dates; 1971-2015 Study designs: RCTs, controlled trials, SRs, meta-analyses Any setting	n=270 studies, of which n=14 adult upper-limb stroke using VR. n=10 RCT VR (697 participants) and 4 SR's (760 participants) Chronicity: unclear	Commercial off-the-shelf gaming and purpose-built systems. Included studies with VR in combination with other interventions (e.g. robotics, electrical stimulation)	Moderate quality evidence that VR is as effective as, but not superior to conventional therapy		

Abd= abduction; ADL = activities of daily living: ARAT- Action Research arm Test; BI= Barthel Index; BBT=Box and Block Test: BI= Barthel Index; CAHAI- Chedoke Arm and Hand Activity Index; CI= Confidence interval; COPM= Canadian Occupational Performance Measure; CT = conventional treatment; D/C= discharged; Ext = extension; FIM= Functional Independence Measure; Flex= Flexion; FMA-UE = Fugl-Meyer Assessment-Upper Extremity; GPT= Grooved Pegboard Test; IQR- Inter quartile range; JHFT= Jebson-Taylor Hand Function Test; LL= lower limb; MAL- Motor Activity Log; mAS= modified Ashworth Scale; MAS= Motor Assessment Scale; mBI= Modified Barthel index; mCIMT= modified Constraint Induced Movement Therapy; MI= Motricity Index; MMSE= Mini Mental Status Evaluation; MMT = manual muscle test; MRC= Medical Research Council muscle power; mRS= Modified Rankin Scale; NIHSS= National Institutes of Health Stroke Scale; NHPT= Nine Hole Peg Test; OT= Occupational Therapist; PGIC= Participant Impression of Change; PNF=Proprioceptive Neuromuscular Facilitation; PRPS= Pittsburgh Rehabilitation Participation Scale; QoL= quality of life; RCT= Randomised controlled trial; ROM=Range of Motion; rot^{n}= rotation; Rx = treatment; SD =standard deviation; SIS= Stroke Impact Scale; SMD= standardised mean difference; SR= systematic review; TEMPA= Test Evaluant Les Membrès superiors des Personnes Agees; TSP=task specific practice; UE= upper extremity; UL = upper limb; VAS= visual analogue scale; VR= virtual reality; WMFT= Wolf Motor Function Test; WMFT-FAS= Wolf Motor Function Test- Functional Assessment Scale

Title Year authors	Search parameters	Study population (stroke unless otherwise stated), stroke chronicity and severity	Description of VR device	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
		Severity: unclear	Level of immersion unclear			
Laver et al. (2017)	Databases: n=8 (including engineering) plus ongoing trials register, reference list scanning, dissertation abstracts, conference proceedings. Search dates: 2010-April 2017 Study designs: RCTs and quasi-RCTs Any setting	n= 72 of which n=35 upper-limb (1,243 participants) Chronicity: any Severity: any	Commercial, off-the-shelf and purpose-built systems Included studies with VR in combination with robotics and exoskeletons All levels of immersion	VR vs CT: no significant difference in upper-limb function, activity, grip strength or self - report amount of use between groups. Rx dose: Trend towards VR in trials providing >15 hours of intervention (SMD 0.13; 95% CI -0.03 to 0.29) Chronicity: trend towards VR for those with chronicity>6/12 (SMD 0.19; 95% CI -0.02-0.39) Severity: Both mild/mod and mod/severe showed non-significant improvements System type: Purpose-built programmes significant benefit (SMD 0.17 95% CI 0.00-0.35). No		No serious adverse effects reported. Occurrence of mild adverse effects reported (headache, dizziness, pain and increased hypertonicity)

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				significant benefit with those using off-the-shelf programmes. VR as means of additional therapy: Significant improvement in upper limb function compared to no intervention (SMD 0.49; 95% CI 0.21-0.77) Rx Dose: Significant effect in trials ≥15 of intervention (SMD 0.54; 95% CI 0.00-1.07) and <15 hours (SMD 0.54; 95% CI 0.14 to 0.80). No significant group differences Chronicity: Significant effect in trials >6/12 only (SMD 0.65; 95% CI 0.19 to 1.11). No significant group effects Severity: not assessed System type: Both types of console found to be effective		

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				when used as an adjunct (no statistical analysis provided) No between group difference		
Pietrzak et al. (2014)	Databases n=3 (none engineering) and reference lists of included articles Search dates: start date not stated. Search performed 2012. Study designs: RCT, control trial, quasi-experimental Included abstracts Any setting	n=13 studies (7 abstracts) Chronicity: Subacute to chronic Severity: one study included those with "very low" function (not defined)	Commercial, off-the-shelf gaming systems Non-immersive	Results by device type: CyWee Zii: (n=1) significant effect of VR; Eyetoy: n=2 no evidence of effectiveness; Wii: n=10 significant improvements in chronic, subacute and in moderate to "very low function"	High satisfaction in 3 studies	Safety reported in 3 studies. No adverse effects in two, mild pain in one
Thomson et al. (2014)	Database: n=9 (none engineering) plus grey literature, ongoing trials register, reference list scanning, dissertation abstracts, conference proceedings.	n=19 studies (215 participants) Chronicity: any Severity: mild to moderate	Commercial, off-the-shelf gaming systems Joints targeted by training not specified Non- immersive	Effective at delivering high intensity practice Weak indication that VR can have positive impact on ADL and UL function and movement	Findings of acceptability appear positive Frustration with level of difficulty expressed.	Only 10 studies reported incidence of adverse effects. 3 reported no adverse effects. 7 reported mild adverse effects (4 mild UL pain, 3 fatigue).

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Title Year authors	Search parameters	Study population (stroke unless otherwise stated), stroke chronicity and severity	Description of VR device	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Search dates: up to January 2013 (start date not stated) Study designs: RCTs, case control, cohort, case report and qualitative Any setting					1 study reported challenges /barriers to use but unclear what these were. Reports that several adaptations were required to enable use. Games difficult. Required additional feedback by therapist
Veerbeek et al. (2014)	Database n=12 (none engineering) plus search of reference lists of included studies, papers in 6 European languages included Search dates: 2001-2011 Study designs: RCT All settings	n= 467 RCTs of which n=15 looked at VR in UL (357 participants) Chronicity: any Severity: unclear	Commercial, off-the-shelf gaming, purpose-built and modified versions of commercially available systems Level of immersion unclear	Significant positive summary effect for VR on basic ADL Non-significant (i.e. neutral) effect for motor function and arm/hand activities No difference by chronicity		Incidence of adverse effects not reported

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3.2 Evidence Table for Off-the-Shelf VR Gaming Technologies

Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
Adie et al. (2017)	n= 235 VR n=117 Age: mean (SD) 66.8 (14.6); Chronicity: mean (SD) 57.3 (48.3) days; Severity: ARAT mean (SD) 41.2 (15.9) Control n=118 Age: mean (SD) 68 (11.9) Chronicity: mean (SD) 56.3 (50.1) days Severity: ARAT mean (SD) 41.0 (16.6)	UK, home - based study RCT	Nintendo Wii Trains shoulder, elbow and forearm Non-immersive	45 mins max (no lower limit) 5/7, 6/52 VR Wii Sports (participant choice of activity) Control tailored arm exercises Both groups had usual care, exercise diary, weekly phone-call Mean (SD) total exercise time VR =1020.2 (721 mins). Control = 998 (554.8) mins	Results included in findings from SRs, reported in Appendix 3.1	See Wingham et al. (2015)	6,027 screened of which 5,689 excluded and 98 declined. More expensive than traditional arm exercises (£1106 vs £730). Therapist set up and taught stroke participants how to use 46 serious adverse effects unrelated to study. Incidence of minor adverse effects not recorded.

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	Had to have MRC score < 5 in any joint plane but able to hold and manipulate the movement sensor. No significant between group differences at baseline						See Wingham et al. (2015)
Carregosa et al. (2018)	n=15 Age: mean (SD) 54.8 (4.6) Chronicity: mean (SD) 38.4 (13.1) months	Brazilian: setting unclear Single-group, pre-test, post-test study design	Nintendo Wii Trains shoulder, elbow and forearm Non-immersive	60 mins, 2/7, 2/12 consisting of stretching + 50 mins of VR games	Improvement post intervention for FMA-UE (mean 10.6 points), strength sustained at 8/52 follow up	Only 5 of 15 completed follow-up. Reasons unspecified	Number screened and eligible not apparent Incidence of adverse effects not reported

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	Severity: able to walk independently without walking aids and hold the Wiimote. Excluded if had sensory changes						
Chen et al. (2015a)	n=24 VR with Wii n=8 Age: mean (SD) 49.8 (16.1) Chronicity: mean (SD) 10.4 (3.1) months Severity: Brunnstrom stage 3.5 – 4; FMA-UE mean (SD) 37.1(19.2)	Taiwanese hospital-based study Controlled trial plus Interviewer administered Likert scale questionnaire	Nintendo Wii and XaviX Trains shoulder, elbow and forearm Non-immersive	30 mins, 3/7, 8/52 of either: VR with Wii (bowling and boxing) VR with XaviX (bowling and ladder climb game) Control CT (used exerciser and climbing board and bar- not explained)	Significant improvement in all groups on FMA-UE mean (SD) Wii =15 (11.4); XaviX =7.6 (20.6); Control =10.9 (4.5) p≤0.001 all groups), FIM, and ROM. Significant improvement in	No significant differences in ratings in motivation between groups. Wii and Xavi X significantly better rating of enjoyment (mean (SD) Wii= 4.25 (0.89); XaviX = 4.38 (0.52; Control = 2.25 (0.89); F=18.55;	Number screened and eligible not apparent Incidence of adverse effects not reported

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	VR with XaviX n=8 Age: mean (SD) 58.2 (12.1) Chronicity: mean (SD) 12.6 (12.6) months Severity: Brunnstrom stage 3.5 – 4; FMA-UE mean (SD) 34 (18) Control: n=8 Age: mean (SD) 48.5 (16.4); Chronicity: mean (SD) 6.3 (3.7) months Severity: Brunnstrom stage 3.5 - 4; FMA-UE			Plus all groups had 1 hour of physiotherapy and OT (frequency, not stated)	BBT in XaviX group only No significant between group differences on any outcome measure	p=≤0.001); trend for increased motivation compared with CT	

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	mean (SD) 27 (6.95) VR with Wii significantly better score distal ROM at baseline.						
Choi et al. (2014)	n=20 VR n=10 Age: mean (SD) 64.3 (10.3) Chronicity: mean (SD) 20.2 (14.1) days Severity: FMA-UE mean (SD) 32.5 (19.4) Control n=10 Age: mean (SD) 64.7 (11.3)	Korean, hospital-based study RCT	Nintendo Wii Trains shoulder, elbow and forearm Non-immersive	30 mins, 5/7, 4/52 of either: VR with Wii Or Control CT (goal and task orientated OT, ADL fine motor and sensory recovery) Plus conventional physiotherapy both groups	Significant improvements post intervention in both groups in FMA-UE VR: mean 7.8; p=0.005. Control 8.7; p=0.010. MFT, BBT Significantly greater improvement in grip strength in CT		Number screened and eligible not apparent Used forearm orthosis to fix Wii sensor for those unable to hold it with hands (number not stated). Allowed to support weak side with other limb for those with shoulder flex ≤3 on MRC Incidence of adverse effects not reported

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	Chronicity: 23.67(120.7) days Severity. FMA-UE mean (SD) 38.5 (17.5) Inclusion: FMA-UE ≤50%, MMT >2 in shoulder No significant between group differences at baseline				No significant between group differences		
Da Silva Ribeiro et al. (2015)	n= 30 VR n= 15 Age: mean (SD) 53.7 (6.1) Chronicity; mean (SD) 42.1 (26.9) months	Brazilian, out-patient based study RCT	Nintendo Wii Trains shoulder, elbow and forearm Non -immersive	VR 60 mins, 2/7, 2/12 (Wii tennis, hula hoop, soccer and boxing) Control CT: 60 mins, 2/7 sessions 60 mins combination of balance,	Results included in findings from SRs, reported in Appendix 3.1	State that the games were fun and that participants "appeared stimulated" (p304)	Screened 72 of which 42 excluded (7 refused and 35 excluded) Supervision of therapist.

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	Severity: Not stated Control n=15 Age: mean (SD) 52.8 (8.6); Chronicity: mean (SD) 60.4 (44.1) months Severity: Not stated. Had to be "able to ambulate" (unclear if ± assistance) and to hold the movement sensor without assistance. No significant between group			stretching and strengthening			Incidence of adverse effects not reported

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	differences at baseline						
Fan et al. (2014)	n=20 divided into 4 groups VR n=5 mean (SD) age: 56.9 (14.9) Chronicity: mean (SD) 2 (1.5) years Severity: mean (SD) FMA-UE = 45.8 (14.3) CT: n=5 Age: mean (SD)= 66.8 (10.6) Chronicity: mean (SD)= 1.8 (1.4) Severity: mean (SD) FMA-UE = 48.8 (12.5)	Taiwanese, outpatient hospital setting RCT	Nintendo Wii Trains shoulder, elbow and forearm Non-immersive	60 mins, 3/7, 3/52 of either: VR CT Board games Control: No additional care	Results included in findings from SRs, reported in Appendix 3.1	Significantly better rating on Intrinsic Motivation Inventory in Wii group (mean = 145.5) compared with board game group (mean = 83.2) p=0.016	142 screened, 115 excluded (FMA-UE<21 n=75; shoulder pain ≥ 4 VAS n=20; mAS >2 n= 33). Drop-outs n=7 (unrelated to intervention) Wii group played with supervision Weaker participants had movement sensor strapped to their hands (number not specified) Incidence of adverse effects not reported

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	Board Games: n=5 Age: mean (SD) 67.2 (15.2) Chronicity: mean (SD) 2.3 (2.3) Severity: mean (SD) FMA-UE 56 (16.1) Control: n=5 Age: mean (SD) 66.6 (12.7) Chronicity: mean (SD) 2.6 (2.2) Severity: mean (SD) FMA-UE = 50.6 (12.4) No significant between group						

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	differences at baseline						
Givon et al. (2016)	n= 47 VR n=23, Age: mean (SD) 56.7 (9.3); range 29-69 Chronicity: mean (SD) 3 (1.8) years Severity: FMA-UE mean (SD) 32.2 (20.5) range 5-60 Control n=24, Age: mean (SD) 62 (9.3); range 42-78 Chronicity: mean 2.6 (1.8) years; range 6-7.6	Israeli study: setting unclear RCT	A combination of commercial devices including Microsoft X-box Kinect, Sony PlayStation 2 Eyetoy, Sony PlayStation 3 MOVE, SeeMe and Nintendo Wii Trains shoulder, elbow and forearm All non- immersive	60 mins, 2/7, 3/12 group sessions of either: VR OT selected gaming console, games, controllers dependent on individual ability Played VR games in pairs (either took turns or together). Control CT picking up and transferring objects from one side of room to other plus stretch	Significant improvement in grip strength of weaker hand in both groups ($F=8.1$; $p=0.007$) maintained at follow-up No significant improvement in ARAT in either group	No statistically significant difference in attendance between groups. Statistically significant higher rating of enjoyment in VR group ($X^2=4.98$; $p=0.026$)	127 screened, 19 not eligible, 55 not interested, 2 referred too late. 3-4 OT's present in both groups and supervised 6-8 participants OT provided verbal guidance as required and supervised to prevent falls Allowed to use non-hemiplegic UL to assist if needed (number not specified)

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	Severity: FMA-UE mean (SD) 26.5 (19.6); range 0-58 No significant between group differences at baseline						No adverse events occurred
Kong et al. (2016)	n=105 VR n=35 Age: mean (SD) 58.1 (9.1) Chronicity: mean (SD) 14.2 (8.9) days Severity: FMA-UE mean (SD) 14.6 (12.6) CT n= 35	Singaporean, hospital-based study RCT.	Nintendo Wii Trains shoulder, elbow and forearm Non-immersive	60 mins 3/7, 4/52 VR Wii sports (games selected dependent on ability and preference). Mean intervention time 481 (±110) mins CT matched duration. Mean intervention time 547.3 (± 96.2) mins Control (n=35) no additional intervention	Results included in findings from SRs, reported in Appendix 3.1		860 screened, 736 excluded and 19 declined. Drop-out 4 (2 did not feel Wii was helping) plus 2 each in CT and control unrelated to the study Wii set up and calibrated by therapist. Time taken to do so resulted in reduced dose to VR group

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	Age: mean (SD) 59 (13.6) Chronicity: mean (SD) 14.2 (9.4) days Severity: FMA-UE mean (SD) 15.7 (11.5) Control n= 35 Age: mean (SD) 25 (71.4) Chronicity: mean (SD) 13.1 (8.6) days Severity: FMA-UE mean (SD) 18 (14.4) No significant between group differences at baseline			All groups also received 60 mins of PT and OT 5/7			Movement sensor strapped onto hands with crepe bandage or customised grasp assist device for some (number not specified) Assistance to move UL provided by therapist when required (number not specified) Pain (≥4/10 on VAS) experienced at week 3: VR 11.4%; CT 5.7%, Control 0. At week 7: VR 25.7%, CT 17.1%; control 14.2%. Week 15 VR 28.5%; CT 20%; Control 28.5%

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							No other serious effects
Lee (2013)	n=14 VR n=7 Age: mean (SD) 71.71 (9.14) Chronicity: mean (SD) 7.29 (1.38) months Severity: not stated Control n=7l Age: mean (SD) 76.43 (5.8) Chronicity: mean (SD) 8.29 (3.4) months Severity: not stated	Korean based study: setting unclear RCT	X-box Kinect Trains shoulder, elbow and forearm Non-immersive	VR Video games on X-box Kinect plus OT. Total of 60 mins, 3/7, 6/52 Control CT 30 mins, 3/7 6/52	Significant improvement in both groups post intervention on FIM (VR mean = 8.71; p<0.005; Control: mean= 4.81; p=<0.05); strength (shoulder flex, ext; elbow flex and ext) No significant difference between groups		Number screened and number eligible not specified No significant effect on muscle tone in either condition. Incidence of other adverse effects not reported

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	Unclear if groups similar at baseline						
Matsuo et al. (2013)	n=28 Age: not stated Chronicity: not stated Severity: not stated but had to have UL weakness Unclear if groups similar at baseline	Japanese, hospital-based study RCT	Nintendo Wii	VR x10 sessions over 2/52 Control CT Unclear if dose matched	Results included in findings from SRs, reported in Appendix 3.1		Number screened and number eligible not specified Incidence of adverse effects not reported
McNulty et al. (2015)	n=42 VR n=21 Age: mean (SD) 59.9 (13.8)	Australian home-based study RCT	Nintendo Wii Trains shoulder, elbow, and forearm	VR: 60 mins, 5/7, 2/52 Wii Sports	Results included in findings from SRs, reported in Appendix 3.1	High levels of satisfaction in both groups reported (precise level not specified).	137 screened, 40 excluded. 3 drop outs (1 death and 1 withdrew in VR group; 1 withdrawn

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	Chronicity: Mean (SD) 11 (3.1) months. Range 2-48. Severity: ≥ 10^0 active movement at shoulder, elbow, wrist and ≥2 digits. mCIMT n=20 Age: mean (SD) 56.1 (17) Chronicity: mean (SD) 6.5 (2.1) months. Range 2-48. Severity: ≥ 10^0 active movement at shoulder, elbow, wrist and ≥ 2 digits.		Non -immersive	mCIMT: 60 mins, 5/7, 2/52 (wore mitt for 90% of waking hours) Additionally, increasing home practice based on individual need/progression and behavioural contract Shaping and VR gaming time, similar between groups (VR= 19.8 hours, mCIMT= 19.9 hours)		13 of 19 VR continued with therapy compared with 8/19 mCIMT	unrelated medical condition CIMT) Self-adhesive wrap used for those unable to hold movement sensor (number not specified) No occurrence of adverse effects Less therapist time required with VR group

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	No significant between group differences at baseline						
McNulty et al. (2013)	n=13 Age: mean (SD) 59.1 (17.6); range 22- 77 Chronicity: mean (SD) 48.1 (69.3) months; range: 3 months -21 years Severity: mean (SD) FMA-UE 17.2 (4.1); range 2-46	Australian, hospital and home-based study Single-group, pre-test, post-test design	Nintendo Wii Trains shoulder, elbow, and forearm Non-immersive	60 mins, 5/7, 2/52 hospital based initially, followed by home practice starting at 15 mins a day, progressively increased to 180 mins by day 14	Statistically significant improvement in FMA-UE (mean 5.6; p=<0.001) WMFT, MAL-Quality of Movement, grip strength On 10-point VAS (higher score indicating positive response) mean (SD) self-perceived improvement 5.4 (0.6)	On 10-point VAS (higher score indicating positive response) mean (SD) therapy satisfaction 9 (0.2)	Number screened and eligible not specified Only 1 able to use bowling game and none were able to play tennis game Unclear how held movement sensor Incidence of adverse effects not reported

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Paquin et al. (2015)	n=10 Age: mean 72.1 Chronicity: mean 38.6 months Severity: FMA-UE at baseline mean 50.1; range 25-61	Canadian outpatient-based study Single-group, pre-test, post-test design	Nintendo Wii and uDraw game tablet Trains wrist and hand Non-immersive	16 sessions, 2/7, 8/52 plus balance and lower-limb circuit class on same day	Statistically significant improvement in JHFT (mean 2.687 p=0.031, d= 0.34), BBT, NHPT	See Paquin et al. (2016)	Number screened and eligible not specified. Drop out of 7 Research assistants with each participant throughout Played seated No adverse events Feasible for use in one colour blind participant
Paquin et al. (2016)	See Paquin et al. 2015	Canadian outpatient-based study One to one, semi-structured interview	See Paquin et al. (2015)	See Paquin et al. (2015)	Themes of increased use of hand, increased confidence and a positive cognitive effect	All would recommend to other chronic stroke survivors	Wii was "easy to use" but all stressed importance of having a trained person. Individual attention still seen as important, especially in the

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						Wii was "fun" "challenging" and novel" Theme of shortage of community rehabilitation options	beginning. Theme of staff motivating patients
Rand et al. (2015)	n=12 VR n=6 Age: median (IQR) 63 (47-64) Chronicity: unclear but inclusion criteria 6-36 months Severity: median (IQR) FMA-UE= 31.5 (28-37); range 28-45	Israeli, home-based study RCT	X-box Kinect, PS2 Eyetoy, PS3 MOVE Non-immersive	60 mins, 6/7, 5/52 of either: VR Control: CT using GRASP programme (Graded Repetitive Arm Supplementary Programme). Both groups: x2 visits by OT (to teach intervention and to check for	See Rand et al. (2017) for full results On 5-point scale (higher score indicating positive response) median (IQR) rating of perceived UL benefit: VR: 3 (1.7 to 3.2); CT 4 (3.2 to 4)	On 5-point scale (higher score indicating positive response) median (IQR) rating of level of overall enjoyment: VR: 4 (2.5-5); Control: 4 (4-4.7); overall satisfaction: VR: 3.5 (2.7-4.2); Control: 4 (3.2-4.7).	Number screened and number eligible not clear. Choice of console dependent on ability to stand while playing (required for Kinect) and ability to hold hand-held controller (needed for MOVE)

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	Control n=6 Age: median (IQR) = 63 (58-65) Chronicity: unclear but inclusion criteria 6-36 months Severity: median (IQR) FMA-UE=42.5 (22-46); range 22-48 No significant between group differences at baseline			problems), training manuals/instructions, diary logs (submitted weekly), daily phone /text contact in first week to aid motivation, weekly phone call.		Overall enjoyment rated as 4/5 by both groups; daily enjoyment higher on 5-point Likert scale for CT (median [IQR] 4.1 [3.6-4.6] CT; 3.7 (2.4-4.5) for VR) Overall satisfaction lower for VR (median [IQR] 3.5 [2.7-4.2] VR compared with 4 [3.3-4.7] for CT 4/5 continued to train in VR group compared with 2/5 in CT	Significantly higher ratings of exertion in VR Incidence of adverse effects not reported

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Rand et al. (2017)	n=24 VR n=13 Age: mean (SD) 59.1 (10.5) Chronicity: mean (SD) 19.6 (11.3) months Severity: mean (SD) FMA-UE 35.4(11) Control: n=11 Age: mean (SD) 64.9 6.9) Chronicity: mean (SD) 13 (6) months Severity: mean (SD) FMA-UE 41.3(10.7)	Israeli community-based study in participants homes Pilot RCT	Microsoft X-Box Kinect for those who could stand or Sony PlayStation 2 Eyetoy for those who needed to play in sitting Trained, shoulder, elbow, forearm Non-immersive.	See Rand et al. (2015) CT group had significantly greater intervention time than VR (mean [SD] over 5 weeks of 27.4 [5.6] hours in control; VR = 18.8 [8] hours	Significant improvements for both groups on <u>ARAT</u> (mean change VR: 3.9; Control 2.3: F=11.2, p<0.01); MAL-Amount of Use No significant between group effects for any measure:	8/11 participants in VR group continued to train compared with 4/9 CT	142 screened 117 (83.1%) excluded. 85 not eligible. 32 not interested or unable to commit. 2 drop outs in VR due to personal reasons. 2 drop outs in CT due to boredom and not wanting to continue OT set up equipment for VR group at home No occurrence of falls or adverse effects Issues with Kinect when seated acknowledged and therefore different console used for those who couldn't

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	No significant between group differences at baseline						play in standing. Use of MOVE stated in Rand et al. (2015)but none appeared to have used.
Rinne et al. (2016)	n=92 Age: mean (SD) 65 (55-75) Chronicity: Acute ≤2/52 Severity: no limits. Used Short FMA (out of 12) to classify: 20% score 0-4 (severe) 20% score 5-8 (moderate)	UK study: setting unclear Feasibility study	Used commercial game to test the feasibility of 4 types of conventional movement detection methods plus an adapted handgrip controller Non-immersive	1 min per trial, each device controller Phase 1: n= 42 assessed on 4 conventional controllers Phase 2: n=57 assessed on best performing conventional vs adapted version			345 screened of which 92 recruited and 87 completed. 90% of mildly impaired able to use conventional controllers, 36% of moderately impaired and 0% of those with severe deficits No statistically significant difference between conventional controller types but

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	60% score 9-12 mild to no impairment						swipe-based controller was easiest in this study Adapted device allowed more than half of severely disabled group to play the game
Saposnik et al. (2016)	n=141 Age: mean (SD) 62 (12); range 18-85 (all participants) Chronicity: within 3/12 of stroke Severity: Chedoke-McMaster Stroke	International multicentre trial (14 hospitals in 4 countries) RCT	Nintendo Wii Trains shoulder, elbow, forearm Non -immersive	60 mins, 5/7, 2/52 of either VR n=71(Wii Sports and Game Party 3). Control n= 70 recreational therapy (e.g. playing cards, Jenga). Plus, CT Similar mean (SD) time of intervention between	Results included in findings from SRs, reported in Appendix 3.1		893 screened of which 752 not eligible, (106 did not met age criteria of 18-85, 282 deficits too mild, 240 medical reasons, 124 other, 47 refused) 4 discontinued Wii after training session. Additional 8 per group dropped out before reassessment.

