Development of a wrist-worn accelerometer feedback intervention to enhance arm recovery after stroke.

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A thesis submitted for the degree of Doctor of Philosophy

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October 2019

Abstract

Background

Arm recovery after stroke is enhanced by frequent practice of functional activities. Remaining motivated to practice and remembering to integrate the impaired limb into daily activities can be difficult.

Methods

A mixed methods approach developed a novel intervention to promote use of the impaired arm after stroke:

1. Systematic review examined reports of self-directed interventions for arm rehabilitation after stroke.
2. Development of a novel intervention using a wrist-worn accelerometer with vibrating alert to prompt arm activity.
3. An un-blinded observational proof of concept study within 4 weeks of stroke refined the intervention.
4. A multi-centre, observer-blind pilot randomised controlled trial (RCT) evaluated feasibility of the intervention for 8 weeks within 3 months of stroke and provided descriptive clinical and biomarker data.

Results

The systematic review showed that high doses of independent practice are possible, with benefits from functional task practice.

A novel intervention was developed consisting of feedback from a wristband accelerometer to prompt increases in functional therapy practice within daily routines.

The proof of concept study showed that feedback was acceptable with refinements to the technology and therapy programme.

Thirty-three participants were recruited to the Pilot RCT. Research assessments were completed for 28/29 and 25/28 patients at four and eight weeks. Wristbands were worn for 79% of the recommended time with a median of 8[IQR: 6-10] prompts delivered per participant/day.

Clinical outcomes were better for intervention participants and continued to improve post-intervention although the small cohort size precluded statistical analysis.

Statistical analysis of the accelerometer data showed impaired arm activity increased for the intervention group and continued to increase further over the follow-up period. In contrast, arm activity in the control group changed marginally.

Conclusion

Feedback from a wristband accelerometer to prompt greater use and independent practice of the impaired arm after stroke is feasible and should be considered for further research evaluation.

Acknowledgements

I would like to thank the following people without whom this work would not have been possible:

First, a big thank you to my supervisors Dr Christopher Price and Dr Sarah Moore for their support and guidance. Particular thanks to Dr Price for seeing the potential in me from the start and providing me with this wonderful opportunity. I am incredibly grateful for all your support, patience and encouragement. To Sarah, you have been an inspiration to me and incredibly supportive both as a friend and supervisor.

To the rest of the WAVES team and my colleagues in the Stroke Research Group at Newcastle University. I feel honoured and privileged to have had the opportunity to work alongside and to have had the benefit of their academic expertise and experiences. Special thanks to Helen Bosomworth for not allowing me to take myself too seriously – plenty time now for Gin Friday!!

To my friends and colleagues at Gateshead NHS Foundation Trust, for their support in allowing me to continue with this work at a time when staffing was particularly tight. Particular thanks to Kathleen O'Neil for keeping me grounded, carrying the clinical load in my absence and reminding me why this work is so important.

To the patients who agreed to take part in this study at such a difficult time in their lives. I hope that your hard work and mine will have been of some benefit and might contribute to helping others in the future.

Finally, thank you to my family for supporting and believing in me. To my parents for never doubting that I could do it. To Sofia, Jack and Daniel for always being there when I needed you and keeping me sane. To my wonderful husband Tony, for your love and support during what has felt like the longest time of me working weekends and evenings. To Ruby for reminding me that there are more important things in life. You are all amazing and it is to you that I dedicate this thesis.

Author contribution

The funding for this project was awarded by the Stroke Association to Dr Christopher Price and co-investigators Dr Madeline Balaam, Dr Katie Brittain, Lianne Brkic, Dr Thomas Ploetz, Prof Helen Rodgers, Dr Lisa Shaw and Prof Frederike van Wijck.

In January 2015, I was seconded to the team, initially on a part-time basis, from my role as a senior NHS occupational therapist specialising in stroke. My role was to develop a therapy programme that could be integrated with the wristband accelerometer intervention and subsequently delivered and evaluated across a number of NHS stroke services. A few months into the project, I was offered the opportunity to using my contribution to the project as the basis for my PhD.

The study design and principal stages of the project were already outlined by the study investigators in the grant application. A recently developed repetitive functional task programme had been identified as a potential basis for the therapy programme as described in Section 2. The extent of my contribution to each part of the project is detailed below:

Development of the intervention

I developed the intervention as a self-directed therapy programme incorporating the findings of a systematic review I carried out on self-directed arm therapy programmes (Chapter 2) with recommendations from the National Clinical Guidelines for Stroke.

I worked closely with members of the computer science department who were developing the technology, sharing with them my clinical knowledge of how the effects of stroke might impact on using the technology. I also supported Dr Madeline Balaam in organising and running workshops with stroke survivors and therapists to obtain their views on the design and implementation of the technology.

Testing and refinement of the intervention

I was responsible for preparing the study protocol, study documents and application for Research Ethics Committee (REC) approval with support from Dr Christopher Price. I attended the REC meeting with Dr Price and was responsible for liaising with NHS research and clinical staff to co-ordinate local study site set up.

I oversaw the running of the proof of concept study and was responsible for recruitment, consent and delivery of the programme to nine participants across two study sites. Dr Sarah Moore delivered the programme to the final two participants. I carried out the data analysis of the descriptive statistics under the supervision of Dr Price. Analysis of the accelerometer data was performed by a member of the computer science department.

I made refinements to the intervention based on the findings of the proof of concept study and in consultation with the rest of the project team

Piloting the feasibility of the intervention in a multi-site pilot randomised controlled trial (RCT)

I wrote the study protocol with Dr Sarah Moore who was responsible for local R&D approvals. I attended the REC meeting with Dr Price, prepared all study documents and was the local Principal Investigator for one of the four study sites.

I oversaw the running of the RCT and provided training and ongoing to support to local site staff. This included Clinical research network staff and physiotherapists / occupational therapists working across inpatient and community settings.

The randomisation of participants to control and intervention groups and the handling of adverse events were carried out by administrative staff at the university.

Dr Richard Francis provided support with writing the SPSS coding required to clean and sort the accelerometer data. I was then responsible for the preparation and analysis of both the accelerometer data and clinical outcome data.

I prepared and submitted annual and end-of-study reports to the Research Ethics Committee and our funder (the Stroke Association).

Finally, I was responsible for interpretation of the results of the study and recommendations for future work.

Publications

Chapter 2

Da-Silva RH, Moore SA, Price CI. Self-directed therapy programmes for arm rehabilitation after stroke: a systematic review. *Clinical Rehabilitation* 2018; 32: 1022-36

Da-Silva RH, Moore SA, Price CIM. A systematic review of self-directed therapy programmes for upper limb rehabilitation after stroke. *In: UK Stroke Forum*. 2017, Liverpool: SAGE.

Chapters 4 and 5

Da Silva R, van Wijck F, Shaw L, Rodgers H, Balaam M, Brkic L, Ploetz T, Jackson D, Ladha K, Price CI. Prompting arm activity after stroke: a clinical proof of concept study of wrist-worn accelerometers with a vibrating alert function. *Journal of Rehabilitation and Assistive Technologies Engineering* 2018, **5**, 1-8.

Chapter 9

Da Silva R[1], Moore SA[1], Balaam M, Brkic L, Jackson D, Jamieson D, Ploetz T, Rodgers H, Shaw L, van Wijck F, Price C. Wristband Accelerometers to motiVate arm Exercise after Stroke (WAVES): study protocol for a pilot randomized controlled trial. *Trials* 2016, **17**, 508.

