Stroke Patients Perceptions of Upper Limb Use in ADL After Rehabilitation Using A Virtual Reality (VR) Intervention

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Thesis submitted to the University of Nottingham

for the degree of Master of Philosophy,

August 2016

Abstract

Virtual Reality interventions are increasingly being researched with regard to their role in upper limb rehabilitation following stroke. Despite emerging evidence to demonstrate their efficacy in increasing motor function, there is weaker evidence to demonstrate an effect on performance in daily living activities. The Motor Activity Log (MAL) was used as a secondary outcome measure in the Wii Stroke Therapy for Arm Rehabilitation (Wii STAR) feasibility Randomised Controlled Trial, to explore whether there is any change in patients' perceptions of how well, and how often they used their paretic upper limb during daily living activities (ADL) .

Method: 27 patients aged 18 or over, with residual arm dysfunction following stroke and, no longer receiving any other intensive rehabilitation were randomly allocated to either the intervention or control groups. The intervention was a low cost, virtual reality system that translates movements of the hand, fingers and thumb into game play. It was left in participants' homes for eight weeks and they were advised to use it three times a day for periods of no more than 20 minutes. Frequency and duration of use were automatically recorded. The control group received no more than usual care. Patients were assessed at three time points using the Wolf Motor Function Test (WMFT), Nine-Hole Peg Test, and Nottingham Extended Activities of Daily Living as well as the Motor Activity Log.

Results: There was a significantly greater change from baseline in the intervention group on the MAL Amount of Use subscale and MAL Total Activities attempted where the other outcome measures (with the exception of the WMFT- Grip at 4 weeks) did not show a difference. The MAL did correlate with some of the other measures on absolute scores, but not on change scores, although, there was a trend towards a correlation between duration of gameplay with change in the MAL Total Activities Attempted at 8 weeks.

Discussion

The results suggest that the MAL can pick up a difference when other outcome measures cannot. However, the small sample size and limited use of the intervention could mean that these results are due to a Type II error. The lack of correlations between the MAL and other outcome measures on change scores is consistent with earlier research indicating it is measuring a different aspect of recovery.

Conclusion:

The MAL 30 item version should be used as an outcome measure in studies which evaluate interventions targeting paretic upper limb after stroke, as it appears to be able to detect improvements, where measures of function, dexterity or ADL may not capture improvements. Additionally the MAL Total Activities Attempted should also be recorded, as it did show a difference between the two groups and a trend towards correlating with gameplay duration in the intervention group.

Acknowledgements

I'd especially like to thank Professor Penny Standen, of the Univeristy of Nottingham for her guidance, patience and support during Wii STAR research project, and especially throughout the writing of this Thesis.

I'd also like to thank Professor Marion Walker, Professor Avril Drummond, Dr. Louise Connell, Dr. Rebecca Fisher, Dr. Fiona Nouri, Dr. Kate Threapleton, Dr. Jane Horne, Dr. Phillip Whitehead, Dr. Joanna Fletcher-Smith, Dr. Kathryn Radford, Marilyn Stonham and Hazel Sayers, for their support and goodwill throughout.

I'd like to thank Professor David Brown, Dr. Andy Burton and Dr. Steven Battersby for developing the technological innovations and for supporting the use of the equipment in participants' homes.

I'd like to thank my colleagues at Derby Community Health Services for their tolerance and support. I'd also like to thank the people who helped with proof reading the document; Mrs Louise Richardson, Mr Fred Higton, Mr Trevor Jones and Mrs Janet Norris.

Finally, I'd like to thank my family, my wife Tracey, and our children for allowing me many hours, of what should probably be time with them, to complete this thesis.

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Chapter One

There is a current emphasis on earlier discharge of stroke survivors from the hospital setting to the community. As a result, there is a shift in the delivery of rehabilitation to the home setting. For those patients still experiencing impairments of the upper limb, successful rehabilitation requires timely and intensive practice of task-specific exercises or activities, irrespective of the medium of the delivery. The expanse and proliferation of technology in modern culture has increased with computer gaming now commonplace in many age groups. Research studies have explored the use of these technological advances in the context of delivering intensive task-specific practice of upper limb exercises or activities in the home.

To establish whether rehabilitation approaches have been successful, there is a need to carefully evaluate the outcomes. The World Health Organisation's International Classification of Functioning (ICF- HD2) (WHO 2001) categorizes several domains by which rehabilitation outcomes can compared and measured.

For patients experiencing problems with their upper limb, outcome measures need to be carefully chosen, that not only explore whether there has been any increase in motor movement, in terms of speed, dexterity and function, but also patients' perceptions of their progress, in terms of how much and how well they are able to use their more impaired upper limb, when participating in daily living tasks. This thesis examines the role of one such measure, the Motor Activity Log (MAL) (Taub et al, 2011) in the evaluation of a home based virtual reality intervention for patients who continue to experience problems with their upper limb following a stroke.

1.1 Stroke – Definition and Description

The World Health Organization (WHO) definition of stroke is: ‘rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin’ (WHO 1988) The types of stroke included in this description are ischaemic stroke, caused by blood clots to the brain, or haemorrhagic stroke, which is caused by bleeding into/of the brain (RCP National Collaborating Centre for Chronic Conditions-Clinical Guidelines for management of acute stroke and T.I.A, 2008 page 21). The area of damaged neural tissue post ischaemic interruption is known as a lesion (Teasell et al, 2008). The site and size of the lesion are determinants of the amount of eventual recovery. As described by Teasell; “As a general rule, the severity of the initial deficit is inversely proportional to the prognosis for recovery” (Teasell, 2008, p 5).

The neurological insult of a stroke can result in many possible impairments, with motor impairment, impairments of vision, communication, swallowing and cognition, being just some of the possible individual consequences. This is because the normal neural transmission is prevented. If neural transmission is prevented from the motor cortex to limb muscle tissue via descending pyramidal (cortico-spinal) tracts as a direct result of a lesion, impairment of motor activity and motor function will result. An impairment of motor function is the main cause of disability after stroke, as it restricts muscle functioning and mobility (Langhorne et al, 2011 p 1695).

174 to 216 people per 100,000 in the UK population each year suffer from the effects of stroke (RCP stroke guidelines 1.4, 2012), and 110,000 people in England suffer a first or recurrent stroke each year (NICE, 2008, 1.3, p4). Stroke is the third most common cause of mortality, and one of the main causes of acquired adult disability (Langhorne et al 2011, The World Health Organisation (WHO) 2003,and Bonita et al 2004) The effects of stroke have a direct cost to the NHS being £3 Billion annually (National Audit Office 2010). There are 900,000 people in England living with the effects of stroke at any one time (NICE, 2008).

1.2 The Consequences of Stroke

Stroke as a disease has an impact at a societal, community and individual level. For the individual, these consequences can impinge on several aspects of their life affecting bodily functions, activities and participation in society. The costs to the UK, in addressing the needs of survivors of stroke are likely to increase as average life expectancy of the population increases, (Wolfe CDA. Stroke Association, 1996, p 40-87). There is therefore, an increasing need to find and direct effective interventions, in an economic and demographic environment where demands on healthcare resources will increase (Walker, Sunnerhagen, and Fisher , 2013 p 293)

Advances in acute management of stroke now mean that three quarters of those who survive the initial event will live with the resulting impairment and disability (Aziz et al, 2010, p 239). However, even with advances in acute stroke medicine, approximately 40% of survivors of stroke are still left with significant functional disabilities, such as difficulties with mobility, balance, impaired gait, and impaired function of the upper limb (Aziz et al, 2010 p 239). The effects of stroke on the individual will vary, i.e., survivors may be ‘left with no disability or with mild, moderate or severe disability’ (Truelsen, et al, 2006 p3). Approximately a third of all stroke survivors need assistance to manage their daily living activities at one year post stroke Truelson, T., Begg, M. and Mathers, 2006), with only 48% to 58% regaining independence with their self-care skills (Teasell et al, 2008 p4).

1.3 Impairment of the Upper Limb

An impairment of motor function that results in a partial or complete inability to activate voluntary, co-ordinated muscle contraction in the affected limb or limbs, is known as Paresis. This is commonly reported as a weakness (or partial weakness) of the limb. Upper limb paresis often occurs as a component of hemiparesis, where neuro-muscular control of both the upper and lower limb, contra-lateral to the side of the lesion, is impaired. This occurs because the axons of upper motor neurones pass through the internal capsule, pons and medulla, below which approximately ninety percent of descending nerve fibres decussate (cross over) to the contralateral side before continuing down the lateral corticospinal tract. (Sourced from; Grays anatomy, 35th Ed 1973 and Heimer, L., 1983)

In normal motor control and movement of the upper limb, purposeful and dexterous movement correspond to sensory feedback via afferent ascending nerve fibres, embedded in both muscle spindles, joints and skin (Prochazka and Ellaway, 2012). Sensory feedback is essential to purposeful dexterous movement, as without sensory feedback fine motor control, grasping or gripping objects in a meaningful way to achieve goal focused activities can be compromised. Lack of knowledge of muscle activation (kinaesthesia), or joint position (proprioception), as well as decreased appreciation of light touch, temperature and pain may prevent successful outcomes in gripping, holding or manipulating objects successfully, even when compensating for a lack of sensory feedback by using vision to identify the object, and cognition to estimate its mass.

In the healthy, neurologically intact adults, participation in purposeful activities involving the upper limb requires the processing of visual information to enhance the accuracy of planned dexterous movements. Impairment of kinaesthetic sensation, visual stimulus (a visual field deficit), or the perception of visual stimulus (visuo-spatial neglect) (Cassidy et al 1999) may also negatively impact on the individual's abilities to use their upper limbs effectively when participating in functional and dexterous activities (Ferro, 1984) even if motor control of limb muscles is not impaired (Prochazka and Ellaway 2012).

According to the Royal College of Physicians (RCP) Stroke Clinical Guidelines 4th Ed. (2012 Guideline 6.7, 'Arm Re-education') 70% of patients experience altered arm function after a stroke. Stevens, and Stoykov, (2003) argue that the intention to execute a movement and the action of executing a movement may be prevented where the neural circuitry is not intact. The severity of the upper limb paresis, and whether any resulting impairment is mild, moderate or severe, relates to the size and territory of the upper motor neurone lesion. (Shelton and Reding, 2001). 40% of those with upper limb paresis, will continue to have a persistent lack of arm function (Royal College of Physicians (RCP) stroke guidelines 2012, 6.7, p 83), although the categorisation of severity of paresis, and an in-depth understanding all of the factors influencing recovery , is ongoing in current and recent literature (Langhorne et al, 2011, Kwakkel, 2015, Wolf et al 2015)

Importantly, even minimal deficits in hand control can have a huge impact on many activities of daily living, social and work-related participation (Adamovich et al, 2009). Recent evidence syntheses, and the development of a prognostic algorithm (Wolf et al 2015 p 2) presented at an international conference, described how those patients who have recovered some finger extension, and some visible shoulder abduction at two days post-stroke, have a 98% chance of making a full recovery by 6 months. Those patients who did not have that ability in the same time-frame, have only a 25% chance of recovering fully from the stroke. The authors also suggest that there is potential for some patients who have a poor prognosis for recovery of upper limb function initially, to regain partial or complete finger extension, and in due course regain the capacity to use the impaired upper limb in functional activities.

Rehabilitation provides the best opportunity for survivors of stroke to regain motor function (Langhorne et al, 2011; Van Peppen et al, 2004). Specialist stroke rehabilitation takes ‘a problem-solving approach’ with the aim of reducing and counteracting the impact of disability and handicap caused directly by the stroke (Langhorne and Legg, 2003 p 1). However, to achieve this aim, a cyclical process of events must occur, involving patients and health care professionals. The rehabilitation process begins with (i) assessment, whereby the patient's needs are identified, and baseline measurements are taken. (ii) Next, realistic, measureable and achievable goals are jointly agreed with the patient, within an agreed timeframe. (iii) Following on from this, there is usually an agreed intervention strategy aimed at achieving the identified goals commencing within the agreed timeframe, (iv) and finally, after the patient has participated in, or received the intervention, their progress is re-assessed, and the need for any further or continued intervention is discussed and evaluated (Langhorne and Legg 2003 p 1-4, Langhorne et al 2011, p 1695 and RCP, 2012, sections 3.12, 3.13 and 3.14, p 31 - 32).

1.4. Evidence based rehabilitation of the Upper Limb

The aim of rehabilitation is to restore function. Current evidence for upper limb rehabilitation suggests that cortical re-organisation can occur, where the survivor of stroke performs high numbers of task-specific repetitions, using their more impaired upper limb. This neural re-organisation is more likely to occur in the first three months following a stroke, therefore the timing of the rehabilitation is also important. However, improvements can also be seen in chronic survivors of stroke, providing that they receive rehabilitation (Dobkin 1997, McCabe 2015) . It is thought that improvements in the chronic stage are due to adaptive strategies rather than any structural neurological changes.

Defining the rehabilitation process, and choosing the most appropriate rehabilitation intervention, can be complex. As discussed earlier in this section, recovery from stroke is partly defined by the size and the site of the initial cerebral lesion, meaning that recovery differs between individual survivors and is therefore heterogeneous (Langhorne et al, 2011). Another complexity is that the neurological impact of stroke and the resulting impairments may have consequences that include areas of physical and psychological health, which in turn can impact on participation in Activities of Daily Living (ADL) , social functioning and quality of life (NICE Clinical Guidelines for Stroke Rehabilitation in Adults, 2013 p 4.)

Rehabilitation interventions therefore need to be tailored to address the physical, psychological and social factors that impact on the person as a result of the stroke, and in this sense cannot be easily defined by a medical model (Wade, and Halligan, 2004, Langhorne, and Legg, 2003 and. Langhorne et al (2011 p1695) argue that stroke rehabilitation should be seen as a complex intervention which has several linked and interacting components.

The rehabilitation process can improve outcomes in upper limb motor function, by encouraging active movement and participation during goal-focused activities (NICE Clinical Guidelines for Stroke Rehabilitation in Adults, 2013) Guideline 'Setting Goals for Rehabilitation', 1.2.8. p16), whereas a lack of rehabilitation may result in poor outcomes such as reduced participation in ADL, and complications including contractures, muscle atrophy and chronic shoulder pain (Price and Pandyan, 2000;

Ada, O'Dwyer, and O'Neil, 2006). Those who are able to participate in intensive, task specific rehabilitation during the early acute and sub-acute phases of recovery (0-12 weeks) are more likely to be more independent in daily living activities than those who do not receive this type of rehabilitation (Kwakkel et al, 2004 p 851, Teasell et al, 3.4, p 10-17, The Evidence Based Review of Stroke Rehabilition, updated 2008; www.ebrsr.com 2008).

Use-dependent cortical re-organisation has been seen in neuroimaging studies involving primates (Nudo, et al 1996). In studies of primates, where restraint of the healthy forelimb forced the monkeys to use a deafferented forelimb, the animals performed many repetitions of the skilled movements involved in moving around and feeding themselves. Within days, the impaired forelimbs dramatically improved, the deafferented limb eventually becoming fully functional (Taub et al 1999 p 3,)

In humans, a study which used neuroimaging to examine the relationship between neurogenesis and the use of intensive task-related skills, identified significant differences in cortical representation in the left hands of musicians who play stringed instruments, suggesting a use-dependent correlation (Elbert et al, 1995). Nudo et al, (2003), argue that in healthy subjects, motor skill acquisition is directly correlated with functional changes in the motor cortex. In studies of humans who received intensive restraint therapy following stroke, positive results have been seen where behavioural shaping techniques have been used in tandem with a restraint mitten on the lesser impaired upper limb for up to six hours per day for 14 days).

Imaging results from these studies demonstrated an increase in cortical re-organisation in those participants who received the restraint therapy with behavioural shaping. According to Taub et al, (1999) certain elements of the therapy process (including the timing of the therapy, the amount of use, and the behavioural shaping conditions) contributed to neural reorganisation in the ipsilesional hemisphere, the adjacent cortex of the opposite hemisphere. However, without the appropriate elements conducive to neuroplasticity, the likelihood is that both animals and humans will tend to use their unaffected limb and neglect their impaired limb, as the effort required to use the impaired limb in early stages of recovery could be perceived as 'punishment' (Taub et al, 2002 p 229). This phenomenon, known as 'learned non-use' (Taub et al, 2002 p 229) may result in diminished cortical representation in the respective cortex areas responsible for initiating and facilitating upper limb movement and actions. The result is that the survivor of stroke may never achieve their potential to maximise the cortical re-organisation which occurs during constraint therapy and in doing so, may lose the functional use of their affected upper limb (Taub, 1999 p 2-3).

However, the processes associated with the initial depression of central nervous function and any subsequent recovery of function after neurological insult in humans is not completely understood. In their review of stroke rehabilitation (Langhorne et al, 2011 p 1693) state that 'Recovery is a complex process that probably occurs through a combination of spontaneous and learning-dependent processes', which could involve 'restitution' (restoring the functionality of damaged neural tissue), 'substitution' (reorganisation of partly spared neural pathways to relearn lost functions), and ‘compensation’ (improvement of the disparity between the impaired skills of a patient and the demands of their environment), by using ‘adaptive control strategies’.

There is strong evidence that the neurological recovery which occurs after stroke, takes place as oedema local to the lesion reduces (in the hours, and up to weeks following stroke) and the resolution of the ischemic penumbra (which can take up to 2 months , though is generally resolved much earlier) (Teasell, 2008 p 7) . This reduction of oedema, and resolution of blood flow, and resolution of diachisis, allows for neural transmission to occur. Neural re-organisation, which is driven by learning dependent processes, may then occur, as a direct result of active participation in meaningful and specific tasks (Langhorne, Bernhardt, and Kwakkel, 2011). 95 % of all stroke survivors reach their optimal neurological recovery at 11 weeks, with the remaining 5% at 12-13 weeks (Teasell, 2008 p 8).