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	Assessment Stage >3 No significant between group differences at baseline			groups (VR = 528 (155) mins vs control = 541 (142) mins			More lost to follow up at 4/52 (unrelated to study) Therapists present for all interventions on 1 to 1 basis (both groups) provided feedback re: avoiding compensation strategies 3 serious adverse effects (1 VR, 2 control, unrelated to study). Similar incidence of fatigue, light headedness, nausea, pain, aches headache between groups

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Sin and Lee (2013)	n=35 VR n=18; Age: mean (SD) 71.78 (9.42) Chronicity: mean (SD) 7.22 (1.21) months Severity: mean (SD) FMA -UE =26.6 (15.81); Control n=17. Age: mean (SD) 75.59 (5.55) Chronicity: mean (SD) 8.47 (2.98) months Severity: mean (SD) FMA-UE 32.29 (20.43).	South Korean, hospital-based study RCT	Xbox Kinect using combination of sports and games Trains: shoulder, elbow, forearm Non-immersive	VR 30 mins VR + 30 mins conventional OT, 3/7, 6/52 Control 30 mins CT (stretching, active active-assisted and passive movements, strengthening, ADL training) 3/7 6/52	Significant improvement in both groups <u>FMA-UE</u> (mean (SD) VR: 10.89 (6.31); Control: 6.53 (2.6): $p<0.05$ both groups) BBT VR significantly greater improvement on <u>FMA-UE</u> $p=0.041$), BBT than control		40 screened, none excluded. Drop-out 5 unrelated to study In discussion mention need to recalibrate system “frequently” due to occlusion errors Incidence of adverse effects not reported

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	No significant between group differences at baseline						
Türkbey et al. (2017)	n= 20 Age: mean 62; range 38-79 Chronicity: mean 47 months; range 13-125 Severity: Baseline mean (SD) BBT VR 18.8 (12.19) Control: 20 (13.13) No significant between group	Turkish, inpatient hospital-based study RCT and feedback survey	Xbox Kinect Trains; shoulder, elbow, forearm Non-immersive	VR 60 mins VR plus 60 mins CT, 5/7, 4/52) Control CT (active and passive ROM, gait, balance, ADL rehabilitation) Mean training time in VR =1048 mins, mean session time 54.1 mins	Significant improvement for both groups on <u>BBT</u> (mean VR 13.7; p=0.005: Control: 4.78: p=0.025) WMFT, FIM, Brunnstrom-UE VR group significantly greater improvement on <u>BBT</u> (p=0.005) and WMFT compared to control	VR group: attended 96% of planned interventions All agreed VR enjoyable, 90% would recommend it to others	131 screened, 111 were excluded. None declined. 1 drop-out in control grp No serious adverse events. Fatigue experienced by 80%. Mean BORG-10 exertion score = 7.8 (very hard); 30% hand and arm pain (severity/cause not discussed); 20% had headache; 40% had nausea (cause unspecified)

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	differences at baseline						Adverse effects in control not reported 30% did not think VR system was safe to use
Vanbellingen et al. (2017)	n=13 Age: mean (SD) 68.2 (17.5); range 24-91 Chronicity: mean (SD) 28.2 (23.2) days; range 8-88 Severity: min of grade 3 MRC shoulder flex and finger ext. Mean (SD) FMA-UE	Swiss, hospital-based study Single-group, pre-test, post-test design and usability study	Leap Motion Controller Trains wrist, hand Non-immersive	30 mins, 3/7, 3/52 with VR Mean (SD) time played 3 hours 56 mins (1hr 16); range 42 mins-4 hours and 45 mins	Significant improvement post intervention in NHPT, (mean =49.96 secs; $X^2_{(3)}$ = 15.34; p<0.001), self-reported Dexterity Questionnaire-24, grip strength. No significant improvement on FMA-UE	Compliance rate 78% n=3 would use at home -dependent on price and technical improvements (not stated).	64 screened but unclear how many eligible, “15 were selected” 5 drop outs (1 new stroke, 3 D/C, 1 stopped due to “lack of motivation”) PRPS scores (measuring amount of active participation) ranged between good and very good. System Usability Scale score mean

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	57.5 (9.3); range 42-65						(SD) 75.4 (13.8) /100 (with higher score indicating greater satisfaction). Stable over time ($F_{(3,21)}$=0.09; p=0.96) n=3 felt they would need help to use at home. All felt they benefitted from presence of therapist for additional instructions No occurrence of severe adverse effects
Wingham et al. (2015)	n =28 (18 stroke survivors and 10 carers)	UK, home-based study	See Adie et al. (2017)	See Adie et al. (2017)	Most stroke survivors and their carers noted	Diligence of play noted over several weeks (“most”	Theme of difficulty manipulating movement sensor and

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	Stroke survivors: Age: median 65; range 35-84. Chronicity: median (IQR) = 46 (25, 100) days Severity: median (IQR) ARAT 51 (25, 100)	Qualitative study using semi-structured interviews (within RCT: Adie et al., 2017)			physical improvements and improved mental well-being post intervention	used for minimum 5/52; n=2<3/52). Some practiced more than advocated 45 mins Liked using at home as offered flexibility and some preferred to exercise in private. A few preferred more ADL activities such as housework as opposed to a game Liked instant feedback and were motivated to beat score	lack of game responsiveness identified Visitors could be a barrier to use at home No serious adverse effects. Hitting hand against side of chair while bowling an issue for some plus some incidence of shoulder pain (mechanism and severity not apparent) Caregiver role in setting up system and room. Some stroke survivors did not want support. Some carers no experience or not interested in computer

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
						Traditional exercise felt to be less motivating. Some disliked graphics as too child like Need to maintain right level of challenge.	games therefore did not offer support Needed setup visit by therapist. Weekly phone call viewed as helpful and especially liked by those spending time on their own

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3.3 Evidence Table for Purpose-Built VR Gaming Technologies

Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Brunner et al. (2017)	n=120 VR n=62 Age: mean 62, range 23-89 Chronicity: mean (SD) 35 (21) days Severity: ARAT<52 and min 20^{o} active shoulder ext and abd. Severe (classified as, <20^{o} active wrist and < 10^{o} active finger ext) n= 25, otherwise mild/moderate n=37 Control n=58 Age: mean 62; range 41-87	European multicentre (5 pan Europe). rehabilitation centre setting. RCT	YouGrabber: data gloves, infrared camera and purpose-built games. Commercially available Trains shoulder, elbow, forearm, wrist, hand Personalisation: choice between reach and grasp, selective finger, forearm or whole arm, unilateral and bilateral movements, adjustment of speed, time between objects, ROM Non- immersive	VR 45-60 mins, 4-5/7 4/52 training (dependant on tolerance/motivation) as additional therapy Control CT (consisting of TSP, gross movement, dexterity, strength training, stretching and ADL training under therapist supervision)	Significant improvement post intervention in all measures, both groups regardless of severity. ARAT (VR: mean (SD)12 (11): Control: mean (SD) 13 (10) p<0.001 both groups) BBT, ABILHAND, PGIC No significant between group differences on any measure, regardless of time-point or severity.		1224 screened of which 1079 excluded (cognitive deficits, motor deficits too mild or severe, medical instability, early discharge) 25 declined. Drop out: 5 in VR, 3 in control for reasons unrelated to study No occurrence of adverse effects Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Chronicity: mean (SD) 34 (19) days Severity: ARAT<52 and min 20º active shoulder ext and abd. Severe (classified as, <20º active wrist and < 10º active finger ext), n= 27, otherwise mild/moderate n=31 No significant between group differences at baseline						
Choi et al. (2016)	n=24 VR n=12 Age: mean (SD) 61 (15.2)	South Korean, hospital-based study	Bespoke system using tablet, smart phone and purpose-developed games Phone strapped	VR 30 mins of OT plus 30 of VR 5/7, 2/52 Control 60 mins CT 5/7 for 2/52	Significant improvement for both groups in FMA-UE, (mean change post	On 5-point scale (higher score indicating positive response) mean (SD) 4.25 (0.75) satisfied with	272 were screened of which, 151 excluded, 51 declined

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Chronicity: Figures provided but unclear if days, weeks or months Severity: FMA-UE mean (SD) 24.5 (22.2); range 4-63 Control n=12 Age: mean (SD) 72.1 (9.9) Chronicity: Figures provided but unclear if days, weeks or months Severity: mean (SD) FMA-UE 21.5 (20.6); range 4-57 VR group significantly younger (P=0.046) No other significant between	RCT and questionnaire assessing device satisfaction	to either upper arm or forearm Trains shoulder, elbow and forearm Personalisation: speed, hold time, ROM Non-immersive		intervention: VR =19.08. Control =9.67) Brunnstrom stage, MMT, mBI post intervention Greater improvements in VR group on FMA-UE, Brunnstrom stage and MMT (unclear if this was statistically significant or not)	VR compared with 3.92 (1) in control Willing to pay mean (SD) $22 US (10) for games (range 10-40).	Phone strapped to either upper arm or forearm during play No occurrence of adverse effects Costs of system unspecified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	group differences at baseline						
Finley and Combs (2013)	n= 10 Age: range 48-79, Chronicity: 11-127 months Severity: Able to "elevate arm" (plane and range not specified) 2 groups: 1st limited experience and second no previous gaming experience	USA based: setting appears to be community but not stated Acceptability study using focus groups n=2	Hand Dance Pro for UE rehabilitation (not stroke specific). Commercially available Trains unilateral and bilateral reaching tasks coordinated to music Personalisation: able to choose music Non-immersive	All watched game and had a single 2-minute session using games before participating in focus group		All enjoyed using games: found music encouraging Feedback during game was distracting. Summary feedback at end was motivating but some feedback "system failure" or "life deleted" was demoralising in those with more severe impairment Background activities (flashing lights, change of colour) distracting for those with greater levels of impairment and more	Number screened and eligible not specified Incidence of adverse effects not reported Costs not reported.

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						limited experience of gaming	
House et al. (2015)	n=10 VR n=7 Age: mean (SD) 69.7 (13) Chronicity: mean (SD) 98 months (42) Control n=3 Age: mean (SD) 70.1 (16.4) Chronicity: mean (SD) 100 (28) months Severity: group mean (SD) FMA-UE 15.6 (11.1)	USA, nursing home-based study Control study design	Bespoke system, uses adjustable table, forearm supports with grasping sense, overhead tracking cameras, purpose-developed and commercial games Trains shoulder, elbow and hand grasp Personalisation: can tilt table, adding physical weights and altering game with increased grasp Non-immersive	VR 16 sessions over 8/52, 4 session booster at 10/52 Control n=3. "Normal maintenance programme"	Significant improvement from baseline to follow-up in VR group on CAHAI (mean 6.7; p= 0.01) in shoulder ext lateral deltoid muscle strength No significant improvement in control	On 5-point scale (higher score indicating positive response) mean score 4, that overall liked the system; would encourage others to use it, not bored while exercising	On 5-point scale (higher score indicating positive response) mean 4.6 that instructions were useful; mean 2.6 that playing games with the system was easy. Incidence of adverse effects not reported Costs not specified

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House et al. and (2016)	n=7 VR: n=7 Age: mean (SD) 69.7 (13) Chronicity: mean (SD) 98 months (42)	USA, nursing home-based study Control study design	See House et al. (2015)	See House et al., (2015)	Significant improvement post intervention in VR group in FMA-UE (mean =1.3; CI =0.4-2.2; p=0.01); CAHAI, active shoulder extension	On 5-point scale (higher score indicating positive response) mean score 4.4 liked the system; mean 4.1 would encourage others to use system;	Number screened and eligible not stated. On 5-point scale (higher score indicating positive response) mean score 4.3 for ease of use and technical reliability; mean 2.7 for ease of use of playing with affected arm and degree of pain/discomfort Incidence of adverse effects not reported
Hung et al. (2016)	n=49 Stroke participants n=30	Taiwanese study: setting unclear	Reha-Slide uses inclinable board, with rod to play purpose-designed games	Participants used the device in rehabilitation but dose unclear		Results reported by number of participants. Liked novelty of system (n=10 stroke; n=15 OT);	Number screened and eligible not stated

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	Age: mean(SD) 55(18) Chronicity: mean (SD) 3 years (3.3); range 4 months -16 years Severity: not stated OT participants n=19 Age: 23-52. Clinical experience: 2-20 years	Face to face survey	Commercially available Trains: shoulder, elbow and wrist Personalisation: none specified Non-immersive			easy to get bored (n=9 stroke; n=19 OT); games were not perceived as being fun (n=8 stroke; n=13 OT). Wanted > diversity of games (n=13 stroke; n=18 OT); more real-life scenarios (n=8 stroke) and greater customisability (n=12 stroke; n=15). Wanted challenging games (n=7 stroke; n=12 OT); intuitive to play (n=12 stroke; n=17 OT)	Costs of this system not specified. Cost cited as important by clinicians and stroke survivors. Participants report being willing to spend $300-1500 US only. Incidence of adverse effects not reported
Jordan et al. (2014)	n=12 Age: mean (SD) 68.6 (8.8) years: range 56-79	American, home-based study Single-group pre-test, post-test study design	Bespoke system uses a smart Skate (a sliding board with a computer mouse embedded) and button; purpose-built games	45 mins, 3/7 ,3/52 (n=9 hours) for participants 1-5. Protocol then adjusted so had 16 hours of	Significant improvement post intervention FMA-UE (mean 4.9 $p<0.01$) maintained at follow-up, increased strength	On 7-point scale (higher score indicating positive response) mean score for enjoyment 6.32; perceived competence 5.52; usefulness 6.63	Number screened and number eligible not stated Level of challenge altered by therapist

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	Chronicity: mean (SD) 12.8 (11.7) months, range 5.9-48 Stroke severity: excluded if able to hold shoulder at 90^0 flex>2 secs or MRC shoulder and elbow grades 0, 1 or 5		Trains shoulder and elbow with skate and fingers if use button option Personalisation: 3 levels and can adjust 3 parameters per level (speed, time pressure and accuracy) Non-immersive	training over 6 weeks in total.	(elbow flex, shoulder ext rot[n])		n=3 had pain or stiffness in shoulder or neck. Therapist supervised throughout Costs not specified
Lee (2015)	n=10 Age: 38-78, Chronicity: not specified Severity: mean (SD) FMA -UE 32.6 (20.7)	South Korean, hospital-based study Single-group, pre-test, post-test design	Interactive Rehabilitation and Exercise System (IREX) provides auditory visual and proprioceptive feedback; purpose-built sports games Commercially available	30 mins of VR, 3/7, 4/52	Significant improvements post intervention FMA-UE (mean (SD) 14.8 (22.17 points; p=<0.05) MMSE, mBI		22 screened of which 12 excluded Incidence of adverse effects not reported Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
			Trains: shoulder, elbow, forearm, fine motor movements (training of wrist and hand not specified) Personalisation: states can be individualised, parameters not specified Non-immersive				
Lee et al. (2016b)	n= 18 VR n= 10 Age: mean (SD) 69.2 (5.5) Chronicity: mean (SD)16.2 (6.5) months Severity: mean (SD) JHFT 219.6 (24.54).	South Korean, hospital- based study RCT	Bespoke system using hand held motion sensor. Type of activity not stated Trains: UL and specifies ROM (0-45$^{0)}$ but which joints not specified. presume shoulder and elbow	VR 30 mins, 3/7, 6/52 Control dose matched physical training Plus, both groups had CT, 30 mins, 5/7, 6/52	Results included in findings from SRs, reported in Appendix 3.1		30 screened of which 10 excluded, Hand had to be strapped to handle for some participants (number not specified) State that is safe but no reporting of

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Control n=10 Age: mean (SD) 73.1(8.9) Chronicity: mean (SD) 17 (6.4) months post stroke Severity: mean (SD) JHFT 227.75 (20.1) No significant between group differences at baseline		Personalisation: none apparent Non-immersive				incidence of adverse effects Costs not specified
Mace et al. (2017)	n= 16 Age: mean (SD) 70.3 (19.7); Chronicity: ≤2/52 of presentation	UK based: setting not stated Single case experimental design using ABAB design	Purpose-built system and game involving squeezing a hand grip to balance a ball on a beam and collect stars. Trains grip strength	Played the game in single player mode and dual player mode (with a neurologically intact player). Stronger player able to compensate for weaker,		Significant preference for dual-player mode (88%; p=<0.001); significantly higher ratings of enjoyment (p=<0.01); effort (p<0.01) for dual player mode	100 screened 84 excluded - none excluded on physical characteristics Incidence of adverse effects not reported Costs not specified

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	Severity: Had to be able to squeeze and hold hand-held controller. FMA-UE at baseline mean (SD) 51.3 (13.6)		Personalisation: calibration of sensitivity with grip strength, play single or collaborative mode Non-immersive	but both players have to contribute to task			
Orihuela-Espina et al. (2013)	n=8 haemorrhagic stroke Age: 24-55 Chronicity: 9-127 months Severity: not stated.	Mexican study: setting unclear Single-group, pre-test, post-test design	Gesture Therapy bespoke system uses handheld movement sensor to track movement and grip force and games developed for the commercially available purpose-built rehabilitation platform (the ARMEO) Trains shoulder, elbow range of movement and grip strength	45 mins of VR, 20 sessions: unclear over how many days/weeks	Significant improvement post intervention in FMA-UE (mean 20 points; p<.05), MI hand grip		Number screened and eligible not specified Movement sensors had to be attached to some participants (number not specified) Incidence of adverse effects not reported Costs estimated at $1,000 US

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
			Personalisation: none in this version (later versions of this system allow degree of personalisation) Non-immersive				
Pallesen et al. (2018)	n=13 Focus group 1: n=3 clinicians (OT and PT) who had used the YouGrabber on ward with stroke survivors with moderate UL impairment Focus group 2: n= 4, clinicians (OT and PT) who had used	Danish hospital-based study Mixed methods: focus groups with clinicians; Semi structured interviews with stroke participants; stroke and clinician questionnaire	YouGrabber uses data gloves, infra-red camera and purpose-developed games. Trains reach and grasp, selective finger, forearm or whole arm unilateral or bilateral movements. Personalisation: speed, time between objects, object placement, bilateral or unilateral	All participants had used the VR system in rehabilitation in the VIRTUES trial	Themes of perceived improvement (fine motor skills, fingers and hand), although 2/6 stroke survivors did not feel improvements were due to VR. Clinicians more sceptical about improvements	Stroke survivor themes of motivational factors (playful-fun, diversion, competition, surprising, maintenance of challenge) Feedback rewarding and motivating. Some stroke survivors wanted a whole UL exercise and not focus on the hand.	Number screened and excluded: See Brunner et al. (2017) Themes of Individualisation (specificity of training, good way to get repetitions, need individual adjustment and importance of therapeutic support (needed to introduce and train).

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	YouGrabber on ward with stroke survivors with moderate to severe impairment Semi-structured interviews n=6, stroke survivors Age: 33-79 Chronicity: range 8-69 days Severity: ARAT scores at baseline 26-44. Questionnaire: regarding satisfaction with VR training; n=45 clinicians and stroke survivors involved in		Non-immersive		being due to YouGrabber On 5-point VAS (lower score indicating positive response) mean (SD) stroke participant rating of effectiveness 1.6 (1) Clinicians considered VR a way of increasing intensity	On 5-point VAS (lower score indicating positive response) mean (SD) rating of satisfaction with system: stroke 1.5 (0.75); Clinician: 2 (0.6); Motivation mean (SD) stroke:1.9 (0.9); Clinician 2.4 (0.8)	Frustration caused by technical issues (layout, freezing, design) noted by therapists in particular On 5-point VAS (lower score indicating positive response) mean (SD) clinician rating of ease of use 2.7 (0.7)

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	the interviews and focus groups						
Perez-Marcos et al. (2017)	n=10 Age: mean (SD) 54.9 (13.) Chronicity: 6-108 months Severity: FMA-UE scores at baseline median (IQR) 42, (24.75-53)	Swiss study, setting unclear. Single-group, pre-test, post-test design	Mind-Motion Pro bespoke system using 3D tracking camera and markers attached to shoulder, elbow and wrist via straps with purpose-designed games Trains: shoulder, elbow, forearm, wrist Personalisation: level of difficulty, number of reps Non-immersive	60 mins, 2/7, 5/52 plus usual therapy Median (IQR) training time 290 mins (246, 329). Median (IQR) total training time across all 10 sessions= 403 mins (331, 417) Median (IQR) number of goal directed movements in final session= 476.5 (432.3, 637.0)	Significant improvement across timepoints FMA-UE ($X^2(2)$= 9.982; p=0.007) shoulder active flex, forearm active pronation On 7-point scale (higher score indicating positive response) mean (range) rating of improvement 7 (5.3-7)	On 7-point scale (higher score indicating positive response) mean (range) rating of: liking the exercises 7 (7-7); ability to focus on task 7 (7-7) would like to continue using at home (7 (5.3-7) more time using	Number screened/eligible not specified Therapist present throughout and adjusted tasks and difficulty level manually No physical assistance to perform movements, although some participants slid arm on table ± towel to decrease friction No serious adverse effects reported. No significant increase in

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							pain or stress. n=1 experienced headache (related to screen exposure) and 2 suffered UL pain. Non- significant increase in fatigue Costs not specified
Rand et al. (2013)	n= 11 Age: mean (SD) 58.7 (7.4) Chronicity: subacute- chronic Severity: able to grasp and remove all NHPT pegs; mean (SD) FMA-UE	Israeli based study: setting unclear Feasibility study	Bespoke system using purpose designed games and exercises played on tablet device Trains: fine finger movement, dexterity Personalisation: not specified	"Experienced" using the training programme on the iPad. Duration not specified		On 5-point scale (higher score indicating positive response) stroke mean (SD) rating of levels of enjoyment 4.2 (0.7) for bowling game High usability for UL stroke rehabilitation on the System Usability Scale (80.4 (13.6) out of 100) with higher score	Number screened/eligible not specified n=1could not use bowling game, n=3 were partially successful and n=1 able to use. One occurrence of hitting hand against chair during bowling.