[1] Joint first authors

Chapter 10

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Da Silva RH, Moore SA, Van Wijck F, Shaw L, Rodgers H, Jackson D, Balaam M, Sutcliffe L, Brkic L, Ploetz T, Price CI. Wristband accelerometers to motivate arm exercise after stroke (WAVES): A pilot randomized controlled trial**.** *In: The Society of Research in Rehabilitation 40th anniversary and Winter Meeting*. 2018, Bristol, UK: SAGE Publications Ltd STM.

Chapter 11

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Poster Presentations

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Da-Silva RH, Moore SA, Price CIM. A systematic review of self-directed therapy programmes for upper limb rehabilitation after stroke. *In: UK Stroke Forum***.** 2017, Liverpool: SAGE. In Preparation

Da Silva RH, Moore S, Jamieson D, Balaam M, Brittain K, Brkic L, Ploetz T, Rodgers H, Shaw L, van Wijck F, Price C. Wrist worn accelerometers with vibrating-alert to prompt exercises after stroke (WAVES). *In: 2nd European Stroke Organisation Conference 2016***.** 2016, Barcelona, Spain: Sage Journals.

Abbreviations

ARAT	Action Research Arm Test
BCT	Behaviour change technique
CIMT	Constraint induced movement therapy
CPM	Counts per minute
EMG	Electromyography
ES	Electrical stimulation
FM	Fugl-meyer
fMRI	Functional magnetic resonance imaging
ICF	International Classification of Functioning, Disability and Health
IQR	Interquartile range
LED	Light emitting diode
MAL	Motor Activity Log
MCID	Minimal clinically important difference
MD	Mean difference
MI	Motricity Index
MRC	Medical Research Council
NHS	National Health Service
NIHSS	National Institutes of Health Stroke Scale
RCT	Randomised controlled trial
RFTP	Repetitive functional task practice
SAE	Serious adverse event
SMD	Standardised mean difference
SVM	Signal vector magnitude
TIDieR	Template for Intervention Description and Replication
WAVES	Wristband accelerometers to motivate arm exercise after stroke

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Introduction

With an annual incidence of around 14 million first-time events, stroke is a global health problem and one of the world's leading causes of death and disability (Stroke Association, 2018, Feigin et al., 2017). An ageing population and significant advancements in stroke care means that the number of people both having and surviving a stroke is on the increase. In the UK, the number of people who had a stroke in 2015 was estimated at 118, 000 and this number is expected to rise by nearly 60% before 2035 (Patel et al., 2017). As stroke is already the primary cause of complex adult disability in the UK (Stroke Association, 2018), there is concern around the impact that a significant increase in stroke survivors living with a disability will have (NHS, The NHS long term plan, Digital, 2018).

Disability occurring from stroke is most commonly caused by motor impairment affecting around 80% of patients (Langhorne et al., 2009). Of these only half will regain useful function in the arm by six months (Kwakkel et al., 2003) and 50% will continue to have persisting problems after four years (Broeks et al., 1999).

Studies on healthy subjects have shown the need to use both arms to efficiently carry out essential activities of daily living (ADLs) (Lang et al., 2017). The loss of functional use in one arm can therefore be severely disabling and have a lasting impact on the ability to be independent. As many as 74% of the 50 million stroke survivors worldwide are thought to require assistance with their ADLs (Miller et al., 2010, Kalra and Langhorne, 2007). This loss of independence places a subsequent burden on stroke survivors and their families as well as health services and the wider community (Patel et al., 2017, Kalra and Langhorne, 2007).

Stroke survivors report arm impairment as the most distressing aspect of stroke (Wyller et al., 1997) and, along with carers and health professionals, have identified it as a top research priority (Pollock et al., 2012).

Clinical studies indicate that high doses of intensive therapy are required to influence motor recovery, but this can be difficult to provide (Hayward and Brauer, 2015, Pollock et al., 2014). To enhance opportunities for additional therapy, interventions have been developed to promote independent arm use and therapy practice outside of formal therapy sessions (Da-Silva et al., 2018). This is not without challenge however, as many stroke survivors find it difficult to remember to use the impaired arm within daily activities and changes in impairment do not automatically translate into better performance in daily activities (Waddell et al., 2017, Rand and Eng, 2012). A common problem after stroke is that patients quickly learn to adapt to loss of use in one arm by using their remaining functional arm to carry out tasks unilaterally often supported by adaptations. This can lead to a phenomenon known as learned non-use of the impaired arm which is difficult to correct and impinges on recovery of the hemi-paretic arm.

Previous trial evidence supports selective use of constraint induced movement therapy (CIMT) (Pollock et al., 2014). Using a mitt to restrain use of the unimpaired arm, CIMT encourages high intensity impaired arm practice and has been found to be effective at reducing learned non-use. CIMT, however, has not been widely adopted due to the prohibitive costs of the associated therapy time and the high demands placed upon patients (Viana and Teasell, 2012, Kwakkel et al., 2015). Furthermore, the number of patients who are eligible for CIMT is limited to those with mild to moderate impairment which accounts for only about 10% of stroke patients (Kwakkel et al., 2015). Alternative approaches are required that can be more readily accessed by a wider cohort of patients.

In 2014 the Stroke Research Group at Newcastle University was awarded funding from the Stroke Association to test the feasibility of a locally developed wrist worn accelerometer device (called the CueS wristband) which could be programmed to vibrate to alert the wearer of low levels of impaired arm activity. The device was not commercially available and had originally been developed to cue swallowing amongst patients with Parkinson's disease. The built-in accelerometer acted as a motion sensor in place of buttons to turn the device on when it sensed movement and off when the device was stationery. The investigators hypothesised that with

further development to include personalised prompting, the device may be able to encourage higher levels of therapy practice and impaired arm use by drawing attention to the arm in a less obtrusive manner than the restraint mitt used in CIMT. This could make it more acceptable and accessible to a wider group of patients.

Aims of the thesis

The aim of this thesis is: to describe the development of a self-directed therapy program using personalised feedback from a wristband accelerometer to promote functional use of the impaired arm after stroke.

Research Objectives:

1. To identify self-directed interventions, with and without technology, to aid recovery of the arm after stroke.
2. To develop, test and refine use of feedback from the accelerometer wristband during a self-directed therapy plan to promote stroke arm activity.
3. To test the feasibility of a multi-centred pilot randomised controlled trial of the accelerometer wristband feedback to improve independent use of the arm after stroke.
4. To describe changes in stroke arm use measured by the built-in accelerometer following delivery of the wristband intervention during the pilot RCT

A theory and evidence based approach was applied following the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (O'Cathain et al., 2019) (Figure 0.1). The MRC describes any intervention containing several interacting components as a 'complex intervention' (Campbell et al., 2000, Craig et al., 2008) and interventions for recovery of the arm after stroke specifically have been described as such (Pollock et al., 2014). Due to the complexities of each component that make up these interventions and how they interact with each other, they can be difficult to standardise and to subsequently evaluate.