Langhorne et al (2011) argue that neuroplasticity and recovery of function, needs to be better understood in humans. The importance of early rehabilitation approaches, targeting specific impairment, can enhance recovery potential. It is recognised that the interventions should commence as soon as possible (RCP, 4.15.1, 2012 p 54) for those survivors of stroke who can tolerate them. Current evidence for stroke rehabilitation suggests that early, intensive, task-specific rehabilitation maximises the opportunity for optimal outcomes (Wolf et al 2016, Kwakkel et al 2015, McCabe et al 2015, Langhorne et al 2011, Kwakkel et al 2004). Kaur et al (2012, p 1) state that, ‘There is now strong evidence that more time spent in task-specific therapy after stroke improves functional outcomes’.

However, in contrast to the argument for early intervention (i.e., in the first 12 weeks after a Stroke), a recent study (McCabe et al, 2015) has highlighted that patients with chronic impairment of the upper limb, can make significant improvements, provided there is intensive repetition of tasks, at a high dosage (5 hours per day, for 5 days a week, for 5 weeks). The authors argue that for these improvements to occur, there should be a significant Motor Learning (ML) component integral to the rehabilitation approach (McCabe et al, 2015 p 981-990).

1.5 Ways of encouraging intensive task-specific rehabilitation for the upper limb

Several ways of delivering intensive, task-specific rehabilitation to survivors of stroke with upper limb impairment have been researched, and are also in use in current practice. The word limits of this thesis do not allow for a comprehensive review or description of all the media of delivering upper limb rehabilitation, and will therefore focus on some of approaches which are most applicable. Due to the heterogeneous nature of stroke, no single medium of delivering upper limb rehabilitation will be applicable to all. Constraint Induced Movement Therapy (CIMT) may be one way of increasing the intensity of task training, whilst also ensuring context-specificity for those with moderate impairment of the upper limb. Both NICE (draft 2013) and RCP (2012) stroke rehabilitation guidelines recommend the use of CIMT for upper limb rehabilitation following stroke.

Kwakkel et al (2015 p 225-226) highlight that in the protocol for the original form of CIMT participants have their lesser impaired upper limb restrained for 90% of waking hours. They then receive graded, intensive upper limb training for 6 hours per day for two weeks, and are supported and encouraged to practice a high number of repetitions of specific tasks or activities. Along with this, the participants receive behavioural shaping in a structured format. The shaping, which includes encouragement, has the aim of enhancing and encouraging the participant to use their more impaired upper limb in real-world activities. This additional behavioural shaping is given so that participants begin to practice activities in their own homes.

The evidence for CIMT suggests that 14 days of forced use of the impaired upper limb, when wearing a constraint for up to 6 hours per day, with additional task-specific, graded activities, has demonstrated significant improvements in upper limb motor function (Langhorne, 2009 p748). However, to benefit from this form of therapy, participants must also receive behavioural shaping using a model aimed at translating the task-specific graded activities into daily use (Kwakkel et al, 2015 p 225, Taub et al, 1999 p 7, Wolf et al, 2006 p 2099).

As yet, the CIMT model has not been widely adopted in the UK. Certainly CIMT is usually limited to those patients who can achieve 20 degrees of wrist extension and 10 degrees of extension at the metacarpophalangeal joints and proximal interphalangeal joints in the impaired upper limb and thus only a portion of the stroke population who have impaired upper limb function would meet the inclusion criteria. Secondly, those patients who are at risk of falling, or who are vulnerable, or else who have cognitive, vision or perceptual impairments following stroke would not be able to participate safely or practically (RCP, 6.16.1, 2012 p 92).

However, in a Cochrane systematic review of upper limb rehabilitation, Pollock et al, (2014) concluded that the current evidence for CIMT is only of moderate quality, and is therefore only 'suggestive' of a positive effect. Earlier systematic reviews of CIMT had also reported null (Corbetta et al 2010) or moderate (Peurala et al 2012) effects for CIMT. Both Pollock et al, (2014) and Kwakkel et al (2015) concur that many of the RCT's that were included in systematic reviews completed so far, are small and under-powered. Also, many of the systematic reviews of CIMT have included modified versions of the intervention or simply 'forced use' Kwakkel et al (2015 p 225) of the more impaired upper limb during functional activities, without the application of other components of the CIMT protocol being applied. Pollack et al (2014) posit that more collaboration in research with larger RCT's is needed to draw stronger conclusions which can guide practice in clinical settings.

Motor Learning (ML), in the context of upper limb rehabilitation following stroke is thought to be a crucial approach in the context of the application of intensive task-specific interventions. A description of the application of ML, is given by McCabe et al (2015). The initial training involved training isolated movements targeting the scapula, shoulder, elbow, wrist, thumb and fingers. Initially skilled movements are practised repeatedly, either with single joints targeted in isolation (in synergy or out of synergy) , or otherwise with multiple joints (in or out of synergy), before then progressing to functional movements (reaching, grasping, releasing movements) using tasks such as stirring with a spoon, reaching up to a cupboard, writing, and using a computer keyboard (as described in appendix 2, McCabe et al 2015 p 989). The ML approach applied by McCabe et al (2015) involves a high number of repetitions of very specific motor movements, building up to ML tasks in a functional context such as reaching tasks, to enhance motivation. The level of complexity of the motor skills or tasks can be matched to the capabilities of the patient. They may then be upgraded or progressed, as the capabilities of the patient improve. The ML training described followed a hierarchy of complexity (as described in Appendix 1, McCabe et al, 2015 p 989).

The findings of McCabe et al's study (2015) are similar to those of a recent systematic review by Veerbeek et al (2014) which suggested that clinically meaningful gains in upper limb function are made with interventions that are both intensive and learning-based. Veerbeek et al (2014 p18) cite Hebb (1949), when they suggest that 'Repetition is an important principle in motor learning which reflects the Hebbian learning rule that connections between neurons are strengthened when they are simultaneously active (i.e., long term potentiation)'. However, a study by Reinkensmeyer et al (2009) reported in Kwakkel et al (2015) p 992, showed that 'the time course of this ML (motor learning) curve depended on the patients' ability to activate the spared portions of the damaged corticospinal tract system'.

The RCP Stroke Clinical Guidelines 4th Ed. (2012) Guidelines 6.17.1, state that there is 'level A' evidence to support using mental practice or mental rehearsal as an adjunct to other upper limb rehabilitation or therapies. However, the additional notes report that more robust research is needed. So far, only small to moderate sized trials have been completed, with differing study protocols, meaning that the available meta-analysis of studies is, at best, limited. Braun et al (2008 p 842), completed a systematic review that led them to conclude that 'There was some evidence that mental practice as an additional therapy intervention had positive effects on recovery of arm function after stroke'.

1.6 Barriers to achieving optimal rehabilitation

The current evidence, as outlined by Kwakkel et al (2015) and also Wolf et al (2016), suggests that the most important factors in upper limb recovery are the site and size of the lesion as these will determine the severity and impact of the stroke and of any resulting paresis. The authors assert that interventions need to commence very soon after the stroke, if they are to have the maximum impact on reducing its effects, as the first 3 months after stroke are critical in terms of maximising the opportunity for neural re-organisation. Early rehabilitation works concordantly with natural recovery processes. In terms of the upper limb, specific movement in the first two days post-stroke is a prognostic marker, although some patients' outcomes may exceed their initial poor prognosis.

Also critical is the intensity (including number of repetitions or amount of use of the impaired upper limb). Another important factor, is that the rehabilitation task has specificity, i.e. to improve dexterity, precise movements must be practised repeatedly. However, practised tasks need to be meaningful and have context. To support the patient, in terms of maximising their recovery, a learning-based approach, or behaviour shaping approach may well be as important as the medium by which the intervention is delivered. Ensuring such a rehabilitation programme is achieved is not straightforward.

A major barrier is that the average length of stay in UK hospital stroke units, and thus the opportunity for intensive rehabilitation is decreasing. The median inpatient stay on a stroke unit has decreased from 18 days in 2004, to 10 days in 2010 (RCP Stroke Sentinel Audit, 2010 p 49). The current climate of economic austerity and subsequent legislation supporting radical reforms of the NHS (NHS White Paper, 2010) have coincided with National Stroke Strategy changes (DOH, 2007, QM13, QM14) to facilitate a change in service organisation and delivery. There are financial and healthcare related incentives for hospitals to discharge patients more quickly, thus meaning a shift in the emphasis of rehabilitation from hospitals into patients' own homes (Walker, Sunnerhagan and Fisher, 2013 p 293,).

Although care and rehabilitation of the more impaired upper limb is undertaken, the increasing financial and efficiency pressures mean that face-to-face therapists- patient time is reduced, perhaps with the upper limb losing out to the time dedicated to mobility and transfer practice. This is because patients who can mobilise independently can be discharged from hospital more quickly for two reasons. Firstly, they are more likely to be less dependent with elements of personal care such as toileting, washing and dressing, therefore reducing the burden of care on carers. Secondly, they may meet the criteria for early (stroke specific) supported discharge into the community (Fisher, et al, 2011 p 1395) as the usual standard criterion to de discharged home with Early Supported Discharge is to be ‘able to transfer with assistance of one person’.

Another complication for some survivors of stroke who have upper limb paresis, is that they are not able to actively participate, at a time when ‘potential to harness neuroplastic changes is greatest, (as the) patient is too paretic to perform hand training.’ (Adamovich et al, 2009 p 3).

In the context of rehabilitation, adherence is the patient’s ability to stick with and eventually complete the treatment or intervention regimen, as offered by the service delivering the rehabilitation. Compliance and adherence to medical or rehabilitation regimes for chronic populations are a concern for health care providers (Davies et al 2010), in terms of the need to make health care in general as effective and efficient as possible. Nonadherence is common when treatment regimens require prolonged and unsupervised self-management (Carter, Taylor, & Levenson, 2003). Between 60% and 80% of people receiving treatment admit to partial or complete nonadherence to home-based exercises (Engström & Öberg, 2005; Sluijs, Kerssens, van der Zee, & Myers, 1998).

According to Perri et al (2002) although activities of higher intensity may produce greater health benefits than low-intensity activities, sedentary individuals are less likely to adhere to a prescription for high-intensity activities. Dishman and Buckworth (1996) see that sedentary persons who are unable to adhere to rehabilitation are more likely to have poorer outcomes in their health and social functioning. Duncan et al (2002) suggest that patients with better compliance scores, have better outcomes, in terms of compliance with evidence based guidance, advice and treatments.

Both compliance and adherence are linked to the suitability, acceptability, the locality and the flexibility of the treatment or services being offered. Treatment regimens in populations receiving rehabilitation, do not usually work if they are fixed and immutable (Clay and Hopps 2003).

Where patients have to attend regular hospital appointments, or where they need lots of assistance from a spouse or carer, adherence may fall below the requested amount. In hospital outpatient clinic settings, the practicalities of transport and access, and the availability of family or carer-time, may be a barrier (Clay and Hopps 2003). The social and home circumstances for each patient could make a difference to the amount of rehabilitation that they receive during the optimal rehabilitation period. Having supportive family members or carers may well make a difference. For example, Di Matteo (2004 p 207) posits that practical support is most highly correlated with adherence to exercise in cohesive families (1.74 times more likely), whereas with ‘families in conflict’ patient adherence to exercise is reduced. This supports earlier evidence (Evans et al, 1987) that by identifying and assessing where dysfunction in families negatively impacts on interaction and has become problematic in relation to adherence issues, then the process of assessment and identification of issues, can facilitate adherence to rehabilitation.

Another potential barrier to facilitating optimal engagement in upper limb rehabilitation, is that the therapists responsible for setting rehabilitation goals, and facilitating rehabilitation regimen with patients, perceive that they lack the knowledge and resources to encourage the massed practice of upper limb exercises and activities. Connell et al (2015 p 3) see the key to driving up the number of patients receiving upper limb rehabilitation at the desired levels of intensity to optimise recovery, is to facilitate a behaviour change in therapist groups. They used the Behaviour Change Wheel (Michie et al, 2011) to identify the barriers to therapists prioritising and targeting the upper limb and addressing these, before motivating and facilitating the therapists to adopt evidence-based methods of facilitating the patients and their carers to engage in the required amount of task-specific, intensive upper limb rehabilitation.

Technology has been proposed as an area for further investigation and research, or as an adjunct to more conventional rehabilitation (Langhorne et al, 2011 p 698; RCP 2012, guidelines 6.13 p 90, 6.15, 6.15.1 p 91 , Crosbie et al, 2005 p 219, Laver et al 2011 p 3, 2014 p 2). Given the current austerity measures currently influencing rehabilitation resources and service provision (Fisher and Walker, 2011 p 55,) evidence based, cost effective ways of increasing intensive participation of task-specific exercise, could increase the opportunity for survivors of stroke to maximise outcomes. Advances in technology have offered potential solutions for survivors of stroke who face barriers to attending rehabilitation in outpatient departments to engage in the massed practice of meaningful, task orientated exercises or activities for the upper limb, and could be central to future service provision. As stated by Brochard et al (2010 p 683) 'Technological devices are well suited to fulfil these rehabilitation principles (high intensity, repetitive, task-specific practice), as they can be used to provide controlled, repeatable, intensive, interactive and motivating rehabilitation with feedback.'

1.7 The use of technological interventions to facilitate intensive exercise for the upper limb following stroke: Virtual Reality and Computer Gaming.

Definitions of technology broadly refer to the use or adaptation of tools or machines, in an attempt to solve a problem, or overcome an obstacle. Health care technologies and assistive technologies are not different in this sense. This section will mainly focus on relatively low-cost, virtual reality and gaming devices which have been designed or used, with the aim of helping survivors of stroke maximise the use of the impaired upper limbs, as they participate in a program of rehabilitation.

1.7.1 Virtual reality and computer gaming

It is important to attempt to distinguish between low-cost Virtual Reality or Computer Gaming devices, and the more expensive hospital-based robotic devices. Although there is an overlap between Virtual Reality (VR) and 'Robotics', distinctions have been made in some systematic reviews and meta analyses. Robotic devices designed to assist with upper limb rehabilitation are often larger, more expensive pieces of equipment, and often designed to be used in hospital environments. Robotic devices are been designed to actively assist the more impaired upper limb of the stroke survivor during task-specific movements (Lo et al 2010, Kwakkel et al 2008). In this way, they can be used to facilitate movements for patients who have chronic, and more severe residual upper limb impairment.

Some robotic devices may incorporate VR technology to make the movements they are encouraging more task oriented. VR and computer gaming devices, are often cheaper, more portable (or transportable), and can therefore be used more easily in non-hospital settings (Standen et al 2016). Some of them may only be appropriate for those survivors of stroke who have some return of activity in their hand, wrist and elbow.

VR has been defined as the use of interactive simulations that are created with the use of computer technology, including hardware and software. The interactive simulation presents the user with the opportunity to engage in an environment that feels similar to interacting with objects in the real world (Weiss et al, 2004 p 1). Control of an avatar or changes on the screen correspond directly to the user's own movements, via their control of the interface device (glove, joystick) employed. There are differences between 'immersive' and 'non-immersive' types of VR interventions which can make them difficult to compare and rank. For example, 'Immersive' VR usually involves the use of head mounted display equipment or a concave screen onto which the image is projected, which enhances the sense of 'presence' or 'immersion' into the three dimensional virtual world.

Non-immersive VR approaches tend to be a more conventional interactive experience, sometimes with added components or elements. Henderson et al (2007 p 53) describe non-immersive VR systems, as those where the ‘users interact to different degrees with the environment displayed on a computer screen’. To interact with the computer software, and engage with the virtual reality in a non-immersive capacity, devices such as a computer mouse, a haptic joystick, a Cyber- glove (or Cyber-grasp), or finally force sensors, are used as the modulator of the interactive engagement.

The terms ‘Virtual Reality’ and ‘Computer Gaming’ (CG) have frequently been used interchangeably in the context of upper limb rehabilitation research. For example Saposnick et al (2010), Saposnick and Levin (2011) describe their intervention, which uses off-the-shelf gaming consoles and games as the main intervention in their study, as ‘virtual reality’. However, some studies of V R have described therapeutic uses which do not have a game component. Edmans et al (2006) created a virtual environment to replicate a kitchen and, in an ongoing / current study, a virtual home environment is being used to simulate home visits for patients who are still on the hospital ward (Threapleton et al 2015). Therefore VR interventions are not always games. To be classified as games they will include common elements of gaming, such as meaningful, clearly defined, ‘goal-focused’ competition (with self or others), increasing in terms of challenge to match user performance, usually with feedback or scoring mechanism. Several studies of low-cost VR and gaming based interventions have recognised these qualities.

Adamovich, et al (2009) argue that VR can facilitate the massed practice of functional and dexterous upper limb movements in a similar way to non-VR interventions such as CIMT. One way in which it can enhance the massed practice of functional movements is that it provides a behavioural incentive during immersion in VR gameplay, in the form of easily perceived feedback (Standen et al 2014). The easily perceived feedback may encourage and motivate the user, by enhancing their interactive experience. Saposnick et al (2010), Crosbie et al (2008) and Saposnick and Levin (2011) also argue that VR has the potential to motivate and encourage survivors of stroke to enhance participation in meaningful functional upper limb movements during gameplay, so that the participant achieves the desired intensity or dosage. (Merians et al (2002) state that the VR interactive experience can be individualized, which may make it more motivating Task-specific and context-specific training are well accepted principles in motor learning (Langhorne et al, 2011). Therefore, software designed for VR interventions should be salient and meaningful enough to encourage the massed practice of functional upper limb movements. Joo et al, (2010) argue that the aesthetic and competitive qualities of the VR interactive gaming equipment can enhance the motivation of the stroke survivor. (Joo et al, 2010 p 437) and can help make rehabilitation exercises both fun to play, but also contextual.

Adamovich et al (2009) believe that VR can also be used to enhance sensory-motor learning as it incorporates the visual interactive elements required to enhance the accuracy of planned dexterous movements .and which play an essential role in the reorganisation of sensorimotor neural circuits which facilitate neuroplastic changes that promote functional recovery.. The authors posit that if the sensorimotor areas are stimulated, during the recovery phase, this may then reduce the risk that neural circuits may otherwise deteriorate due to lack of use.