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	54.9 (8.9); range 30-60					indicating a more positive experience	Occurrence of other adverse effects not specified
Schuster-Amft et al. (2015)	n=2 Age: 47 and 63 Chronicity: 3 and 4 years Severity: CAHAI scores 61 and 86	Swiss study: setting unclear Single-case, pre-test, post-test design (n=2	YouGrabber uses data gloves, wrist mounted accelerometer, limb markers, overhead tracking camera and purpose-developed games Commercially available Trains shoulder, elbow, wrist, hand Personalisation: speed, ROM, time between objects Non-immersive	45 mins VR, 5/7, 4/52 Total 398-356 mins training time achieved; 5478-7805 "grasps" in total for hemi UL	Improvement in CAHAI (4 and 14 points) post intervention, maintained at 2/52 and 3/12 follow-up	Motivation and enjoyment "generally rated to be high" by both participants (no statistical support)	Convenience sample Says feasible and safe. Unclear what this is based on. Incidence of adverse effects not reported Costs not specified

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Shin et al. (2016)	n=46 VR n=24 Age: mean (SD) 77.2 (10.3) Chronicity: mean (SD)13.6 (13.4) months Severity: Baseline FMA-UE mean (SD) 43.4 (8.7) Control: n=22 Age: mean (SD) 59.8 (13) Chronicity: mean (SD) 15 (14.6) months Severity: Baseline FMA-UE mean (SD) 48.2 (12.3).	South Korean, hospital-based study RCT	Bespoke system using SmartGlove and purpose-built games and ADL activities Trains forearm, wrist and finger movements Personalisation: ROM, duration, speed Non-immersive	30 min, 5/7, 4/52 VR Control CT (ROM, strengthening and ADL activities focused on distal UE)	Significant improvement post intervention in VR group only on FMA-UE (mean (SD) 4.9 (1); p= <0.001); JHFT; SIS. Improvements in FMA-UE and JHFT maintained at follow-up Significantly greater improvement in FMA-UE in VR than control (F=6.48, df=1.46; p=0.006)		225 screened. 179 excluded of which 25 declined and 154 did not meet inclusion criteria. Drop outs explained (5 in VR and 8 in CT mainly due to "lack of cooperation") No serious adverse events. 1 drop out due to dizziness unrelated to study Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	No significant between group differences at baseline						
Shin et al. (2014)	Efficacy study reported in systematic review section Usability study n=20 combination of physiatrists, OT and stroke participants	South Korean hospital-based study Usability Study: focus groups, semi-structured interviews and completion of questionnaire	Bespoke system, RehabMaster uses depth sensors, and purpose- built games Trains shoulder and elbow Personalisation: target size, speed, ROM, endurance Non-immersive	Usability study: stroke participants used VR 20 mins, 2/7, 2/52 under therapist supervision	Results included in findings from SRs, reported in Appendix 3.1	Usability Study: Positives of the system in terms of increasing flow (attention, motivation, enjoyment, effectiveness)	Played under supervision of therapist. No automatic adjustment Study 1: 50 screened, 38 excluded (unclear on what basis) and 5 declined Study 2: 73 screened, 50 excluded Usability study: 5/5 clinicians felt could adjust system to individual requirements

Abd= abduction; ADL = activities of daily living: ARAT- Action Research arm Test; BI= Barthel Index; BBT=Box and Block Test: BI= Barthel Index; CAHAI- Chedoke Arm and Hand Activity Index; CI= Confidence interval; COPM= Canadian Occupational Performance Measure; CT = conventional treatment; D/C= discharged; Ext = extension; FIM= Functional Independence Measure; Flex= Flexion; FMA-UE = Fugl-Meyer Assessment-Upper Extremity; GPT= Grooved Pegboard Test; IQR- Inter quartile range; JHFT= Jebson-Taylor Hand Function Test; LL= lower limb; MAL- Motor Activity Log; mAS= modified Ashworth Scale; MAS= Motor Assessment Scale; mBI= Modified Barthel index; mCIMT= modified Constraint Induced Movement Therapy; MI= Motricity Index; MMSE= Mini Mental Status Evaluation; MMT = manual muscle test; MRC= Medical Research Council muscle power; mRS= Modified Rankin Scale; NIHSS= National Institutes of Health Stroke Scale; NHPT= Nine Hole Peg Test; OT= Occupational Therapist; PGIC= Participant Impression of Change; PNF=Proprioceptive Neuromuscular Facilitation; PRPS= Pittsburgh Rehabilitation Participation Scale; QoL= quality of life; RCT= Randomised controlled trial; ROM=Range of Motion; rot^{n}= rotation; Rx = treatment; SD =standard deviation; SIS= Stroke Impact Scale; SMD= standardised mean difference; SR= systematic review; TEMPA= Test Evaluant Les Membrès superiors des Personnes Agees; TSP=task specific practice; UE= upper extremity; UL = upper limb; VAS= visual analogue scale; VR= virtual reality; WMFT= Wolf Motor Function Test; WMFT-FAS= Wolf Motor Function Test- Functional Assessment Scale

Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
							No occurrence of adverse effects Costs not specified
Slijper et al. (2014)	n=12. Age: mean 58; range 26-66 Chronicity: median (IQR) 11 (6-42) months Severity: median (IQR) FMA-UE 44 (6-63) median (IQR) ARAT 26 (0-56)	Swedish, home based study Single case experimental ABAA design	Bespoke system using hand-held cylinders attached to the console with strings and purpose- built games Trains shoulder, elbow and hand Personalisation: speed, level of precision, ROM visual and audio feedback Non-immersive	5/52 of training in home setting plus weekly clinic visit for assessment and coaching (played game in front of therapist who checked movement quality) Mean (SD) intervention time = 1070 mins (267-4727)	Statistically significant improvement in FMA-UE (median 7; p=0.005), ARAT at post intervention, maintained at follow-up.	In discussion authors note results from interviews reveal positive attitudes	Number screened and eligible not specified Set up and taught at home by therapist. Then provided with short instruction manual. Incidence of adverse effects not reported Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Stockley et al. (2017)	n= 12 VR n=6 Age: median 70.8; range 58.5-82.3 Chronicity: 2.1 years; range 1.2-5.9 Severity: median BBT 20.5; range 2-49 Control n=6 Age: median 70.6; range 44.2-82 Chronicity: 2.2 years; range 1.8-4.6 Severity: median BBT 22.5; range 3-46 No significant between group	UK community rehabilitation centre-based study Mixed-methods using semi-structured interviews and RCT	YouGrabber, uses data gloves and purpose-developed games Commercially available Trains dexterity, finger, hand Personalisation: none specified Non-immersive	18 sessions over 12 weeks of either: VR 30 mins VR, plus CT (length of CT not stated) Control personalized therapeutic exercise in gym. Unclear if intervention time matched between groups	Significant improvement in MAL-Amount of Use (median [range] 0.59 [0.2-1.25] p=0.03) and MAL- Quality of movement (median [range] 0.56 [0.27-0.35]; p=0.03) in VR group but not in control. No between group differences Thematic codes related to improvement	Themes related to enjoyment (motivation and social elements) identified	13 screened for inclusion, 1 declined All had standby assistance while using YouGrabber No adverse effects occurred although fatigue scale scores and interview theme, indicate fatigue Theme of frustration with technical issues (such as freezing of software) need for support and increased specificity in games Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	differences at baseline						
Subramanian et al. (2013)	n=32 VR n=16 Age: mean (SD) 62 (9.7) Chronicity: mean (SD) 3.7 (2.2) years Severity: mean (SD) FMA-UE 41.1 (17.7) Control n=16 Age: mean (SD) 60 (11) Chronicity: mean (SD)3 (1.9) years Severity: mean (SD) FMA-UE 42.1 (15.1) No significant between group	Canadian study; setting unclear RCT	CAREN (Computer Assisted Rehabilitation Environment) system and purpose-developed activity Commercially available Trains shoulder, elbow and forearm Personalisation: ROM Immersive	45 mins, 3/7, 4/52 of repeatedly pointing towards targets in either: VR 3D supermarket scene auditory feedback and increasing size of object with better performance plus game score at end Control Pointed towards numbered physical targets on wooden frame in the physical environment. Targets similarly placed to VR	Results included in findings from SRs, reported in Appendix 3.1	Enjoined training in both environments equally.	Unclear number screened and eligible Report all comfortable and no side effects Cost not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	differences at baseline						
Tanaka et al. (2013)	n = 6 Age: mean (SD) 57.6 (9.5) Chronicity: mean (SD) 47.8 (31) days Severity: not clear	Japanese study: Setting not stated Single-group, pre-test, post-test design	Bespoke system using hand-held movement sensors and purpose-developed activities using a virtual teacher (shown at same time as participant avatar) Trains shoulder, elbow and forearm Personalisation: range and speed Non -immersive	Unclear	Significant improvements post intervention in FMA-UE (mean 10 points; $p<0.05$) WMFT, FIM and kinematic variables		Unclear number screened and eligible Must be able to grasp hand-held movement sensor Incidence of adverse effects not reported Costs not specified
Turolla et al. (2013)	n= 376 VR n=113	Italian, hospital-based study	Bespoke Virtual Reality Rehabilitation System uses 3-D motion	VR 60 mins CT plus 60 mins of VR, 5/7, 4/52	Results included in findings from SRs,		Number screened and eligible not clear

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Age: mean (SD) 60.2 (14.3) Chronicity: not clear but no limit Severity: not stated Control n=263 Age: mean (SD) 65 (12.5) Chronicity: not clear but no limit Severity: not stated VR group younger by mean of 4 years. No other significant between group differences at baseline	Controlled trial	tracking system using receivers placed onto objects; purpose-designed activities involved placing virtual objects on a shelf. Therapist performs movement in VR while holding a real object with receiver in it; participant sees trajectory of movement on screen and attempts to copy. Trains: shoulder, elbow and forearm Personalisation: speed, trajectory Non-immersive	Control 120 mins CT, 5/7, 4/52	reported in Appendix 3.1		Therapist present throughout in VR setting to guide set up adapt and instruct- limits feasibility No complaints of nausea, headache "or other discomforts" but unclear how this was assessed Costs not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Wittman et al. (2015)	n=5 Age: mean 62.4 (range 48-79) Chronicity: "chronic" Severity: FMA-UE, mean 39.8 (range 14-60)	Swiss, home-based study Pre-test, post-test design	ArmeoSenso system using 3 movement sensors (secured by straps onto upper and lower arm and trunk (hand not tracked) and purpose-built games Commercially available Trains: shoulder elbow and forearm Personalisation: speed, number of objects, time interval between objects Non-immersive	6/52 home -based therapy: asked to use as much as they wanted Trained mean of 16.8 hours (range 7.2-34.3 hours)	All improved on FMA-UE average 5 pts (range 4-7) Improvement in use of 3D workspace by 10.7% (range: 6.8-14.4%)		Numbers screened and eligible not stated Incidence of adverse effects not reported Costs not stated
Yin et al. (2014)	n=23 Age: mean (SD) 58.35 (13.45)	Singaporean, hospital-based study	Bespoke system, using hand held movement sensors and purpose-built ADL activities	VR n=11. x9, 30 mins, over 2/52 plus CT. Total training	Results included in findings from SRs, reported in Appendix 3.1	All participants in VR found enjoyable and helpful (no scores provided)	151 screened; 116 excluded (physical limitations main reason for exclusion).

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for <u>primary outcome measure</u>)	Acceptability	Feasibility
	Chronicity: mean (SD)16.3 (7.44) days Severity: FMA-UE at baseline in VR: median (IQR) 33 (21-59); control: median (IQR) 37 (11- 56) VR slightly older at baseline otherwise no significant between group differences at baseline	Pilot RCT plus survey in VR group	Trains shoulder, elbow and forearm Personalisation: ROM Non -immersive	time mean (SD)17.07 (2.86) mins Control n=12 CT mean (SD) training time 15.50 (2.79) mins			5 drop outs (reasons not specified) Movement sensors strapped on for those without enough grip strength (number not specified) plus a table and UL skateboard if unable to sustain movement against gravity No serious adverse effects. Back and/or LL pain (n=2) associated with standing

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3.4 Evidence Table for Modified Versions of Commercial VR Gaming Technologies

Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Adams et al. (2018)	n=22 Age: 46-91 (median 68) Chronicity: median 18 months; range 8-108 Severity: FMA-UE mean (SD) 22 (6.3); range 14-34	USA, outpatient clinic Single- group, pre-test, post-test study design	Saebo VR system uses Kinect and purpose designed ADL activities. Commercially available Trains shoulder, elbow and forearm movement (not hand) Personalisation: Virtual Occupational Therapy Application-therapist can alter ROM no of reps and difficulty level, motor and cognitive element	60 mins, 3/7, 8/52 Various activities in ADL suite individually prescribed Time actively playing game =mean (SD) 36.2 (8.8) per session (i.e. mean 14.48 hours) 198.3 functional reaches per session	Significant improvement in FMA-UE: mean (SD) 6.1 (6.8) (95% CI 3.8-8.4; p<0.001;) and mean WMFT time: -2.0 seconds (95% CI -3.6—0.4; p=0.049;) and mean WMFT-FAS: 0.48 (CI -0.40-0.77; p=0.001 95%)		Number screened and eligible not reported Drop out n=7 (unrelated to trial) Cost not specified No follow up No occurrence of adverse effects

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
			Non-immersive				
Aşkin et al. (2018)	n=40 Age: mean (SD) 55.1 (10.2) Chronicity: mean (SD) VR: 20.27 (5.47) months Control: mean (SD) 19.4 months (4.48) Severity: mean FMA VR: 39 Control: 30.5 No significant between group differences at baseline	Turkish, clinic-based study RCT	Uses Kinect with purpose-developed games Trains shoulder, elbow, wrist Personalisation: not specified Non-immersive	VR: 60 mins, 5/7, 4/52 of VR plus unspecified time of CT, 5/7, 4/52 Control: 20 sessions of CT (amount unspecified) Total time played not specified but aimed for 20 hours including breaks and time between games	VR: Significant improvement in FMA-UE (median 3; p<0.001), mAS proximal, Brunnstrom stage, BBT, MI. Significantly better performance in FMA - UE (p=<0.001) MI and active ROM (shoulder elbow and wrist) than control Control: statistically significant improvement in FMA (p=0.034), BBT and MI		43 screened. 3 excluded 2 lost to follow-up No occurrence of adverse effects Cost not specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Ballester et al. (2017)	n=39 VR: n=20 Age: mean (SD) 65 (10.3) Chronicity: mean (SD) 1073 (767.7) days Severity: CAHAI mean (SD) 52.8 (23.1) Control: n=19 Age: mean (SD) 61.7 (12.9) Chronicity: mean (SD) 798 (421.8) days post stroke Severity: CAHAI mean (SD) 53.5 (22.5) No significant between group	Spanish home-based study RCT	Rehabilitation Gaming System. Uses Kinect, data gloves, with purpose-developed games Trains shoulder, elbow, forearm, wrist and hand Personalisation: speed, trajectory and size of object Non-immersive	1-3 sessions a day, 5/7, 3/52 of either: VR: 3 activities on VR system plus a functional motor assessment using VR lasting (approximately 10 mins exercise with the hemiplegic UL) Control: 20 mins of alternate arm cup stacking	VR: Significant improvement on CAHAI mean (SD) 1.53, (2.4) (p=0. 01) post intervention, not maintained at follow-up. Significant greater improvement in CAHAI compared to control (mean [SD] VR= 1.53 [2.4]; Control = -0.67 [6.01]; p=0.05; Cohen's d =0.48) Difference not significant at follow-up No significant improvement on FMA-UE		Number screened and eligible not apparent 1 drop out Independently able to set up and use system although states that all were able to put gloves on with assistance. Incidence of adverse effects not reported Costs not reported

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	differences at baseline						
Cameirão et al. (2017)	n= 13 VR: n=7 Age: mean (SD) 64.7 (9.5); range 57-83 Chronicity: mean (SD) 51.4 (9.2) days Severity: MI score for elbow and shoulder combined minimum of 28 but had to have some impairment. Control: n=6 Age: mean (SD) 62.2 (14.8) Chronicity: mean (SD) 47.1 (37.4) days	Portuguese, hospital-based study Controlled trial	Rehatask uses PlayStation Eye camera and tracking handle/joystick with purpose-developed games Trains attention, memory and reaching (shoulder and elbow) Personalisation: progressive difficulty in speed, number of targets and distractors	CT plus x12, 45 mins sessions over 4-6/52 of either: VR: Training cognitive and UL movement Control: Training same competencies in physical environment .	Significant improvement in CAHAI for both groups over time (VR: mean 9.6 p=0.008; Control: mean 8, p=0.018); Significant improvement in BI for VR only No significant improvement in FMA-UE either group No significant between group differences on any measure		170 admitted, 45 not assessed, 95 excluded, 12 declined. Included if had cognitive deficit, excluded if had neglect. 5 drop-outs Incidence of adverse effects not reported Costs not specified

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	Severity: MI score for elbow and shoulder 28 minimum but had to have some impairment. No significant between group differences at baseline						
Chen et al. (2015b)	n=10 Age: mean (SD) 68.5 (14.7) Chronicity: mean (SD) 14.7 (7.6) months; range 3-24 months	Taiwanese hospital-based study Single-group, pre-test, post-test study design and questionnaire based on Technology	Uses Kinect with purpose-developed game Personalisation: 3 levels of difficulty with increasingly difficult movement patterns Trains shoulder and elbow	30 min, 3/7 8/52 plus CT	Significant improvement in FMA-UE post intervention; (mean= 9.4. p= 0.016) No significant improvement on FIM or BBT On a 7-point Likert scale (higher score indicating positive	On a 7-point Likert scale (higher score indicating positive response) 90% said increased motivation (mean 5.4); 90% said the game was enjoyable (mean =5.3); 90% wanted to continue using it in rehabilitation (mean=5.6); 80%	Number screened and eligible not apparent On a 7-point Likert scale (higher score indicating positive response) mean rating of feasibility and acceptability (together) = 5.4; 60% said games were easy to operate (mean 5.1)

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	Severity: Mean (SD) FMA-UE at baseline 53.3 (10.7)	Acceptance Model.	Non-immersive		response) 80% felt system improved UL recovery (mean 5)	found feedback useful (mean = 5)	Had to be able to stand unsupported to use Incidence of adverse effects not reported Costs not specified
Chiu et al. (2017)	n=2 Age: Not stated Chronicity: Not stated Severity: Stated as moderate and severe impairment (unclear on what this is based). Had to be able to pinch	Taiwanese study, setting not stated Single-group, pre-test, post-test study design	Uses Novint Falcon haptic device (produces force sensations) and purpose-built game Trains hand /pinch Personalisation: none specified Non-immersive	30 mins 3/7, 8/52 using VR	Improvements in FMA-UE (distal) by 1-2 points, WMFT (distal) (by .25 and .75 points) BBT (3-7 blocks) post intervention	High acceptability for both participants on a purpose-developed questionnaire	Number screened and eligible not stated Needed to use thumb and finger to interact with device. Supervised by OT Incidence of adverse effects not reported Costs not specified

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Demers et al. (2018)	n= 14 Clinicians focus group for clinicians n=7: OT x6 Physiotherapists x1; 2-28 years clinical experience Stroke participants n=7 Age: 38-73 Chronicity: 2-10 months Severity: Chedoke McMaster Stroke Assessment scale (3-6)	Canadian, hospital-based study Mixed methods convergent parallel design. Focus group for clinicians, standardized assessments and semi-structured interview of stroke participants	Used Kinect with purpose-developed ADL games Trains reach and grasp and cognitive processes. Personalisation: unilateral, bilateral Non-immersive	Clinicians used device for 15-20 or minutes mins per difficulty level Stroke participants used device for 20-45 mins		Themes of fun, motivation and perceived usefulness with VR system 7 of 8 (stroke) report highly satisfied with intervention. Liked realism of shopping task. 1 of 8 (stroke) said tasks were boring On 5-point scale (higher score indicating positive response) mean rating for enjoyment =4.1 (1.6), realism 4.4 (1); feedback 3.3 (1.4); discomfort 1.1 (0.4)	Number screened and eligible not stated. Clinicians report fast and easy to set up Annoyed by inaccuracy of tracking device (stroke) Clinicians report too difficult for more severely impaired On 5-point scale (higher score indicating positive response) mean (SD) rating of difficulty 2.3(1.3) Eye fatigue in 57.1% (stroke) no other adverse effects occurred Costs unspecified

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Demers et al (2017).	As above but reports from 6 stroke survivors only	As above	As above	As above	As above	On 5-point scale (higher score indicating positive response) mean (SD) rating of enjoyment and realism (together) =4.7 (0.8)	On 5-point scale (higher score indicating positive response) mean (SD)rating of difficulty 2.3 (1.4); discomfort 1.2 (0.4). Temporary eye fatigue noted by n=4 (66.7%)
Ellington et al. (2015)	N=14 Aged: 48-87, Chronicity: 2 weeks to 96 months Severity: Not specified but had to have 0-45^0 elb flex, and 15^0 shoulder flex, abd ext and 15^0 shoulder external rot^n	USA, hospital-based study Mixed methods using questionnaire (based on Technology Acceptance Model) and interview	Uses Kinect and purpose-developed software: VOTA (Virtual Occupational therapist assistant). Trains ADL Personalisation: none specified Non-immersive	60 mins (approximate) x4 sessions using VR (putting groceries away and meal prep)	Theme that increased use of affected UL	84.3% perceived system was useful (95% CI 67.3-93.3) 98.3% had a favourable attitude to technology: (95% CI 88.9-99.7) Behavioural intention to use 97.6% favourable (95% CI 85.6-99.7)	Convenience sample Perceived ease of use: 85.8% favourable (95% CI: 70 – 93.9) Qualitative themes that system was user-friendly and reflects real life situation Themes of barriers to use: annoyance at inability to recognise hand movements and the need for greater sensitivity and instruction

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						Significant relationship between perceived usefulness and intention to use (p=0.006); anxiety and attitude to technology (p=0.006) and attitude to technology and intention to use (p=0.029) Theme of enjoyment	Incidence of adverse effects not reported Costs not specified
Kato et al. (2015)	n= 2 stroke participants who performed UL reaching task Age: 50-83 Chronicity: 17-32 days	Japanese hospital-based study Single-subject, pre-test, post-test study design	Uses Kinect camera and haptic feedback with vibration device, 3D glasses, (± telerehabilitation set-up) and purpose-developed activity Trains: shoulder, elbow, forearm	10 trials of each of three movement tasks daily (30 reps) in addition to 20/7 CT	Improvements in shoulder flexion kinematics (between 0.5 and 7.2^0) elbow extension for both participants		Number screened and eligible not stated Therapist set up and operated the computer No occurrence of cyber sickness. Incidence of other adverse effects not stated Costs not specified

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	Severity: different measures used for each but all equates to mild to moderate UL deficits.		Personalisation: ROM Semi-immersive				
Kizony et al. (2013)	n= 20 VR: n=10 Age: mean (SD) 59.3 (11.3) Chronicity: mean (SD) 39.4 (19.9) months Severity: No baseline measure but had to have >45^0 shoulder flex or abd. Control: n=10 Age: mean (SD) 54.6 (13.6)	Israeli based, quasi-home set up (i.e. in hospital but set up like a home) RCT	The Gertner Tele-motion Rehab (TMR) system uses the Kinect and purpose-developed games Trains shoulder and elbow Personalisation: speed Non-immersive	30 mins x12, over 4/52 VR: exercised in quasi-home set up. Control: dose-matched, self-training UL exercise programme at home	Significant improvement post intervention for both groups on FMA-UE (VR: X^2=10.7; p=0.005. Control: X^2=14; p=0.001) No significant change in CACHAI. Significant improvements in MAL-Amount of use for VR group No significant between group effects		100 screened, 80 excluded (unclear on what basis) Therapist present in VR for 1st, 4th, 9th and 12th session to instruct, teach new games and adjust level of challenge in VR and to ensure compliance No adverse effects or technical problems reported Costs not specified

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	Chronicity: mean (SD) 39.7 (23.2) months Severity: No baseline measure but had to have >45^0 shoulder flex or abd. No significant between group differences at baseline						
Lee et al (2016a)	n=26 VR: n=13 Age: mean (SD) 66.46 (7.26) Chronicity: mean (SD) 7.59 (3.99) years.	South Korean outpatient community facility RCT	Uses Kinect and purpose-developed software showing virtual therapist performing PNF movements plus avatar of self	30 mins, 3/7, 8/52 of VR based PNF or Control: group-based rehabilitation practicing same PNF movement patterns	Significantly greater improvement in VR compared to control in FMA-UE (adjusted mean difference =7; 95% CI= 2.47-11.52; p=0.004), Total Manual Function Test	No significant differences between groups on 5-point scale (higher score indicating positive response) for satisfaction mean (SD) score 4.15 (1.07) for both groups; mean (SD) score for intention	34 screened, 6 excluded, 2 declined Therapist present throughout Incidence of adverse effects not reported Costs not specified

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	Severity: mean (SD) FMA -UE 38.85 (17.64) Control: n=13 Age: mean (SD) 69.92 (7.18) Chronicity: mean (SD) 8.23 (5.13) Severity: mean (SD) FMA-UE 47 (17.76) Control group significantly better FMA-UE scores at baseline therefore between groups adjusted mean differences used		Trains shoulder, elbow, wrist and hand Personalisation: none specified Non-immersive		Significant improvement in mBI in control group only.	of adherence 4.31 (1.11) in VR and 4.62 (.51) in control	
Moldovan et al. (2017)	n= 1 Age: 81	Romanian, hospital-based study	Uses Kinect (for arm) and Leap Motion (hand) sensors and	30 mins, 5/7, 2/52 using VR plus CT	Clinically significant improvements on the ARAT (improvement of 11 points) FMA-UE	System rated as "very efficient"	No occurrence of adverse effects Costs not specified

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	Chronicity: not stated Severity: "mild" ataxia and hemiplegia. ARAT score 46/57	Single-subject, pre-test, post-test design	purpose-developed games Trains shoulder, elbow, forearm, wrist, hand and coordination Personalisation: ROM Non-immersive		(improvement 6 points)		
Seo et al. (2016)	n= 10 Age: mean 63; range 43-76 Chronicity: mean 8 years; range 3-13 Severity: mean FMA-UE 42; range 2-66	USA laboratory-based study Feasibility and acceptability study using purpose-developed questionnaires	Uses Kinect and P5 glove and purpose-built games Trains arm and hand Personalisation: none specified Non-immersive	Dosage not stated		Acceptance linked to ease of understanding, ease of use, interesting and motivating games, adequate level of challenge, clinical feedback and perceived effectiveness.	No inclusion/ exclusion criteria stated All participants asked to independently set-up system and play with different games using written instruction. Help was provided when unable to solve issues independently (number requiring help not stated)

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
						Preferred sport and fictional games as opposed to ADLs (n =not specified) Wanted a device to rehabilitate hand and arm together (n=10) Split preference for having a therapist there (n=5) or not (n=5). Some felt learn better through trial and error. All wanted therapist to be able to access records for motivation and correction High ratings of enjoyment and fun felt to be challenging	Difficulty donning and doffing glove noted (n=5) Frustration with motion tracking (unclear if Kinect and/or glove) n=5 n=4 felt game rules and goals were easy to understand/intuitive Incidence of adverse effects not reported Costs Kinect camera $160 and P5 glove $40

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
						(specific rating not specified). 7/10 participants wanted clinical evidence of effectiveness	
Standen et al (2017)	n=27 VR: n=17 Age: mean (SD) 59 (12.03); Chronicity: median (IQR) 22 (16-59.5) weeks Severity: median (IQR) NHPT 45.17 secs (40.16-292.5 secs) Control: n=10 Age: mean (SD) 63 (14.06)	UK home-based setting Feasibility RCT	Used x2 Wii movement sensors located on top of monitor, a virtual glove with hand mounted power-unit and 4 infra-red LEDs on fingers and purpose-built games Trains hand, fingers and thumb	VR: 8/52 gradually increasing amount of VR play aiming for 3x 20 mins daily. Received therapist support + repeat visits until participant felt confident with system + phone support + offer of further visits + Visited weekly or fortnightly. No limit to number of visits +had research team phone number of needed +	Significantly greater improvement from baseline in VR than control in WMFT grip test at midway point (mean 5.62 effect size r=0.51, p=<0.05) and final MAL. No significant change WMFT-timed, NHPT	See Standen et al 2015	Screened 47, 27 included. 8 did not meet inclusion criteria. Drop out n=1 in control (found measures onerous) n=8 in VR: 4 in VR did not complete training (arm pain n=2, "not his thing" n=1, family issues n=1; 1 drop out following seizure unrelated to study) plus further 4 dropped out unrelated to study. Considerable home support offered. VR group needed 78 visits between them (median