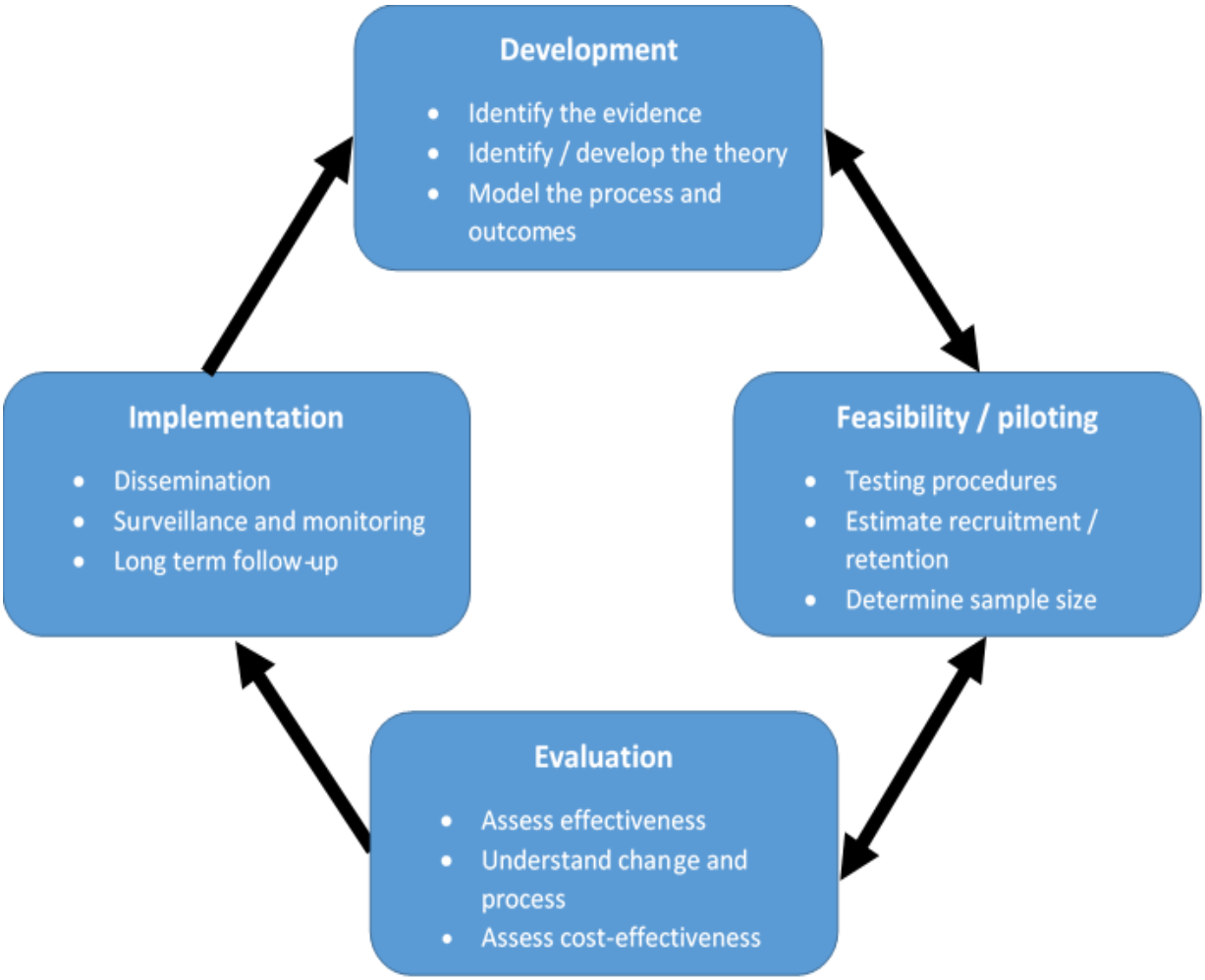


Figure 0.1 Cycle of development, evaluation and implementation of complex interventions (Craig et al., 2008)

To support developers of complex interventions, O'Cathain et al (2019) developed a framework of actions from the planning stage right through to the end of the development stage (O'Cathain et al., 2019). A timeline of actions related to this

project are outlined in Appendix A. The initial actions involving the planning of the development process for this piece of work had already taken place prior to this author starting work on the study in January 2015. As such, a project outline had already been written outlining the problem being targeted, the potential benefits of the proposed intervention based on the current literature at that time and a protocol of the development process produced for the funder.

This author's involvement in the project started after the initial planning stage at what O'Cathain describes as the 'intensive development phase'. The intensive development phase involves developing and refining the intervention and subsequently testing it against feasibility objectives. An iterative approach was adopted involving constant change and review based on feedback from stroke survivors, emerging evidence and problems that were encountered (O'Cathain et al., 2019).

Structure of the thesis

Section 1: Examining the evidence base and developing the theory

In Chapter 1, an overview of the effects of stroke on arm impairment and disability will be presented. The mechanisms of recovery after a stroke will be described with theories, evidence and recommendations around interventions to maximise recovery of the arm. This chapter concludes with an introduction into how the CueS wristband might be used to support a self-directed therapy approach to integrate and maximise use of the impaired arm in functional tasks.

In Chapter 2, the process and results of a systematic review of self-directed interventions for arm recovery after stroke will be presented with meta-analysis of homogenous randomized studies. The findings of this review were used to refine the development of the intervention prior to the pilot randomised controlled trial.

Section 2: Development, testing and refinement of the intervention

In chapter 3, the development of a self-directed therapy intervention to support use of feedback from the CueS wristband will be described using the Template for Intervention Description and Replication (TIDieR) checklist as a framework.

In Chapter 4, the methodology for a proof of concept study will be described to explore the technical feasibility of the CueS wristband to provide feedback on arm activity and the acceptability of the newly developed intervention to patients

In Chapter 5, the results of the technical feasibility and clinical applicability of using feedback from the CueS wristband to improve impaired arm use are presented

In Chapter 6, participants' views on the acceptability of the new intervention are presented based on their experiences of using the intervention.

In Chapter 7, evaluation and refinement of the components of the intervention will be described, with justification for any modifications made to the intervention based on the findings of the proof of concept study.

Section 3: Piloting the feasibility of the intervention to inform further evaluation in a multi-site randomised controlled trial (RCT).

In Chapter 8, the aims and objectives for a pilot RCT will be presented.

In Chapter 9, the methods used to carry out a pilot RCT will be described.

In Chapter 10, the results of the feasibility objectives from the pilot RCT will be presented with recommendations including sample size for a future randomised controlled trial.

In Chapter 11, changes in impaired arm movements during and after the intervention will be reported with cautious conclusions about what effect the intervention might have had on arm activity between the randomisation groups.

In Chapter 12, will describe how individual participants responded to the intervention and any patterns between functional recovery, activity counts and increased use of the impaired arm.

In Chapter 13, a summary and discussion of the results from the pilot RCT will be presented.

Section 4 Thesis summary, discussion and conclusion

In Chapter 14, the findings of the thesis and conclusions will be drawn along with discussion around the limitations of the work and recommendations for a future phase III trial of the intervention.

Section 1: Examining the evidence base and developing the theory

Chapter 1. Recovery of the arm after stroke

1.1 Definition of stroke

Stroke is defined by the World Health Organization as:

> "a clinical syndrome typified by rapidly developing signs of focal or global disturbance of cerebral functions, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin" (World Health Organization, 1978).

In other words, stroke occurs when the supply of blood to the brain is suddenly interrupted. The depletion of oxygen to the part of the brain where the stroke occurred results in brain tissue in that area becoming damaged and dying (World Health Organisation, 2012). This can be due to a blood vessel either bursting (haemorrhagic) or becoming blocked by a clot (ischaemic) (World Health Organisation, 2012). Ischaemia accounts for around 85% of all strokes.

When an ischaemic stroke occurs there are two key areas of damage - the core and the penumbra. The core is the direct area of damage and is associated with non-salvageable tissue death within a few minutes of the stroke occurring. The penumbra is the brain tissue surrounding the core. Neurons in the penumbra continue to receive a limited supply of oxygen and glucose from surrounding blood arteries for a few hours before ultimately dying off. If the flow of blood is restored in time, naturally or through reperfusion treatment, some of the damage to the penumbra can be reversed but damage to the core is likely to be permanent.