Cameirao et al (2010 p 2) describe how their VR gaming system encourages users to practice bi-manual tasks, whereby they observe virtual limbs capturing and placing spheres that move towards them. The virtual movements are controlled by the user's own finger and arm movements. This observation of virtual limbs that 'mirror the intended movement' is thought to facilitate the process of cortical re-organisation in the pre-motor and motor areas.

Systematic reviews of virtual reality (VR) technology (Saposnick & Levin, 2011; Henderson, Korner-Bitensky & Levin, 2007, Laver et al, 2015) have identified some promising results. In a meta-analysis of 5 pooled RCT's, Saposnick & Levin, (2011) reported that their analysis incorporated RCT's with both immersive and non-immersive types, as well as studies that incorporated commercial computer gaming as the intervention. They found that the effect of VR rehabilitation on motor impairment was significant (95% CI: 1.31 to 18.3, p<0.02), although conversely, the results were not significant when analysed in relation to the specific outcome measures used in the majority of the RCT's (The Box & Block Test, and Wolf Motor Function Test respectively) (p 1384). Many of the studies included in the systematic review were either observational studies with a pre/ post-test design (seven in total), or small scale RCT's (five in total).

The largest RCT, in the review, (Piron et al, 2005) had twelve subjects in each group. Other RCT's included had as few as five subjects in each group. There were however, some methodological differences between the RCT's, as well as a small total number of participants. Not surprisingly, the authors could not make conclusions that can definitively inform current practice although they called for further, well designed RCT's.

In a recent systematic review of VR by Laver et al (2015), data from 37 RCT's with a total of 1019 participants was used in the final analysis. The authors found evidence that the use of virtual reality and interactive video gaming could improve upper limb function, with a Standardised Mean Difference (SMD) of 0.28, and a 95% Confidence Interval (CI) of 0.08 to 0.49. For the 12 studies included in this section of the analysis, several outcome measures of function or activity were used. These included The Wolf Motor Function Test, The Action Reach Arm Test, The Box and Block Test, The Fugyl-Meyer (Upper Limb) Scale. VR (compared with conventional therapy) was also seen to have a moderate significant effect on Activities of Daily Living (ADL), (SMD 0.43, 95% CI 0.18 to 0.69) and a moderate signicant effect on ADL 'when used as an adjunct to usual care (to increase overall therapy time)' SMD 0.44, 95% CI 0.11 to 0.76.(Laver et al 2015 p 18) . Measures of ADL described by Laver et al (2015 p 7) were the Functional Independence Measure (FIM).

Laver et al (2015) concluded that overall the reduced methodological quality of many of the studies included was low or very low, which affected the overall quality of the results of the systematic review. However, Laver et al (2015 p 20) suggest that the evidence from the systematic review suggests that clinicians who have access to VR interventions can be reassured that using it as part of a 'comprehensive rehabilitation program', can be effective. The authors also made several recommendations for researchers. One of the recommendations was that researchers should use common outcome measures. They also recommend measuring motivation to engage in the therapy, and levels of enjoyment.

It notable that although several systems have reached the development stage, (Li et al 2009, and Chen et al,2015), there have been very few studies of VR or commercial gaming interventions completed in the subjects' own homes. Laver et al (2011) identified just one study (Piron, 2009) that used a tele-rehabilitation approach to deliver the intervention in the participant's own home. Another systematic review (Saposnick & Levin 2011) did not mention whether any of the studies they included in their meta-analysis had taken place in participants' homes.

1.7.2 Commercial gaming systems

Popular gaming consoles such as the Nintendo© Wii©, and Microsoft™ X-box©, have mass market acceptability. They are relatively small, storage friendly, portable, and light-weight. They also have aesthetic properties which may enhance their acceptability (Rhodes & Fiala, 2009) Importantly, mass market gaming consoles and software are relatively inexpensive, and they have ‘easily perceived feedback’ (Standen et al (2010) p140. Increasingly they have been used in the context of upper limb rehabilitation for survivors of stroke (Saposnick et al, 2010, Joo et al, 2010). Joo et al (2010 p 438) used an off-the-shelf computer gaming device (Nintendo Wii) with its own games as an intervention in their recent feasibility study.

Although movements involving the shoulder, elbow, arm and potentially the wrist are required to play off-the-shelf systems, functional hand movements, such as ’pinch and release’, are not required to operate the standard Nintendo© Wii© equipment, during game-play. However, in rehabilitation trials, Saposnick et al’s, (2010 p1476-1484) feasibility RCT demonstrated that Nintendo© Wii© gaming systems can be used for upper limb rehabilitation for some survivors of stroke. For those who are unable to grip the games controller, making simple modifications, such as fitting the Wiimote™ into a mitten, or strapping it on using a bandage (Joo et al, 2010 p 438,) allows for gross tracking of the upper limb during game-play.

Another potential problem with commercial systems is that the games themselves were designed for healthy populations and the games and the equipment required to play them may not be entirely appropriate with regard to stroke-specific rehabilitation. Saposnick and Levin (2011) included some commercial games in their systematic review and concluded that there are ‘a variety of non-immersive video game systems developed by the entertainment industry for home use, making this technology less costly and more accessible to clinicians and individuals’. However, the authors (p1381) suggest that although the clinicians have used these games for rehabilitation purposes, the games have not been specifically designed for that purpose. There are risks, such as incurring musculo-skeletal injury as a result of repetitive game play, such as “Wii shoulder”, Wii elbow” and “Wiiinitis”. (Joo et al 2010 p 440)

Wisely, Joo et al, (2010) p 440 acknowledged the risk posed to the vulnerable hemiplegic shoulder joint, suggesting that therapy staff need to ensure that the participants do not experience or suffer pain or adverse symptoms, because the survivor of stroke may have muscle weakness, shoulder subluxation and sensory impairment that make the hemiplegic upper limb susceptible to trauma. The authors also emphasis that the duration of intervention needs to be short and supervision is important. No seizures were reported during their study, however, it was acknowledged as a risk to the population of stroke survivors.

More recent gaming systems, such as the Microsoft® Kinect™ for the X-Box 360® do not require the player to hold a device. However, in the commercial format the games are designed for able bodied persons, and the player generally has to stand upright, and perform gross active synergies of upper body and upper limb movements, (e.g. bowling or table tennis actions) rather than refined, selective or specific movements, as the commercial version has no capacity to differentiate selective finger positions. The Microsoft® Kinect™ also has a drawback in that it requires a relatively large space for it to work which may not be practical in all community dwellings.

Despite these drawbacks, the benefits of similar types of low-cost gaming based technologies are influencing the research and development of adapted versions of off-the-shelf gaming devices. (Standen et al 2011, Chortis 2008, Saposnick et al 2010, King et al 2012, Jordan et al 2013) which utilize the positive qualities of the systems for the purpose of rehabilitation.

1.8 A low cost virtual reality system for home based rehabilitation of the upper limb following stroke

Given the recommendation that rehabilitation should take place in patients' own homes (National Audit Office report: Progress in improving Stroke Care, 2011, Fisher et al 2011, Walker et al 2013) a low cost system was developed by Standen et al (2010) which utilises the favorable qualities of the mass-market gaming consoles and commercial games, such as easily perceived feedback, user acceptability, portability, and storage. It was designed specifically for home-use and used games designed specifically for rehabilitation of the upper limb. In particular, the games facilitate dexterity and function, as well as providing a challenge to the participant. Each of the games has three levels so that they can be adjusted to suit the participants initial upper limb function and dexterity (as assessed by a therapist) and then later altered, to challenge the participant's abilities as they improve throughout the duration of the rehabilitation program.

The different levels of difficulty provide a challenge to the participant, so to ensure that gameplay is stimulating but is not so difficult as to be discouraging. In this way the VR system may also facilitate the user's motivation to continue to participate by providing an engaging, interactive experience (Standen et al 2010). Although not strictly task or context specific, the games are designed to be fun, engaging and meaningful, and in this way the VR system works in a similar way to the Motor Learning principles discussed by Langhorne et al, (2011 p 1695).

The design, based on Nintendo Wii technology, is a comparably low-cost technology when compared with contemporary robotic and other assistive technologies. A 'Virtual Glove' (Battersby, 2008, Barker 2009) has been designed which uses light-emitting diodes (LED) positioned on the ends of the fingers. The diodes are housed in hard plastic casing, attached with made-to measure elasticated strapping (Standen et al 2010 p 143). This allows the system to track the movement and position of the Infra red light emitted from the finger-mounted diodes during gameplay. The games are designed to use functional upper limb movements, such as 'reach to grasp', (useful when reaching for an object in a cupboard) and 'pinch and release' (holding a book or a plate, and placing it on a table), supination and pronation (opening a door, or using a screwdriver), as well as other combinations of these movements which require increased shoulder, elbow and wrist movements.

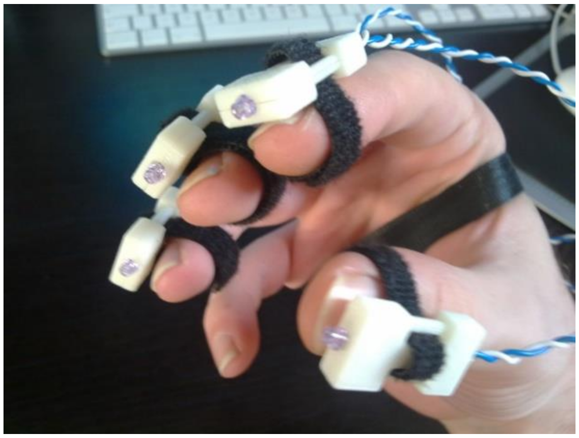

Figure 1: The Wii Glove

This photograph shows the finger mounted diodes attached to the ends of three fingers and a thumb.

In total, four games have been designed, using a six-stage iterative design process, in consultation with survivors of stroke, physiotherapists and occupational therapists. (Standen et al, 2010 p 142, Standen et al, 2012 p 2). Each individual game facilitates the user to produce specific movements, whilst participating in interactive game play with their paretic upper limb. Fig. 1 shows the diodes mounted on three fingers and the thumb, allowing the system to track their movements during gameplay. Only three games were produced in time for this study.

One of the three games was named ‘Space Race’ (see fig. 3 below). The game requires mainly pronation and supination movements of the forearm. Providing the user is able to sustain enough finger and wrist extension for the duration of a game, the system is able to track their position though a range of movement between 0°- 90°, as they navigate a virtual space craft through a series of horizontal and vertical gaps in walls.

A second game, titled ‘Sling Shot’, requires the user to perform pinch/ release movements. The game involves grasping tennis balls and then firing them at a target by releasing them. Increasing challenge is produced by making the user account for wind direction and moving the target further back. https://www.youtube.com/watch?v=WzLcLmvnpw0

A final game, named ‘Balloon Pop’ (see fig. 2 below) involves reach to grasp movements. A balloon has to be grasped as it moves around in space, before being dragged downwards and popped on a spike. The complexity increases in several ways. The grabber that holds the balloon has spikes on at level three, and would inadvertently burst the balloon if grabbed too robustly. The speed at which the balloons move arounds also varies, depending on the level the player is playing at.

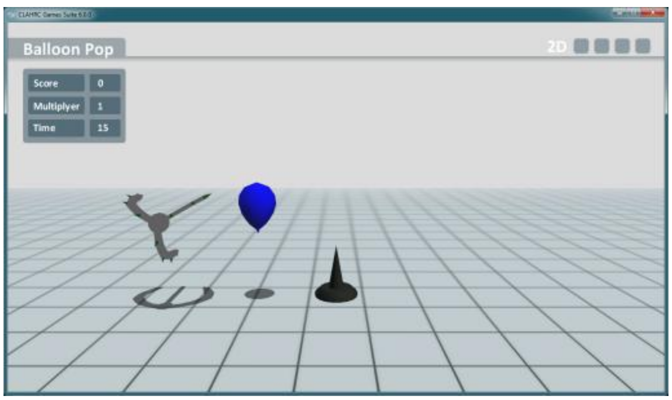

Figure 2: Screen shot of 'Balloon Pop' game

A screen shot of the Balloon Pop Game. The player performs reach-to-grasp movements, to grasp a balloon, and drag it down to the pin to ‘pop’ the balloon.

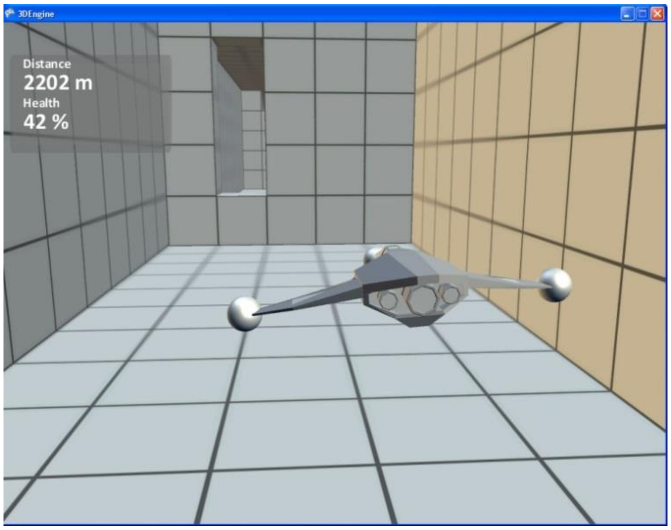

Figure 3: Screen shot of 'Space Race' game

This is a screen shot of the ‘Space Race’ game. The player is required to navigate the spacecraft through gaps in the walls, by rotating their forearm.

The system can be calibrated to the individual’s own level of ability, with regard to the amount of dexterity and functional range of movement the user has. This way, even those with limited ability can perform a movement sufficient to achieve a score. For example, initially quite a large gap between thumb and fingers would qualify as a ‘grasp’ but as the user improves, the distance between the thumb and fingers necessary to gain a score can be reduced. Only those survivors of stroke who have not yet regained enough active upper limb movement and hand function, or are unable to extend their fingers , extend their wrist, or move their thumbs (or for other reasons such as spasticity, oedema, pre-existing upper limb pathology, or severe pain) would be prevented from playing all of the games.

Participation at the optimum intensity levels required to drive neuroroplastic re-organisation, and make significant improvements in motor function and the performance of daily living activities (Langhorne, Bernhardt, & Kwakkel, 2011) requires the user to be adherent to an intensive regimen. To make significant improvements in upper limb motor function, the recommended exposure is thought to be in advance of ’16 hours augmented to usual care’ (Kwakkel et al 2004), or ’45 minutes per day (per therapy discipline)’ (National Institute of Clinical Excellence – Guidelines for Stroke Rehabilitation- 2013). Adherence as discussed in the previous section (1.6) is more likely to be achieved if there is flexibility built-in to the treatment regimen (Clay and Hopps, 2003). Being able to use the system at a time agreeable to the user’s own needs could be an effective way of improving adherence.

Stroke rehabilitation is a complex intervention, (Langhorne et al, 2011 p 1695) which requires thorough, multiple-faceted evaluation. For example, any improvement in upper limb movement and dexterity can be measured in terms of the range of movement, or the speed of movement, or the functional ability of the upper limb to perform certain task. However, the aim of rehabilitation is usually to increase participation and independence in meaningful and purposeful activities. The Wii STAR intervention’s aim was to reduce impairment, and promote participation through the medium of intensive task-focused upper limb rehabilitation. In order to fully evaluate the potential outcomes and possible benefits of the Wii STAR intervention, a broad range of outcome measures was deemed to be required.

1.9 Outcome measures – measuring the efficacy of interventions targeting the impaired upper limb

Kwakkel et al (2008) suggest, is that to detect change or improvement that is meaningful in the context of upper limb function, hand dexterity, and participation in meaningful daily living activities, appropriate and sensitive outcome measures should be utilised. The authors identified a need for outcome measures to be both sensitive and appropriate to the context of the aims of the rehabilitation process. Kwakkel et al (2008 p 117) argue that 'It is common knowledge that the Functional Independence Measure (like the Barthel Index) (do not) measure dexterity of the upper paretic limb properly', and therefore 'scales that measure dexterity specifically, such as the Action Research Arm test, the Wolf Motor Function Test, and the Jebsen Test or Nine-Hole Peg Test, are preferred' (Kwakkel et al, 2008 p171). In this sense, choosing outcomes measures involves a decision making process, whereby several factors need to be evaluated. An important step in the decision making process with regard to selection, is evaluating the psychometric properties of outcome measure.

The psychometric properties of outcome measures include their interrater, and test-re-test reliability, their content validity and criterion related validity (Connell and Tyson, 2012 p 222,) and also their sensitivity and responsiveness to detecting change. These properties are crucial to ensuring scientific objectivity and rigor, both in the context of research and clinical utility. Field (2009 p 792) describes reliability as 'The ability of a measure to produce consistent results, when the same entities are measured under different conditions'. The reliability of an outcome measure is crucial to its scientific worth (Cronbach, 1951 p 297). Without strong reliability, the value of the outcome measure as a scientific research instrument is questionable.

The inter-rater reliability is how reliable the test is when different researchers use the instrument. Bennell et al (1998 p 175), explain: ‘Many measures may be taken by the same and by different therapists in the management of one patient. Therefore it is necessary to determine if the measurements used are reliable both within and between therapists.’ The test-retest reliability of an outcome measure is its ability to consistently measure the same variables in the target population, if repeated in exactly the same way at another time.

The validity of an outcome measure is described by Field (2009 p 795), as ‘a test measures what it sets out to measure’. Validity can be sub-categorized into Content Validity , which is described as ‘evidence that the content of a test corresponds to the content of a construct it was designed to cover’ (Field, 2009 p 783) and Criterion Validity, which is described as ‘evidence that scores from an instrument correspond with, or predict concurrent external measures, which are conceptually related to the measured construct (Field, 2009 p 784).

Connell and Tyson (2012 p 225) suggest that for outcome measures to be valid, they need to be meaningful, and therefore measure what is important. However, establishing validity may challenge reliability. Connell and Tyson (2012 p 225) explain: ‘Given the primacy of patient-centered rehabilitation, there is a clear need to accurately and robustly measure activities that are meaningful and important to an individual. However, the more individualized an activity or treatment goal, the less generalizable it is likely to be, which defies standardization in an objective measurement tool'.