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
	Chronicity: median (IQR) 12 (7.75-20.25) weeks Severity: median (IQR) NHPT = 45.66 secs (31.50-136.41) Significantly longer chronicity in VR group. No other significant between group differences		Personalisation: speed, ROM and precision Non-immersive	instruction manual with FAQ's. Control: "usual care" (not described). Therapist visit to take outcome measures only			4 range 3 to 14 visits) in addition to data collection visits and visits to hospital. n=2 required > 10 visits (on top of assessment) to help resolve technical issues. VR group required 92 hours 45 mins therapist contact time to deliver intervention median 6 hrs 10, range1 hr 20 to 18 hrs 10 mins. Training took median of 230 minutes per patient (range 50-540 minutes) plus a median of 45 minutes (range 0-430) sorting technical issues plus a median 65 minutes (range 0-135) in other communication

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
Standen et al. (2015)	n=17 Age: mean (SD) 59 (12.03); Chronicity: median (IQR) 22 (16-59.5) weeks Severity: median (IQR) WMFT 2.6 (1.65-6) seconds	UK home-based study. Efficacy (reported in Standen et al., 2017) plus semi structured interviews with n=8 participants in VR group	See Standen et al. (2017)	See Standen et al. (2017)	See Standen et al. (2017)	Variability in adherence to use of VR: days used ranged from 10-100%. Adherence to recommended time ranged from 1.46% - 70% Facilitators identified from thematic analysis of interview were flexibility in time of therapy, motivating games (competition and flow) alleviates boredom, belief in effect, family support and enhancing relationship with grandchildren	Barriers to use identified from analysis were technical issues (e.g. disrupted by bright sunlight, interference from other infra-red equipment), amount of time to set-up, requiring help to use (e.g. to change batteries) Low technical confidence and limited experience limited use of equipment Other barriers included competing commitments, illness, fatigue and depression, wanting to return to normal life No costs specified

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
						Frustration with technical issues apparent Experience with computer games related to boredom	
Tsekleves et al. (2016)	Useability study n=3 Age: 33-57 Chronicity: 14-18 months Severity: mRS 2-4 Single case pre-post study n=1, Age: 31 Chronicity: 11 years Severity: FMA-UE 39	UK, laboratory based Usability and single-case, pre-test, post-test design	USed 2 Wii movement sensors and purpose-built activity and games Trains, shoulder, elbow and forearm Personalisation: adjustable speed, ROM and duration Non-immersive	Usability study: 50 minutes using the device Single case pre-post study: 3/7, 2/52. Average playing time 18 mins using 3 activities: 2 games and 1 virtual therapist	Single case pre-post study Significant improvement in FMA-UE (8-points) NHPT Field notes of participant reporting physical improvements and increased spontaneous use	Usability Study: System feedback felt to be useful. Single case pre-post study enjoyment linked to level of challenge. Bored with “easy” game and frustrated with very difficult game. Motivated to continue	No inclusion or exclusion criteria stated Usability study: all able to interact with activities once personalised to ensure correct level of challenge. More severely impaired required movement sensors to be strapped to UL Spasticity levels stable. Incidence of other adverse effects not reported

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Title Year authors	Study population (stroke unless otherwise stated), stroke chronicity and severity	Study setting Study method	Description of VR device	Intervention	Efficacy (where available, point measures and measures of variability presented for primary outcome measure)	Acceptability	Feasibility
							Costs not specified
Yeh et al. (2017)	n=16 Age: range 28-82 Chronicity: 1-18 months Severity: had to have ability to pinch	Taiwanese study: setting unclear Single-group, pre-test, post-test design	Used Novint Falcon gaming device to provide haptic feedback and purpose-developed pinching activities Trains hand Personalisation: none specified Non -immersive	30 mins, 3/7, 8/52 practicing two tasks: pinch task (x20 using thumb and each finger) and pinch and lift task (20 times for thumb and index and then thumb and middle finger)	Significant improvements post intervention in FMA - wrist and hand score (mean increase 34%; z -2.994, p<0.01), WMFT-distal control, TEMPA, BBT, hand strength. Maintained at 4/52 follow up in FMA-UE wrist and hand, TEMPA, BBT and hand strength Significant improvement in acute and subacute groups in FMA, BBT, chronic only in BBT	On 5-point User Technology Acceptance Questionnaire (with higher score indicating greater satisfaction) mean (SD) scores for usefulness 4.35 (0.55); playfulness 4.47 (0.61); intention to use 4.85 (0.28);	Unclear how many screened and eligible On 5-point User Technology Acceptance Questionnaire (with higher score indicating greater satisfaction) mean (SD) scores for ease of use 4.19 (0.53) Incidence of adverse effects not reported

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3.5: Synopsis of Study Characteristics

	VR Gaming Technology Type Results presented as number (n) of studies addressing each factor			
		Off-the-shelf systems.	**Purpose-built systems**	**Modified systems**
Number of original studies (n=57)		n=19	n=22	n=16
	Studies addressing efficacy (n=36)	n=10 (281 participants)	n=13 (277 participants)	n=13 (219 participants)
	Studies addressing acceptability (n=37)	n=12	n=15	n=10
	Studies detailing study exclusion rates (n=26)	n=12	n=9	n=5
	Studies recording occurrence of adverse events (n=31)	n=10	n=13	n=8
	Studies recording feasibility of use (n=35)	n=13	n=12	n=10
	Studies providing system costs (n=4)	n=1	n=1	n=2
Commercially available system (n=28)		n=19	n=8	n=1
Study setting	Home (n=10)	n=4	n=3	n=3
	Clinic or laboratory (n=31)	n=11	n=10	n=10
	Home/clinic combination (n=1)	n=0	n=0	n=1
	Setting unclear (n=15)	n=4	n=9	n=2
System personalisation (n=26)		n=0	n=17	n=9
Use of immersive VR (n=2)		n=0	n=1	n=1 (semi-immersive)
Activity type	Traditional rehabilitation activity (n=9)	n=0	n=5	n=4
	Game/sport (n=46)	n=19	n=15	n=12
	Combination of game and traditional exercise (n=1)	n=0	n=0	n=1
	Unclear	n=0	n=1	n=0
Targeted treatment area	Whole upper-limb (n=11)	n=0	n=6	n=5
	Shoulder to forearm (n=32)	n=17	n=9	n=6
	Shoulder to wrist (n=1)	n=0	n=0	n=1
	Wrist and hand (n=12)	n=2	n=6	n=4
	Unclear (n=1)	n=0	n=1	n=0

4: TIDieR Checklist for Phase 1

Item	Item description	Where located
Brief Name	Provide the name or phrase which describes the intervention	Section 4.1
Why	Describe the rationale, theory, or goal of the elements essential to the intervention	Section 1.4.1
What: Materials	Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information as to where materials can be accessed (e.g. on-line appendix, URL)	Sections 4.4.1- 4.4.3; 4.5.1.2
What: Procedures	Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities	Section 4.5.1.4 & 4.5.1.5
Who provided	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, back ground and any specific training given	Sections 4.5.1.4 & 4.5.1.5
How	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	Section 4.5.1.4
Where	Describe the type(s) of location where the intervention occurred, including any necessary infrastructure or relevant features	Section 4.5.1.2
When and how much?	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Section 4.5.1.4
Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	Section 4.5.1.4
Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when and how)	Section 4.5.3
How well: planned	If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity then describe them	Section 4.5.3.
How well: Actual	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	Section 4.5.2

5: TIDieR Checklist for Phase 2

Ite	Item description	Where located
Brief Name	Provide the name or phrase which describes the intervention	Section 5.1
Why	Describe the rationale, theory, or goal of the elements essential to the intervention	Section 1.4.1
What: Materials	Describe any physical or informational materials used in the intervention, including those provided to participants or used intervention delivery or in training of intervention providers. Provide information as to where materials can be accessed (e.g. on-line appendix, URL)	Sections 4.4.1- 4.4.3; 5.6, 5.8.1; 6.10.1
What: Procedures	Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities	Section 5.7
Who provided	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, back ground and any specific training given	Sections 5.7 & 5.8
How	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	Section 5.7
Where	Describe the type(s) of location where the intervention occurred, including any necessary infrastructure or relevant features	Section 5.6
When and how much?	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Section 5.7
Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	Section 5.7
Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when and how)	Section 6.6
How well: planned	If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity then describe them	Section 5.
How well: Actual	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	Sections 6.4 & 6.5

DO YOU HAVE PROBLEMS USING YOUR ARM AS A RESULT OF A STROKE?

If so, we need you!

We are looking for volunteers, with reduced movement in their arm following a stroke, to participate in a research study looking at exercising the arm using video gaming technology that has been developed especially for use with stroke survivors.

The study will take place at Brunel University London and has ethical approval.

Brunel UNIVERSITY LONDON

ReWiiRe Research for Wii Rehabilitation

If you have suffered a stroke more than 12 weeks ago that has affected your arm

Are aged over 18

Are no longer receiving treatment for your arm

Are interested in participating or learning more about a potential new therapy for the arm....

THEN

PLEASE CONTACT

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ReWiiRe: Exploring the use of adapted video gaming technology, for treatment of the arm after stroke

An Invitation to Participate

You are being invited to take part in a research study looking at the use of adapted video gaming technology in the recovery of arm movement following stroke. Before you decide whether to participate or not, it is important that you understand why the research is being done and what it will involve.

This information sheet provides an overview of the relevant information. Please read it carefully, discuss it with others if you wish and take time to decide whether or not you wish to take part. Please ask us if there is anything that is not clear or if you would like more information. We are also happy to go through this information with you in person or on the telephone and answer any questions that you may have.

What is the purpose of the study?

Most people who suffer a stroke, experience problems with arm movement and this lack of recovery has been linked to increased dependence on others and a reduced quality of life. It has been suggested that playing video games may help to provide the right kind of practice to help with arm recovery after stroke. However, systems developed for use in hospitals and therapy departments are expensive and complicated to set up and use. While commercially available systems (such as the Nintendo Wii© and Microsoft Kinect©) have been found to be too difficult for many stroke survivors to use, as people often lack the range of movement, speed and dexterity required to use these systems following stroke.

In a previous study, undertaken by this research team, physiotherapists and stroke survivors used the commercially available Nintendo Wii© video gaming system as part of treatment. They then told us about what they liked and disliked about it, what they found difficult about using it and what improvements they would like to see. Engineers involved in the study then developed a new system, using adapted video game technology, to address the issues raised. This new system has the ability to be personalised (i.e. adapted to each

person's individual needs after stroke) and is known as a **P**ersonalised **S**troke **T**herapy device (**PST**).

Before introducing a new therapy into practice is important to understand whether it is practical to use it, whether it is acceptable to use it from the service-user's viewpoint, whether there are challenges associated with using it and whether it works. The planned study aims to examine these issues with the PST.

Why have I been invited to take part?

You have been invited to participate in this study as you had a stroke more than twelve weeks ago that has affected your arm movement and you have now finished all treatment for your arm. As some movement of the arm is required in order to use the PST, people who do not have any movement at all in their arm are not suitable for the present study.

Do I have to take part?

As participation is entirely **voluntary**, it is up to you to decide whether or not to take part. If you decide to take part, you are still *free to withdraw at any time and without giving a reason. Refusal to participate or withdrawing from the study at any time will not affect any care or services you are receiving currently or may receive in the future.*

If you decide you would like to take part, you will be asked to sign two copies of a consent form. You will be given one copy of the consent form along with this information sheet to keep.

What will happen if I do take part?

You will be required to attend the university for 12 sessions lasting between 45 and 90 minutes each. The plan of what will happen is outlined in the diagram below and is discussed on the next page.

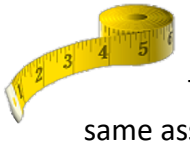
Baseline Assessment

If you decide that you would like to take part, you will be asked some questions by telephone so we can start to assess your suitability to take part in the study. You will then be asked to attend the university to undergo some assessments to ensure that you are definitely suitable to take part in the study and to enable us to see how the stroke has affected you. You will also have the opportunity to discuss the study, ask any questions you may have and then decide whether you wish to take part or not. This first appointment will last between one and one and a half hours.

Treatment intervention

Following the first assessment appointment (described above), you will be required to attend the University for nine treatment sessions lasting for approximately 60-75 minutes each. These will be spread out over three days a week for three weeks. During this time you will play a game and practice activities using the PST with your arm affected by the stroke. In addition, the researcher will ask you a few questions about how you are and about your experience using the device.

Reassessment



The eleventh session will occur within three working days of you completing the treatment part of the study and involve you undergoing some of the same assessments you did in session 1 and having a short, audiotaped interview with the researcher about your experiences using the PST. It is anticipated that this session will last approximately 1 and a half hours. The twelfth and final session (lasting for about an hour), will occur four weeks after the eleventh session and again will involve you completing some of the same assessments as you did in the first session.

During each appointment you should wear loose fitting clothing on your upper body so you can freely move your arm. Refreshments will also be provided so you do not need to bring anything with you unless you would like to.

Is there anything I can't do during the study?

So we can make a fair assessment of the effect of the PST on your arm movement, it is important that you do not use video games that involve the arm affected by your stroke for the duration of the study and that the person who will perform most of the assessments of your arm does not know what treatment you have been having. Therefore it is important that you do not discuss the study with them. You will be reminded about this at the start of each assessment session.

Where is the study taking place?

All assessments and treatment sessions will take place in a laboratory in the Mary Seacole Building at Brunel University. Free parking will be organised on request and travel expenses paid.

Who is doing the study?

The study is being carried out by physiotherapists and engineers from Brunel University, London. All physiotherapists are experienced in stroke rehabilitation.

What are the possible benefits of taking part?

The information provided by this study will enable researchers to examine whether it is possible, acceptable and safe to use the PST and whether it can help with arm recovery following stroke. It is possible that your arm function *may* improve during the study, but this will not be known until after the study has been completed.

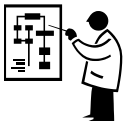
What are the possible disadvantages of taking part?

During its development, the PST has been used with a several stroke survivors, none of whom suffered adverse effects. However, a number of risks remain including *arm pain and discomfort* as a result of using the device (these effects will be closely monitored and assessed throughout the study and you will be advised regarding appropriate management should this occur). In addition, there is a risk of *motion sickness.* The risk is very low but occurrences will be monitored and if moderate to severe, you will be withdrawn from the study. There is a risk of *muscle stiffness* ("spasticity") associated with effort (as this is common with any effortful activity following stroke and usually resolves on rest, it is considered as low risk but will be monitored during each session). There is a very small risk of you tripping or *falling* when using the PST. One of the researchers will be watching throughout to minimise the risk should a fall look likely to happen. There is a theoretical risk of the PST inducing epilepsy *(*"a fit"). However, this has not been reported in any previous studies using video gaming devices and recommendations for decreasing the risk will be adhered to. All researchers have experience with managing people suffering from epilepsy and are familiar with the NHS protocol for dealing with someone who is experiencing a fit. Finally, there is a low risk that you may *feel upset* when exercising with the PST or when answering questions about your experience. Please let the researcher know if this is the case and she will signpost you to appropriate services for help. Also remember that you do not have to answer any questions that you do not want to and that you may withdraw from the study at any time without giving a reason and without this affecting any care you are or will receive in the future.

Will my taking part in this study be kept confidential?

Personal information collected during the research will be kept securely and will only be used to inform the findings of this study. All information and data about you will be treated as highly confidential. Direct quotes from the interview and other data and will be anonymised, meaning that it won't be possible to identify you in any part of the study that is written up or presented.
Although unlikely, should poor practice on behalf of health care staff become apparent, the research team have a duty to pass on this information in order to protect current and future patients.

What will happen to the results of the research study?



The information gained during this study will be used to write a PhD thesis. The results will also be presented to other people interested in the research and may be published in journals and presented at conferences. You will be provided with a copy of the research findings should you wish to be.

Will I be paid to take part in the study?

This PhD study is unfunded and you will not be directly paid for taking part. However, travel costs will be reimbursed.

Who has reviewed the study?

Permission for this study has been given by The Research Ethics Committee of the School of Health Sciences and Social Care, Brunel University.

What if something goes wrong?

This study is insured by Brunel University. If you wish to have further information about this please contact a member of the research team.

What happens if I have a complaint?

Should you wish to make a complaint about any part of the study, please contact the chair of the ethics committee, Dr Elizabeth Cassidy at Elizabeth.cassidy@brunel.ac.uk

Contact for further information

If you would like further information about this study or would like to take part, please contact:

Alyson Warland (lead researcher)	Alyson.warland@brunel.ac.uk	07854 066001 or 01895 268851
Dr Cherry Kilbride (PhD supervisor)	Cherry.kilbride@brunel.ac.uk	01895 268675

Thank you for taking the time to read this!

8: Screening Form

Participant ID_____

Part 1 Telephone screening

Assessor name_____Date of assessment_____

1. Date of birth (18 years or above)_____
2. Gender: (circle) MALE/FEMALE
3. Date of stroke (exclude if < 12 weeks)_____
4. Location and type of stroke if known (not cerebellar) _____
5. Unilateral stroke? (exclude if bilateral) YES/NO
6. Side of hemiplegia: LEFT/RIGHT
7. Do you have a pacemaker? (Exclude if yes) YES/NO
8. Have you had a heart attack in the last three months? (Exclude if yes) YES/NO
9. Do you suffer from angina that is not controlled by medication? (Exclude if yes) YES/NO
10. Have you ever suffered from epilepsy bought on by flashing lights ("photosensitive epilepsy") as an adult? (Exclude if yes) YES/NO
11. Do you suffer from movement problems with your arm that was affected by the stroke? (Exclude if no) YES/NO
12. Are you able to move your arm at all following the stroke? (Exclude if no) YES/NO
13. Do you suffer from arm pain when you move your arm affected by the stroke (Exclude if yes) YES/NO
14. Are you able to stand or sit independently for 5 minutes at a time either with or without a walking aid? (Exclude if no) YES/NO
15. Are you still receiving treatment for your arm? YES/NO
    a. If yes, how often, with whom, type of activity (exclude if formal and involving upper limb)

       _____
       _____
       _____
       _____
       ____

16. **Modified Rankin score (circle)** As reported by participant

    Please rate how your stroke affected you out of the following options:

    0 = no symptoms at all

    1 = no significant disability despite symptoms: able to carry out all duties and activities

    2 = slight disability: unable to carry out all previous activities but able to look after own affairs without assistance

    3 = moderate disability: requiring some help, but able to walk without assistance

    4 = moderate severe disability: unable to walk without assistance and unable to attend to own bodily needs without assistance

5 = severe disability: bed ridden, incontinent and requiring constant nursing care and attention

Date and time to attend Brunel for screening _____

Volunteer provided with details of where to come YES/NO

Parking permit required? YES/NOT REQUIRED

Car registration number_____

Do you require a taxi to attend the study? YES/NO

Part 2: Physical screening

Assessor Name _____

Date of assessment_____

17. **Motricity Index:** Need to score between 14-25 inclusive for both shoulder and elbow movements. To be assessed in sitting.

Ask the participant to perform the following movements in sitting. Assessor to demonstrate each movement first:

a. elbow flexion from 90 degrees. Voluntary contraction. Score_____
b. shoulder abduction from chest. Score _____

0= no movement,

9= palpable contraction in muscle but no movement,

14= movement seen but not full range, not against gravity,

19 = full range against gravity but not against resistance,

25 = movement against resistance but weaker than other side,

33= normal power

18. Passive Range of Motion (ROM) Assess in sitting

Movement	Range	Limiting factors
Sh flex		
Sh abd		
Sh lat rotn		
Elbow flex		

Elbow ext		

Exclude if have fixed contracture, active disease or orthopaedic conditions (such as RA, fracture or heterotropic ossification) affecting movement in the arm

Other

19. Handedness as assessed using the Edinburgh handedness inventory: LEFT/RIGHT
20. Visual field deficit score (exclude if score on star cancellation test < 44)_____

Capacity and communication.

21. Able to state broadly what the study is about and attendance requirements? (Allowed to reread the PIS and discuss requirements with lead researcher if necessary). (Exclude if no) YES/NO
22. Able to follow two-point command? (e.g. put the index finger of the hand not affected by stroke on your nose) (Exclude if no) YES/NO
23. Able to be understood by any means? (Exclude if no) YES/NO.
24. Communication: VERBAL / WRITTEN /COMMUNICATION AID (state)_____
25. Understanding that should not participate in virtual reality video games involving the affected arm for the duration of the study? YES/NO
26. Understanding that must not discuss details of what activities and the study activities with the person performing the reassessments for the study? YES/NO
27. Consent to participate YES/NO
28. Date for intervention phase_____
29. Provided with copy of PIS (assessor sign when done)_____
30. Provided with copy of Consent form (assessor sign when done)_____
31. Provided with travel expenses form YES/NO/NOT APPLICABLE

CONSENT FORM

Exploring the use of a personalised stroke therapy (PST) device, using adapted video gaming technology, for arm rehabilitation following stroke: A feasibility and acceptability study.

The participant should complete the whole of this sheet him/herself

Please tick the appropriate box	**YES** 	**NO** 
I have read the Research Participant Information Sheet		
I have talked to the researcher Alyson Warland about the study		
I have received satisfactory answers to all my questions		
I understand that I will not be referred to by name in any report, presentation or publication concerning the study		
I understand that my involvement with the study is voluntary		
I understand that I am free to withdraw from the study: • at any time • without having to give a reason for withdrawing • without affecting any services/care I am currently receiving or may receive in the future		
I agree to my interview being audio taped		
I agree that the words I say may be used as anonymous quotations when the study is written up or published.		
I agree to take part in this study		

Signature of Research Participant:_____Date:_____

Name in capitals:_____

Witness Statement: I am satisfied that the above named has given informed consent.

Witnessed by:_____Date:_____

Name in capitals:_____

Research ethics approval has been obtained from the School of health Sciences and Social Care Research ethics Committee REF: 14/06/PHD/02

Intervention Data Collection Form

Participant ID _____ Date_____

Assessor name_____ Session number_____

1. **Pain/ discomfort since last visit** YES/NO

If yes, detail:

Duration_____

Location of pain _____

Severity (VAS) at worse_____

Type of pain (DOMS/other)_____

Pain at rest? YES/ NO

VAS at present at rest_____ and on movement_____

If pain related to DOMS advise re gentle stretching and analgesics

If pain >6/10 on VAS and unrelated to DOMS and appears to be related to use of PST use, advise regarding rest and analgesics and participant will be withdrawn from the study. Detail reasons in comments section and inform lead researcher.

Have you taken any medication for this? (detail type, when taken, effect)

_____

_____

_____

Participant feels able to continue with study today? YES/NO

Participant willing to continue with study on another day but not today? YES/NO

2. **Modified Ashworth Score**:

Participant is sitting. For each muscle group, the examiner moves the arm passively through the full range of movement available on three occasions. On the fourth occasion, the examiner rates the resistance felt to the passive movement using the rating scale given. E.g. To test shoulder adductors, passively abduct the shoulder on 3 occasions prior to rating the resistant felt to shoulder abduction.

	MARK YOUR RATING HERE (0-4)
SHOULDER ADDUCTORS	
SHOULDER INTERNAL ROTATORS	

ELBOW FLEXORS	
WRIST FLEXORS	
FINGER FLEXORS	

No increase in tone	0
Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end range of motion when the limb is moved in flexion or extension	1
Marked increase in tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but limb easily moved	2
Considerable increase in tone- passive movement difficult	3
Limb rigid in flexion or extension	4

Intervention

Each exercise should be calibrated to the individual's ability prior to starting. Therapist to demonstrate each exercise prior to the participant's first attempt.

"I am now going to ask you to practice these activities for up to 10 minutes each. You can practice this in sitting, standing or a combination of both. Should you feel the need to rest at any time during the study please let me know. While it is usual to feel some shortness of breath and increased heart rate during exercise, please let me know if this is above the level you would expect with exercise or should you feel pain or begin to feel unwell in any way. Do you have any questions?"

Ensure a minimum of 2 minutes rest between activities

	Exercise 1	Exercise 2	Exercise 3	Exercise 4
Exercise name				
Position (sit or stand)				
Time played total				
Time of and duration of any breaks (e.g. at what minute stopped				

playing and how long break lasted)*				
Score achieved on PST				
BORG rating (see scale)				
Level of enjoyment (See scale)				
Technical issues (record yes or no. Detail incidences) *.				

*continue in comments section if required

Adverse Events

Tick as appropriate. Fill in scores as appropriate. Provide further details in comments section.

	Exercise 1	Exercise 2	Exercise 3	Exercise 4
Arm pain • use VAS pain score • record whether at rest or on movement • detail type of pain • **If> 6/10 on VAS stop study today**. **Report incidences to lead researcher**				
Actual fall • detail incident in comments section • assess for injury. Refer onwards if appropriate				
Near fall				

• detail incident in comments section				
Motion sickness • use simulator sickness questionnaire • withdraw from study if >10/20				
Epilepsy/fitting • detail event (at which time point in study. length of fit) • follow NHS recommendations for fitting • Call for an ambulance				
Chest pain • detail time point in study it occurred • if it is mild but does not settle within 10 minutes call ambulance • if severe and or not settling within 10 minutes of resting call for ambulance				
Other: Please describe				

Comments:_____

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Continue on another sheet if necessary.

Date for next appointment made_____

If before assessment session, remind participant not to discuss the study or their previous scores with the assessor.

Outcome Measures: Standard Operating Procedure

Time 1: initial assessment

To be completed by the lead researcher

Participant number……..

Date……..

Name of assessor…….

Thank you for coming in today.