The mechanism of damage around a haemorrhagic stroke is similar, but also involves the effects of compression from the haematoma and reactive vasospasm.

1.2 Arm impairment after stroke

Impairments resulting from a stroke are associated with the area of the brain that has been affected and include motor impairment, speech and language deficits, difficulty swallowing, cognitive deficits, visual impairments and sensory loss. Due to the high proportion of cortex dedicated towards the precise control of muscle groups, loss of co-ordinated movement - particularly for the arm - is common and debilitating (Langhorne et al., 2011).

Approximately three quarters of all stroke patients initially experience difficulties due to an impairment of the arm (Sousa et al., 2009). Only between 30 and 66% of these will regain useful function by 6 months (French et al., 2016) and at least half will continue to have persisting problems four years later (Broeks et al., 1999). Often, patients who do improve and regain movement in the arm can find it difficult to translate these improvements to performance within functional tasks (Waddell et al., 2017).

1.3 Mechanisms of recovery

Motor recovery after stroke refers to the restoration of motor movements associated with body structure and function, the ability to perform tasks and restrictions on an individual's ability to participate in life situations (Bernhardt et al., 2017). The World Health Organisation's International Classification of Functioning, Disability and Health (ICF) (Figure 1.1) provides a useful framework to illustrate this where an improvement in any domain of the ICF can be considered to be an indication of recovery (Bernhardt et al., 2017, Langhorne et al., 2009, Levin et al., 2009).

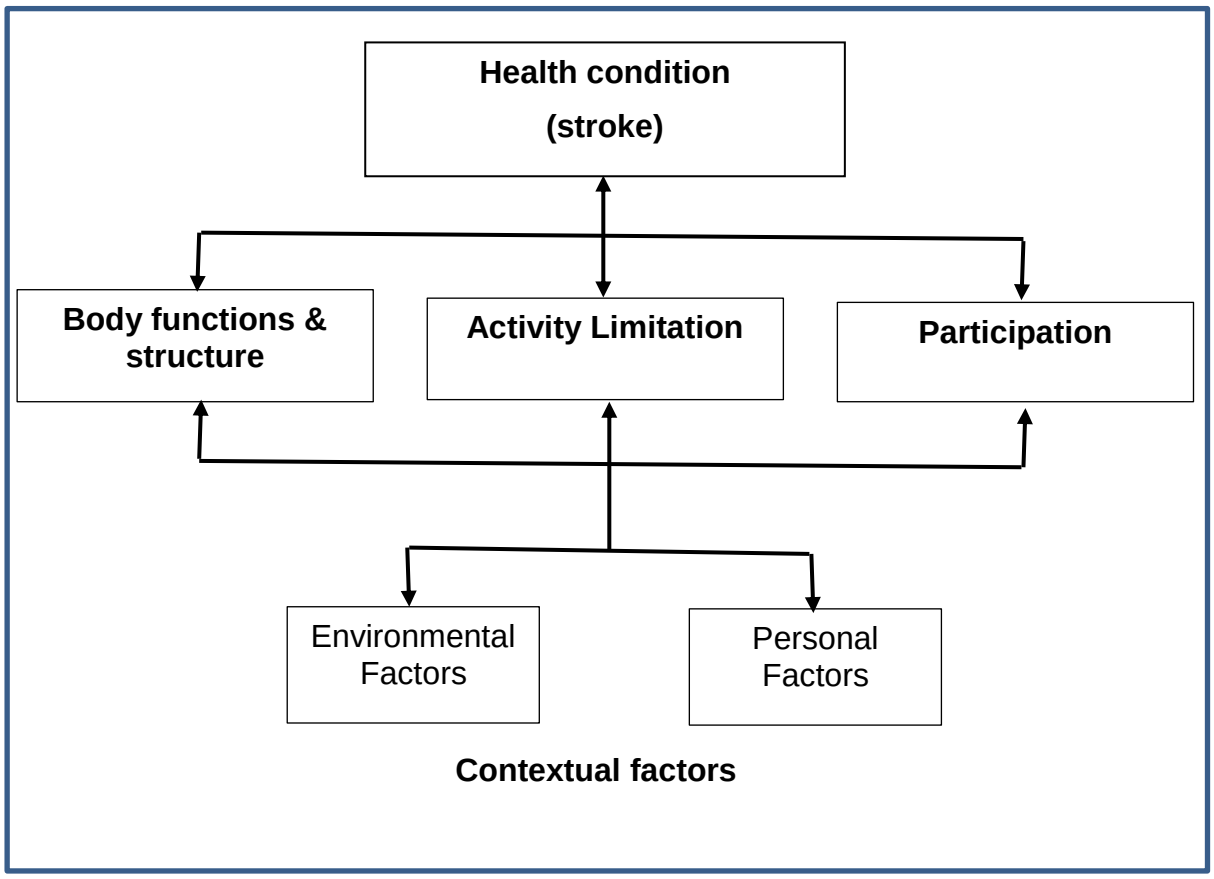


Figure 1.1 International Classification of Functioning, Disability and Health (World Health Organisation, 2002)

1.4 Neuroplasticity

Neuroplasticity is:

> "the capability of the cerebral cortex to alter its functional organisation as a result of experience" (Nudo, 2006).

Throughout the lifespan of an individual, the plasticity of the brain enables it to constantly adapt and modify how neural components connect in the central nervous system in response to new experiences and to facilitate new learning. The basic principle underpinning all learning at a neurophysiological level is that the repeated firing of two neurons simultaneously strengthens the synaptic connection between those neurons thereby increasing the potential for change (Hebb, 1949). The repeated practice of a skill therefore is expected to create stronger connections and facilitate quicker recall and execution of the skill (Hebb, 1949).

A high degree of plasticity is associated with the young and developing brain however this gradually reduces with age. Following any kind of trauma to the brain, excitability is increased for a limited window of time to facilitate adaptation and repair of neural connections (Nudo, 2006). This natural and spontaneous part of the recovery process serves to restore function of the damaged neural tissue and facilitate re-organisation of the remaining neural pathways and relearning of lost function (Langhorne et al., 2011).

1.5 Motor relearning

When relearning motor skills there is an assumption that stroke survivors learn in much the same way as healthy individuals with an emphasis on time spent practising a skill (Kwakkel, 2006, Subramanian et al., 2010).

Neuroplasticity can either assist or hinder this process depending on the nature and experience of the new learning (Kleim and Jones, 2008). A set of key principles (Table 1.1) have been proposed suggesting how to shape the learning experience in order to maximise the benefits of neuroplasticity during rehabilitation (Kleim and Jones, 2008) .

When applied to motor recovery, these principles underpin most modern evidence-based interventions supporting why some interventions are more effective than others. Task-based interventions which draw on the active engagement of the patient to initiate, execute and repeat practice of a skill are encouraged. Hundreds of repetitions of these movements are thought to be required for plasticity and lasting neural changes to occur. Rehabilitation interventions which focus on practising movements based around patient chosen goals are associated with better outcomes as they motivate and actively engage the patient in the process (Langhorne et al., 2011).