The sensitivity of a measure is its ability to detect change (Igl, 2007 p 13,). Synonyms for sensitivity are 'responsiveness', 'longitudinal validity' and 'evaluative validity' (Igl, 2007 p 13,). Considering the sensitivity is important, as measures that are not sensitive enough to measure (a) change in general, or (b) a clinically significant change , or (c) the change of a construct of interest (Terwee et al, 2003 p 349-350) would not be useful scientific instruments in the given context.

There are numerous outcome measures available to both researchers and clinicians working in the field of stroke. Such variety, in terms of the measures used, can make meta-analysis of data from upper limb RCT's complex and difficult to synthesise accurately (Saposnick and Levin 2011 p 1385, Kwakkel et al, 2008 p 118, Laver et al, , 2012 p 18, Connell and Tyson, 2012 p 221,), thus making comparison of trials difficult and limiting the development of the evidence base for rehabilitation. Laver et al (2011) also call for consistency across studies, in terms of using agreed outcome measures.

One way of identifying appropriate outcome measures in upper limb rehabilitation is to use the World Health Organisation's (WHO) ICF-DH2 (Buma et al, 2013 p 718) Table 1 uses the ICF-DH2 to demonstrate how some of the frequently utilised outcome measures for stroke can be used to evaluate the different impacts of the stroke. The table categorises the impact of stroke into: Pathology (type of stroke), Body structure and function (Impairment) Activity (Disability) or Social Participation (Handicap). The outcome measures highlighted in the model can be completed before and after a single intervention or a service level intervention aimed at ameliorating the effects and consequences of stroke, with the aim of measuring the intervention's efficacy.

Table 1: The World Health Organisation - International Classification of Functioning Disability and Health Model applied to the impact of stroke.

Pathology	Body Structure and Function	Activity	Participation	
Ischaemic stroke (about 80%) **Haemorrhagic stroke (about 15%)**	**Most Relevant Body Functions Affected (Impairment)**	**Most Relevant Activities Affected (Disability)**	**Most Relevant Restrictions in Participation (Handicap)**	Categories affected by stroke
	Mobility and stability of joints **Muscle power, tone and reflexes** **Muscle endurance** **Control of involuntary movement**	**Washing and dressing** **Eating and drinking** **Meal preparation** **Transporting / carrying objects** **Writing** **Housework** **Using Technology** **Communication**	**Recreation and leisure** **Doing housework** **Remunerative employment** **Social participation**	
Diagnostics **CT** MRI **Examinations**	**Fugyl-Meyer Motor Assessment** Nine Hole Peg Test **Motor Assessment Scale** Motricity Index Chedoke McMaster Stroke Assessment – Impairment inventory **Wolf Motor Function Test** Action Reseach Arm Test	**Wolf Motor Function Test** Motor Activities Log **Barthel Index** Frenchay activities Index **Functional Independence Measure** Action Reseach Arm Test **Nottingham Extended Activities of Daily Living Scale**	Nottingham Extended Activities of Daily Living Scale **Motor Activity Log** Euroqol 5D **Stroke Impact Scale** SF 36	Outcome measures or scales of outcome

These OM's are categorised in three of the four vertical columns in Table 1.0. However, there is some overlap between categories. For example, some measures that are used for evaluating outcomes for participants at the level of Body Structure and Function (Impairment) may also be able to measure outcomes at the level of Activity (Disability). Similarly, other measures that measure Activity also overlap into the category of Participation (Handicap).

For example, the Wolf Motor Function Test (WMFT) (Taub et al, 2011) has two scales. One is an observed measure of movement and the second, a timed measure of various motor functions that are required for daily living tasks. It has components that will measure impairment of movement, yet it also has components that clearly measure upper limb functions (reaching to pick up a pencil, or a cup) and in that sense, they are functions required to regain further independence in daily living tasks.

The Motor Activity Log (MAL) (Taub et al 2011) (See Appendix p 147) and the Nottingham Extended Activities of Daily Living scale (NEADL) (Nouri & Lincoln, 1987) have components that may be used to measure specific daily living activities such as preparing a meal. However, preparing a meal may also apply to participation in a social role or work role, such as being a parent (in the sense that one would prepare food for children) or alternatively, in the role of a housekeeper. In the context of work; meal preparation could be identified as the role of a cook. The NEADL overlaps into 'extended' activities, which in a broader context could be 'work' and 'leisure', and therefore fits in the ICF-DH2's 'participation' category. Another example is that one of the items on the NEADL asks about walking on uneven ground, which could mean walking along a pavement to the cinema, or walking in the park, and where another item that asks the patient about driving independently, this could be viewed in the context of returning to a work, social or a leisure role. The ICF-DH2 is therefore a useful tool for researchers and clinicians to use when considering how to evaluate the effect of an intervention. However, the discussion above illustrates that some outcome measures do not all fit neatly into one of the ICF-DH2 categories, as some measures arguably fit into more than one.

1.9.1 A range of outcome measures are required to evaluate upper limb rehabilitation

As discussed in section 1.2, the range of possible impacts resulting from a stroke mean that in terms of rehabilitation, evaluation requires outcome measures that address both specific impairments, but also more globally, explore how impairments impact on participation in meaningful activities.

In relation to assessing technology based interventions, Saposnick and Levin (2011) recommend that an evaluation should include function, activities, and social participation. Different tools (eg, scales) are available to assess each domain. However, outcome measures which incorporate activity, participation, social interaction and quality of life are perhaps underrepresented in studies where VR technology is the main intervention. Saposnick and Levin (2011 p 1385) noted that in the studies they reviewed, the main outcome measure was motor function using WMFT or the Box and

Block Test in 6 of 12 studies, and only 1 included social participation/quality of life (Stroke Impact Scale).

Connell and Tyson (2012 p 225) agree with Langhorne et al (2011 p 1695) citing Kwakkel et al (2004), Murphy et al (2009) and Levin et al (2009[3]), that evidence for 'true neurological repair' is scarce, and that functional recovery is largely down to the patient adopting adaptive strategies that compensate for impaired body functions. If this is the case (as current evidence for neurological rehabilitation would suggest), then there is a requirement to evaluate interventions that focus on measuring outcomes levels of 'activity' and 'participation' (as described by the WHO ICF-HD 2 (2001)). Therefore to further understand and adequately evaluate the potential benefits of the interventions available, there needs to be a range of outcome measures that capture change in the respective domains of the WHO ICF-2.

Measures of participation in daily living activities that incorporate elements of self-care, domestic activities, and other general or extended daily living activities, such as the Nottingham Extended Activities of Daily Living scale (Nouri & Lincoln, 1987), the Barthel Index (Collin et al 1988) and the Functional Independence Measure (Pollack et al 1996) do not address improvements in the upper limb after stroke specifically, and indeed, would probably be more likely to be sensitive to improvements in lower limb functioning (Kwakkel et al, 2004 p 2533). The reason for this is that any improvements in mobility allow more independent access and therefore the opportunity for independent participation in ADL (e.g., toileting, washing, bathing, meal preparation or other housework) and finally, for the most independent, participation in outdoor mobility and leisure activities. All of the aforementioned activities have corresponding items on the respective ADL measures discussed.

However, there are drawbacks with current measures of ADL. For example, none of the ADL measures have questions which specifically ask whether the paretic upper limb was used or included in the completion of the activity. Therefore any improvements in upper limb use during participation in ADL, which may have been attributed to the effect of an intervention, would not be captured by using the aforementioned outcome measures (Hammer and Lindmark, 2010 p 1185)

1.9.2 The Motor Activity Log – an Upper Limb outcome Measure at the level of Activity and participation

Since it was first mentioned in a publication in 1993 (Taub et al, 1993) there has been an incremental increase in the use of the Motor Activity Log (MAL) to measure interventions targeting the more impaired upper limb in survivors of stroke. Authors, including Blanton et al (1999), Wolf et al (1999), Liepert et al (2000), van de Lee et al (2004) and Hammer and Lindmark (2010) have all used or evaluated the use of the MAL.

The MAL was originally designed to measure the participants' improvement in the practice of daily living activities with their affected upper limbs, in a study where the intervention group received Constraint Induced Movement Therapy (CIMT, discussed in section 1.5). The MAL does this by measuring patients' perceptions of how much, and also, how well they use their more impaired upper limb when participating in specific daily living activities.

The MAL is a semi-structured questionnaire which asks questions about whether the participant has used their paretic upper limb during specific daily living activities over the course of the past week (or, occasionally, since the questionnaire was last administered). If the participants indicate that they have used their limb, they are then asked to rate how often they used the limb ('Amount of Use' AOU) compared with the use of the limb prior to their stroke and how well they believe that their limb performed (Quality of Movement – QOM), giving themselves a score between 0 and 5, with '5' relating to a high score (normal use, no difficulty) and '0' being the lowest rating (unable to use, didn't use) .

However, there have been other versions of the MAL with different numbers of items on the scale. According to Uswatte et al (2006) the original version of the MAL had 14 items. Subsequently, 16 items were added and four were replaced to include activities of daily living (ADL) that might be accomplished by individuals with greater impairment of their hemiparetic arm than participants in early CIMT studies. However, the fact that there are different versions, is perhaps a little confusing, and could pose difficulties in selection for researchers. Uswatte et al (2006) point out that there are difficulties in discerning which is the best measure and also comparing them directly. Their data did not allow them to compare the MAL-28 with the relatively brief MAL-14 because only eight of the MAL-14 items are included in the MAL-28.

In terms of its psychometric properties, although Van de Lee et al (, 2004) p 1411 reported that 'Claims of good internal consistency, test–retest reliability, and inter-rater reliability were not supported by published data, Uswatte et al (2005) and Uswatte et al (2006) did report data on the psychometric analysis of the MAL's 14 and 30 Item versions, respectively.

The research by Uswatte et al (2006) was initially completed on the (then) 30 item scale. However, two items had less than 20% response rate. One Item was 'writing on paper', the other was the item related to putting (either) shaving cream or face cream (on the face), with the more impaired hand. Uswatte et al (2006) report that they believe that the shaving / face cream item had a low response because many men switch to electric powered shavers after a stroke. The low response to the handwriting item was thought to be related to the more impaired upper limb possibly being the non-dominant hand. If so, the participant would never usually write with that hand anyway, thus explaining the lower response rate. Consequently, both of these items were dropped in analysis of scores for all subjects which explains why they refer to a 28 item version of the MAL..

Uswatte et al (2005) state that the MAL is a valid outcome measure specifically when measuring upper limb use, for survivors of stroke with mild to moderate hemiparesis, for use with subjects or participants outside of any laboratory setting. Uswatte et al's (2005) evaluation of the 14-item version of the MAL involved testing for construct validity and reliability in two studies. The first study (study 1) randomly allocated subjects into two groups. The intervention group (IG) received CIMT and the control group (CG) received an equal duration placebo of lower limb and fitness exercises with some added cognitive rehabilitation and relaxation (N = 41). The second study (study 2) gave participants in the IG (N = 27) an automated version of CIMT ‘Autocite’ (Taub et al 2005, cited in Uswatte et al 2005, p 2496). In their study, Uswatte et al administered the MAL scale to both carers and patients.

The authors reported ‘Study 1 indicated that the patient MAL QOM scale was internally consistent (Cronbach $\alpha = 0.87$), and was reliable, stable, and very responsive. Convergent validity of the patient QOM scale was supported. The Intraclass Correlation between patient and caregiver scores (pre-treatment) was 0.52 ($p< 0.01$); for changes (from pre-treatment to post-treatment), it was 0.7 ($p < 0.0001$). The patient AOU and caregiver QOM and AOU scales were internally consistent (Cronbach $\alpha = 0.82$), stable, and responsive but were not reliable’. Uswatte et al (2005) also reported that ‘The Pearson correlation between this scale and the accelerometer recordings for test 1 was 0.7 ($P< 0.05$); for changes from test 1 to 2, it was 0.91 ($P<0.01$; Figure). Internal consistency was adequate (Cronbach α 0.81), and responsiveness was very high (Table 2 The authors also reported that results from study 2 supported the concurrent validity of the patient QOM scale.

In their discussion Uswatte et al (2005 p 2495), argue that the lack of agreement at baseline between caregiver and patient QOM scores was higher when evaluating treatment change (ICC = 0.7) than when evaluating arm use before treatment (ICC =

0.52). Uswatte et al's (2005) explanation for the weaker agreement beween the carer and patient scores at the outset, was that there are possible differences in the frame of reference between individual members of caregivers and patients arranged I pairs. However, the authors were not unduly concerned by this. They argued that, (p 2495) on analysis of change from pre-treatment to post-treatment scores whatever differences in frames of reference existed (at baseline) were distributed randomly and cancelled each other out when the data were aggregated.

In the 2006 study the other outcome measures were (i) accelerometry measurements and (ii) the Stroke Impact Scale (SIS) (Duncan et al, 1999). Uswatte et al (2006 p 1189) concluded that their findings supported the use of the MAL as an appropriate, reliable and valid outcome measure for individuals with subacute stroke , and that it can be used to 'assess the real-world effects of upper extremity neurorehabilitation and detect deficits in spontaneous use of the hemiparetic arm in daily life'

The University of Alabama's Constraint Therapy team (Taub et al, 2011) published results of further analysis of the 30 Item MAL. The study indicated that the 30 item MAL is psychometrically robust: inter-test reliability for the 2 MAL scales = .99 and .96; correlation of the scales of the MAL with the Abilhand Test - .88 and .71. These findings were published without the omission of the two items in the 2006 paper by Uswatte et al. However, there has been an amendment to item 24 (handwriting), it now has some administration guidance. (see appendix p 135, 30 Item MAL).

Park et al (2008), report that a clinically meaningful difference for the MAL QOM scale, (in relation to patients who met the inclusion criterion for their CIMT EXCITE study, p 487) was a score of 3 or more at posttreatment. The results reported by Uswatte et al (2005) are the only ones to consider Criterion validity and that was only for the Quality of Movement (QOM) with a correlation of 0.72 with the Stroke Impact Scale hand function scores.

However, some other studies have critiqued the MAL. Michielson et al (2012) that. Even though the MAL has been validated against an objective measure (accelerometry) it is still a subjective instrument that focuses on how well, and how much patients use their most impaired arm in a defined category of activities. Michielson et al (2012) suggest that the MAL is therefore not without limitations. They argue that, because of its subjectivity, the MAL cannot measure participation in activity as well as a technological device such as an accelerometer.

The MAL was designed to measure the moderately impaired population of survivors of stroke who meet the movement inclusion criteria for CIMT i.e. that they can achieve >20° of active wrist extension and at least >10° of metacarpo-phalangeal, and inter-phalangeal joint extension in all digits, at the pretreatment stage. This therefore raises the question of the validity of using the MAL for any populations of survivors of stroke who cannot achieve this active range of movement at baseline, and in this sense is perhaps a limitation of the MAL.

The MAL's longitudinal construct validity has been critiqued by Van de Lee et al (2004 p 1409 -1414). 61 chronic survivors of stroke were either given intensive upper limb rehabilitation for two weeks (with or without restraint), or they received intensive bi-manual upper limb rehabilitation. However, records were lost for 5 participants due to disorganization, as reported by the authors. The participants were tested twice at baseline or (prior to commencement of the intervention), then were re-assessed at 1 week follow up using the MAL (QOM and AOU) and the Action Reach Arm Test (ARAT, Yozbatiran et al 2007) as well as a Global Change Rating scale (GCR) (Cited in van de Lee et al, 2004 p 1411) .

Of the 56 participants who completed all the assessments (and for whom all data were available) data from the MAL were tested for internal consistency, test-retest reliability, cross-sectional construct validity and longitudinal construct validity (measure of change scores). The authors report that the MAL has high internal consistency (AOU Cronbach $\alpha = 0.88$ and QOM Cronbach $\alpha = 0.91$) and that there was reasonable Test-Retest agreement (Bland and Altman method). There were concerns over the longitudinal construct validity when comparing MAL and ARAT change scores between baseline and follow up (1 week after intervention).

The authors argue that it is a concern that despite the MAL and ARAT correlating significantly at baseline (Spearmans ρ 0.63, $P< 0.001$), the correlation of change scores between the MAL and ARAT was not significant (Spearmans ρ 0.16, $P < 0.23$). Van der Lee et al state that 'considering the correlation between the baseline scores on both measures, the lack of correlation in the change scores is surprising.'(van de Lee et al 2004 p 1413). Hammer and Lindmark (2010 p 1191) also reported that their findings show that the MAL did not correlate as strongly with other outcome measures on change scores. However, the authors conclude that the MAL is a responsive measure of daily hand use for patients in the sub-acute phase of recovery after stroke.

However, Uswatte et al (2005) refute Van der Lee et al's claim that the MAL lacks longitudinal construct validity. Uswatte et al argue that the MAL was not designed to correlate with the Action Reach Arm Test (ARAT) over change, when measuring the effect of CIMT. They state that (p 2495) 'This approach is flawed because the ARAT is a measure of motor ability as opposed to use, and, as noted previously, CIMT therapy has differential effects on these two parameters.'

The MAL is recognised by Wolf et al (2006) and Uswatte et al (2005) as being a valid and reliable tool for measuring patients' perceptions of their upper limb performance in daily living activities, which involve the use of the paretic limb. Uswatte et al (2005 p 2493) assert that 'The participant MAL QOM scale can be used exclusively to reliably and validly measure real-world, upper-extremity rehabilitation outcome and functional status in chronic stroke patients with mild-to-moderate hemiparesis.'

Unlike more generalized measures of performance in daily living activities, such as the NEADL, and the Barthel Index, the MAL is a measure which can be used to explore how the impact of an intervention designed to facilitate recovery of upper limb function following a stroke, translates into the participant's use of the paretic upper limb during participation in personal, domestic and extended activities of daily living.