Today I am going to ask you to perform some tests and answer some questions so I can see how your stroke has affected you. After this, I will leave the room and the lead researcher will ask you some further questions.

Remember there is no pass or fail mark for any of the tasks nor any wrong answers to the questions – we are just trying to assess how the stroke has affected you and what you thought about the study.

This may take up to an hour to complete. If you feel very tired, unwell, would like a rest at any time or would like to stop the assessment for any reason, then please let us know.

Do you have any questions?

FMA

Manual for the Fugl-Meyer Assessment upper limb section. Deakin et al. (2003). Minor changes from the published protocol to ensure clarity and improve reliability are highlighted in yellow.

The starting position for all the items is, unless otherwise stated, with the patient seated on a dining type chair without arms. The patient's forearms and hands should rest on the thighs in pronation. If sitting balance is a concern a Velcro trunk strap may be used for safety. Instructions should be given to the patient as shown in *italics*. At the same time the examiner should demonstrate the movement. If the patient is unable to follow this, the movement should be modelled on the patient.

Shoulder/elbow/forearm

1.1 Reflex activity

Scores are shown in boxes. See figure 1. Score for flexors (biceps and finger flexors) and extensors (triceps)

Figure 1

No activity	0
Reflex activity present	2

1.2 Flexor synergy

Touch your ear with your weaker hand. (Figure 2)

The patient may be asked to repeat the movement up to three times to enable observation (sh retn, elevation, abd, ext rotn, elb flex, forearm supn)

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

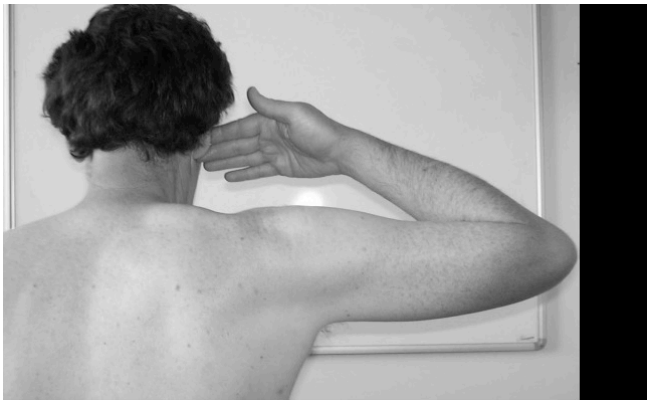


Figure 2

1.3 Extensor synergy

Starting position is the full flexor synergy (fig 2). The patient may be helped to achieve the starting position.

Move your hand from your ear to your opposite knee (Figure 3).

The patient may be asked to repeat the movement up to three times to enable observation. (sh add/int rotn, elb ext, forearm pron)

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

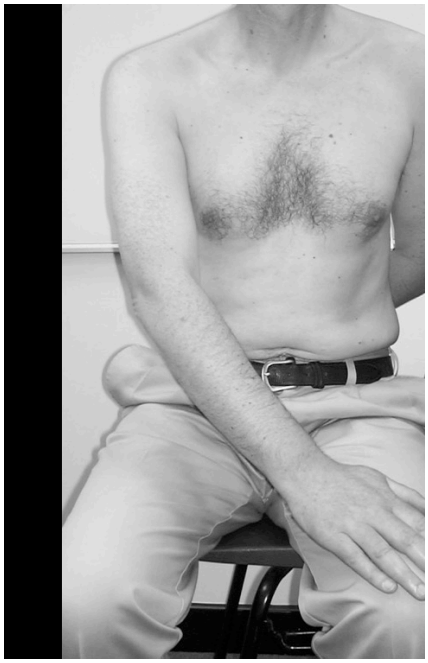


Figure 3

1.4 Volitional movement mixing synergies

1.4.1 Hand on the lumbar spine

Put your hand on your back.

The patient has to move forward on the chair for this item and may be given some support for balance.

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

Score 1 if hand reaches or passes ASIS but faults apparent (e.g. hand does not clear and has to be dragged up sacrum). For a score of 2 the patient performs the movement faultlessly, (i.e. patient's hand clears the ASIS hand must go higher than the ASIS)

1.4.2 Shoulder flexion 0-90°

Lift your arm straight up, keep your thumb pointing up and your elbow straight.

Score 0 if the arm abducts at the start of movement.
Score 1 if elb flex or Sh in towards the end of movement.
The elbow must remain fully extended for a score of 2.

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

1.4.3 Forearm pronation/supination

Turn your palm face up and face down.

Starting position elbow actively held at 90°, sh 0°
Score 0 if unable to achieve starting position. Score 1 if able to maintain sh and elb position and some but incomplete pron/supn. Score 2 maintain sh and elb position, full pron/supn.

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

1.5 Volitional movements without synergy

1.5.1 Shoulder abduction 0° to 90°

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

Lift your arm out to the side, keep your elbow straight

Score 0 if initial elb flexn or supn occur. Score 1 for incomplete movement or if elb flexn or supn occur in later stages of movement. Score 2, if elbow must be extended and forearm pronated throughout entire full range movement

1.5.2 Shoulder flexion 90°to 180°

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

Examiner may help the patient to achieve the starting position.

Lift your hand towards the ceiling, keep your elbow straight and thumb pointing up.

Score 0 if initial elb flexn, or sh add or forearm supn occur at the beginning of movement. Score 1 if achieve full range at shoulder but elb flexn, sh add or supn occur in latter movement stages. Score 2 if movement performed faultlessly maintaining elb ext, and midline of sh and forearm

1.5.3 Forearm pronation/supination

Cannot be performed	0
Detail partly performed	1
Detail is performed faultlessly	2

Shoulder should be between 30°and 90° of flexion.

Turn your palm face up and face down, with your elbow straight.

Score 0 if unable to attain start position or if no supn/pron.
Score 1 if elb and sh position maintained but pron/supn not full range. Score 2 if movement full range and performed faultlessly while maintaining elb and sh positions

1.6 Normal reflex activity

2 or 3 markedly hyperactive	0
2 lively or 1 hyperactive	1
1 or no lively reflexes	2

Test only if full marks given in section 5.
Test the three reflexes as in figure 1

2. Wrist

2.1 Wrist stability (elbow 90°, shoulder neutral)

Apply resistance at 15° dorsiflexion. The elbow may be supported if needed.

Lift your hand and hold it there, keep your elbow bent.

15° Dorsiflexion cannot be performed	0
Dorsiflexion performed but not against resistance	1
Position can be maintained against slight resistance	2

2.2 Wrist flexion/extension (elbow 90°)

The elbow may be supported if needed.

Lift your hand up and down, keep your elbow bent.

No voluntary movement	0
Voluntary movement but not through total passive range	1
Movement through total passive range	2

2.3 Wrist stability (elbow 0°, shoulder neutral)

15º dorsiflexion cannot be performed	0
Dorsiflexion performed but not against resistance	1
Position can be maintained against slight resistance	2

Apply resistance at 15° dorsiflexion.

Lift your hand, hold the position with your arm straight

2.4 Wrist flexion/extension (elbow 0°)

Lift your hand up and down with your arm straight.

No voluntary movement	0
Voluntary movement but not through total passive range	1
Movement through total passive range	2

2.5 Wrist circumduction (sh 0°, elb 90°)

Move your hand around, keep your elbow bent and your arm still.

Movement cannot be performed	0
Jerky motion or incomplete circumduction	1
Detail performed fully and adequately	2

3. Hand

For all the items the examiner may support the patient's elbow at 90° and help attain starting position passively if required.

3.1 Mass flexion

Make a fist.
Start from full extension

No flexion	0
Some but not full active finger extension	1
Full active flexion (compared to unaffected hand)	2

3.2 Mass extension

Stretch out your hand.
Start from full flexion

No extension occurs	0
Can release mass flexion grasp	1
Full active extension (compared to unaffected hand	2

3.3 Distal finger grasp (Figure 4)

Grip my finger – hold it.

Required position cannot be achieved	0
Grasp is weak	1
Grasp maintained against resistance	2

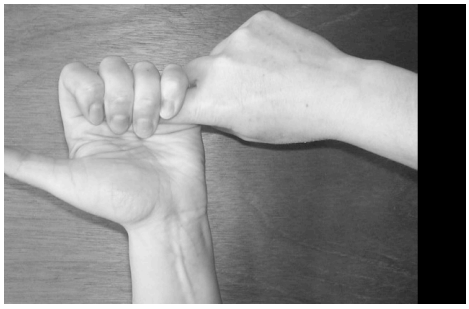


Figure 4

3.4 Thumb adduction grasp (Figure 5)

Grip the paper between your thumb and hand.

Function cannot be performed	0
Paper held between thumb and index metacarpal can be kept in place but not against a tug	1
Paper is held well against a tug	2

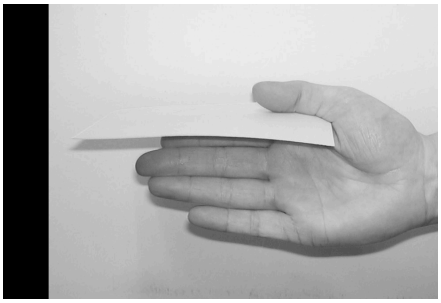


Figure 5

3.5 Thumb to index finger grasp (Figure 6)

Hold the pencil – keep it there.

Pencil cannot be held	0	
Pencil can be held but not against a tug		1
Pencil is held against a tug	2	

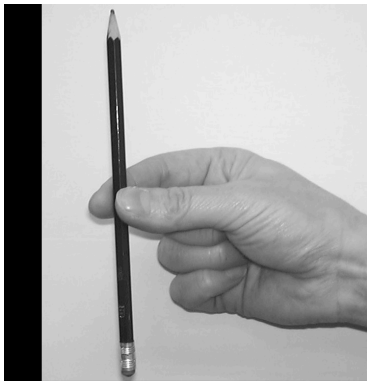


Figure 6

3.6 Cylinder grasp

Plastic mug diameter 8 cm. Hold body of mug not handle

Hold the mug – keep it there.

Mug cannot be held	0
Mug can be held but not against a tug	1
Mug is held against a tug	2

3.7 Spherical grasp

Ball cannot be held	0
Ball can be held but not against a tug	1
Ball is held against a tug	2

Tennis ball.

Hold the ball – keep it there.

Ball must not be stabilised against another object or body part

4. Co-ordination and speed

Finger to nose test: With eyes closed. He first performs the test with the nonparetic side then the paretic side. Each test is timed.

Touch your finger to your nose five times as quickly as you can

4.1 Tremor

No tremor	2
Slight tremor	1
Marked tremor	0

4.2 Dysmetria
(error in endpoint destination)

No dysmetria	2
Slight dysmetria	1
Marked dysmetria	0

4.3 Speed

Less than 2 seconds difference between sides	2
2-5 seconds difference	1
At least 6 seconds difference	0

FMA Score Sheet

Participant ID…… Date…….
Name of assessor…… Time 1 Time 2 Time 3

		0	1	2
1	**Shoulder / elbow / forearm**			
1.1	**Reflex activity**			
1.1.1	Flexors (biceps and finger flexors)			
1.1.2	Extensors (triceps)			
1.2	**Flexor synergy – volitional movement within synergy**			
1.2.1	Shoulder retraction			
1.2.2	Shoulder elevation			
1.2.3	Shoulder abduction			
1.2.4	Shoulder external rotation			
1.2.5	Elbow flexion			
1.2.6	Forearm supination			
1.3	**Extensor synergy – volitional movement within synergy**			
1.3.1	Shoulder adduction / internal rotation			

1.3.2	Elbow extension			
1.3.3	Forearm pronation			
1.4	**Volitional movement mixing the dynamic flexor and extensor strategies**			
1.4.1	Hand on lumbar spine			
1.4.2	Shoulder flexion			
1.4.3	Forearm pronation / supination			
1.5	**Volitional movements are performed with little or no synergy dependence**			
1.5.1	Shoulder abduction			
1.5.2	Shoulder flexion			
1.5.3	Forearm pronation-supination			
1.6 0	**Normal reflex activity**			
2	**Wrist**			
2.1	Wrist stability – elbow 90°			
2.2	Wrist flexion/extension – elbow 90°			
2.3	Wrist stability – elbow 0°			
2.4	Wrist flexion/extension – elbow 0°			
2.5	Circumduction			
3	**Hand**			
3.1	Mass flexion			
3.2	Mass extension			
3.3	Grasp A – distal finger grasp			
3.4	Grasp B – thumb adduction grasp			
3.5	Grasp C – thumb to index finger grasp			
3.6	Grasp D – cylinder grasp			
3.7	Grasp E – spherical grasp			
4	**Co-ordination/speed**			
4.1	Tremor			
4.2	Dysmetria			
4.3	Speed			

ABILHAND –Manuel Ability Measure

The ABILHAND questionnaire is administered on an interview basis (patients do not realise the activities).

Patients are asked to estimate the ease or difficulty in performing each activity, when the activities are done:

- Without other technical or human help (even if the patient actually uses help in daily life)
- Irrespective of the limb(s) actually used to do the activity
- Whatever the strategy used (any compensation is allowed)

During the evaluation, a three-level response scale is presented to the patients. Patients are asked to rate their perception on the response scale as either “impossible”, “difficult” or “easy”. Activities not attempted in the last three months are not scored and are entered as missing responses (tick the “?” column). For any activity the four potential answers are:

- Impossible: the patient is unable to perform he activity without using any other help
- Difficult: the patient is able to perform the activity without any help but experiences some difficulty
- Easy: the patient is able to perform the activity without any help and experiences no difficulty
- Question mark: the patient cannot estimate the difficulty of the activity because he/she has never done the activity. Note when a patient has never attempted the activity, the rater needs to make sure why this is so. If an activity has never been attempted because it is impossible, it must be scored as “impossible” rather than a question mark.

Ref: Penta, M., Tesio, L., Arnould, C., Zancan, A., & Thonnard, J-L. (2001). The ABILHAND questionnaire as a measure of manual ability in chronic stroke patients: Rasch-based validation and relationship to upper limb impairment. *Stroke*, 32, 1627-34.

ABILHAND Questionnaire

Participant ID number……

Date……

Assessor name……Time 1 Time 2 Time 3

	How difficult are the following activities?	Impossible	Difficult	Easy	?
1	Taking the cap off a bottle				
2	Buttoning up a shirt				
3	Sharpening a pencil				
4	Opening mail				
5	Fastening a press stud (jacket, bag)				
6	Washing one's hands				
7	Tearing open a packet of crisps				
8	Wrapping up gifts				
9	Opening a screw top jar				
10	Shelling hazelnuts				
11	Filing one's nails				
12	Fastening the zip of a jacket				
13	Squeezing toothpaste onto a toothbrush				
14	Pulling up the zip on trousers				
15	Peeling onions				
16	Spreading butter on a slice of bread				
17	Cutting one's toenails				
18	Threading a needle				
19	Cutting meat				
20	Unwrapping a bar of chocolate				
21	Peeling potatoes with a knife				

22	Buttoning up trousers				
23	Hammering a nail				

ARAT

Yozbatiran et al (2008) A Standardized Approach to Performing the ARAT. *Neurorehabilitation and Neural Repair,* 22(1), 78-90.

Positioning of the Subject

Appropriate body posture for ARAT testing has the subject seated upright in a standard chair that has a firm back and no armrests. The assessor may provide foam padding to the back of the chair to ensure that upright position is maintained. The trunk must remain in contact with the back of the chair throughout testing. In this regard, the subject is instructed and regularly reminded not to lean forward, stand up, or move sideways. The head is held in a neutral upright position. The subject's legs are in front of the chair, with feet in contact with floor throughout testing.

All ARAT tasks are performed unilaterally. To promote this and keep the non-tested hand in view, the subject is always asked to start with both hands in pronated position on the table, except for the "gross movement" subscale, which requires starting with both hands pronated on the lap. The testing-table level should approximate the subject's mid-abdomen, with the difference in chair-table height of about 30 cm considered optimal.

Equipment set up

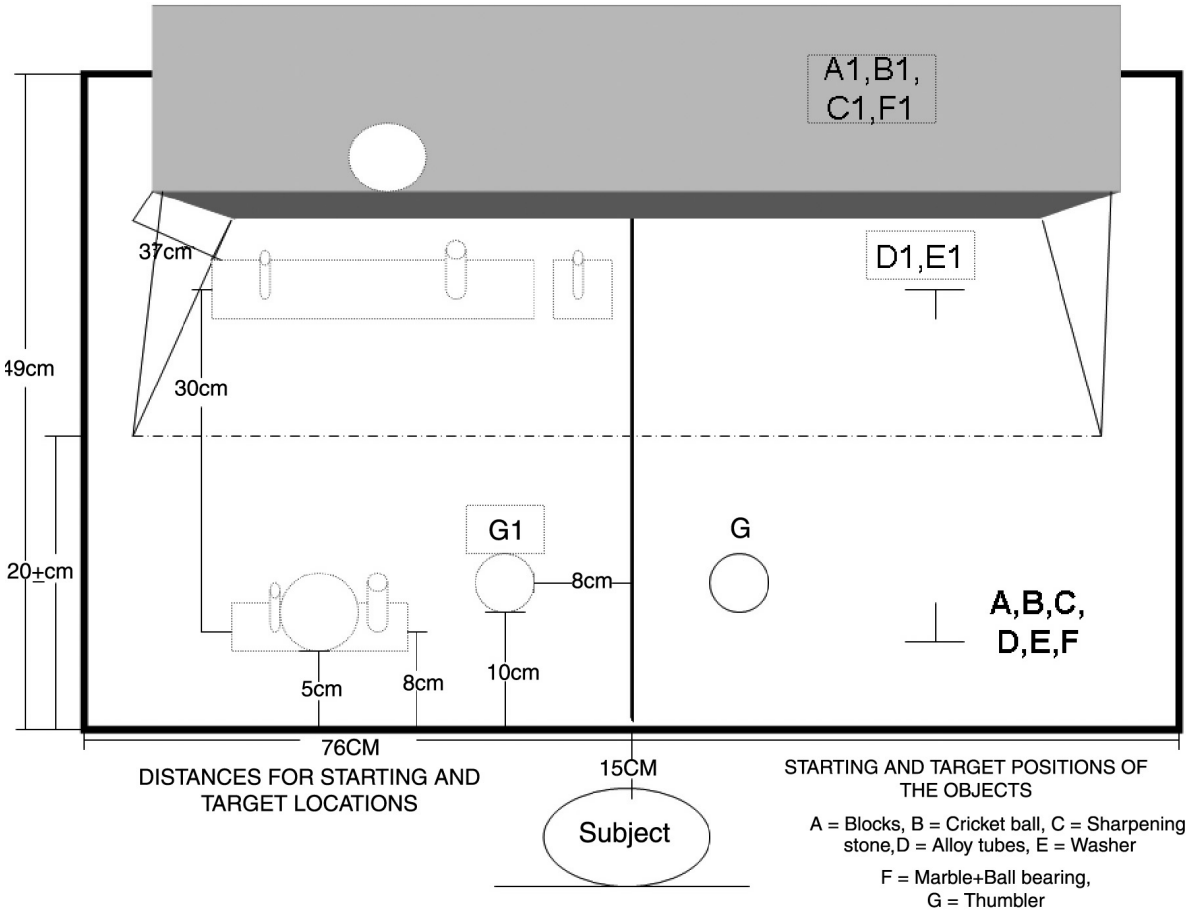


Figure 1. Mat dimensions and object placement positions are indicated for ARAT testing.

SCORING

General Scoring Instructions

Instructions for each task are read aloud to the subject; however, if the subject has any difficulty understanding instructions, such as in the presence of aphasia, the assessor has the option of also providing a visual demonstration of the requested task. The subject is allowed to practice the task repeatedly to ensure that instructions are fully understood.

Each task runs until the subject completes the task or until reaching a time limit of 60 seconds. The quality of the task is rated on an ordinal 4 point-scale. A score of 3 is given when the task is performed normally. This requires the task be completed in less than 5 seconds, appropriate body posture, normal hand movement components, and normal arm movement components. A score of 2 is given when the task is completed but either "with great difficulty or takes abnormally long." We define "great difficulty" as task completion in the setting of either (1) abnormal hand movement components (e.g., use of wrong grasp), (2) abnormal arm movement components (e.g., the elbow does not flex as required), or (3) abnormal body posture (e.g., used as a substitute for impaired arm movements). "Abnormally long" is taken as 5 to 60 seconds to complete. A score of 1 is given when the subject only partially completes the task within the 60 seconds allotted for examining each task, regardless of the quality of hand and arm movement components or posture requirements. For grasp, grip, and pinch subscales, the subject cannot achieve a score of 1 for arm movements only. In order to attain a score of 1, the subject must initiate some form of hand movement, abnormal or normal, that achieves holding and lifting the object—simply pushing an object across the table with the dorsum of the hand does not constitute partial completion of the true task. A score of 0 is given when the subject is unable to complete any part of the hand or arm movement components within the 60 seconds allotted for examining each task.

The score is based on the best performance. A subject is not penalized if a testing object is dropped and re-lifted. All performances must be performed with only 1 hand.

Specific Scoring Instructions for the Grasp Subscale

Object positioning. The non-slippery mat is placed over the table, and then the shelf and testing objects are placed in their pre-drawn positions (Figure 1). This approach has the shelf placed lengthwise, 20 ± 5 cm away from the proximal edge of the table on the mat; however, if the subject does not have sufficient range of motion for the fingertips to reach the top of the shelf, such as due to contractures or increased tone, then the examiner can adjust this distance as needed.

The items are placed, one at a time during the appropriate test, halfway between the subject's mid-sagittal line and the axillary line of the arm being tested. The hand being tested should be placed pronated, immediately lateral to the testing object, with the other hand also pronated atop the table. For all of the blocks, the assessor should not stabilize the object, nor can the subject stabilize the object with the non-tested hand. For the sharpening-stone task, the stone has to be placed on its narrow long side in a slightly diagonal position (parallel to the axis of the palmar creases) for ease of grasping. If the sharpening stone falls to its side during grasping attempts, it can be repositioned onto its narrow long side by the examiner for up to 60 seconds. The 2 tin lids are used as the initial and final sites for the cricket ball. The distance between the proximal edge of the lower tin lid and the proximal

edge of the table is 5 cm, whereas the proximal edge of the upper tin lid is the same as the proximal edge of the shelf. If desired, the upper tin lid can be attached to the top of the shelf using Velcro, in order to maintain stability, while the lower lid can be stabilized by the assessor as needed during task performance.

Instructions to subject. The subject is asked to grasp, lift vertically, place, and then release each object (block, ball, or stone) onto the top of the shelf. The instructions spoken to the subject are to:

"grasp the block [cricket ball, sharpening stone] that I have placed here, lift it up, and place then release it on top of that shelf."

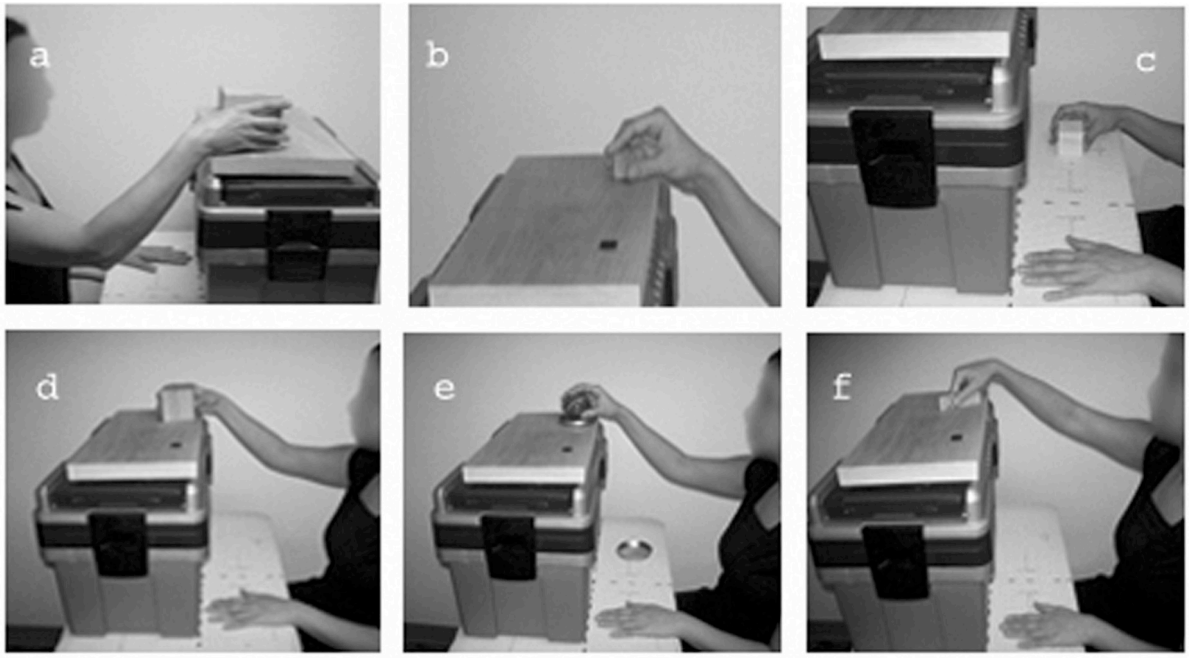


Figure 2 A-F Correct performances are shown (a-f).

Scoring. Start with the task of grasping the 10-cm block (the most difficult task in this subscale); if the score is 3, then the total score for this subscale is 18 for the arm being tested, and no further tasks need be tested for this arm on this subscale. If the score is 0 to 2, then continue to the task of grasping the 2.5-cm block (the easiest task in this subscale). If the score is 0, then the total score for this subscale is 0, and no further testing is required for this arm on this skip to subscale. If the score for the 2.5-cm block task is 1-3, however, continue with scoring all tasks in this subscale.