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

Adapted from "Principles of experience-dependent neural plasticity: implications for rehabilitation after brain damage" (Kleim and Jones, 2008)

Table 1.1 Principles of experience-dependent plasticity

Whilst simple repetition of a movement may lead to improvements within a discrete training session, this type of training on its own is unlikely to ensure that the movement has been fully learnt (Krakauer, 2006). Learning theory suggests that better retention and generalisation of a skill to other tasks is possible if movements are practised within a training schedule incorporating: distributed practice (frequent blocks of practice broken up with longer rest periods); variable practice and presenting tasks in random order (Krakauer, 2006). In addition to improving the movement itself, practising skills in this way helps to develop the cognitive components associated with motor learning. These include, amongst others, the ability to plan and initiate the movement, adjust and fine tune the skill and to problem solve and adjust to unpredictable situations as they occur (Levin, 2016). As cognitive impairment is a common problem after stroke, to some extent, the potential for motor

recovery may depend as much on the level of cognitive and perceptual impairment as it does on the level of physical impairment.

A common problem after stroke that is associated with this, is the brain's ability to adapt and compensate for loss of movement. Edward Taub found that negative feedback from repeated, failed attempts to use the impaired arm in tasks resulted in a learned behaviour of favouring use of the unimpaired arm over the impaired one (Taub et al., 2006). This increased use of the un-impaired arm will strengthen neural connections on this side which further inhibits use of the impaired arm despite improvements in arm movements. This phenomenon has become known as 'learned non-use' and can be difficult to avoid or correct.

1.6 Types of recovery

To understand the role of rehabilitation in motor recovery, it is important to consider how recovery occurs and the limitations that therapy might have on the extent of the recovery (Bernhardt et al., 2017). There is very little evidence to suggest that therapy can influence true restitution of normal movement as this process relies on spontaneous repair at a neuronal level. Therapy and rehabilitation are most effective when targeting learning based interventions that can restore function through compensation (Bernhardt et al., 2017, Langhorne et al., 2011, Levin et al., 2009). These two concepts of true recovery and compensation are explained further in relation to the levels of ICF framework.

1.6.1 'True' recovery

True recovery refers to the return of normal patterns of motor control in response to neural repair and only occurs within the Health condition domain of the ICF which covers the pathology of a condition (Bernhardt et al., 2017, Levin et al., 2009). If the flow of blood is restored in time, either naturally or through reperfusion treatment, some of the damage to the penumbra can be reversed and function restored (Bernhardt et al., 2017). This 'true' recovery can be seen on functional magnetic resonance imaging (fMRI) where areas of the brain that were previously inactivated by the stroke show up as being reactivated (Levin et al., 2009).

1.6.2 Compensation

Where brain tissue has been permanently damaged, new connections form allowing activity that was previously associated with the damaged regions to be transferred to a different part of the brain. Rehabilitation intervention can influence the forming of these new connections at the body functions and structure level to encourage normal patterns of movement. If successful, the previously impaired limbs are observed being used in a similar way when carrying out a task to that of a non-stroke arm but on fMRI, a different part of the brain is noted to be activated than would normally be seen in healthy individuals (Levin et al., 2009). These structural changes indicate that the brain has made compensatory changes at a neuronal level in the Health condition domain of the ICF to make up for loss of function at the site of the stroke.

Where normal patterns of movement are not achieved in the impaired arm, adaptive movement patterns can be observed where different body segments or body parts are used to accomplish a task. For example, coming forward more at the trunk when reaching for an object to compensate for reduced elbow extension (Levin et al., 2009). In this way, the movement and task can be achieved but the quality of the movement may not be as efficient as previously.

Therapy approaches such as the neurodevelopmental approach aim to restore normal movement by discouraging any movements that might cause maladaptive or compensatory movements and are commonly used in practice despite there being a lack of evidence to support this (Kwakkel, 2006). There is a better understanding now to suggest that compensation is the brain's natural way to adapt to achieve a goal. In order to increase repetitions of movements and influence activity limitations some degree of compensation is inevitable and should perhaps be embraced as part of the recovery process rather than avoided (Kollen et al., 2009). With further practice and refinement of a goal, compensatory techniques might be expected to reduce over time and to be influenced and corrected using feedback.

Despite the recovery trajectory mentioned above, not all stroke patients will have the potential to make a functional recovery in their arm (Stinear et al., 2012). Outcome is

largely dependent on the location and size of the brain tissue injury and the severity of damage to the cortico-spinal tract (Stinear et al., 2017a). For those patients without the potential to recover useful hand movements, an alternative approach is required which focuses on regaining independence and successful execution of a task rather than restoration of movement.

This type of approach occurs at the Activity level of the ICF where consideration is given to how limitations resulting from impairment impact on executing a task or action. In the absence of any return of movement or function in the arm, these limitations can be compensated for by adapting the task itself or the environment. For example, dressing the impaired arm first when putting a shirt on or using one-handed kitchen aids to assist with meal preparation tasks.

An adaptive approach can be essential to people with severe impairment and little or no potential for recovery as it allows them to have some functional independence. In mild to moderate impairment, however it can be associated with increasing maladaptive neuro plastic changes on the unaffected hemisphere which hinder the potential to change the impaired side as discussed above (Kleim and Jones, 2008).

In developing the new intervention for this project, consideration was given to ensure that participants were carefully monitored by qualified therapists and that the appropriate level of support was provided to shape self-directed therapy practice in a positive manner. The technology was initially intended to support motor recovery at the Body functions and structure level of the ICF as well as the Activity limitation level. As will become clear through the development of the intervention in Chapter 7, the feedback was found to be most useful at the Participation level to integrate use of the arm back into normal daily use.

1.7 Evidence based interventions to support recovery of the arm

Many of the aforementioned concepts are based on theories derived from neuroscience however, applying these theories to stroke patients is not always straight forward and does not always elicit the response expected. Some of the challenges around translational research and establishing an evidence base for rehabilitation interventions include the complexity of interventions involving several interrelated components and interventions to target more than one problem. Under-powered studies and heterogeneity between studies create further difficulties when drawing conclusions regarding an intervention (Langhorne et al., 2011). This section provides a brief overview of previous interventions evaluated for their ability to rehabilitate the arm after stroke and briefly describes the types of intervention that could complement deployment of the CueS wristband. The next chapter will then review more specifically, interventions that follow a self-directed approach and report on some of the benefits and problems that have been reported when using technology to support this mode of delivery.

A wide range of different interventions have been investigated for managing recovery of the arm after stroke and are frequently used in combination by therapists according to their training and assessment of individual patients. Establishing the evidence to support widespread use of these interventions can be difficult due to the variability and complexity of different components within each intervention and the complexity of confounding factors across the stroke population and services providing the treatment.

A Cochrane overview identified 40 systematic reviews of 18 different types of intervention to improve arm function after stroke (Pollock et al., 2014). When graded according to the quality of the evidence, the review found a lack of high-quality evidence to support any of the interventions that are currently used routinely in practice and insufficient evidence to support which ones are most effective.

There was, however, some moderate quality evidence to indicate a modest benefit for some interventions on upper limb impairment, upper limb function and the ability to perform activities of daily living. Interventions that showed a benefit included repetitive task practice of more than 20 hours; constraint-induced movement therapy; virtual reality; mirror therapy, mental practice and interventions for sensory impairments (Pollock et al., 2014). Due to the lack of high quality evidence available, adequately powered, robust randomised controlled trials (RCTs) were recommended to confirm the effectiveness of these interventions in addition to evidence related to adequate dose of interventions (Pollock et al., 2014).

Based on the Cochrane review, The National Clinical Guidelines for Stroke made the recommendation that interventions for recovery of the arm after stroke should include "intensive, repetitive, task-orientated and task-specific training" and that opportunity should be given to practise functional activities (Intercollegiate Stroke Working Party, 2016).

The two forms of intervention that are most closely aligned to this recommendation are repetitive task practice and constraint-induce movement therapy (CIMT) both of which have been studied extensively in different forms and dosage.