To summarise this section, the MAL is potentially a useful measure of the impact of an intervention on participants' perceived uses of their upper limb, during ADL and EADL activities as defined by ICF-DH2's categories of Activity and Participation (Langhorne et al, 2011) . We are therefore suggesting that it is added to a range of outcome measures, with the aim of evaluating outcomes for participants in a randomized controlled feasibility trial, using VR technology for upper limb rehabilitation after stroke.

1.10 Wii STAR:- A Randomised Controlled Trial using VR technology

The Wii Stroke Therapy for Arm Rehabilitation (Wii STAR) feasibility RCT (National Institute of Health ClinicalTrials.gov protocol registration and results system: registration number NCT02637791) was a rehabilitation trial funded through the Collaboration for Leadership in Allied Health, Research and Care, Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL) by the National Institute for Health Research (NIHR). Further details can be found here:http://www.clahrc-ndl.nihr.ac.uk/clahrc-ndl-nihr/research/stroke-rehabilitation/wiistar/index.aspx. One of the aims of the feasibility study was to gather information from the outcomes and drop outs from either group to allow the calculation of the required sample size for a definitive study. This required the researchers to have a range of outcome measures that could be appropriate for the sample, whilst also meeting the standards required in terms of psychometric rigour. The author was a member of the research team with a responsibility for liaising with recruitment sites, recruiting participants, training and monitoring patients' use of the intervention and collecting outcome measures. At his suggestion the MAL was used as a secondary outcome measure and evaluated as part of this MPhil study.

1.11 Aims of this MPhil thesis:

As an amendment to the original protocol of the Wii STAR VR upper limb project, the MAL was added as a fourth outcome measure, to explore the aims detailed below.

Specifically, with regard to the effectiveness of the Motor Activity Log, as used in the context of a single-blinded feasibility randomised trial involving Virtual Reality technology:

1. Is there a bigger increase in Motor Activity Log Amount of Use (AOU) and Quality of Movement (QOM) scores in the group receiving the Wii STAR intervention compared to the control group? i.e., does intervention cause them to use their arm more in other activities?

2. Does a change in MAL (AOU and QOM) scores correlate to a change in other outcome measures, namely the Wolf Motor Function Test (WMFT), the Nine Hole Peg Test (9HPT), and the Nottingham Extended Activities of Daily Living Scale (NEADL) at four weeks, and eight weeks after the baseline assessments?

3. Within intervention group is there a correlation between use of the Wii STAR intervention (time spent playing/ exercising using the WiiSTAR equipment) and a change in the MAL subscales ?

Chapter Two

2.0 Method

2.1 Design

A feasibility single-blind two group randomised controlled trial comparing a home based virtual-reality intervention with usual care.

2.2 Participants

Participants of the Wii STAR study who were recruited, were all aged 18 years or over. To meet the inclusion criteria, all of the participants had to have a confirmed diagnosis of stroke and to have completed any other intensive rehabilitation (intermediate care, early supported discharge). The participants still had to have some residual impairment of their arm. Potential participants were excluded if they had no detectable upper limb or arm movement, or if they had any premorbid disability of their upper limb, or hand function. They would also be excluded if they had any severe (symptomatic) arm or shoulder pain, or if they had any severe visual impairment. Any potential recruits to the study were excluded if they had any other neurological condition, such as a traumatic brain or head injury or if they had multiple sclerosis.

Also, potential participants were excluded if they had an unstable medical condition, psychiatric illness, or epilepsy triggered by screen images. Finally, potential participants were also excluded if they were fitted with a cardiac pacemaker, unable to tolerate sitting in a chair for 30 minutes, unable to follow a two-stage command, or if they were living in a care home.

Other exclusion criteria were severe cognitive difficulties (as screened by the referring therapist or their team), not being able to communicate in English language or having a severe visual impairment. Patients with aphasia were not usually excluded, unless their condition was so severe, as to prevent them from being able to comprehend the instructions required to use the Wii STAR equipment, even with support from a spouse, partner or carer.

2. 3 The Intervention

As described in section 1.7 of this thesis, a system had been designed by the Wii STAR research team to facilitate intensive massed practice of functional upper limb movements. Full details of the system have been described in other journal articles (Battersby, S., et al 2008 (cited in Standen et al, 2012); Burton, A., et al., 2011; Standen, P., et al., 2010, 2011, 2012, 2014, & 2016). As described earlier in section 1.7, the system involved the utilization of the glove-like device which was fitted to the impaired hand of the participant, allowing them to play three bespoke interactive VR games without having to hold a handset or console. The games had been designed specifically to facilitate the intensive practice of functional upper limb and hand movements during interactive gameplay. These movements involved reach-to grasp, pinch and release and pro/supination movements of the forearm, wrist and hand. Figure

4.0 below shows a participant using the Wii STAR equipment. A Wiimote is positioned on one side of the PC screen. The Wiimote is mounted on the table. It acts like a camera, tracking the infra-red light emitted from diodes, which are attached to three of the participant's fingers and also the thumb with small or elastic straps. The diodes are powered by a small battery pack, which is mounted on the back of the participant's hand.

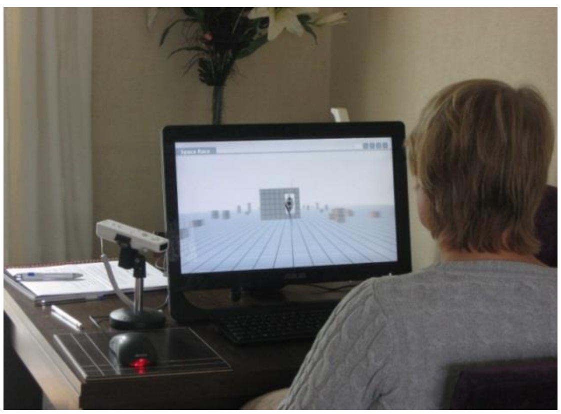

Figure 4: Shows the pc and wiimote

The photograph above shows how the PC is set up on a table in the user's own home.

As described in Section 1.7, the software for three different games, each requiring the participant to use different selective, functional movements, was developed by the research team from Nottingham Trent University (Standen et al 2010). Those participants in the intervention group had the virtual glove in their homes for a period of

8 weeks and were advised to try to build up to using the system for a maximum of 20 minutes 3 times a day for 8 weeks (Standen et al, 2016)

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2.4 Outcome Measures

The MAL was one of four outcome measures used to evaluate the feasibility of recruiting, randomising, and collecting data, as part of the Wii STAR feasibility randomised controlled trial. The other measures; the Wolf Motor Function Test (WMFT), the Nottingham Extended Activities of Daily Living scale, (NEADL) and Nine Hole Peg Test (NHPT) were selected as discussed in section 1.9. The MAL was chosen as an additional outcome measure to capture patients' perceptions about the use of their impaired upper limb in daily living activities.

2.4.1 The Motor Activity Log (MAL)

The Motor Activity Log (Taub, et al 2011) is a researcher-administered set of questions, which uses a 6 point ordinal scale (Lin, K., et al, 2009) to measure any relevant change in participants' self-reported use and function of their upper limbs before and after a rehabilitation targeting the impaired upper limb. The MAL measures how well and how often the survivors of stroke report that they use the limb during performance in daily living activities . In the context of a controlled trial, the MAL has been used to capture any differences between those who receive the intervention, and those who are allocated into the control group (Park, S-W., et al, 2011)

The version of the MAL selected for this project is the 30 item questionnaire version.

The 30 item version was selected, following initial discussion with Professor David Morris, a member of the CIMT research team based at University of Alabama (USA). Professor Morris advised that the 30 Item version had been the one used for the EXCITE study. The authors of the EXCITE (Wolf et al 2006) study believed that this 30 item version of the MAL was the most comprehensive and psychometrically robust and stable version. The 30 Item version is freely available here: https://www.uab.edu/citherapy/images/pdf_files/CIT_Training_MAL_manual.pdf

There are two distinct sub-scales named separately as the Amount of Use (AOU) and Quality of Movement (QOM) subscales .

2.4.2 Subscales of the MAL

the Amount of Use subscale (AOU) measures how often participants use their impaired upper limb, when considering performance in daily living activities over the duration of the previous week, compared with how often they used the limb for specific activities of daily living before their stroke. The Amount Of Use (AOU) subscale is scored out of 0-5, with 0 being “Did not use my weaker arm (not used)” and 5 = “Used my weaker arm as normal, as before the stroke (same as pre-stroke) ”.

The other subscale is the Quality of Movement (QOM) subscale which asks participants to rate how well they are using their impaired upper limb when considering their participation in specific items such as “switch on a light switch ” or “Open a drawer“, at any given stage in their recovery. For example, a score of 0 represents “I did not use my arm at all for this activity (Not Used)”, a score of 3 = “My weaker arm was used for that activity, but the movements were slow or made with some effort (fair) “and a score of 5 = “the ability to use my arm was a good as before the stoke (normal)”.

For the current project we also used the number of MAL activities (or items) attempted.

On the first administration of the MAL, the participants are given instructions in relation to the separate subscales, with verbal illustrations of how they may rate themselves using the ordinal scores. A distinction is made between the two scales, and the assessor checks that the participant has made the distinction between the two scales. To assist the participant in recognising that there is a difference between the two subscales, the assessor (or tester) is asked to remind the participant about the difference. This extract from the MAL training manual (Comment 3, on page 7, Taub, E; et al 2011) illustrates how the difference should be highlighted “Remember that I am asking you to rate something different on this scale, the How Well Scale, than you did before on the Amount Scale. Before you were supposed to rate how much you used your more affected arm. Now I would like you to rate how well you used your more-affected arm, if you did use it.”

2.4.3 The MAL: Negotiation with the participants to establish a frame of reference

During the initial (baseline) assessment, the assessor also assisted the participants in establishing a congruent and relatively accurate construct of the rating scales. The MAL's narrative and administration notes (see pages 152 – 175 in the Appendix) encourages a negotiation between the participant and the assessor, with the aim of reducing the occurrence of the participant greatly over estimating, or underestimating their performance. For example, the MAL's training manual states:

"When a clear disparity exists between a participant's QOM rating and what the tester has observed concerning the subject's motor ability, the tester should explain the meaning of the HW rating scale for the task in question with examples being given for each step, especially those that focus on the HW rating in question (e.g., "*You rated that activity a "3". However, you moved your arm very slowly to do the activity. So, for this project that would be more like a "2". Do you agree?"*). Participants will usually be influenced by the tester's explanation. If they are not and they continue to reiterate the original estimate, the tester should politely continue the discussion until the patient accepts the laboratory/clinic's frame of reference." (Taub, E., et al, UAB CI Therapy Research Group, page 5, 2011)

The MAL's authors recommend that the MAL is used to measure carers' perceptions of how well and how often their respective participants use their paretic upper limbs following a stroke. Taub et al (2011) state that the results can then be used to compare participants and carers perceptions.

2.4.4 The Wolf Motor Function Test

The Wolf Motor Function Test (WMFT) (Wolf et al 1989, Taub et al 1993) was selected by the research team on the basis of its (i) strong psychometric properties (Morris et al, 2001) and its (ii) applicability, with regard to evaluating intensive interventions that target the effects of upper limb paresis following a stroke (Wolf et al 2008). The WMFT has two separate sections. There is a section with 16 timed movements and functions of the upper limb, plus a grip strength test. The second component is the Functional Ability Scale. The latter scale was not used for this study, as it would have involved complications including extra training for the research team to ensure reliability and validity. Using the Functional Ability Scale would also have required the research staff to film participants as they completed the timed task. For this study, researchers recorded individual item times as the participants completed the 16 timed items. The final time score used was the median time required for all timed tasks executed. (Taub et al 2011).

For the grip strength test (WMFT Grip) the mean of three Dynamometer readings of grip strength exerted (kg) were recorded. (Taub et al, 2011)

2.4.5 The Nine Hole Peg Test

The Nine Hole Peg Test (NHPT) Mathiowetz et al (1985), CITED IN Connell and Tyson (2012) was selected as a measure of upper limb dexterity. Again, the NHPT generally has good psychometric properties. Connell and Tyson (2012) describe its validity and test-re-test reliability as strong and it has been widely used in upper limb research as a measure of dexterity and upper limb function (Sunderland et al 1989, Chen et al 2009 and Feys et al 2002, all cited in Connell and Tyson, 2013, p221- 227). The test involves picking up small pegs from a bespoke container and inserting them into the nine small holes on a bespoke peg board. Then, without pausing, all the pegs have to be retrieved and placed back into the container. For this study the scores used were the individual times taken to complete the test with the more affected upper limb in seconds.

2.4.6 The Nottingham Extended Activities of Daily Living

The Nottingham Extended Activities of Daily Living scale (NEADL) (Nouri and Lincoln, p 301-305, 1987) was selected as a measure of function and participation. It has been broadly used in Stroke research. It has good responsiveness (Standardized Response Mean (SRM = 0.9) and it also correlated strongly with the Frenchay Activities Index (Spearman Correlation Coefficient $\rho = 0.8$ before and after treatment) on a study of N= 70 Survivors of Stroke (Wu et al, p 175, 2011).

The NEADL is a 22 item self-administered questionnaire, which asks the participant to score themselves on a 4 point scale ranging from 0 to 3 where zero is scored if the participant is unable to carry out the task and the remaining points on the scale for completing the task with varying degrees of capability. For example, one item asks participants to rate whether and how easily, they can prepare a hot drink. The participants are asked (can you) ‘Manage to make yourself a hot drink?’. If the participants believe they are easily capable of managing this task, they rate themselves as being able to complete the task on their own 'easily', and therefore, they would afford themselves the maximum score of '3' points. If participants are unable to manage the task, they would score a '0' , which equates to not being able to perform the task at all. A task that is achieved, but with some difficulty is given a score of 2, and a task that is achieved with help is given a score of 1. The maximum score is 66 and the minimum is 0.

The total score for each individual participant was recorded for each participant, at each timepoint and subsequently used in the analysis.

2.5 Procedure

Ethics approval was received from the local NHS committee before recruitment started. The initial plan was then to identify and recruit patients from the inpatient stroke unit and outpatient rehabilitation service at Nottingham City Hospital NHS trust. They were receiving on average a combined number of between 80 and 100 new referrals per month during this period. Ward-based Physio and Occupational Therapists and the outpatient neuro-physiotherapists were given instruction on inclusion and exclusion criteria and they were provided with demonstrations of any assessment procedures if required (Standen et al ,p 2, 2016).

As part of the training for the ward based staff, therapists were advised to use the Medical Research Council (MRC) power scale (The Aids to the Examination of the Peripheral Nervous System (Memorandum No. 45 is licensed under the Open Government Licence 3.0., downloaded and used with the permission of the MRC Crown Copyright © 1975). The referring therapists were also asked to complete a general assessment of patients' active range of movement in the more impaired upper limb, (i.e. whether patients had any active shoulder abduction or flexion, whether they could lift their arm against gravity, and whether they had any notable wrist and finger extension, or thumb abduction and extension). This initial assessment helped the therapists to establish which of their patients they might be able to refer for the study. (Standen et al, p 3, 2016).

Referring therapists were also given instruction and information on the procedures for gaining the potential participants' permission for the research team to contact them. . Each of the 47 potential recruits were contacted and asked whether they would be happy for a member of the Wii STAR team to visit them and discuss the consent process. At this point, 18 participants declined, or declared themselves unavailable. In total 29 participants completed the consent process. The consent process included the research assistant or research therapist describing (i) the study (ii) the intervention (iii) the obligations of the Wii STAR team, and (iv) the obligations of the participants, including the expected length of time and amount of time for which would be asked to participate in the study. All the details were also outlined in a patient-friendly information sheet.

To drive up the rate of suitable participants, the research team's steering group advised on attempting recruitment from the following services: Nottingham and Nottingham City Community Stroke teams, Nottingham City Early Supported (Stroke) Discharge team and the Stroke Outreach Service (which provided an early supported discharge service for county patients).Therapists from the teams and services mentioned above were all then contacted and given the same training as described above.

If participants met the referral criteria, informed consent was obtained and baseline assessments were collected during a home visit prior to randomising the patient to either the control group or the intervention group. The control group received usual care. Usual care was variable and dependent on the needs of participants. Some were still receiving intermittent therapy visits, where perhaps they needed advice, reviews or re-assessment. Some of the others required monitoring from one of the community stroke services as they continued with a home exercise plan or other therapy-linked goals.

The randomisation process was managed by a research administrator. A web generated list was used to randomly select a two group randomisation sequence. This sequence was concealed from the research team members. The researcher who had collected baseline data telephoned the randomisation administrator, who was then able to state the next unallocated number on the list. This number determined the allocation of the recruit into either the intervention or the control group. Recruitment began in March 2011 until the end of recruitment in March 2013.

An Occupational Therapist (OT) or a Research Assistant (RA) took out an ASUS ET2011ET slim line, touch screen PC with a 20” screen 16:9, wireless keyboard and mouse, together with a Wiimote with a small angle- adjustable stand to enable it to be mounted at approximately 5” height. Further height adjustment was possible, either by using a smaller stand or by placing the Wiimote below the PC screen. A specially designed IR Glove, with a selection of four different sizes, based on the European norms for the hand sizes of males and females, was then adjusted to fit the participant’s exact hand size by making final adjustments to the glove elastic and therefore ensuring that the infra-red Glove fitted comfortably and securely to the participant’s hand.

The participants in the intervention group received support in three different ways. Firstly, either the Research Therapist (RT) or the Research Assistant (RA) described and demonstrated to the participants how to switch the PC on and connect up the Wii STAR system, using the set up program, and switching on and connecting the Wiimotes. The RT did assess the movement of all the participants who were allocated into the IG. Participants were observed setting up the system and fitting the glove to their more impaired upper limb. Occasionally, carers were also involved in the instruction process if participants had dysphasia or a mild cognitive impairment that may have made the set-up process difficult to achieve.

Participants were shown how to switch on the infra-red glove and check that it was being tracked by the system. They were then observed playing the games using their more impaired upper limbs. They were given advice on posture, positioning and how to be seated when playing the games by the RT. This training procedure was repeated if necessary, until the participants felt comfortable with setting up the system and playing the games. Depending on the initial ability and stamina of the participants the therapists drew up a guidance sheet for each one, advising what games to start with and at what level (Standen et al, 2016)

Secondly, participants were given the telephone number of the research team and asked to call the team if they had any difficulties in setting up or playing the Wii STAR games. Finally, the participants were shown how to use and refer to the information and set-up booklet, which had photographs as visual prompts, as well as simple stage by stage written instructions. The booklet also contained a list of frequently asked questions, with the answers provided.