Score 3 indicates normal, complete, timely task completion. The subject must grasp the object, lift it up, and release it onto the shelf, all within 5 seconds, to obtain a score of 3. Appropriate hand movement components and arm movement components (Table A3) must be used, as well as posture requirements. The subject should not have the score reduced if the object falls off the shelf after successful task completion. The subject may release the object on any place on the shelf (Figure 2a-f).

Score 2 is given when the subject completes the task but does so “with great difficulty and/or takes abnormally long time.” The subject can display great difficulty when (1) not using appropriate hand movement components even if the task is otherwise completed (Figure 3g-h); (2) the subject displays abnormal arm movement components, such as abnormal object release when the object is brought to the shelf; or (3) abnormal posture is evident (e.g., if subject’s trunk completely loses contact with the back of the chair). A score of 2 is also assigned if task completion takes 5 to 60 seconds.

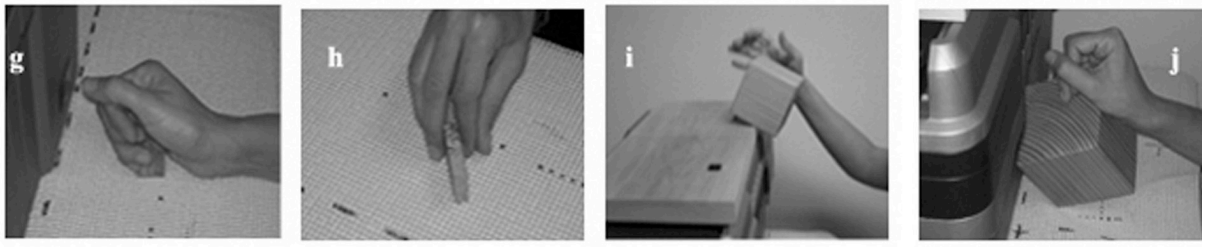


Figure 3 g-j Grasp subscale. Examples of incorrect performance: (g) thumb is not involved grasping the 2.5 cm3 block, (h) incorrect grasp for lateral pinch, (i) block falls off the shelf before release is completed, (j) object is held while only via pushing it against the box.

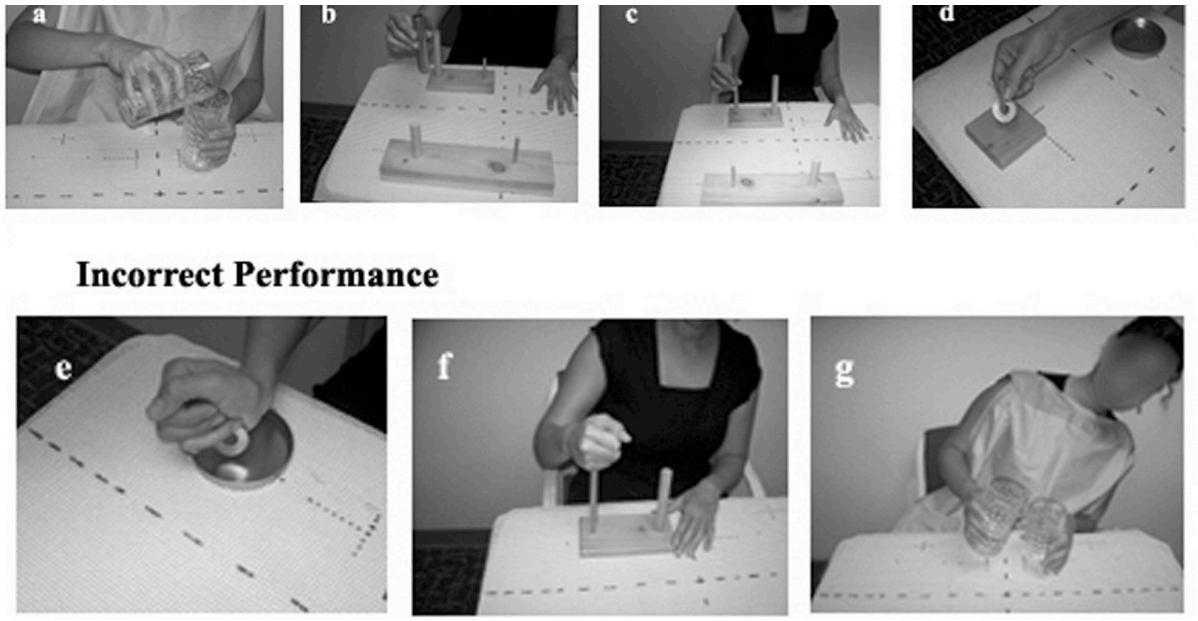
For score 1, there are several possible means by which the subject can partially perform the task and thus receive a score of 1. For example, if the subject grasps and lifts the object, but does not reach the level of the shelf within the 60 seconds. A subject who can hold and lift the object—even with abnormal hand movement components and arm movement components —and lift it off the table any distance would score a 1 (Figure 3g and 3h). The subject must initiate some form of hand movement component to hold and lift the object, in order to attain a score of 1.

Score 0 indicates that the subject is unable to perform any part of the task within 60 seconds. A score of 0 would apply, for example, if the subject cannot open the hand to grasp the object, cannot extend and/or abduct the fingers or thumb to the size of object, at all within 60 seconds and/or the subject attempts to manipulate the object into the hand on the side being tested by stabilizing the object against the shelf or against the nontested hand, and/or moves the object across the table without any voluntary hand opening (Figure 3j). These are all permitted but provide no points and cannot be used to achieve a hold and lift hand movement component.

Specific Scoring Instructions for the Grip Subscale (ARAT Test Items 7-10)
Object positioning. The objects being tested are placed in their positions on the mat (Figure 2). For the pouring task, the cups are placed 8 cm apart on each side of the midline of the subject and 10 cm away from the proximal edge of the table. For alloy tube displacement, the starting plank is placed on the table so that the first peg is 8 cm away from the front edge of the table and the target plank is placed perpendicular to the proximal table edge so that the second peg is 30 cm distal to the first one. For washer displacement, the tin lid with the washer in it is placed 5 cm from the proximal edge of table and on the side being tested, whereas the washer’s target peg is placed 30 cm distal to the middle of the tin lid. For the pouring task, the tumbler is filled with 4 ounces of water as indicated by a predrawn line on the cup.

Instructions to subject. The subject is asked to pour water from one cup to the other or to horizontally displace 2 different sized alloy tubes from a starting peg on a plank to a target peg on a plank and to horizontally displace a washer from a tin to a peg or bolt on a plank. The instructions spoken to the subject are to
"pour the water from this cup to that other cup" or "grasp this tube [washer] and place it here [onto the peg on the plank]."

Scoring. Start with the task of pouring water from one glass to the other, which is the most difficult task in this subscale; if the score is 3, then the total score for the arm being tested on this subscale is 12, and no further testing on this subscale is required for that arm. If the score is 0 to 2 for the pouring task, then continue to the task of displacing the 2.25-cm alloy tube, which is the easiest task in this subscale. If the score on the 2.25-cm tube task is a 0, then the total score for this subscale is 0, and no further testing on this subscale is required for this arm. If the 2.25-cm tube task score is 1 to 3, continue with scoring all tasks in this subscale.



1. **Figure 4 a-g**

To score a 3, for the pouring task, the subject grasps the cup, lifts it, pours all of the water from 1 cup to the other without spilling, and releases the cup on the table. For the other 3 tasks, the subject must grasp the tube/washer, lift it off the plank/out of the tin, and displace it horizontally to the target plank peg and release. For all tasks, the effort must be completed within 5 seconds of starting the task (The subject must complete the task with the appropriate hand movement components, arm movement components and posture.
A score of 2 is given when a subject completes the task (1) without the appropriate hand movement components, for example, uses alternative hand movement components as shown in Figures 4e-f; (2) with abnormal quality of arm movements, for example, for pouring task: subject grasps the cup, lifts it, pours water from 1 cup to the other with adequate forearm pronation, but spills some water; for tubes/washer: subject grasps the tube/washer, lifts it off the plank/out of the container, displaces it horizontally, places it in its target position, but is unable to release the object; or (3) without maintaining proper posture (e.g., if

subject's trunk completely loses contact with the back of the chair). A score of 2 is also given if task completion takes 5 to 60 seconds.

To score a 1, the subject partially completes the task and must initiate some type of hand movement that includes holding and lifting the object. For the pouring task, the subject might grasp the cup and lift it off the surface of the table but be unable to pour any water, or forearm pronation does not occur but is substituted, for example, by compensatory excessive lateral bending of the trunk (Figure 4g). For the other tasks, a score of 1 might be awarded if the subject extends the fingers sufficient to grasp the tube/ washer, lift it up off the plank/out of the tin, but is unable to make any horizontal movements or release the object within 60 seconds. As mentioned previously here, when scoring a 1, the subject must initiate some form of hand movement, abnormal or normal, that achieves holding and lifting the object; any type of hand movement is permitted (Figure 4e-f).

For a score of 0, the subject is unable to open the hand to grasp the cup/tube/washer (ie, extend and/or abduct the fingers or thumb to the size of the object) and/or takes greater than 60 seconds. A score of 0 is also given if the subject stabilizes the object in order to manipulate it into the hand and/or moves the object without any voluntary hand opening.

Specific Scoring Instructions for the Pinch

Object positioning. The mat is placed over the table, with testing objects placed in their predrawn positions. The 2 tin lids are placed in the same positions as stated in the grasp subscale. Each marble or ball bearing is placed within the lower tin lid, and the subject is asked to grasp the object with the appropriate fingers, lift it up to the shelf, and release it into the target lid.

Instructions to subject. The subject is asked to grasp a ball bearing or a marble from a tin lid, lift it up vertically, then place and release it into a target tin lid placed on the shelf. This requires that the subject independently move the fingers in opposition to the thumb with accompanying distal mobility and stabilization. The instructions spoken to the subject are to *"grasp the ball bearing [marble] using these fingers, lift it up, and place it in the tin on top of the shelf."*

Scoring. This subscale starts with the task of lifting the 6-mm ball bearing, the most difficult task; if score is 3, then the total score for the arm being tested on this subscale is 18, and no further testing is needed for this arm on this subscale. If the score is 0 to 2, then next is the task of lifting the marble with the first finger and thumb, that is, the easiest task in this subscale. If the score is a 0, then the total score for this arm on this subscale is 0, and no further testing is required for this arm on this subscale. If the score is 1 to 3, continue with scoring all tasks in this subscale.

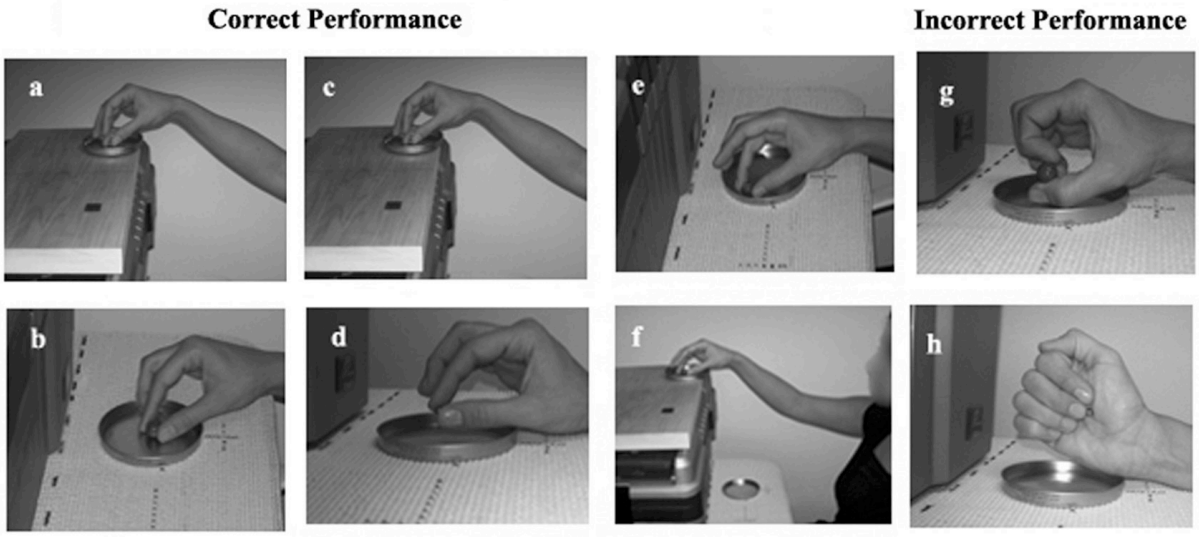


Figure 5 a-h

An important note specific to pinch subscale tasks is that correct hand movement components (finger opposition; see Figure 5a-d) must be present to score more than 0. Thus, regardless of arm movement components, posture, and time used, the score can only be 0 if an incorrect finger opposition is employed, for example, holding the object in the palm with all 4 fingers flexed and thumb adducted/flexed (Figure 5h). As an extension of this note, task completion, necessary for a score of 2 or 3, is only deemed to be present if correct hand movement components are used. In addition, a score of 3 can only be generated if the finger opposition specifically uses the pads of the fingers.

A score of 3 is awarded for normal, complete, timely task completion. The subject grasps the marble or ball bearing from the tin, lifts the object up to the shelf, and releases it into the target tin, all within 5 seconds (Figure 5a-f). The task is completed using correct arm movement components, as well as hand movement components, including finger pads while maintaining proper posture. The score is not reduced if the object bounces off the shelf after successful task completion.

A score of 2 is awarded if (1) the quality of the arm movement component or the hand movement component is abnormal, as might occur for example with inability to release the object from the fingers into the target tin, or if the object falls out of the tin/off the shelf when attempting to release, or if the subject is unable to use the pads of the fingers to grasp the object (Figure 5g); (2) abnormal posture is displayed (e.g., if subject's trunk completely loses contact with the back of the chair); or (3) performance takes 5 to 60 seconds.
A score of 1 is awarded if the subject partially completes the task, for example, grasps the object, lifts it up, but drops the object or is unable to reach the height of the shelf. The task must be completed within 60 seconds.

With a score of 0, the subject is unable to initiate the task within 60 seconds or, again for this subscale only, does not display the correct hand movement components, that is, finger opposition. The subject (1) is unable to open the hand to grasp the test object, that is, to extend and/or abduct the fingers or thumb to at least the size of the object; (2) attempts to manipulate the object into the fingers by stabilizing it with the nontested hand or some other

object; (3) moves the object in the tin lid without any voluntary finger/thumb extension; or (4) attempts take greater than 60 seconds.

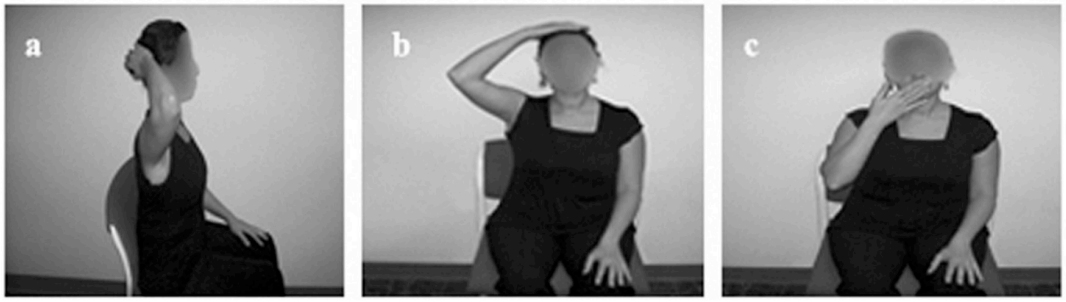
Specific Scoring Instructions for the Gross Motor Subscale

Object positioning. The subject starts with both pronated hands on the lap. The assessor reminds the subject to keep the head still and in a neutral upright position. For item 17, the subject must touch the back of the head with the palmar side of the hand being tested; for 18, the subject must touch the top of the head, with the palmar side of the hand being tested, and for 19, the subject must touch the mouth with the palmar side of the hand being tested. The subject's hand can be in flexed posture if full finger extension/abduction cannot be maintained.

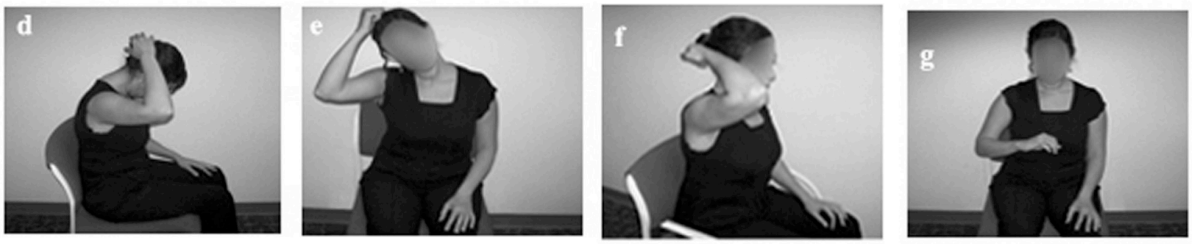
Instructions to subject. These tasks require the subject to move the shoulder and elbow across a wide range of motion, with accompanying forearm movement. The instructions spoken to the subject are to
"touch the back of your head [top of your head, mouth] with the palm of your hand."

Scoring. Start with the task of placing the hand behind the head; if the score is 3, then the total score for this subscale is 9 for the arm being tested, and ARAT testing is completed. If the score is a 0, then the total score for the arm being tested is 0 on this subscale, and ARAT testing is completed. In this regard, the gross movement subscale is an exception in that the hardest and the easiest task have effectively been collapsed into a single task. If the score is 1 or 2, the arm being examined is then tested for the other tasks in this subscale. For a score of 3, the subject places the hand behind the head not the neck), on top of the head (not the forehead), or to the mouth (not the chin) with the palmar side of the hand while maintaining the head in an upright, neutral position and the task is completed within 5 seconds (Figure 6a-c). A subject scores 2 if the movement is completed abnormally (e.g., the subject completes the task by flexing the neck [Figure 6d-f], or the trunk loses contact with the back of the chair, or the task takes 5 to 60 seconds to complete). For a score of 1, the subject only partially completes the task (e.g., starts shoulder/elbow flexion but the hand does not reach the target position within 60 seconds) (Figure 6g). For a score of 0, the subject is unable to initiate any part of the task within 60 seconds.

Correct Performance



Incorrect Performance



ARAT

Subject ID number…… **Date……**

Assessor name…… **Time 1** **Time 2** **Time 3**

Instructions

There are four subtests: Grasp, Grip, Pinch, Gross Movement. Items in each are ordered so that:

- if the subject passes the first, no more need to be administered and he scores top marks for that subtest;
- if the subject fails the first *and* fails the second, he scores zero, and again no more tests need to be performed in that subtest;
- otherwise he needs to complete all tasks within the subtest

Activity Score

Grasp

1. Block, wood, 10 cm cube (If score = 3, total = 18 and to Grip) _____
Pick up a 10 cm block
2. Block, wood, 2.5 cm cube (If score = 0, total = 0 and go to Grip) _____
Pick up 2.5 cm block
3. Block, wood, 5 cm cube _____
4. Block, wood, 7.5 cm cube _____
5. Ball (Cricket), 7.5 cm diameter _____
6. Stone 10 x 2.5 x 1 cm _____

Coefficient of reproducibility = 0.98
Coefficient of scalability = 0.94

Grip

1. Pour water from glass to glass (If score = 3, total = 12, and go to Pinch) _____
2. Tube 2.25 cm (If score = 0, total = 0 and go to Pinch) _____
3. Tube 1 x 16 cm _____
4. Washer (3.5 cm diameter) over bolt _____

Coefficient of reproducibility = 0.99
Coefficient of scalability = 0.98

Pinch

1. Ball bearing, 6 mm, 3rd finger and thumb (If score = 3, total = 18 and go to Gross mt) _____
2. Marble, 1.5 cm, index finger and thumb (If score = 0, total = 0 and go to Gross mt) _____
3. Ball bearing 2nd finger and thumb _____
4. Ball bearing 1st finger and thumb _____
5. Marble 3rd finger and thumb _____
6. Marble 2nd finger and thumb _____

Coefficient of reproducibility = 0.99
Coefficient of scalability = 0.98

Gross Movement

1. Place hand behind head (if score = 3, total = 9 and finish)
2. (if score = 0, total = 0)

3. Place hand on top of head
4. Hand to mouth

Notes……
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Motor Activity Log

Upper Extremity Amount of Use

Participant ID_____Date_____

Assessor Name_____ Time 1 Time 2 Time 3

"The purpose of this test is to examine how much you use our more affected arm when you are outside the laboratory. You will use a rating scale to describe how often you use your weaker arm while you are doing specific activities. Please note that you can give half ratings if that best describes your performance for the activity in question. If for some reason you do not perform some tasks, we will try to establish why. It is important that you realise that these questions are about what you actually do outside the laboratory setting-not what you think you can do with your weaker arm. There are no right or wrong answers: simply select ratings that you believe best describes what you do. Do you have any questions?"
Assessor may record answers for participants who have difficulty writing. Participants to have score sheet and code sheet in front of them.
"Please rate how often you have used you affected arm for the following activities during the past week"

	Activity	**Score**	**Code for non use/comment**
1	Turn on a light with a light switch		
2	Open drawer		
3	Remove an item of clothing from a drawer		
4	Pick up phone		
5	Wipe off kitchen counter or other surface		
6	Get out of a car *(includes only the movement needed to get body from sitting to standing outside of the car once the door is open)*		
7	Open refrigerator		
8	Open a door by turning door knob/handle		

9	Use a TV remote control		
10	Wash your hands (*includes lathering and rinsing hands: does not include turning water on and off with a faucet handle)*		
11	Turning water on/off with knob/lever on faucet		
12	Dry your hands		
13	Put on your socks		
14	Take off your socks		
15	Put on your shoes *(includes tying shoelaces and fastening straps)*		
16	Take off your shoes *(includes untying shoelaces and unfastening straps)*		
17	Get up from a chair with armrests		
18	Pull chair away from table before sitting down		
19	Pull chair toward table after sitting down		
20	Pick up a glass, bottle, drinking cup or can *(does not need to include drinking)*		
21	Brush your teeth *(does not include preparation of the toothbrush or brushing dentures unless they are brushed while left in the mouth)*		
22	Put on foundation, cream or shaving lotion on the face		
23	Use a key to unlock a door		
24	Write on paper (*If hand used to write prestroke is more affected score item. If non*		

	writing hand pre stroke is more affected drop item and leave as Not applicable)		
25	Carry an object in your hand (*draping item over arm is not acceptable)*		
26	Use a fork or a spoon for eating (*refers to the action of bringing food to mouth with fork or spoon)*		
27	Comb your hair		
28	Pick up a cup by the handle		

Amount of use scale

0 Did not attempt to use my weaker arm (**Not used**)

0.5

1 Occasionally used my weaker arm, but only very rarely (**Very rarely**)

1.5

2 Sometimes used my weaker arm but did the activity **most of the time** with my stronger arm (**rarely**)

2.5

3 Used my weaker arm about half as much as before the stroke (**half pre stroke**)

3.5

4 Used my weaker arm almost as much as before the stroke (**3/4 pre stroke**)

4.5

5 Used my weaker arm as often as before the stroke (**same as pre stroke**)

Possible reasons for not using the weaker arm for the activity

A "I used the unaffected arm entirely""

B "Someone else did it for me"

C "I never do that activity, with or without help from someone else because it is impossible". For example combing hair for people who are bald

D "I sometimes do that activity, but did not have the opportunity since the last time I answered these questions"

E "This is an activity that I normally did only with my dominant hand before the stroke and continue to do with my dominant hand now"

Uswatte G, Taub E, Morris D, Light K & Thompson A (2006) Assessing daily use of the hemiparetic arm after stroke. Neurology, 67, 1189-1194

Quality of life: SIPSO

Participant ID_____**Date**_____

Assessor Name_____ **Time 1** **Time 2** **Time 3**

Please answer the following questions. Assessor may complete for participants who have difficulty.

Please answer all the questions

1. Since your stroke, how much difficulty do you have dressing yourself fully? (Circle One Number)

No difficulty at all 4
Slight difficulty 3
Some difficulty 2
A lot of difficulty 1
I cannot dress myself fully 0

2. Since your stroke, how much difficulty do you have moving around *all* areas of the home? (Circle One Number)

No difficulty at all 4
Slight difficulty 3
Some difficulty 2
A lot of difficulty 1
I cannot move around all areas of the home 0

3. Since your stroke, how satisfied are you with your overall ability to perform daily activities *in and around the home*? (Circle One Number)

Completely satisfied 4
Mostly satisfied 3
Fairly satisfied 2
Not very satisfied 1
Completely dissatisfied 0

4. Since your stroke, how much difficulty do you have shopping for and carrying *a few items* (1 bag of shopping or less) when at the shops? (Circle One Number)

No difficulty at all 4
Slight difficulty 3
Some difficulty 2
A lot of difficulty 1
I cannot shop for and carry a few items 0

5. Since your stroke, how independent are you in your ability to *move around your local neighbourhood*? (Circle One Number)

I am completely independent 4
I prefer to have someone else with me 3
I need occasional assistance from someone 2
I need assistance much of the time 1
I am completely dependent on others 0

6. Since your stroke, how often do you feel bored with your free time at home? (Circle One Number)

I am never bored with my free time 4
A little of my free time 3
Some of my free time 2
Most of my free time 1
All of my free time 0

7. Since your stroke, how would you describe the amount of communication between you and your friends/associates? (Circle One Number)

A great deal 4
Quite a lot 3
Some 2
A little bit 1
None 0

8. Since your stroke, how satisfied are you with the level of interests and activities you share with your friends/associates? (Circle One Number)

Completely satisfied 4
Mostly satisfied 3
Fairly satisfied 2
Not very satisfied 1
Completely dissatisfied 0

9. Since your stroke, how often do *you visit* friends/others? (Circle One Number)

Most days 4
At least once a week 3
At least once a fortnight 2
Once a month or less 1
Never 0

10. Since your stroke, how do you feel about your appearance when out in public?
(Circle One Number)

Perfectly happy	4
Slightly self-conscious	3
Fairly self-conscious	2
Very self-conscious	1
I try to avoid going out in public	0

Time 2: Reassessment

To be completed by the blinded assessor/research assistant

Participant number……..