1.7.1 Repetitive task practice

Repetitive functional task practice (RFTP) involves the repeated practice of a task combining intensity of practice with functional relevance (French et al., 2016). The practice can involve whole task practice such as picking up a cup, or practice of part of the task such as reaching to touch the cup (Brkic et al., 2016, French et al., 2016). The principles of RFTP are founded in the movement science approach and high intensity practice of more than 17 hours over 10 weeks is recommended to include a high number of repetitions around a functional goal during each session (French et al., 2016, Pollock et al., 2014, Veerbeek et al., 2014). However, establishing an optimum dose that can be quantified has proven difficult (Lang et al., 2015, Lang et al., 2016) and may be attributed to the training schedule used and an emphasis on

sessional practice. Constraint-induced movement therapy has attempted to address this problem with the inclusion of increasing use of the impaired arm throughout the day.

1.7.2 Constraint-induced movement therapy

Constraint-induced movement therapy (CIMT) is derived from Edward Taub's theory of learned non-use (Taub et al., 2006) and has been described as, "the most investigated intervention for treating stroke patients" (Kwakkel et al., 2015). It is a form of RFTP involving high intensity repetitive practice of the impaired arm whilst the unimpaired arm is restrained in a sling or mitt (Wolf et al., 2002). It is recommended by the National Clinical Guidelines for Stroke for mild to moderate arm impairment (Intercollegiate Stroke Working Party, 2016). CIMT in its original form is based on three main principles:

1. Restraining use of the non-impaired arm for up to 90% of waking hours.
2. Intensive, repetitive, practice of task orientated practice with progressive difficulty (shaping) for up to 6 hours a day over 2 weeks.
3. Adherence-enhancing behavioural techniques designed to transfer the gains obtained in a clinical setting into the home environment (transfer package) (Kwakkel et al., 2015)

Despite trial evidence to support selective use of CIMT, it has not been widely adopted largely due to the prohibitive costs of the associated therapy time and the high demands placed upon patients (Viana and Teasell, 2012, Kwakkel et al., 2015). In an effort to make CIMT more appealing for patients and therapy services, various modified versions have been developed by reducing the amount of time that the unimpaired arm is restrained, reducing the amount of therapy training or removing the transfer package (Kwakkel et al., 2015). Whilst modifying CIMT interventions in this way does not appear to compromise the benefits (Kwakkel et al., 2015), simply forcing use of the impaired arm by wearing a glove has not been shown to be beneficial suggesting that the dose of functional task practice and transfer package may be key.

1.8 Delivering intensive therapy within current service provision

Delivering any intensive task-orientated intervention potentially requires a high amount of trained therapy staff. Therapy services in the United Kingdom already struggle to provide the minimum daily recommendation of 45 minutes and during this time other therapy needs also need to be met (Clarke et al., 2018). To achieve amounts of more than two and a half hours of therapy on the arm alone (Daly et al., 2019) alternative approaches to the way therapy is delivered may be required.

1.8.1 Self-directed interventions

Within hospital settings, semi-supervised and group sessions are being adopted to increase the amount of therapy input without the need for additional resources (Tyson et al., 2016). Outside of therapist working hours and in the community, patients are being provided with therapy programmes that they can practise independently or with the support of a family member or carer (Harris et al., 2009). The structure and format of these programmes can vary with some following a set of structured exercises or functional activities, whilst others simply promote and facilitate opportunities to enhance use of the stroke arm in normal routines beyond 'usual care'.

1.8.2 Technology to augment the dose of rehabilitation

An increasing variety of technologies are being developed and evaluated to support self-directed therapy practice (Da-Silva et al., 2018). These will be reviewed in detail in Chapter 2. Qualitative studies indicate that patients and therapists are keen to embrace the use of technology to support high intensity upper limb rehabilitation, but barriers include impractical designs, lack of integration into individual therapy programmes and insufficient evidence for cost-effectiveness (Demain et al., 2013, Hochstenbach-Waelen and Seelen, 2012). Whilst technology such as robot-assisted approaches may safely achieve high levels of precise repetitions without direct supervision from a therapist, the high cost and portability prohibits home therapy[9]. Furthermore, these devices often focus on training specific joint movements and do not always translate well into everyday life (Timmermans et al., 2009, Rodgers et al.,

2019). Rehabilitation video game systems have potential therapeutic benefits (Demain et al., 2013) however, patients may not be able or wish to frequently play video games and the resulting movements may not promote motor learning which is directly useful for daily activities (Adie et al., 2016). There is clearly a need to develop affordable technology which promotes personalised upper limb rehabilitation activities that can be practised independently by the patient regardless of whether they are in hospital or at home.

1.8.3 Promoting arm activity using accelerometers

Accelerometers are relatively low-cost small electronic components commonly found in modern technology including mobile phones, video game systems and more recently commercial activity monitors. They measure applied acceleration and can be used to measure the rate and intensity of body movement in up to three planes (anterior–posterior, mediolateral and vertical) (Godfrey et al., 2008). Accelerometers have been on the market for some time now and over the last two decades, have been increasingly used to monitor physical activity (Gebruers et al., 2014), however their use in arm rehabilitation is still in its infancy (Noorkoiv et al., 2014). A big advantage of accelerometers is their objective reporting of real-world activity within a more natural environment than a clinical setting (Bailey and Lang, 2013, Lang et al., 2017, Uswatte et al., 2005, Uswatte et al., 2006a).

At the time that this project started there had been no report of accelerometers being used therapeutically to inform decisions around an arm rehabilitation intervention (Noorkoiv et al., 2014). Rather, studies reported on using the devices to describe and measure therapy outcomes or to compare the data with clinical outcome measures (Noorkoiv et al., 2014). Data collected from accelerometers worn by stroke patients have been particularly useful in showing the relationship between recovery noted in a clinical outcomes and how this translates to actual use of the impaired arm in daily routines (Rand and Eng, 2012, Waddell et al., 2017).

Since the review in 2014 (Noorkoiv et al., 2014), only one study has reported on the use of accelerometers to provide feedback to stroke survivors on the use of their impaired arm in a real-world community setting (Whitford et al., 2018). In this study,

eight participants between 20 and 155 months post stroke, wore bilateral wrist-worn accelerometers over a three week period. During twice weekly sessions, participants viewed reports of their activity data presented on a series of charts and graphs with a researcher. Having reviewed the data, participants then set two activity related goals aimed at increasing the use of their impaired arm. High compliance to the intervention was reported and a benefit demonstrated for the perceived amount of use of the arm, although the objective measurement of arm use by the accelerometers did not show any change. The authors recommended that future research should investigate combining accelerometer feedback with traditional rehabilitation.

Another study investigated the effect of intermittent vibro-tactile cueing to reduce unilateral neglect after stroke using a modified actometer. Actometers originated from modified self-winding watches and were popular for recording frequency of movements until the late 1980s (Tryon, 2008) and have since been replaced with accelerometers. An actometer was worn on the wrist to measure activity and delivered a vibration cue with auditory signal every five minutes over a three hour period (Fong et al., 2013). The cue would continue for up to three minutes unless the wearer cancelled it using a de-activation button. Although this regular sensory cueing delivered by the actometer was not found to benefit unilateral neglect, participants had been advised to carry out five prescribed arm movements when cued and consequently an increase in arm movements was found for the intervention group. This is likely to reflect the repetitive nature of the arm movements participants were asked to perform (Fong et al., 2013) but it did not lead to a benefit in functional performance.