Participants were visited at home by a research team member when outcome measures could be completed and collected. Outcome measures were taken at baseline (0 weeks) and at midpoint (4 weeks) by the RT or the RA for participants in both groups. It was not always possible to keep the assessor blinded at this stage, as sometimes the equipment may have been visible, or the participants may have unwittingly mentioned the equipment, therefore revealing their allocation identity.

At the 8 week (final) timepoint, all outcome measures were recorded by a blinded assessor. At this timepoint, as the intervention was complete, a research team member collected the equipment from the homes of the participants who had received the intervention, prior to the blinded assessor's visit. The data collected were anonymised and coded, then recorded on an EXCEL spreadsheet, before being transferred onto SPSS for analysis

Each research team assessor had previously completed joint training with the other assessors on the procedure of administering, completing and collecting outcome measurements. This training was completed to achieve an agreed level of competence, and to facilitate the inter-rater reliability. The training included practising the outcome measures with patient representatives on the project steering committee. The research team assessors observed each other as the Outcome Measures (OM's) were administered to the patient representatives. Any queries or discrepancies on administration of the OM's were discussed by the research team and agreement on procedure was achieved.

For those who received the intervention, short semi-structured interviews (Standen et al, 2014) were completed to establish an understanding of the participants' experience in using the equipment and whether the participants had perceived any barriers to use during the 8 weeks that it was left with them in their homes. The interviews were also concerned with whether there were any barriers to achieving the level of recommended use (in terms of gameplay).

2.6 Analysis

2.6.1 Demographic Analysis

The two groups were compared on age using an unpaired 't' test , and on time since onset of stroke using the Mann Whitney U-test as these data did not meet the requirements for parametric analysis.

Fishers Exact Probability test was used to compare the groups on gender split and numbers whose dominant side was affected by the stroke as at least one of the cells had an expected value of less than five.

2.6.2 Outcome measure analysis

The scoring from the outcome measures was entered into SPSS and stored in the trial's data base.

At the beginning of the study, the plan was to use an analysis of Covariance (ANCOVA) to compare outcome measures between the groups, with baseline scores as covariate, and then to analyse separately those who completed outcome measures at 4 weeks and those completing at 8 weeks. However, there was significant heterogeneity of variance ($p < 0.05$) between the groups on comparison scores. The two groups were therefore compared on changes from baseline using the Mann-Whitney U test, and summarised using medians and their inter-quartile range.

As not all of the absolute or change scores for the outcome variables were normally distributed, the relationships between the MAL and other outcome measures were analysed using Spearmans rho.

2.6.3 Wii-Glove data

Records were kept of each episode of play and on how many days it was used out of the total number of days the kit was in the participants' homes. The frequency of the infra-red (Wii-Glove) glove use was collected by the game software data. The data were then collated from individual html files into Excel spreadsheets. These data were then transferred to SPSS v20 for summarising. To calculate gameplay duration, the number of hours of individual use was converted into a percentage. (Standen et al, 2014). As the data were not always normally distributed, the relationships between the MAL and duration of use was analysed using Spearmans rho. .

Chapter Three

3.0 Results

3.1 Recruitment

47 subjects agreed to being recruited into the Wii STAR study initially, however 18 dropped out before giving consent.

2 Participants withdrew after having given consent but before baseline measures were collected. One withdrew because of changing medical symptoms and a new diagnosis of epileptic seizures. A second participant withdrew as they believed that the rehabilitation that they were receiving at the time was sufficient, and didn't want any other or any extra rehabilitation. Twenty seven completed baseline measures. Seventeen were randomly allocated into the intervention group (IG) and 10 were allocated into the control group (CG).

Five participants withdrew from the study before midpoint outcome measures (4 weeks) could be completed. One participant withdrew as they had little interest in computers and had poor general and computer literacy, which were barriers to them being able to use the equipment independently. Another participant was experiencing complex and progressive symptoms such as pain, oedema and paraesthesia throughout the impaired upper limb. The participant was prevented from continuing in the intervention group, after concerns about their safety could not be resolved, following a discussion with their stroke consultant.

A third participant began to experience severe upper limb pain between completing the baseline outcome measures and the intervention beginning. The participant had been referred back to their G.P. and general rehabilitation had been discontinued whilst the cause of the upper limb pain was being assessed. This participant also withdrew. Another participant withdrew due to complex and changing social circumstances, where their main carer had stated that a start date could not be identified, due to unresolved social issues. Finally a fifth participant experienced another suspected stroke and did not want to continue until she had completed and received any outstanding results from further medical assessments, including diagnostic imaging. This left a total N = 22 (N = 12 (54.54%) (IG) and N = 10 (45.45%) (CG) who completed midpoint outcome measures.

A further 4 participants (N = 3 IG, N = 1 CG) withdrew from the study before the final outcome measures could be completed. One of these participants had a deterioration in their medical status. Another participant booked a visit to the USA to see their grandchild and would be staying there for 3 weeks. A third participant's son was diagnosed with a severe illness, and their changing circumstances meant that they felt that they could not continue. Finally, a participant dropped out of the control group (CG) because they had returned to a work role and felt disinclined to continue due to time constraints. Therefore at total of 18 participants completed final outcome measures (8 weeks) (N= 9 IG, N = 9 CG) and N = 17 completed the whole study including participant interviews (N = 8 IG, N = 9 CG) as (N=1) declined to be interviewed after completing the 8 weeks. (See fig. 4).

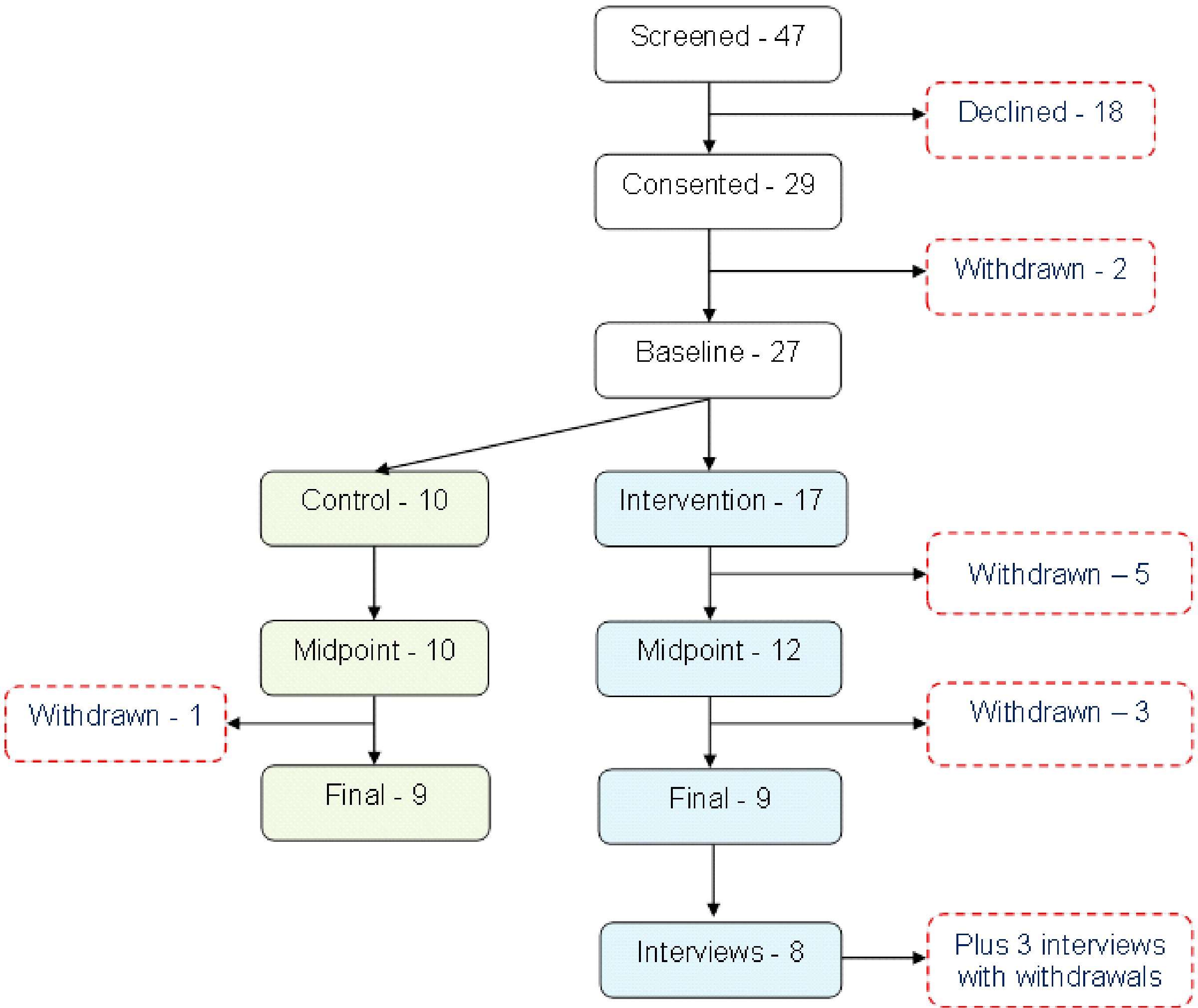

Figure 5. Flow diagram of recruitment

3.2 Demographics

The characteristics of the sample are shown in Table 2.0 There was no statistical difference between the groups in terms of the age, sex of the participants or whether their dominant or non-dominant side was affected. However, the median time since onset of stroke was significantly longer in the intervention group (Mann-Whitney $U = 126$, $z = 2.06$, $p < 0.05$) than the control group

Table 2: Group Characteristics

	Intervention	**Control**
Mean Age (SD)	59 (12.03)	63 (14.06)
Male / Female	8/9	8/2
Median Time Since Stroke 25th & 75th Percentiles	22 Weeks (16.00, 59.50)	12 Weeks (7.75, 20.25)
Dominant Side Affected	13	7

3.3 Comparison of outcome measures between the groups

22 participants completed outcome measures at 4 weeks. There were no significant difference between the groups in the change scores from baseline to 4 weeks for WMFT score, NHPT, NEADL Scale, the MAL Amount of Use, MAL Quality of Movement and Total MAL Activities Attempted. However, there was a significant difference between the intervention and control group ($p < 0.05$, $U = 96.00$, $z = 2.37$) in change from baseline to 4 weeks for the WMFT Grip component, indicating a greater improvement in grip strength in the intervention group. (See **Table 3.0**, p 86)

18 participants completed outcome measures at 8 weeks.There was no significant differences between the IG and CG on change scores from baseline to 8 weeks for the WMFT score, the WMFT Grip, the NHPT or the NEADL scale, However there was a significant difference between the groups ($p < 0.03$, $U = 66.00$, $z = 2.25$) on the MAL Amount of Use score, indicating a greater improvement in the intervention group in the amount of use of the impaired upper limb between baseline and 8 weeks and in the MAL Total Activities Attempted (Total MAL) score ($p < 0.02$, $U = 68.50$, $z = 2.49$), indicating a greater increase in the amount of MAL scale items attempted in the intervention group. (See **Table 3.0**, p 86)

Table 3: Medians of Change Scores from 0-4 weeks and 0-8 weeks, both groups

	4 weeks		**8 weeks**	
Outcome measures	**Intervention**	**Control**	**Intervention**	**Control**
WMFT N Median Range	 12 -0.45 (-1.12, 0.41)	 10 -2.63 (-0.44, 0.77)	 9 0.14 (-1.01, 0.52)	 9 -0.09 (-2.45, 0.25)
WMFT (Grip) N Median Range	 12 2.61* (0.78, 4.37)	 10 0.35 (-12.13, 1.91)	 9 2.37 (-0.77, 5.67)	 9 -0.23 (-10.78, 2.65)
NEADL N Median Range	 12 2.50 (-1.50, 7.50)	 10 2.00 (-2.0, 6.0)	 9 2.00 (-1.50, 7.00)	 9 -2.00 (-7.00, 11.50)
NHPT (aft.) N Median Range	 10 -3.14 (-8.89, 12.78)	 8 -0.57 (-9.97, 2.54)	 7 -2.64 (-5.35, 5.66)	 7 -10.95 (-13.93, -2.79)
MAL Act. Att. N Median Range	 12 2.50 (1.00, 4.00)	 10 2.50 (-1.25, 5.00)	 9 3.00 ** (2.50, 4.00)	 9 0.00** (-1.50, 2.00)
MAL AOU N Median Range	 12 0.52 (0.27, 0.57)	 10 0.43 (-0.02, 0.87)	 9 0.73* (0.17, 1.07)	 9 -0.2.0* (-6.00, 0.42)
MAL QOM N Median Range	 12 0.52 (0.21, 0.65)	 10 0.583 (-0.06, 0.65)	 9 0.53 (0.33, 1.02)	 9 0.00 (-4.67, 0.65)

*Significance $p < 0.05$, ** significant at 0.01, Mann-Whitney U test

3.4 Relationship between the MAL and other outcome measures

The relationship between the MAL and other outcome measures was analysed in two ways. Firstly, an analysis of the relationship between the raw scores of the MAL and the other outcome measures was completed at the three time points, and secondly a comparison of correlations of change scores from baseline to 4 weeks and baseline to 8 weeks.

3.4.1 Raw score correlations of OM's at baseline.

Table 6.0 in the Appendix, presents the Spearman's rho correlations of the MAL subscales (Amount of Use, Quality of Movement and Total Activities Attempted) with the other outcome measures used in the Wii STAR study. At baseline, all of the MAL subscales (Amount of Use, Quality of Movement and Total Activities Attempted) correlated significantly (all probabilities $p < 0.01$) with the NEADL, the WMFT (score) , and the WMFT (Grip). Rather unsurprisingly, each subscale of the MAL correlated with the other ($P< 0.01$). However, none of the MAL subscales correlated with the NHPT (affected side).

3.4.2 Raw score correlations of OM's at 4 weeks and 8 weeks

At 4 weeks, all of the MAL subscales (Amount of Use, Quality of Movement and Total Activities Attempted) correlated significantly ($p < 0.01$) with NEADL. Both Amount of Use and Total Activities Attempted correlated significantly ($p < 0.05$) with the WMFT score, whilst the Quality of Movement subscale correlated significantly ($p < 0.01$) with the WMFT score. The subscales of the MAL also correlated ($p < 0.01$) with each other. However, none of the MAL subscale scores correlated significantly with the WMFT Grip or NHPT (see Table ii in the Appendix).

At 8 weeks, all of the MAL subscales correlated with the NEADL, WMFT Score and each other ($p < 0.01$). However, there was no significant correlation with the WMFT (Grip) or the NHPT (see table 6.0 in the Appendix).
In summary, there were no significant correlations between any of the MAL subscales and the NHPT. All of the subscales correlated well with most of the other outcome measures at baseline, and for the WMFT (score) and NEADL this pattern was maintained at 4 weeks and 8 weeks. However there was was no correlation between the subscales of the MAL and WMFT (Grip), as the intervention period progressed.

3.4.3 Correlations of Change Scores between OM's

Each of the three MAL subscales correlated significantly with each other on change scores from baseline to 4 weeks, and baseline to 8 weeks. However, there was no correlation with any of the change scores on the other scales (WMFT Score, WMFT Grip, NEADL, and NHPT) at either 4 or 8 weeks . See Table 4.0

Table 4: Correlations of Change Scores for the MAL with other Outcome Measures, and between the three MAL subscales

* Correlation is significant at p< 0.05 level (2 tailed), ** Correlation is significant at p< 0.01 level (2 tailed)

		0-4 weeks	N	0-8 weeks	N
WMFT score	MAL AOU	-0.224	22	-0.089	18
	MAL QOM	-0.302	22	-0.106	18
	MAL Act. Att	-0.303	22	0.146	18
WMFT Grip	MAL AOU	-0.226	22	0.007	18
	MAL QOM	-0.154	22	0.067	18
	MAL Act. Att	0.057	22	0.149	18
NEADL	MAL AOU	0.203	22	0.212	18
	MAL QOM	0.135	22	0.180	18
	MAL Act. Att	0.386	22	0.146	18
NHPT	MAL AOU	-0.035	18	-0.073	14
	MAL QOM	-0.052	18	0.055	14
	MAL Act. Att	0.057	18	0.162	14
MAL AOU	MAL QOM	0.651**	22	0.850**	18
	MAL Act. Att	0.772**	22	0.728**	18
MAL QOM	MAL AOU	0.651**	22	0.850**	18
	MAL Act. Att	0.784**	22	0.809**	18
MAL Act. Att.	MAL AOU	0.772**	22	0.728**	18
	MAL QOM	0.784**	22	0.809**	18

3.4.4 Correlations of Absolute Game Duration (Gameplay) and Change Scores: All Outcome Measures.

There was no significant correlation between Game Duration and any of the outcome measures on change scores between 0 to 4 weeks or 0 to 8 weeks, although there was a trend towards a correlation between Absolute Game Duration and Total MAL Activities Attempted at 8 weeks (Spearman's rho, 0.621, $p < 0.074$, 2-tailed) (see Table (7.0) in the Appendix). Those participants with longer game durations were more likely to have greater increases in the reported number of activities attempted.

Chapter 4

4.0 Discussion

4.1 Summary of Findings

The study found that the MAL Amount of Use and MAL Total Activities Attempted scores showed a significant difference between the groups on change from baseline to endpoint, whereas the other outcome measures (with the exception of the WMFT- Grip at 4 weeks) did not.

The MAL correlated with some of the other measures on absolute scores but not on change scores. There was a trend towards a correlation between duration of gameplay with the MAL Total Activities Attempted at 8 weeks. However, there were no other correlations between duration of gameplay and other outcome measures.