Date……..

Name of assessor…….

Thank you for coming in today.

Today I am going to ask you to perform some tests and answer some questions so I can see how your stroke has affected you. After this, I will leave the room and the lead researcher will ask you some further questions.

Remember there is no pass or fail mark for any of the tasks nor any wrong answers to the questions – we are just trying to assess how he stroke has affected you and what you thought about the study.

This may take up to an hour and a half in total. If you feel very tired, unwell, would like a rest at any time or would like to stop the assessment for any reason, then please let us know.

Do you have any questions?

Complete outcome measure battery as described in Time period 1

FMA

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To be completed by lead researcher

Quebec user evaluation with assistive technology questionnaire

QUEST (version 2.0)

ID number_____Date of assessment_____

Participant completed/ assessor completed (please circle)

Instructions:

Assessor may read out the questions and options and fill in the questionnaire for participants who find this difficult

The purpose of this questionnaire is to evaluate how satisfied you are with the PST.

For each item please rate your satisfaction with the assisted device using the following scale.

1	***2***	***3***	***4***	***5***
Not at all satisfied	*Not very satisfied*	*More or less satisfied*	*Quite satisfied*	*Very satisfied*

Please circle or mark one number that best describes your degree of satisfaction with each item.

Do not leave any question unanswered.

Remember there are no right or wrong answers. It is your opinion that is important!

N.B. four items assessing satisfaction with service issues have been omitted as irrelevant for the present study

1	2	3	4	5
Not at all satisfied	Not very satisfied	More or less satisfied	Quite satisfied	Very satisfied

How satisfied were you with					
1. The **dimensions** (size, height, length, width) of your assisted device?	1	2	3	4	5
2. The **weight** of your assistive device?	1	2	3	4	5
3. The **ease in adjusting** your assistive device	1	2	3	4	5
4. How **safe and secure** your assistive device is	1	2	3	4	5
5. The **durability** of your assistive device	1	2	3	4	5
6. How **easy it is to use** your assistive device	1	2	3	4	5
7. How **comfortable** your assistive device is	1	2	3	4	5
8. How **effective** your assistive device is	1	2	3	4	5

Below is a list of the 8 items. Please select the THREE items that you consider to be the most important to you. Please put an X next to the relevant items.

Dimensions_____ Weight_____

Adjustments_____ Safety_____

Durability_____ Easy to use_____

Comfort_____ Effectiveness_____

Demers L, Weiss-Lambrou R & Ska B (1996) The Quebec user evaluation of satisfaction with assistive technology: QUEST. Assistive Technology, 8(1), 3-13

Comments:

_____

_____

Patient Interview Schedule: To be completed by lead researcher

To be completed by lead Researcher

IGroup Presence Questionnaire

Experiences in Virtual Worlds

Study ID number_____Date of assessment_____

Self completed / assessor completed (please circle)

Instructions:

Please answer all questions with reference to your most recent interaction with a "virtual environment".

Assessor may read out the questions and options and fill in the questionnaire for participants who struggle with this

Remember there are no right or wrong answers. It is your opinion which is important!

1. How long did you interact with the virtual world?_____minutes

2. What was your perspective into the virtual world? (in the case of changing perspectives, please describe the one most frequently used) Please tick

__ "through the eyes of my own character" so called *first person perspective*

__"behind/above my character" so called *third person perspective*

Now you'll see some statements about experiences. Please indicate whether or not each statement applies to your experience. There are no right or wrong answers, only your opinion counts.

3. How aware were you of the real world surrounding while navigating in the virtual world? (I.e. sounds, room temperature, other people etc)

Extremely aware			Moderately aware			Not at all aware
-3	-2	-1	0	+1	+2	+3

4. How real did the virtual world seem to you?

Completely real						Not real at all
-3	-2	-1	0	+1	+2	+3

5. I had a sense of acting in the virtual space, rather than operating something from outside

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

6. How much did your experience in the virtual environment seem consistent with your real world experience?

Not consistent						Very consistent
-3	-2	-1	0	+1	+2	+3

7. How real did the virtual world seem to you?

Extremely about as real as an imagined world						Indistinguishable from the real world
-3	-2	-1	0	+1	+2	+3

8. I did not feel present in the virtual space

Did not feel present						Felt present
-3	-2	-1	0	+1	+2	+3

9. I was not aware of my real environment

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

10. In the computer generated world, I had a “sense of being there”.

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

11. Somehow I felt that the virtual world surrounded me

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

12. I felt present in the virtual space

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

13. I still paid attention to the real environment

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

14. The virtual world seemed more realistic than the real world

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

15. I felt like I was just receiving pictures

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

16. I was completely captivated by the virtual world

Fully disagree						Fully agree
-3	-2	-1	0	+1	+2	+3

www.igroup.org/pq/ipq/ipq_english.htm accessed: 28/4/14

Blinding

Name of assessor at time 2_____

Blinded to study purpose?

_____

_____

_____

Blinded to previous scores?_____

_____

Time 3: Reassessment 2

To be completed by the blinded assessor/research assistant

Participant number……..

Date……..

Name of assessor…….

Thank you for coming in again today.

Today I am going to ask you to perform the same tests and to answer the same questions you did during your initial assessment so I can see how the stroke is affecting you now.

Please remember that there is no pass or fail mark for any of the tasks nor any wrong answers to the questions – we are just trying to see how the stroke has affected you

This may take up to an hour to complete. If you feel very tired, unwell, would like a rest at any time or would like to stop the assessment for any reason, then please let us know.

So I can be sure that this is a fair assessment, it is important that I do not know what you have done in the study or what the results were from your initial test so please do not discuss details of this with me today.

Do you have any questions?

Complete outcome measure battery as described in Time period 1

FMA

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MAL

SIPSO

Name of assessor at time 3_____

Blinded to study purpose?

_____

_____

_____

Blinded to previous scores?_____

_____

_____

12: Semi-Structured Interview Topic Guide

Listed below are sample questions. The content is indicative. Questions will not necessarily be asked in this order nor phrased in the way presented here.
State date and time of interview and participant ID number
Thank participant for agreeing to be interviewed.
Reminder that this interview will be audio recorded to enable me to recall what we have discussed but any answers and direct quotes used in any publication or presentation will be anonymised meaning that you will not be referred to by name and that identifiable information will not be used.

As we are trying to establish the acceptability and feasibility of using the PST, it is important that you answer honestly and that you should not be concerned or worried about giving a negative response.

General Questions regarding technology

- In general, how do you feel about using computers/technology?
    - Prompts: questions about confidence and perceived competence, whether consider self as being computer literate/confident to use technology
- Would you consider yourself as a person who is confident to try new technology? Prompt: happy by self/once shown how to use it/not confident at all/worried/dislike
- Have you ever used computer games before? Can you tell me about them? Prompts: which games/activities, amount of use, frequency, types of games, level of enjoyment Are there any particular games you like? what is it about them you like? If you do not play games why is that?
- Did you use video games –other than the PST- during the study period? (if so, please discuss context of use- how often, how long, what played- and why used)

Questions regarding the PST

- In your own words can you tell me about your experience of using the PST as part of this study?

  Prompt questions
    - Was there anything in particular you liked about it?
    - Anything you particularly disliked about it?
    - Which activities did you like the most/least? Can you tell me why/what about it you liked/disliked?
- Would you have liked to exercise for longer/shorter using the PST? Can you explain why?
- Did you find the activities challenging/interesting/boring?
- Can you tell me about what you thought about the feedback it gave you (motivating/demotivating/distracting/humorous/insulting)
- Do you think the PST helps with exercising? Can you elaborate on this? Prompt: motivation, adherence, time flies/length of time would exercise
- Did you suffer from any problems/adverse effects while using the PST (pain, motion sickness, headaches, falls, fear of falls, other concerns?)

- Is there any advice you could offer us about trying to incorporate technology like the PST into treatment? Should we do anything differently?
- If you had the knowledge/skills to design games for stroke survivors what type of game would they design?
- Would you prefer playing games on their own, or against other players (stroke survivors or others)?

Thinking back to when you were in hospital after your stroke

- Can you tell me about the physiotherapy and OT you had? Prompt: How often, amount of time, time spent on rehabilitation of the arm.
- IF PST had been available, would you have wanted to use it? Prompt: Can you elaborate more? Why?
- If would have like to have used it, how would you have wanted to use it? Prompt: would you have wanted it as part of usual session, instead of, in addition to.
- If would like to use, where would you want to use it? Prompt: dayroom, ward, therapy. Why? (?concerns re safety, being seen by others. ? feeling would open up communication and interaction)
- Once trained, do you think you could have used it by yourself? (prompt: ? set up independently, affixed arm sensors, selected activities, safety)

Thinking back to when you were discharged from hospital

- Can you tell me about the therapy you received if any? Prompt: OT/PT, amount, amount on arm, frequency, where took place, how long went on for.
- Were you given home exercises to do? If so can you tell me about them (how long to perform, how often, whether did perform? Did you have arm/hand exercises? Either way, what were the reasons for performing or not?)
- Do you think having a PST at home would be a useful tool for rehabilitation?
- If PST had been available in your home/and or in outpatient/community rehab setting do you think you would have used it? Can you tell me why?

Teletherapy: explain what it is and how it potentially could be used as two way communication and monitoring

- What do you think the pros and cons of such a system could be?
- Would you have any concerns about using this at home? Prompts: snooping/big brother, safety, difficulty with set up
- Would you be happy to have this at home? Can you explain why?
- Do you think it would make a difference to how often and how long you exercised? In what way?
- If this game/intervention was available how often would you use it?
- Which part/time of the day would you most likely use it and why?
- Would you like the system to store their game/activity performance and progress in order to send to their therapist?
- Would you like the system to send it automatically to the therapist or for them to do it manually? How often should the data been sent (e.g. Weekly, bi-weekly, etc)?

Questions regarding the study:

- Can you comment on the time commitment required from you for this study? (too long/short, too often. What would have preferred longer/shorter sessions, spread over more weeks/fewer weeks, more sessions per week/fewer)
- Current guidelines recommend that therapy should be five times a week and 45 minutes long to drive recovery. Would this be a schedule that you would feel able to incorporate into your daily life/how realistic do you feel this is?
- If equipment set up for a study in your own home would you feel you could commit to using for a month long trial, 5 x a week 45 min long? (time of day to perform exercise and days of week unimportant)

Any other comments about any aspect of the PST or study?
Thank them for their time.
Remind them not to discuss the study with the blinded assessor

Prompts and probes

How did that make you feel?
That's interesting can you tell me more about that?
Can you elaborate a little more?
Could you clarify that?
I am not quite sure I understand. You were saying?
When you say …….. Did you mean that …?

The Borg Scale of Perceived Exertion

Instructions:

Look at the rating scale below while you are engaging in an activity; it ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Choose the number from below that best describes your level of exertion. This feeling should reflect how heavy and strenuous the exercise feels to you, combining all sensations and feelings of physical stress, effort, and fatigue. Do not concern yourself with any one factor such as leg pain or shortness of breath, but try to focus on your total feeling of exertion.

Try to appraise your feeling of exertion as honestly as possible, without thinking about what the actual physical load is. Your own feeling of effort and exertion is important, not how it compares to other people. Look at the scales and the expressions and then give a number.

6 No exertion at all

7

Extremely light (7.5)

8

9 Very light

10

11 Light

12

13 Somewhat hard-feels Ok to continue

14

15 Hard (heavy)

16

17 Very hard – can still go on but have to really push myself -It feels very heavy, I am very tired.

18

19 Extremely hard

20 Maximal exertion

Borg RPE scale

Level of Enjoyment Scale

1 Don’t enjoy at all

2

3

4

5

6

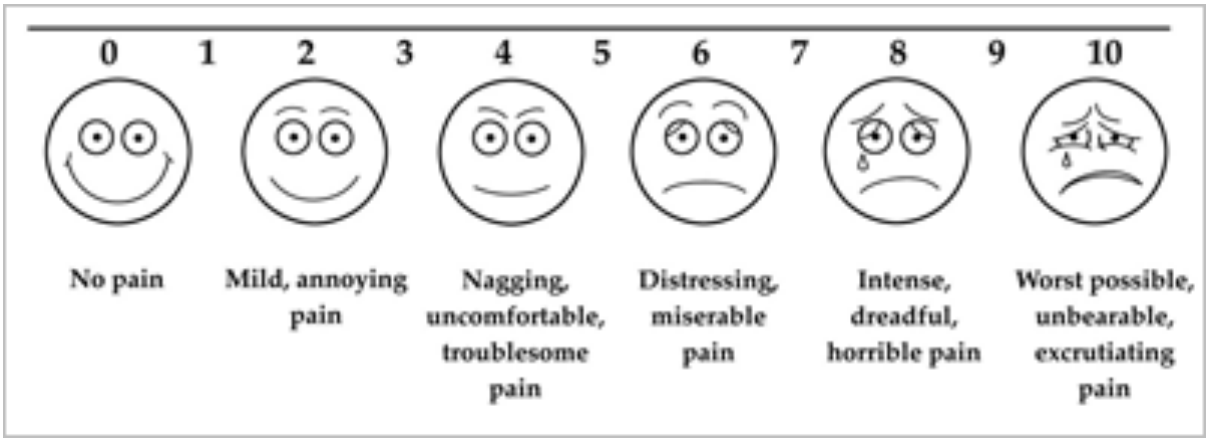
7

8

9

10 Enjoy very much

15: Pain Visual Analogue Scale



16: FAST Motion Sickness Scale

0 No sickness at all

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20 Frank vomiting

17: Ethical Approval

Brunel UNIVERSITY LONDON

School of Health Sciences and Social Care
Research Ethics Committee

School of Health Sciences and Social Care
Brunel University,
Uxbridge
Middlesex UB8 3PH
Telephone: +44 (0)1895 274000
Web www.brunel.ac.uk

18 July 2014

Proposer: **Alyson Warland - PhD**

Title: **ReWiiRe: Exploring the use of a personalised stroke therapy (PST) device, using adapted video gaming technology, for arm rehabilitation post stroke: A feasibility and acceptability study**

Reference: **14/06/PHD/02**

LETTER OF APPROVAL

The School Research Ethics Committee has considered the amendments recently submitted by you in response to the Committee's earlier review of the above application.

The Chair, acting under delegated authority, is satisfied that the amendments accord with the decision of the Committee and has agreed that there is no objection on ethical grounds to the proposed study. Approval is given on the understanding that the conditions of approval set out below are followed:

- *The agreed protocol must be followed. Any changes to the protocol will require prior approval from the Committee.*

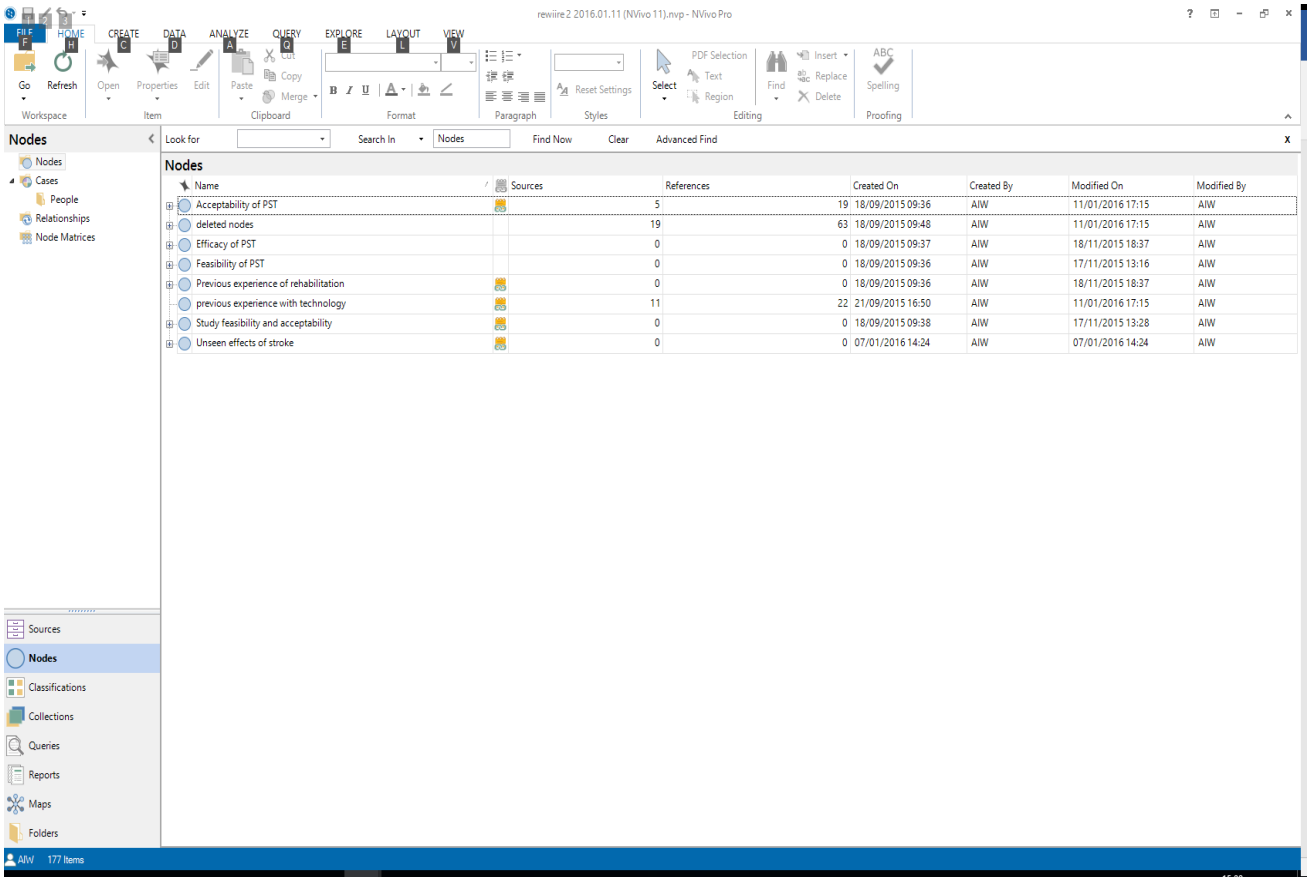
Please note that:

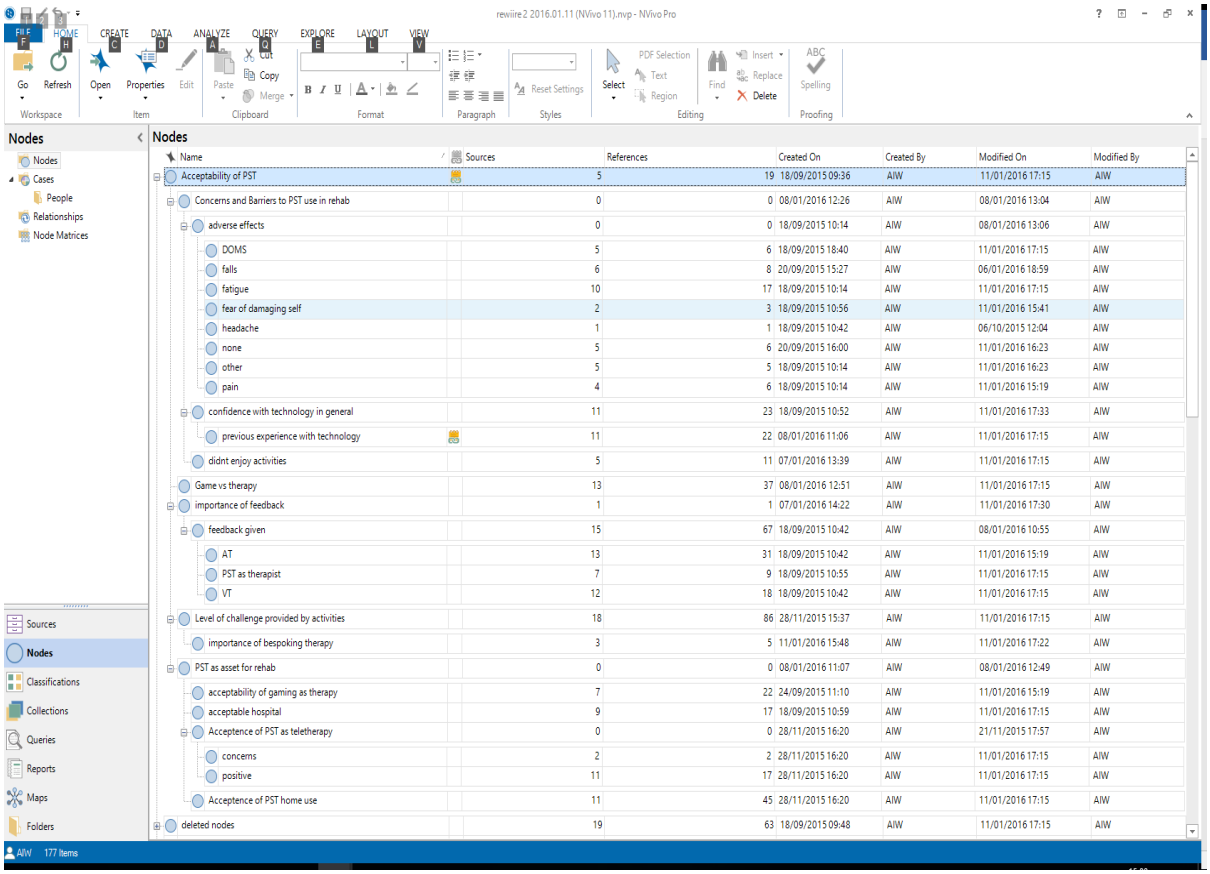
- **Research Participant Information Sheets and (where relevant) flyers, posters, and consent forms should include a clear statement that research ethics approval has been obtained from the School of Health Sciences and Social Care Research Ethics Committee.**
- **The Research Participant Information Sheets should include a clear statement that queries should be directed, in the first instance, to the Supervisor (where relevant), or the researcher. Complaints, on the other hand, should be directed, in the first instance, to the Chair of the School Research Ethics Committee**
- **Approval to proceed with the study is granted subject to receipt by the Committee of satisfactory responses to any conditions that may appear above, in addition to any subsequent changes to the protocol.**
- **The School Research Ethics Committee reserves the right to sample and review documentation, including raw data, relevant to the study.**

Paul W Roden

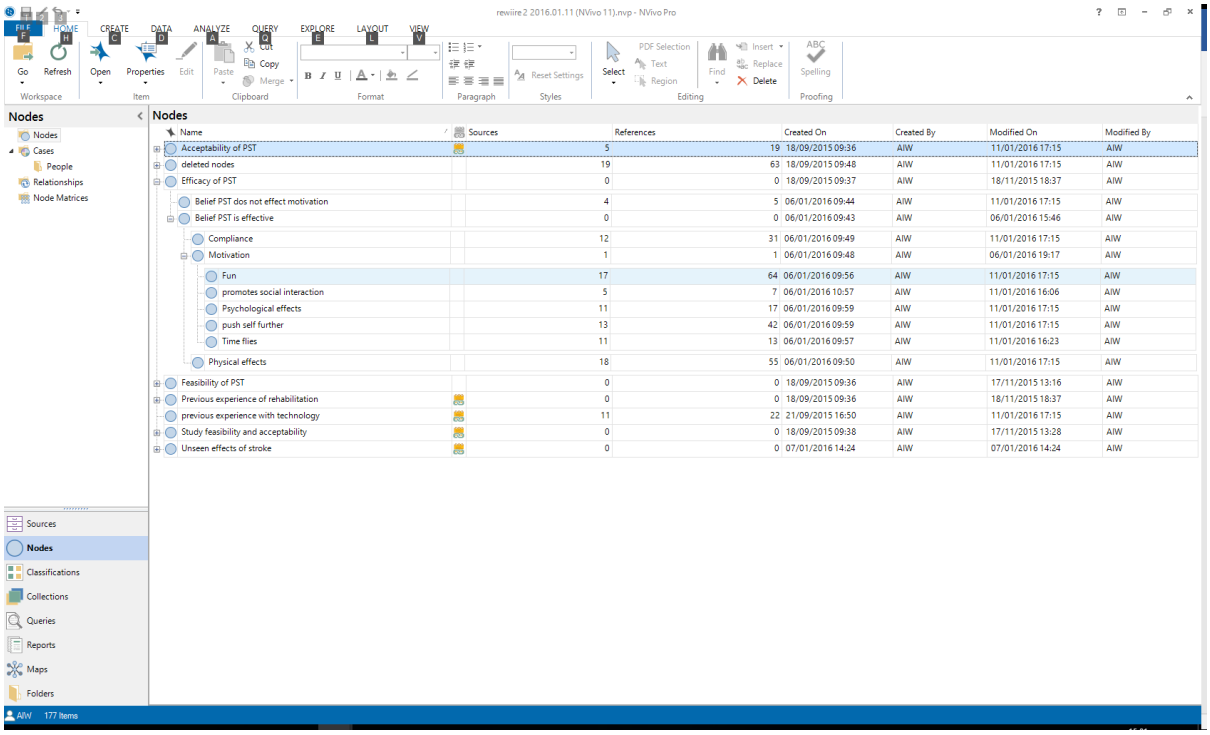
Paul Roden
Deputy Research Ethics Officer, School Research Ethics Committee
School of Health Sciences and Social Care