In a pilot randomised controlled trial in China, 30 inpatients were randomised to either receive visual feedback of activity data over a 9 hour period displayed on a smartwatch or no feedback (Lawrie et al., 2018). Real-time feedback on the activated smartwatches indicated how close participants were to hitting activity targets within a 2-hour timeframe. The preceding day's recorded activity was automatically increased by 5% to set the target for the same time period of the current day. Although adherence improved throughout the intervention phase, this was in response to

regular reminders from staff. Although outcomes were not compared, the intervention group exceeded their baseline activity for 65% of days compared to 55% for the control group.

There were key differences in the type and frequency of feedback between the aforementioned studies which may have contributed to the variations in results. Despite this, they all support the concept that feedback can facilitate modification and refinement of motor skills.

1.9 Summary

This chapter has described current theories and evidence for treating arm impairment after stroke. Despite a large number of studies investigating ways to support recovery, there is a lack of high quality studies on which to base clear recommendations. High dose functional task based practice is recommended but pragmatic considerations about the best use of therapist resources often dominate intervention design, setting and target population. The optimal content for individual patients has not been defined. Accelerometers have the potential to support unsupervised therapy practice by monitoring and providing personalised feedback on arm activity, but how best to deliver this type of intervention is unclear.

The next chapter will explore and describe previously investigated self-directed interventions for arm recovery, with and without technology, to report their effectiveness for improving arm function and provide some context for the new CueS wristband intervention.

Chapter 2. Self-directed interventions for recovery of the arm after stroke: a systematic review

2.1 Introduction

This chapter describes a systematic review of previously reported self-directed interventions for arm recovery after stroke both with and without technology.

Whilst the value of specific arm interventions has already been described (Pollock et al., 2014), the evidence relating to the delivery of self-directed arm rehabilitation across therapeutic modalities has not previously been summarised and could provide important insights about using this approach to enhance delivery. Due to the implications for patient selection, user acceptability, staff training and resources, it is also of particular interest whether differences exist in the feasibility and effect of arm rehabilitation according to the type of technology being delivered under self-direction.

2.2 Aim: To review existing self-directed interventions for recovery of the arm after stroke

Objectives:

- To identify and describe the content of interventions for rehabilitation of the arm after stroke which have taken a predominantly self-directed approach (with or without the involvement of technology)
- To report the effectiveness of self-directed interventions for improving arm function after stroke.
- To report the effectiveness of self-directed interventions for increasing use of the stroke arm in daily activities.

2.3 Methods

The review was conducted according to guidelines set out by the Cochrane collaboration (Higgins and Green, 2011) . The protocol was published on the PROSPERO International prospective register of systematic reviews website (Reference number: 38619) (Da Silva et al., 2016).

Electronic searches of MEDLINE; EMBASE; CINAHL; SCOPUS and IEEEXplore were carried out from the time of origin to February 2018. The search strategy used a combination of selected MeSH terms with keywords for MEDLINE, which was then altered appropriately for other databases (Da Silva et al., 2016) (Appendix B). A search of the Cochrane Database of Systematic Reviews was also conducted and the reference lists of relevant reviews screened manually for additional studies.

We included studies of self-directed arm interventions for participants over the age of 18 with any stroke-related arm deficit regardless of time since onset. Populations with mixed impairment aetiology were included if at least 50% of participants had experienced a stroke. An intervention was classified as self-directed if more than 50% of the overall intended duration of therapy practice, was independently initiated and carried out by the participant outside of direct contact sessions in accordance with a pre-defined study protocol.

When identified studies described that direct clinical or research supervision was required for some aspect of the intervention (e.g. application of electrical stimulation electrodes, or review of functional activity goals) the methods and results were carefully scrutinised to be sure that overall there was a dominant self-directed component. If the self-directed therapy formed part of another programme (e.g. the transfer package of constraint induced movement therapy), then the self-directed component of the programme needed to be clearly described or evidence provided that participants had recorded details of their independent practice.

In order to describe the full range of self-directed interventions, any study design was accepted providing that it reported an arm function outcome for two or more participants.

The primary review author (RDS) initially screened the titles of all records and removed duplicates. The titles and abstracts of the remaining papers were independently assessed by two review authors (RDS and CP) to identify studies meeting inclusion criteria. The full text of all potentially relevant papers were retrieved and final studies selected. Discrepancies were resolved through discussion and involvement of a third author (SM).

A data extraction form was designed to meet the criteria of the review and tested on the first five studies. Data were extracted by the primary author (RDS) including: study design; sample size; intervention content; amount of therapy practice; amount of therapist time; main outcomes and adherence to protocol. Any equivocal data were discussed and resolved between all authors. Interventions were grouped according to no-technology or the type of technology described. Where an intervention involved more than one form of technology a joint author decision was made regarding the primary technology being tested. Devices were still included if they had not been specifically designed with a rehabilitation purpose provided they followed a protocol intended to help people to recover arm movement. Where data were missing or incomplete, authors were contacted.

To report effectiveness, meta-analysis was carried out with data from those studies where participants had been randomised and clinical outcomes of arm function and / or independent use in daily activities were reported. For studies with a cross-over design, only the first phase data (prior to cross-over) were included in the meta-analysis to avoid any possibility of data contamination through carryover or learning effects.

Treatment effect sizes were calculated using Revman 5 software (Review Manager (Rev Man), 2014) based on mean scores and standard deviations from the randomised studies. Where the standard error or confidence interval was reported the standard deviation was calculated using formulas provided in the Cochrane handbook's guidelines (Higgins and Green, 2011). As studies were small in size,

mean change from baseline was used where available to allow for a more accurate comparison between control and intervention (Higgins and Green, 2011).

Due to the wide range of interventions being studied we anticipated that a variety of outcome measures would be reported. For this reason meta-analysis was carried out within each technology sub-group in an attempt to reduce heterogeneity. When the same outcome measure was used by all studies within a sub-group the mean difference was calculated, otherwise outcomes were pooled using the standardised mean difference. Most outcome measures rated improvement by an increase in score however, where a reduced outcome score indicated improvement (i.e. a decrease in time taken to complete a task) the scale direction was aligned with others by multiplying the mean score by -1 (Higgins and Green, 2011).

Each of the randomised studies underwent an assessment of risk of bias using the Cochrane Risk of bias tool (Higgins and Green, 2011).

There were two pre-planned sensitivity analyses. One was to look at the influence of time post stroke and the second was to consider if there was a benefit shown for more time spent practising. The amount of time post stroke was categorised as < 3 months; 3-6 months; 6 to 12 months and > 12 months based on the mean time post-stroke reported by original authors. The amount of time spent in self-directed versus supervised therapy practice was calculated according to each study's protocol (Table 2.1). If the precise amount was unclear, a minimum estimated amount of time was calculated as follows: where a range was given (e.g. 1-3 hours per day) the lower value was used; where the amount of time was described as a number of sessions each session was estimated at 30 minutes unless otherwise stated; a telephone contact was allocated 15 minutes per contact. Any pre-intervention training was excluded from the amount of practice i.e. only the amount provided within the actual therapy programme was included.

2.4 Results

The PRISMA diagram (Moher et al., 2009) in Figure 2.1 summarises the results of the literature search. The searches identified 1380 records of which 128 were removed as duplicates. One thousand two hundred and fifty-two records were screened by primary author (RDS) and the full texts of 106 articles subsequently retrieved for full text assessment. Sixty-six of these records were excluded leaving a total of 40 studies (1172 participants) for inclusion.