The Wii STAR's study had a small sample size and the participants did not use the intervention as much as recommended. With a larger sample, the results may have been different. However, the fact that the MAL did pick up a difference suggests that it is measuring something differently from each of the other measures. For example, the MAL has some constructs that differ from those of the other outcome measures.

Firstly, the WMFT and the NHPT are objective clinical observations of the time it takes to perform a given functional or dexterity task, while the MAL is not timed.

The MAL's Amount of Use scale (and therefore the total number of MAL Activities Attempted score) is asking participants to rate how often they attempted or completed activities, compared with before their stroke. The MAL is not measuring how quickly or effectively the participants performed a functional or dexterous task with their more impaired upper limb. In this sense the MAL Amount of Use scale is measuring some constructs that are different from timed tests of function and dexterity.

In contrast, the fact that the MAL Quality of Movement scale did not detect a significant difference between the groups on change from baseline to endpoint scores, could be because the (self) rating of the quality of a performed functional movement is more closely associated to the timed performance of functional and dexterous tasks, characteristics that are being measured by the WMFT and NHPT. This is probably because they are more similar constructs.

Secondly, the MAL is a measure of patient's perceptions of their amount and quality of use (considering the more affected upper limb, in relation to pre-stroke use). Using the MAL requires the participant to remember their pre-stroke ability with their more affected upper limb, in the items described by the MAL's scale. Thirdly, the measured activities items of the MAL are common functional movements used in daily living where the WMFT gradually builds from (less complex) components of functional movements into more dexterous actions and activities, all of which are timed. This is very different and perhaps fits more clearly into the WHO-ICF's category of Function (or Disability) where the MAL also bridges into the WHO-ICF's category of Participation (or Handicap)

The MAL is also different to the NEADL. Although both scales are asking the user to rate their ability concerning daily living tasks, the NEADL includes questions about activities that depend on mobility, such as walking outdoors. The MAL however, focuses solely on the affected upper limb,

One explanation to be considered for why there were so few differences between the groups is the nature of the intervention. Participants in the intervention group did not use the WiiSTAR kit as much as recommended. Therefore few participants came close to the intensity in participation of gameplay thought to be needed to facilitate a change in outcomes.

Also, the participants in the intervention group were only using their more impaired arm against gravity. In other words, there was no resisted strength training which would normally be required to increase muscle strength in higher performing patients, for example use of weights or other equipment (Eng, 2004). Therefore increases in WMFT Grip Strength scores are more likely to be related to natural recovery of strength, in tandem with upper limb recovery of function.

The research therapist tried to ensure that the participants in the intervention group performed movements correctly and did not use compensatory movements, by providing training visits for those who were more likely to have adopted compensatory movements or poor postural positioning. Compensatory movements are described by Levin et al (2009[1] p 316) as being different from the patient's usual movement patterns, in that they use 'additional or different degrees of freedom, changes in muscle activation patterns such as increased agonist/antagonist coactivation'.

One example of what the authors (p 317-318) describe as 'adaptive compensation' is the patient's use of 'excessive elevation and retraction to lift the arm when the active range of shoulder flexion is decreased'. The training given to participants in the study aimed to reduce the use of compensatory movements, which are not considered to be an indication of true motor function recovery (Levin et al, 2009[1]) and are also deemed to be inefficient slower or larger movements than for neurologically intact individuals (Levin et al 2009[2]). However, as the participants in this study were not filmed or observed for the majority of the time we cannot be sure whether their movements consisted of compensatory movements at other times during the 8 weeks the intervention was left with them.

The MAL training manual gives specific and quite detailed advice to the assessors, on how to advise, instruct and negotiate with the participant, also how to complete the rating (scoring) of their performance. This process helps shape the participant's frame of reference in relation to the concept of the MAL and its scoring system. Training on use of the Wii STAR kit and use of the more impaired upper limb during gameplay could also have partially influenced what the participants considered to be the quality of their movement, because repeated information and instruction related to the participants' posture and selective movements of the more impaired upper limb may well have encouraged them to think more about their posture and selective, rather than synergistic movements. In one sense, this may have influenced performance on the MAL, as the reinforced messages could have influenced their thoughts and perceptions on the quality of movements during participation in the 30 MAL items, all of which are components of, or complete daily living activities.

However, it is difficult to say how much the training and advice given on posture and selective upper limb movements influenced the constructs of the MAL, compared with the constructs of the WMFTL, NHPT and NEADL. For example, although the WMFT and NHPT are timed tests of function and dexterity, the participants in the intervention group may well still have been mindful of posture and selectivity of movement when completing these outcome measures.

Unlike other similar interventions the Wii STAR intervention did involve dexterity as well as gross arm movements,so should not have differentially favoured for MAL over other outcome measures.

The trend for duration of gameplay to correlate with the number of activities attempted cannot be definitely interpreted as a causal link but it is possible that another variable (for example, motivation) is influencing both outcome measures. Those with high levels of motivation to play the games may also have had high levels of motivation to get back to their previous level of activity and independence.

However, Interviews with the participants in the intervention group (Standen et al, 2015) indicated that some participants believed playing the games benefitted them therapeutically. One participant explained their high levels of game play “Because it helps - well, it helps you a lot in your movement. First and foremost, with the position, you know.” (Standen et al, 2015 p 357). It is conceivable that a belief in the therapeutic value of playing the games might have led to a belief that engaging in activities of daily living would also be beneficial.

Alternatively, the exposure to the intervention may have positively influenced their self-efficacy. Hellstrom et al (2003 p 202) defines self-efficacy as “the degree of confidence possessed by persons in their ability to perform specific acts successfully”. Achieving success in the games could then have had the effect of these participants increasing their participation in daily living tasks. This increased engagement in daily living activities using their paretic upper limbs could perhaps explain the significant difference between the groups in MAL Amount of Use change scores from baseline to endpoint. One reason to suppose this, is that in a previous study (Chortis, 2008 p 7), a patient who had engaged in the intervention (a low cost commercial gaming system, aiming to facilitate increased upper limb use, following stroke) reported that his involvement in the research had led him to increase his participation in specific daily living activities, such as opening jars. One explanation for this spontaneous advantageous occurrence, is that the participant, having gained confidence from using their more impaired upper limb when practicing in a non-threatening situation (active participation in computer game technology) may then have begun to develop or gain a sense of self-confidence, and was able to attempt to use it in situations which could have been perceived previously as risking failure.

For example, if when attempting to use the more impaired upper limb, the movements are awkward or clumsy, or when attempts to complete a daily living task, such as opening a jar, or dressing oneself are unsuccessful the failure could be perceived by the participant as a punishment. Taub et al (1999, p 2 to 3) argue that this perception of failure or the feelings of punishment may lead to what has been described as learned non-use (as described in section 1.5.2). Hellstrom et al (2003, p202-207) explored the relationship between self-efficacy and regaining function after stroke. Their study found that those with high self-efficacy at discharge (after treatment targeting motor impairment) were likely to be more active and independent than those with low self-efficacy. The authors report that there is a significant interaction between self-efficacy and change in physical performance. Barlow (2010 p 5) report that in the context of rehabilitation, higher self-efficacy is associated with less anxiety or depression, more tolerance of pain, being more independent with personal care activities and having better or greater physical functioning.

It could be posited that the participants in the intervention group, having gained confidence through successful participation in the virtual reality gameplay, then began to attempt more activities of daily living than prior to the commencement of the intervention. While there were some significant correlations at baseline between the MAL subscales and the other outcome measures, there were no correlations with other outcome measures on change scores. This could be as a result of the small sample size and low exposure to the intervention. However, it is also highly likely that it is because the MAL measures something different to the other measures. Van der Lee et al (2004 p 1413) also failed to find a correlation in the change scores between the MAL and the ARAT when they had found correlations with the ARAT at baseline (0.63 , *P*_0.001).

Similarly, Hammer and Lindmark (2010) found no correlation between the MAL and the ARAT on change scores, despite also having correlated with the ARAT moderately well at baseline. Uswatte et al (2005 p 2495) explanation for this was that the ARAT was a measure of motor ability as opposed to use. In their study they found significant correlations in change scores between the MAL and accelerometry thus confirming it as a measure of use even though it is collected through participant self- report.

That the MAL did not correlate with the WMFT, NHPT or NEADL on change from baseline to endpoint scores in this study is perhaps not surprising given the arguments put forward above about the different constructs underlying the different outcome measures. As Uswatte et al (2005) suggest, the constructs of the MAL are related to use (in the context of daily living), whereas WMFT and NHPT are timed tests of motor ability and dexterity.

The MAL change scores do not correlate so well with the NEADL over time as the NEADL does not ask any questions that directly concern the use of the more impaired upper limb. As discussed above some of the NEADL's items do not concern the upper limb at all, and specifically concern mobility or daily living tasks that are more associated with mobility, such as getting out of the house to walk outdoors. Often, particularly in acute and sub-acute stroke stages of recovery, transfers and mobility will improve more quickly than upper limb movement dexterity and use. Improvements in the more impaired lower limb are more likely to show changes in improvements in measures of ADL than any improvements in the dexterity of the more impaired upper limb would (Kwakkel et al 2004).

It is also probable that those receiving the intervention improved at different rates during its course from baseline to endpoint. It is likely that there was a disassociation between the outcome measures for this reason. This would explain why the MAL correlated more with the most of the other outcome measures at baseline, but not when measuring the change scores.

No-one else has used Total Activities Attempted as an outcome measure. The fact that it is showing a difference may well make it worth using in other studies. However, again, it may well be related to some of the factors discussed above. For example, there were some drop outs, and those who remained in the study (in the intervention group) may have been more motivated to attempt daily living tasks with their more impaired upper limbs.

4.2 Methodological considerations.

The difficulties of the small sample exacerbated by a large number of dropouts in the intervention group have already been referred to and it is possible that because of this the lack of differences picked up by the other outcome measures is due to a Type II error. However, there was a broad spread of abilities so it is more likely to be representative of the population requiring further or ongoing rehabilitation of the upper limb. There were some differences between the groups, for example women were under represented in the control group (there were only 2 females although there were 8 males in the control group, compared with 8 females and 9 males in the intervention group).

It should also be noted that a statistical difference is not the same as a clinically significant difference. Wolf et al (2010 p 2310) calculated the clinically important MAL scale improvement as greater than a score of 3. They state that: ‘A score of > 3 on both the quality of movement and amount of use MAL scales, provides the first indication of ADL item initiation without use of the less impaired limb’. The differences obtained in this study were considerably smaller than this.

The large number of correlations (54 raw score correlations, 39 of which were significant, 36 correlations of change scores, 12 of which were significant, and 14 correlations with absolute game duration, of which none were significant) may have led to some being found significant at the 5% level by chance. In a definitive study, a Bonferroni correction would have been applied. However, this being a feasibility study and explorative in nature, leaving the alpha level at 5% was thought to be more informative.

The original protocol for the study of which this MPhil is a part, did not include plans for determining inter-rater reliability on the collection of the outcome measures. As discussed in the method (P 82) the research team attempted to ensure there was no variation due to rater assessment differences by practising and rehearsing the use of the respective outcome measures. Ideally outcome measures would have been carried out by all the raters on a sub sample of participants. However, this is ethically and practically challenging. One solution might have been to carry this out on a sample of volunteers who matched the characteristics of the potential study sample.

The intervention was left in patient’s homes for 8 weeks allowing a long period of exposure for those participants who took the full opportunity. Anticipating early drop outs, outcomes were collected at three timepoints. However, it was not possible to carry out a blind assessment at the midpoint, as the equipment was still being used in participants’ homes at that point, and any assessor would have seen the equipment. However, at endpoint, all the assessments were completed by blinded assessors, which is quite a difficult methodological issue to overcome in a home based study.

4.3 Future directions

Further evaluation with a larger sample is required, to reduce the probability that the results are related to a type II error.

The study suggests that the MAL 30 item version completed by patients should be used as an outcome measure in studies which evaluate interventions targeting paretic upper limb after stroke, as it appears to be able to detect improvements, where measures of function, dexterity or activities of daily living may not capture improvements.

The study also suggests that the MAL Total Activities Attempted is recorded, as it differed between the two groups on change scores and did show a trend towards correlating with gameplay duration in the intervention group.

There are alternative versions of the MAL (14 item, 28 item) and in some studies (van der Lee et al (2004), Uswatte et al (2005) it has also been administered to carers. This was not done in the present study as not all participants had a carer who could complete it. Therefore these conclusions only apply to the 30 item version completed by the patient themselves.

It is possible that those who attempted more MAL items, or who rated the amount they used their more impaired upper limb more highly, also had higher self-efficacy. The relationship between the VR technology and the self-efficacy of the participants warrants a more thorough evaluation in further research. Further research, aiming to explicitly evaluate the relationship between VR interventions for survivors of stroke and their self -efficacy, may require a measure of self-efficacy at pre-intervention/ control , and post intervention/ control in an RCT design.

One of the difficulties described in the discussion pages above, was that it was possible that participant MAL scores could have been influenced by the repeated training performed for some clients, who needed support to ensure that their body movements and posture did not involve over-using compensatory or synergist movements patterns during gameplay. In this study there was no way of monitoring participant's movements when they were unsupervised and the games could be 'played' in a way which involved compensatory movements. However, a recent development in VR technology based on the Microsoft® X-Box One-Kinnect®, may allow the user to have immediate feedback of their body positions and posture (Sarsfield et al, 2016), as well as providing a record for the therapist.

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Appendices:

Upper Extremity Motor Activity Log

(UE/MAL)

Constraint-Induced Therapy Research Group
University of Alabama at Birmingham and Birmingham VA Medical Center

1. General: This instrument is a structured interview intended to examine how much and how well the subject uses their more affected arm outside of the laboratory setting. Subjects are asked standardized questions about the amount of use of their more affected arm (Amount Scale or AS) and the quality of their movement during the functional activities indicated ('How Well" Scale or HW). The scales are printed on separate sheets of paper and are placed in front of the subject during test administration. Subjects should be told that they can give half scores (i.e., 0.5,1.5,2.5,3.5,4.5,5.5) if this is reflective of their ratings.

2. Rating Scales: The Amount Scale (AS) is used only during the second test administration (pre-treatment testing) and during follow-up testing. The How Well Scale (HW) is used during all test administrations. **(See Comment** 1; **attached).** When the AS scale is used, subjects should rate all tasks with the AS scale first. The tester then differentiates between the AS and HW scales (as suggested in the instructions), and the subject then rates all tasks with the HW scale.

Amount Scale

0 - Did not use my weaker arm (**not used**).
1 - Occasionally tried to use my weaker arm (**very rarely**).
2 - Sometimes used my weaker arm but did most of the activity with my stronger arm (**rarely**).
3 - Used my weaker arm about half as much as before the stroke (**half pre-stroke**)
4 - Used my weaker arm almost as much as before the stroke (**3/4 pre-stroke**).
5 - Used my weaker arm as normal as before the stroke (**same as pre-stroke**).

How Well Scale

0 - My weaker arm was not used at all for that activity (**not used**).
1 - My weaker arm was moved during that activity but was not helpful (**very poor**).
2 - My weaker arm was of some use during that activity but needed some help from the stronger arm, moved very slowly, or with difficulty (**poor**)
3 - My weaker arm was used for that activity but the movements were slow or were made only with some effort (**fair**).
4 - The movements made by my weaker arm for that activity were almost normal but not quite as fast or accurate as normal (**almost normal**).
5 - The ability to use my weaker arm for that activity was as good as before the stroke (**normal**).

3. <u>Asking Questions</u>.
Step One: The tester should remind the subject that these questions pertain to what they <u>actually do</u> outside of the laboratory setting - not what they think they <u>may be able to do</u>.

Step Two: The project staff member should inquire about each activity (the bolded words) using the following questions:

a. <u>First Test Administration (screening evaluation</u>) - "Considering your activities during the past week, did you (state the activity)?"(If no, check no and skip to Section B of the question and ask why; If *Yes,* go to step three).

b. <u>Second Test Administration (pre-treatment testing</u>) - "Considering your activities during the past week, did you (state the activity)?"(If *no,* check no and skip to Section B of the question and ask why; If *Yes,* go to step three). **Note:** if the screening evaluation took place less than one week prior to pre-treatment testing, say " Since the last time you were evaluated for this project, did you (state the activity)?"

c. <u>All Other Test Administrations</u> - "Since the last time I asked you, did you (state the activity)? (If no, check no and skip to Section B of the question and ask why; if *Yes,* go to step three).

(See **Comment 2**)

Step Three: "Using the Amount Rating Scale, tell me how you would rate the <u>amount</u> you used your weaker arm to (state the activity)." Once the subject selects a rating, repeat the selected rating in the following manner; " So, you believe that you (read the selected AS rating) – Is that correct?" Once they agree, record the response in the blank AS space provided for that question.

"Using the How Well Rating Scale, tell me how you rate <u>how well you used</u> your arm when you did use it to (state the activity)." For the first and second administrations (screening evaluation and pre-treatment testing), emphasize the difference between the AS and HW scales (See **Comment 3**). Once the subject selects a rating, repeat the selected rating in the following manner; " So, you believe that you (read the selected HW rating scale) - Is that correct?" Once they agree, record the response in the blank HW space provided for that question.

Note: During the second test administration (pre-treatment testing) and after the subject provides a HW rating, ask the subject to demonstrate an approximation to the activity by saying, "please show me how you do that activity." (See **Comment 4**)

Step Four: Verify the response

a. During The Second Test Administration (Pre-treatment testing): In this test administration, the tester sets up an agreed upon rating framework with the subject. If obvious discrepancies exist between what is observed and the rating provided, the tester should discuss the rating with the subject to develop a common frame of reference (i.e., You rated that activity a "S". However, you moved your arm very slowly to do the activity. So, for this project that would be more like a "2". Do you agree?"). The final rating is determined by the subject.