18: Screen Shots of Candidate Themes and Nodes Generated in NVIVO

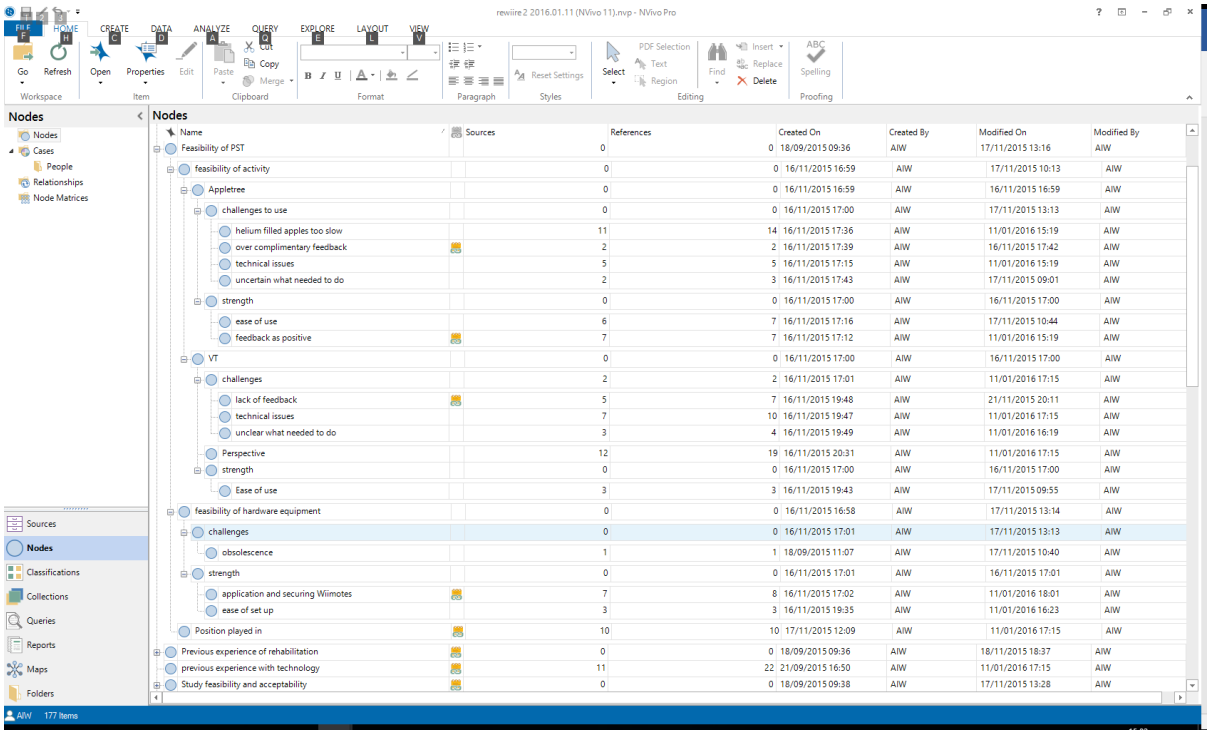




Name	Sources	References	Created On	Created By	Modified On	Modified By
Acceptability of PST	5	19	18/09/2015 09:36	AIW	11/01/2016 17:15	AIW
Concerns and Barriers to PST use in rehab	0	0	08/01/2016 12:26	AIW	08/01/2016 13:04	AIW
adverse effects	0	0	18/09/2015 10:14	AIW	08/01/2016 13:06	AIW
DOMS	5	6	18/09/2015 18:40	AIW	11/01/2016 17:15	AIW
falls	6	8	20/09/2015 15:27	AIW	06/01/2016 18:59	AIW
fatigue	10	17	18/09/2015 10:14	AIW	11/01/2016 17:15	AIW
fear of damaging self	2	3	18/09/2015 10:56	AIW	11/01/2016 15:41	AIW
headache	1	1	18/09/2015 10:42	AIW	06/10/2015 12:04	AIW
none	5	6	20/09/2015 16:00	AIW	11/01/2016 16:23	AIW
other	5	5	18/09/2015 10:14	AIW	11/01/2016 16:23	AIW
pain	4	6	18/09/2015 10:14	AIW	11/01/2016 15:19	AIW
confidence with technology in general	11	23	18/09/2015 10:52	AIW	11/01/2016 17:33	AIW
previous experience with technology	11	22	08/01/2016 11:06	AIW	11/01/2016 17:15	AIW
didnt enjoy activities	5	11	07/01/2016 13:39	AIW	11/01/2016 17:15	AIW
Game vs therapy	13	37	08/01/2016 12:51	AIW	11/01/2016 17:15	AIW
importance of feedback	1	1	07/01/2016 14:22	AIW	11/01/2016 17:30	AIW
feedback given	15	67	18/09/2015 10:42	AIW	08/01/2016 10:55	AIW
AT	13	31	18/09/2015 10:42	AIW	11/01/2016 15:19	AIW
PST as therapist	7	9	18/09/2015 10:55	AIW	11/01/2016 17:15	AIW
VT	12	18	18/09/2015 10:42	AIW	11/01/2016 17:15	AIW
Level of challenge provided by activities	18	86	28/11/2015 15:37	AIW	11/01/2016 17:15	AIW
importance of bespoking therapy	3	5	11/01/2016 15:48	AIW	11/01/2016 17:22	AIW
PST as asset for rehab	0	0	08/01/2016 11:07	AIW	08/01/2016 12:49	AIW
acceptability of gaming as therapy	7	22	24/09/2015 11:10	AIW	11/01/2016 15:19	AIW
acceptable hospital	9	17	18/09/2015 10:59	AIW	11/01/2016 17:15	AIW
Acceptence of PST as teletherapy	0	0	28/11/2015 16:20	AIW	21/11/2015 17:57	AIW
concerns	2	2	28/11/2015 16:20	AIW	11/01/2016 17:15	AIW
positive	11	17	28/11/2015 16:20	AIW	11/01/2016 17:15	AIW
Acceptence of PST home use	11	45	28/11/2015 16:20	AIW	11/01/2016 17:15	AIW
deleted nodes	19	63	18/09/2015 09:48	AIW	11/01/2016 17:15	AIW



Name	Sources	References	Created On	Created By	Modified On	Modified By
Acceptability of PST	5	19	18/09/2015 09:36	AIW	11/01/2016 17:15	AIW
deleted nodes	19	63	18/09/2015 09:48	AIW	11/01/2016 17:15	AIW
Efficacy of PST	0	0	18/09/2015 09:37	AIW	18/11/2015 18:37	AIW
Belief PST dos not effect motivation	4	5	06/01/2016 09:44	AIW	11/01/2016 17:15	AIW
Belief PST is effective	0	0	06/01/2016 09:43	AIW	06/01/2016 15:46	AIW
Compliance	12	31	06/01/2016 09:49	AIW	11/01/2016 17:15	AIW
Motivation	1	1	06/01/2016 09:48	AIW	06/01/2016 19:17	AIW
Fun	17	64	06/01/2016 09:56	AIW	11/01/2016 17:15	AIW
promotes social interaction	5	7	06/01/2016 10:57	AIW	11/01/2016 16:06	AIW
Psychological effects	11	17	06/01/2016 09:59	AIW	11/01/2016 17:15	AIW
push self further	13	42	06/01/2016 09:59	AIW	11/01/2016 17:15	AIW
Time flies	11	13	06/01/2016 09:57	AIW	11/01/2016 16:23	AIW
Physical effects	18	55	06/01/2016 09:50	AIW	11/01/2016 17:15	AIW
Feasibility of PST	0	0	18/09/2015 09:36	AIW	17/11/2015 13:16	AIW
Previous experience of rehabilitation	0	0	18/09/2015 09:36	AIW	18/11/2015 18:37	AIW
previous experience with technology	11	22	21/09/2015 16:50	AIW	11/01/2016 17:15	AIW
Study feasibility and acceptability	0	0	18/09/2015 09:38	AIW	17/11/2015 13:28	AIW
Unseen effects of stroke	0	0	07/01/2016 14:24	AIW	07/01/2016 14:24	AIW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HOME
CREATE
DATA
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Edit
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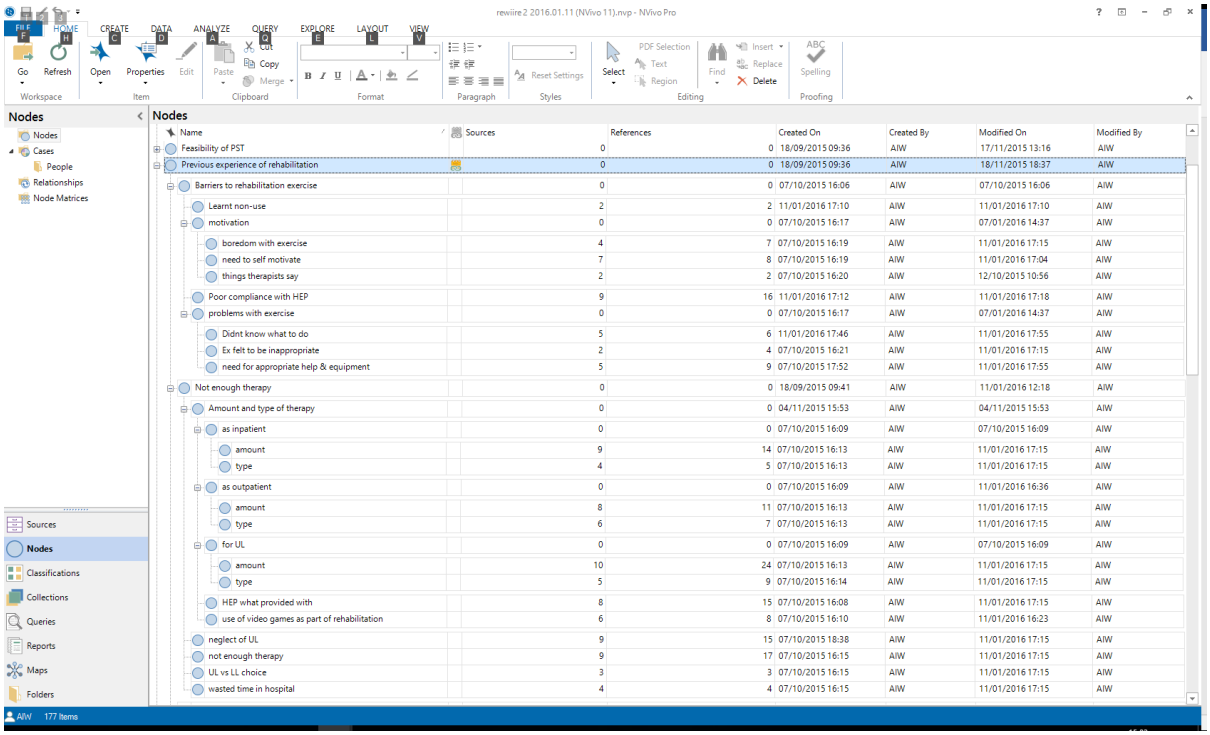
Cut
Copy
Merge
Reset Settings
Select
PDF Selection
Text
Region
Find
Insert
Replace
Delete
Spelling
Workspace
Item
Clipboard
Format
Paragraph
Styles
Editing
Proofing
Nodes
Nodes
Cases
People
Relationships
Node Matrices
Sources
Nodes
Classifications
Collections
Queries
Reports
Maps
Folders
AIW
177 Items
Name
Sources
References
Created On
Created By
Modified On
Modified By
Feasibility of PST 0 0 18/09/2015 09:36 AIW 17/11/2015 13:16 AIW
feasibility of activity 0 0 16/11/2015 16:59 AIW 17/11/2015 10:13 AIW
Appletree 0 0 16/11/2015 16:59 AIW 16/11/2015 16:59 AIW
challenges to use 0 0 16/11/2015 17:00 AIW 17/11/2015 13:13 AIW
helium filled apples too slow 11 14 16/11/2015 17:36 AIW 11/01/2016 15:19 AIW
over complimentary feedback 2 2 16/11/2015 17:39 AIW 16/11/2015 17:42 AIW
technical issues 5 5 16/11/2015 17:15 AIW 11/01/2016 15:19 AIW
uncertain what needed to do 2 3 16/11/2015 17:43 AIW 17/11/2015 09:01 AIW
strength 0 0 16/11/2015 17:00 AIW 16/11/2015 17:00 AIW
ease of use 6 7 16/11/2015 17:16 AIW 17/11/2015 10:44 AIW
feedback as positive 7 7 16/11/2015 17:12 AIW 11/01/2016 15:19 AIW
VT 0 0 16/11/2015 17:00 AIW 16/11/2015 17:00 AIW
challenges 2 2 16/11/2015 17:01 AIW 11/01/2016 17:15 AIW
lack of feedback 5 7 16/11/2015 19:48 AIW 21/11/2015 20:11 AIW
technical issues 7 10 16/11/2015 19:47 AIW 11/01/2016 17:15 AIW
unclear what needed to do 3 4 16/11/2015 19:49 AIW 11/01/2016 16:19 AIW
Perspective 12 19 16/11/2015 20:31 AIW 11/01/2016 17:15 AIW
strength 0 0 16/11/2015 17:00 AIW 16/11/2015 17:00 AIW
Ease of use 3 3 16/11/2015 19:43 AIW 17/11/2015 09:55 AIW
feasibility of hardware equipment 0 0 16/11/2015 16:58 AIW 17/11/2015 13:14 AIW
challenges 0 0 16/11/2015 17:01 AIW 17/11/2015 13:13 AIW
obsolescence 1 1 18/09/2015 11:07 AIW 17/11/2015 10:40 AIW
strength 0 0 16/11/2015 17:01 AIW 16/11/2015 17:01 AIW
application and securing Wiimotes 7 8 16/11/2015 17:02 AIW 11/01/2016 18:01 AIW
ease of set up 3 3 16/11/2015 19:35 AIW 11/01/2016 16:23 AIW
Position played in 10 10 17/11/2015 12:09 AIW 11/01/2016 17:15 AIW
Previous experience of rehabilitation 0 0 18/09/2015 09:36 AIW 18/11/2015 18:37 AIW
previous experience with technology 11 22 21/09/2015 16:50 AIW 11/01/2016 17:15 AIW
Study feasibility and acceptability 0 0 18/09/2015 09:38 AIW 17/11/2015 13:28 AIW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Feasibility of PST 0 0 18/09/2015 09:36 AIW 17/11/2015 13:16 AIW
Previous experience of rehabilitation 0 0 18/09/2015 09:36 AIW 18/11/2015 18:37 AIW
Barriers to rehabilitation exercise 0 0 07/10/2015 16:06 AIW 07/10/2015 16:06 AIW
Learnt non-use 2 2 11/01/2016 17:10 AIW 11/01/2016 17:10 AIW
motivation 0 0 07/10/2015 16:17 AIW 07/01/2016 14:37 AIW
boredom with exercise 4 7 07/10/2015 16:19 AIW 11/01/2016 17:15 AIW
need to self motivate 7 8 07/10/2015 16:19 AIW 11/01/2016 17:04 AIW
things therapists say 2 2 07/10/2015 16:20 AIW 12/10/2015 10:56 AIW
Poor compliance with HEP 9 16 11/01/2016 17:12 AIW 11/01/2016 17:18 AIW
problems with exercise 0 0 07/10/2015 16:17 AIW 07/01/2016 14:37 AIW
Didnt know what to do 5 6 11/01/2016 17:46 AIW 11/01/2016 17:55 AIW
Ex felt to be inappropriate 2 4 07/10/2015 16:21 AIW 11/01/2016 17:15 AIW
need for appropriate help & equipment 5 9 07/10/2015 17:52 AIW 11/01/2016 17:55 AIW
Not enough therapy 0 0 18/09/2015 09:41 AIW 11/01/2016 12:18 AIW
Amount and type of therapy 0 0 04/11/2015 15:53 AIW 04/11/2015 15:53 AIW
as inpatient 0 0 07/10/2015 16:09 AIW 07/10/2015 16:09 AIW
amount 9 14 07/10/2015 16:13 AIW 11/01/2016 17:15 AIW
type 4 5 07/10/2015 16:13 AIW 11/01/2016 17:15 AIW
as outpatient 0 0 07/10/2015 16:09 AIW 11/01/2016 16:36 AIW
amount 8 11 07/10/2015 16:13 AIW 11/01/2016 17:15 AIW
type 6 7 07/10/2015 16:13 AIW 11/01/2016 17:15 AIW
for UL 0 0 07/10/2015 16:09 AIW 07/10/2015 16:09 AIW
amount 10 24 07/10/2015 16:13 AIW 11/01/2016 17:15 AIW
type 5 9 07/10/2015 16:14 AIW 11/01/2016 17:15 AIW
HEP what provided with 8 15 07/10/2015 16:08 AIW 11/01/2016 17:15 AIW
use of video games as part of rehabilitation 6 8 07/10/2015 16:10 AIW 11/01/2016 16:23 AIW
neglect of UL 9 15 07/10/2015 18:38 AIW 11/01/2016 17:15 AIW
not enough therapy 9 17 07/10/2015 16:15 AIW 11/01/2016 17:15 AIW
UL vs LL choice 3 3 07/10/2015 16:15 AIW 11/01/2016 17:15 AIW
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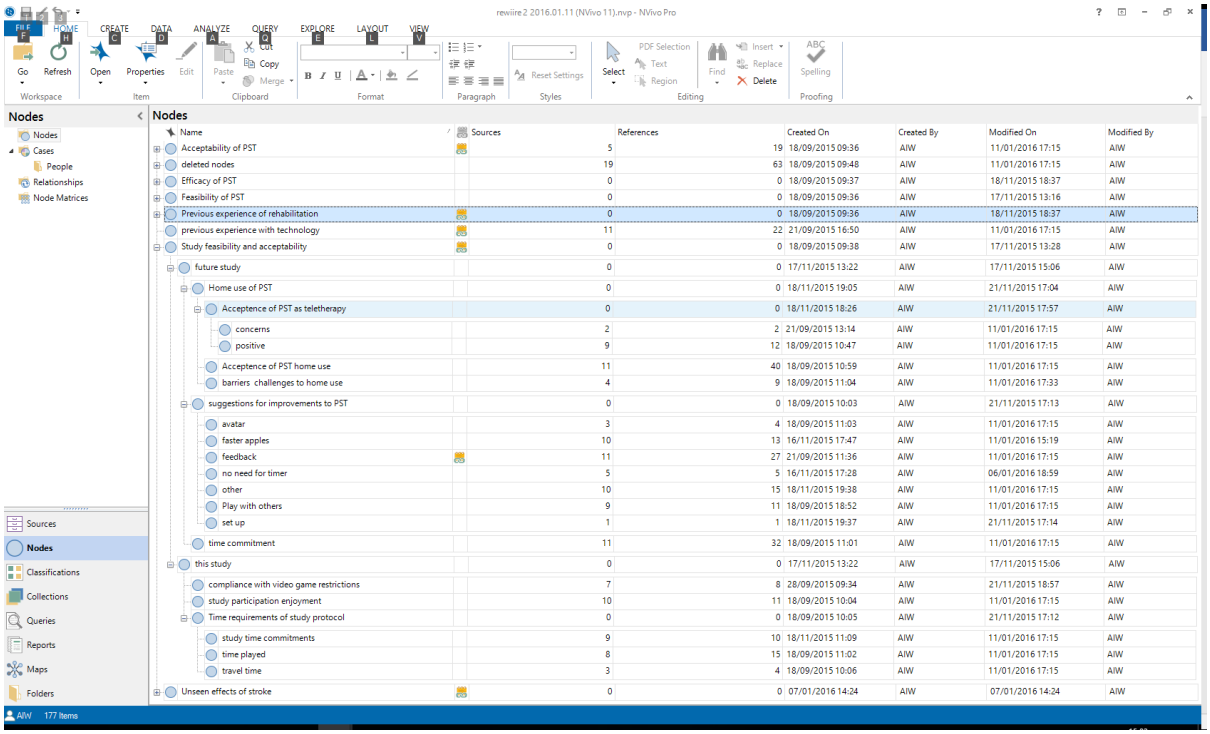
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Workspace Item Clipboard Format Paragraph Styles Editing Proofing
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Study feasibility and acceptability 0 0 18/09/2015 09:38 AIW 17/11/2015 13:28 AIW
future study 0 0 17/11/2015 13:22 AIW 17/11/2015 15:06 AIW
Home use of PST 0 0 18/11/2015 19:05 AIW 21/11/2015 17:04 AIW
Acceptence of PST as teletherapy 0 0 18/11/2015 18:26 AIW 21/11/2015 17:57 AIW
concerns 2 2 21/09/2015 13:14 AIW 11/01/2016 17:15 AIW
positive 9 12 18/09/2015 10:47 AIW 11/01/2016 17:15 AIW
Acceptence of PST home use 11 40 18/09/2015 10:59 AIW 11/01/2016 17:15 AIW
barriers challenges to home use 4 9 18/09/2015 11:04 AIW 11/01/2016 17:33 AIW
suggestions for improvements to PST 0 0 18/09/2015 10:03 AIW 21/11/2015 17:13 AIW
avatar 3 4 18/09/2015 11:03 AIW 11/01/2016 17:15 AIW
faster apples 10 13 16/11/2015 17:47 AIW 11/01/2016 15:19 AIW
feedback 11 27 21/09/2015 11:36 AIW 11/01/2016 17:15 AIW
no need for timer 5 5 16/11/2015 17:28 AIW 06/01/2016 18:59 AIW
other 10 15 18/11/2015 19:38 AIW 11/01/2016 17:15 AIW
Play with others 9 11 18/09/2015 18:52 AIW 11/01/2016 17:15 AIW
set up 1 1 18/11/2015 19:37 AIW 21/11/2015 17:14 AIW
time commitment 11 32 18/09/2015 11:01 AIW 11/01/2016 17:15 AIW
this study 0 0 17/11/2015 13:22 AIW 17/11/2015 15:06 AIW
compliance with video game restrictions 7 8 28/09/2015 09:34 AIW 21/11/2015 18:57 AIW
study participation enjoyment 10 11 18/09/2015 10:04 AIW 11/01/2016 17:15 AIW
Time requirements of study protocol 0 0 18/09/2015 10:05 AIW 21/11/2015 17:12 AIW
study time commitments 9 10 18/11/2015 11:09 AIW 11/01/2016 17:15 AIW
time played 8 15 18/09/2015 11:02 AIW 11/01/2016 17:15 AIW
travel time 3 4 18/09/2015 10:06 AIW 11/01/2016 17:15 AIW
Unseen effects of stroke 0 0 07/01/2016 14:24 AIW 07/01/2016 14:24 AIW
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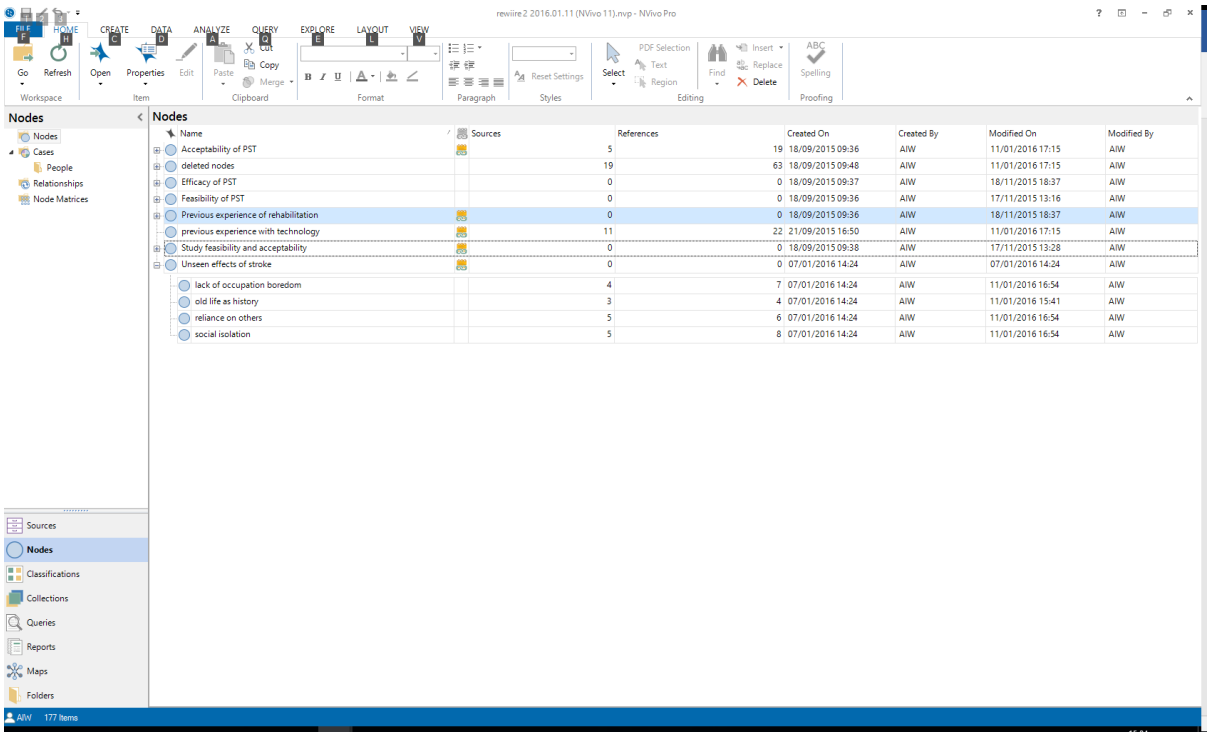
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Previous experience of rehabilitation 0 0 18/09/2015 09:36 AIW 18/11/2015 18:37 AIW
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Study feasibility and acceptability 0 0 18/09/2015 09:38 AIW 17/11/2015 13:28 AIW
Unseen effects of stroke 0 0 07/01/2016 14:24 AIW 07/01/2016 14:24 AIW
lack of occupation boredom 4 7 07/01/2016 14:24 AIW 11/01/2016 16:54 AIW
old life as history 3 4 07/01/2016 14:24 AIW 11/01/2016 15:41 AIW
reliance on others 5 6 07/01/2016 14:24 AIW 11/01/2016 16:54 AIW
social isolation 5 8 07/01/2016 14:24 AIW 11/01/2016 16:54 AIW
AIW 177 items

19: Photographs of Initial Thematic Maps