Establishing a common frame of reference during the pre-treatment testing, before therapy has begun, is a critically important step. For suggestions on how to accomplish this, see **Comment 4** – attached. The first administration of the MAL is very important and an hour or more should be devoted to it so that an appropriate frame of reference is established. This should include showing the patient the MAL Demonstration videotape (See **Comment 1**).

b. During All Other Test Administrations: During testing, the tester should refer back to the immediately previous test administered. The form should be out of view of the subject. If a rating change occurs, the tester should verify the response using the following questions:

1. During the last test, you rated this activity (state either "higher" **or** "lower" - whichever is accurate) than today by giving it a (repeat the previous score). Why? or Does this represent a real change?

2. So, now that you have thought about it more, how would you rate it now?

3. So, you believe that the rating should be (read the specified rating). Is that accurate? (If *Yes*, record and move on. If No, ask "Why" and go back to question 2.) (See **Comment 2**).

4. Significant Other Testing: The MAL should be administered to a significant other on two occasions (pre-treatment and post-treatment testing days), the patient should not be present. The same significant other should be tested on both occasions and is preferably someone living with the subject. Both the AS and HW rating scales are used both times.

5. Administration times: The MAL is to be administered at the following times:

a. During the screening evaluation.

b. During the pre-treatment testing day (Significant other MAL also).

c. Each morning after the first full treatment day (1/2 of a MAL is administered after each full day of treatment, an entire MAL is administered after weekends).(See **Comment 6)**

d. During the post-treatment testing day (Significant other MAL also).

e. During each follow-up testing day.

6. Scoring: After administering the MAL, a mean MAL score is calculated by adding the rating scores and dividing by the number of items asked. If a subject answers “no” (they did not do the task) and you find that it is impossible for the subject to carry out the activity (e.g., can't comb hair because they are completely bald, can't brush teeth because false teeth are used), the question is dropped from that and all other MALs and the mean score is calculated with the remaining items only (e.g., divide by 29 instead of 30). Otherwise, a rating score of zero is entered for “no” responses, and the mean score is calculate using the entire MAL (e.g.. divide by 30).

Comments

Comment 1: Using the rating scales

The AS rating scale should be only used during the test administrations conducted before treatment (screening evaluation and pre-treatment testing) and follow-up testing. It should not be used during treatment and immediately after treatment (post-treatment testing), as the treatment involves constraint of the less affected arm thereby inducing greatly increased use of the more affected arm. This would artificially inflate the appearance of a therapeutic effect and might not persist after the end of treatment. Thus, the meaning of ratings en the AS scale during treatment and immediately after removal of the constraint (post-treatment) would be rendered questionable.

Comment 2: Time frames used in questions

In the first test administration (screening evaluation), ratings should be obtained for activities carried out during the previous week. Use of a one week time frame should increase the likelihood that subjects will have had opportunities to perform a representative sample of their full range of activities. During the second test administration (pre-treatment testing) ratings should also be obtained for activities carried out during the previous week. However, at times, the second MAL administration will occur less than one week after the first administration. In such cases, the second administration (pre-treatment testing) should involve obtaining ratings for activities carried out since the first administration (screening evaluation) (e.g., 3 days). In all other test administrations, ratings should be obtained for the time since the subject was last asked about that specific task. Since only one half of the MAL should be administered daily during the treatment period, this time frame will typically be 2 days.

Comment 3: Differentiating between the two rating scales

When both scales are being used to rate activities, particularly during screening evaluation and pretreatment testing), it is very important to make sure that the subject understands the difference between the scales. The following phrases may be used before asking about the HW rating scale to accomplish this. “Remember that I am asking you to rate something different on this scale, the How Well Scale, than you did before on the Amount Scale. Before you were supposed to rate how <u>much</u> you used your more affected arm. Now I would like to rate <u>how well</u> you used your more affected arm, if you did use it. For example, you might have used your more affected hand to pick up a glass and drink only rarely. The Amount rating might therefore be a 1.5 or 2. However, when you did use it, your use of the hand was really quite good: let us say between fair and almost normal, or a 3.5. Is the difference between the two types of ratings I am asking you to make clear?"

Comment 4: Establishing a context or a common frame of rating reference for the HW scale:

a. During the second test administration, the subject should be asked to demonstrate a number of activities they have rated on the HW scale. The activities for which demonstration is requested will most usefully be many of the activities at the beginning of the MAL; this will allow the tester to get an idea of the subject's general frame of reference and will reduce the need for demonstration of activities on later MAL items. Demonstration of the performance of an activity should also be requested whenever the tester is unsure of what the subject means by a rating. The demonstration should be carried out after the subject attempts to rate the activity and only when using the HW rating scale. Observation of the demonstration of an activity allows the tester an opportunity to discuss the subject's HW rating in order to set an agreed-upon rating context. This process should increase the likelihood that the subject understands the intended motor reference or meaning of the HW rating scale. Therefore, it should increase the comparability of results across subjects. The tester need not have the subject demonstrate every item on the MAL if in their opinion the HW rating is consistent with the performance previously demonstrated on a similar task (e.g., opening a refrigerator and opening a door by turning a door knob). Establishing a context should be used during pre-treatment testing only, so that experimenter bias and demand characteristics resulting from this procedure cannot artificially increase the appearance of a treatment effect.

b. When a clear disparity exists between the subject's HW rating and what the tester has observed concerning the subject's motor ability, the tester should explain the meaning of the HW rating scale for the task in question with examples being given for each step, especially those that focus on the HW rating in question (e.g., You rated that activity a "3". However, you moved your arm very slowly to do the activity. So, for this project that would be more like a “2”. Do you agree?). Subjects will usually be influenced by the tester’s explanation. If they are not and they continue to reiterate the original estimate, the tester should politely continue the discussion until the patient accepts the laboratory/clinic’s frame of reference. Thus, the MAL has aspects of both a self-report instrument and a structured interview. Again, this process should be completed prior to the beginning of treatment to decrease the chance that experimenter bias will influence the HW rating scores.

c. **Videotape:** This laboratory has developed a MAL Demonstration Videotape that provides examples of different rating levels for several MAL activities. This videotape is extremely helpful in establishing a common frame of reference with a patient. It should be shown to the patient at the pre-treatment test administration and discussed thoroughly at that time. During therapy, if the tester, based on direct observation of behavior, believes that the subject’s frame of reference has shifted, the MAL Demonstration Videotape should be shown again and discussed. The videotape may be obtained by sending a $25 check, made out to the Constraint-Induced Movement Therapy Research Group, to defray the cost of copying and mailing. Send the check to: Edward Taub, Ph.D., Department of Psychology, 415 CH, University of Alabama at Birmingham, Birmingham, AL 35294.

Comment 5: Verifying the response after the beginning of treatment

During the standardized questioning, the subjects are not told their previous scores However, if their report reflects a change in score, whether an increase or a decrease, the change in rating should be probed to determine whether it reflects a true change. The most common type of situation in which probing has been found to increase response accuracy sometimes occurs approximately half way through the intervention period. The subject sometimes becomes so pleased with their large and rapid improvement in motor function that they tend to magnify and overestimate it. Thus, the majority of errors made by subjects represent an overestimation of the HW rating score. Probing usually results in revisions in the direction of performance decrement (i.e., a lower HW rating score), which therefore lead to a more conservative (and more accurate) estimate of the treatment effect than would otherwise be obtained

During early experiments in the UAB lab (Taub et. al., 1993), probing was not carried out for the first two patients. The graphs of the daily MAL records for these two patients presented a jagged appearance, with days of decrement following days of large improvement. This variability appeared to testers not to be reflective of the reality of the situation. The improvements were frequently greater than appeared warranted and decrements seemed to underestimate performance. When the probing procedure was implemented, the curve connecting the MAL data points became smooth. However, it is important that the final performance was not greater than that recorded for the first two patients (where probing was not used). The project staff had the clear opinion that the smoothed curves more accurately described subjects' performance and that this was acheived by eliminating "noise" from the rating process (e.g., lack of attention by subjects during the testing, spontaneous change in the subjects' frame of reference, etc.).

Comment 6: Administration times

Administration of the MAL during treatment provides valuable data and tracks a patient's progress during the therapy phase. Concerns have arisen because it was felt that administration of the MAL during the treatment period might have a “treatment effect" in itself. If this were so, it would jepordize the MAL's credibility as an outcome measure. It was felt that the treatment effect might result from the way in which the test focuses attention on the subject's activities at home. However, it should be noted that the entire CI Therapy approach focuses attention on using the mere affected arm in the tab and at home. Consequently, the effect produced by the MAL would be minimal in relation to the treatment effects brought about by the various aspects of the CIT package (i.e., wearing a mitt for 90% of waking hours, the behavioral contract, prolonged and concentrated task practice, etc.). Evidence indicating that the administration of the MAL does not have a therapeutic effect in itself has been obtained in two experiments. First, in Wolfgang Miltner's group research laboratory at the University of Jena (including Heike Bauder and Monika Semmer), the MAL was administered to eight chronic stroke patients two weeks prior to treatment and en the pretreatment testing day. Analysis revealed no reliable difference in the rating scores obtained during these two administrations. In addition, ten subjects participating in a two-week general fitness program designed as a placebo control procedure for the UAB CI Therapy Project were given the MAL repeatedly on the same basis as experimental subjects (i.e., pretreatment, on a daily basis during the placebo treatment, post-treatment, and in followup). This group did not show a significant change in MAL scores as a result of therapy. These two studies thus provide a data basis that strongly suggests that the MAL administration does not produce a treatment effect.

UE/MAL

Part 1

Patient:

Rater: Date:

lA. Turn on a light with a light switch.
Yes:
Amount____

How Well ______

No: (skip to Section B)

1B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____ Other.

2A. Open a drawer.
Yes:
Amount____

How Well ______

No: (skip to Section B)

2B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____ Other.

3A. Remove an item of clothing from a drawer.
Yes:
Amount____

How Well ______

No: (skip to Section B)

3B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

4A. Pick up a phone.
Yes:
Amount____

How Well ______

No: (skip to Section B)

4B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

5A. Wipe off a kitchen counter or other surface.
Yes:
Amount____

How Well ______

No: (skip to Section B)

5B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

6A. Get out of a car.
Yes:
Amount____

How Well ______

No: (skip to Section B)

6B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

7A. Open a refrigerator.
Yes:
Amount____

How Well ______

No: (skip to Section B)

7B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

8A. Open a door by turning a door knob.
Yes:
Amount____

How Well ______

No: (skip to Section B)

8B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

9A. Use a TV remote control unit.
Yes:
Amount____

How Well ______

No: (skip to Section B)

9B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

10A. Wash your hands.
Yes:
Amount____

How Well ______

No:(skip to Section B)

10B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

11A. Dry your hands.
Yes:
Amount____

How Well ______

No: (skip to Section B)

11B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

12A. Put on your socks.
Yes:
Amount____

How Well ______

No: (skip to Section B)

12B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I

answered these questions.
_____Other.

13A. Take off your socks.
Yes:
Amount____

How Well ______

No: (skip to Section B)

13B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

14A. Put on your shoes.
Yes:
Amount____

How Well ______

No: (skip to Section B)

14B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

15A. Take off your shoes.

Yes:

Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)

_____ I used the unaffected arm entirely.

_____ Someone else did It for me.

_____ I never do that activity, with or without help from someone else.

_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.

_____Other.

UE/MAL
Part 2

Patient:

Rater: Date:

16A. Get up from a chair with armrests.
Yes:
Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

17A. Pull chair away from a table before sitting down.
Yes:
Amount____

How Well ______

No: (skip to Section B)

17B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

18A. Pull chair toward table after sitting down.
Yes:
Amount____

How Well ______

No: (skip to Section B)

18B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

19A. Pick up a glass.
Yes:
Amount____

How Well ______

No: (skip to Section B)

19B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

20A. Brush your teeth.
Yes:
Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

21A. Put on makeup(shave).
Yes:
Amount____

How Well ______

No: (skip to Section B)

21B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

22A. Use a key to open a door.
Yes:
Amount____

How Well ______

No: (skip to Section B)

22B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

23. Write on paper (if dominant arm was most affected do you use it to write?: if non-dominant arm was most affected, do you use it to stabilize the paper when writing?).
Yes:
Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

24A. Steady yourself while standing.
Yes:
Amount____

How Well ______

No: (skip to Section B)

24B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

25A. Carry an object from place to place.
Yes
Amount____

How Well ______

No (skip to Section B)

25B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

26A. Use a fork or spoon for eating.
Yes:
Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

27A. Comb your hair.
Yes:
Amount____

How Well ______

No: (skip to Section B)

27B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

28A. Pick up a cup by a handle.
Yes:
Amount____

How Well ______

No: (skip to Section B)

28B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

29A. Button a shirt.
Yes:
Amount____

How Well ______

No:(skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)
_____ I used the unaffected arm entirely.
_____ Someone else did It for me.
_____ I never do that activity, with or without help from someone else.
_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.
_____Other.

3OA. Eat half of a sandwich or finger foods.
Yes:
Amount____

How Well ______

No: (skip to Section B)

15B. Why did you not do the activity or use the affected arm as you did the activity, since the last visit? (Check all that apply)

_____ I used the unaffected arm entirely.

_____ Someone else did It for me.

_____ I never do that activity, with or without help from someone else.

_____ I sometimes do that activity, but did not have the opportunity since the last time I answered these questions.

_____ Other.

Amount Scale

0 - Did not use my weaker arm (not used).

1 - Occasionally tried to use my weaker arm (very rarely).

2 - Sometimes used my weaker arm but did most of the activity with my stronger arm (rarely).

3 - Used my weaker arm about half as much as before the stroke (half pre-stroke).

4 - Used my weaker arm almost as much as before the stroke (3/4 pre-stroke).

5 - Used my weaker arm as normal as before the stroke (same as pre-stroke).

How Well Scale

0 - The weaker arm was not used at all for that activity (never).

1 - The weaker arm was moved during that activity but was not helpful (very poor).

2 - The weaker arm was of some use during that activity but needed some help from the stronger arm or moved very slowly or with difficulty (poor).

3 - The weaker arm was used for the purpose indicated but movements were slow or were made with only some effort (fair).

4 - The movements made by the weaker arm were almost normal but not quite as fast or accurate as normal (almost normal).

5 - The ability to use the weaker arm for that activity was as well as before the injury (normal).

Table 5: Medians and percentiles of Raw Scores - all Outcome Measures at each time point

Raw Scores	Baseline – 0 weeks	Midpoint – 4 weeks	Endpoint – 8 weeks
NEADL N	27	22	18
Median	38.00	45	42.00
25th & 75th Percentiles	(22.00, 45.00)	(27.75, 53.00)	(29.50, 54.25)
WMFT Score N	27	22	18
Median	2.7	2.25	2.33
25th & 75th Percentiles	(1.79, 5.67)	(1.66, 2.94)	(1.79, 3.32)
WMFT Grip N	26	22	18
Median	11.20	13.50	12.66
25th & 75th Percentiles	(6.65, 28.50)	(7.08, 21.43)	(8.80, 23.34)
NHPT – Affected UL			
N	23	19	15
Median	51.29	50.41	50.25
25th & 75th Percentiles	(41.72, 77.46)	(33.14, 101.06)	(37.23, 94.27)
MAL – AOU			
N	27	22	18
Median	2.3	2.7	2.46
25th & 75th Percentiles	(1.23, 2.93)	(1.74, 3.81)	(1.40, 3.51)
MAL - QOM			
N	27	22	18
Median	1.8	2.16	2.35
25th & 75th Percentiles	(1.00, 2.36)	(1.33, 3.21)	(1.21, 4.48)
MAL – Act. Att.			
N	27	22	18
Median	16	19	19
25th & 75th Percentiles	(10.00, 22.00)	(13.00, 22.25)	(12.00, 25.00)

Table 6: Correlations of Raw Scores

WMFT Score	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	-0.62**	27	-0.54*	22	-0.67 **	18
MAL QOM	-0.65**	27	-0.60**	22	-0.74 **	18
MAL Act. Att.	-0.57**	27	-0.52*	22	-0.68 **	18
WMFT Grip	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	0.43*	27	0.34	22	0.34	18
MAL QOM	0.45*	27	0.18	22	0.46	18
MAL Act. Att.	0.35*	27	0.34	22	0.47	18
NEADL	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	0.66**	27	0.65**	22	0.71**	18
MAL QOM	0.64**	27	0.71**	22	0.68**	18
MAL Act. Att.	0.61**	27	0.64**	22	0.68**	18
NHPT	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	-0.25	23	-0.22	19	0.11	15
MAL QOM	-0.21	23	-0.20	19	-0.05	15
MAL Act. Att.	-0.11	23	-0.07	19	0.09	15
MAL AOU	0 weeks	N	4 weeks	N	8 weeks	N
MAL QOM	0.98**	27	0.97**	22	0.97**	18
MAL Act. Att.	0.96**	27	0.94**	22	0.95**	18
MAL QOM	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	0.98**	27	0.97**	22	0.97**	18
MAL Act. Att.	0.97**	27	0.96**	22	0.96**	18
MAL Act. Att.	0 weeks	N	4 weeks	N	8 weeks	N
MAL AOU	0.96**	27	0.94**	22	0.95**	18
MAL QOM	0.97**	27	0.96**	22	0.96**	18

* Correlation is significant at P< 0.05 level (2 tailed)

** Correlation is significant at P< 0.01 level (2 tailed)

Table 7: Correlations of Game Duration and change in Outcome Measures

	4 weeks N = 12		8 weeks N = 9	
	Spearmans rho	**Sig. 2 Tailed**	**Spearmans rho**	**Sig. 2 Tailed**
WMFT Score	-0.077	0.812	0.150	0.700
WMFT Grip	0.392	0.208	0.533	0.139
NEADL	0.056	0.862	-0.050	0.898
	4 weeks N = 10		**8 weeks N = 7**	
	Spearmans rho	**Sig. 2 Tailed**	**Spearmans rho**	**Sig. 2 Tailed**
NHPT	-0.491	0.150	0.464	0.294
	4 weeks N = 12		**8 weeks N = 9**	
	Spearmans rho	**Sig. 2 Tailed**	**Spearmans rho**	**Sig. 2 Tailed**
MAL AOU	0.00	1.000	0.276	0.472
MAL QOM	0.238	0.457	0.250	0.516
MAL Act. Att.	0.011	0.974	0.621	0.074