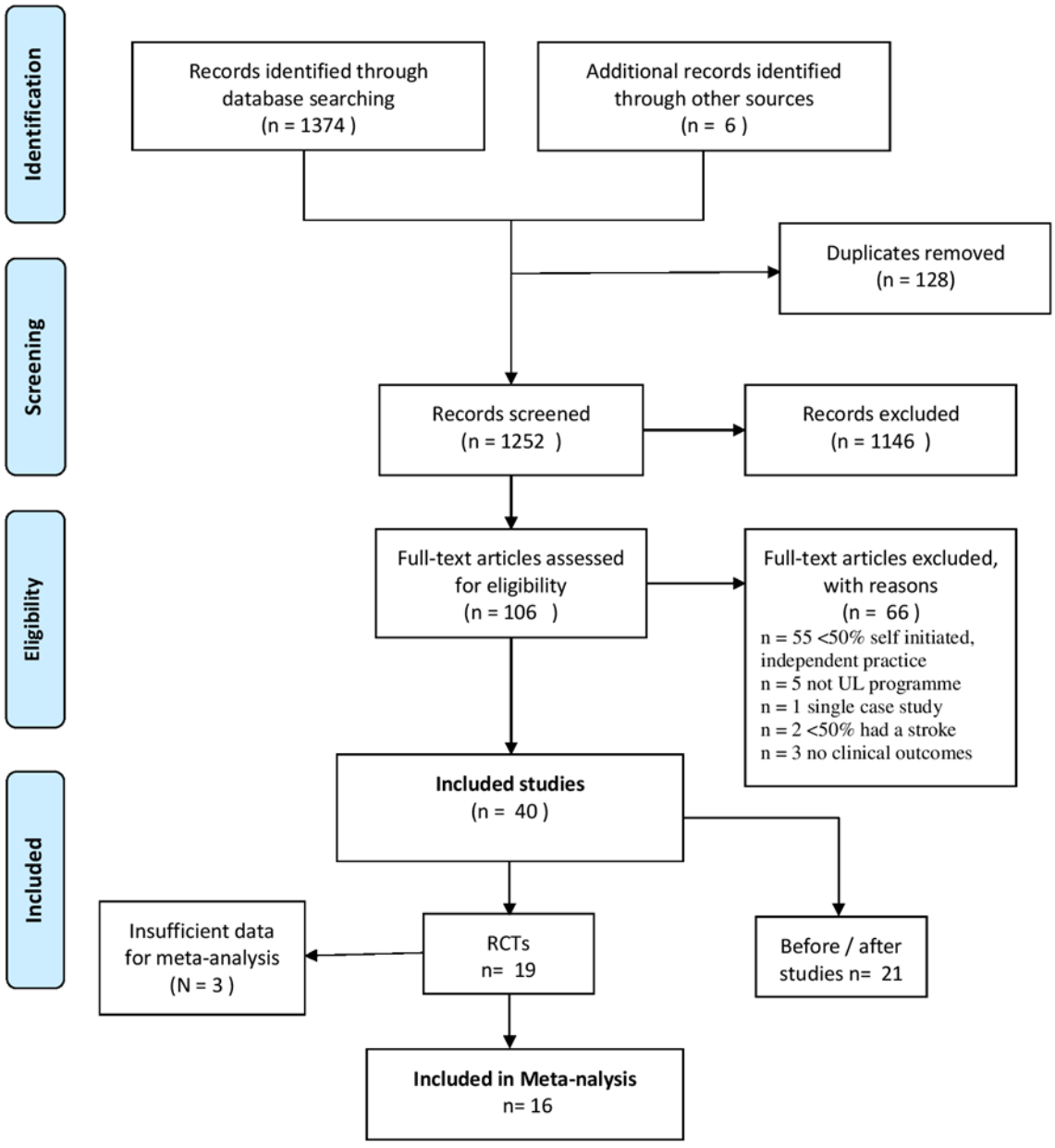


Figure 2.1 PRISMA diagram of the process used to identify studies (Moher et al., 2009)

Table 2.1 provides an overview of the interventions for each included study consisting of 19 randomised controlled / cross-over trials (Adie et al., 2016, Brkic et al., 2016, Brunner et al., 2012, Burridge et al., 2017, Dos Santos-Fontes et al., 2013, Gabr et al., 2005, Hara et al., 2008, Harris et al., 2009, Kimberley et al., 2004, Michielsen et al., 2011, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Stinear et al., 2008, Sullivan et al., 2012, Tariah et al., 2010, Turton et al., 2016, Wolf et al., 2015, Zondervan et al., 2015) and 21 before and after studies (Alon et al., 2002, Alon et al., 2003, Burridge et al., 2011, Da Silva et al., 2018, Donoso Brown et al., 2014, Langan et al., 2013, Lee and Kim, 2013, Mawson, 2011, Mouawad et al., 2011, Niama Natta et al., 2015, Nijenhuis et al., 2015, Page and Levine, 2007, Page et al., 2015, Pickett et al., 2007, Sivan et al., 2014, Sullivan and Hedman, 2007, Turk et al., 2008, Wittmann et al., 2016, Wittmann et al., 2015, Zhang et al., 2011, Chen et al., 2017)

The amount of time spent in therapy practice across all interventions ranged from seven (Mawson, 2011) hours to 366 (Page and Levine, 2007) hours over a period that ranged from two weeks (Mawson, 2011, Mouawad et al., 2011, Niama Natta et al., 2015, Pickett et al., 2007, Smania et al., 2012) to five months (Hara et al., 2008). It was not possible to calculate the amount of practice time for one study (Da Silva et al., 2018) as the amount of activity was described as a summary value of accelerometer data (i.e. signal vector magnitude) rather than time and defined by the baseline activity of each participant.

Most interventions included some form of additional technology with only five studies that did not (Brkic et al., 2016, Harris et al., 2009, Lee and Kim, 2013, Niama Natta et al., 2015, Turk et al., 2008). All interventions in the “no technology” group (Table 2.1) involved some form of functional task practice ranging from simple reaching and grasp of everyday objects to more complex functional tasks. Typically these approaches relied on low-cost equipment most of which could be easily sourced at home. Only two studies included participants who were still inpatients although both these interventions would also be suitable for home-based use. Two studies based the choice of task to be practised on participant-identified goals (Brkic et al., 2016, Turton et al., 2016). Adherence to these programmes was high with the total amount

of therapy practice ranging from 26 to 56 hours of which 67% to 93% was self-directed across a time period ranging between 2 and 10 weeks.

Studies that used technology fell into seven groups according to the type used (Table 2.1). There was some overlap within these groups as several studies employed more than one mode of technology in order to deliver their intervention e.g. computer games were often use to support robotic devices (Sivan et al., 2014, Wolf et al., 2015, Zhang et al., 2011, Wittmann et al., 2016, Wittmann et al., 2015, Burridge et al., 2017, Page and Levine, 2007, Pickett et al., 2007). Tele-rehabilitation was used alongside interventions such as constraint-induced movement therapy (Burridge et al., 2017, Page and Levine, 2007, Pickett et al., 2007, Langan et al., 2013) as a method of delivering or monitoring the intervention without the need for a face to face therapist contact (Mawson, 2011, Wolf et al., 2015). The wearable device monitored the amount of use of the stroke hand and provided feedback to the wearer to encourage them to use it more within a functional task practice programme that normally would be delivered without additional technology (Da Silva et al., 2018).

Electrical stimulation was the most commonly studied intervention and these studies also recorded the highest consistent amounts of practice ranging from 20 hours across a 4 week programme (Sullivan and Hedman, 2007) to 106 hours over 5 months (Hara et al., 2008). Participants in the electrical stimulation group were all more than six months post-stroke at the time of enrolment and demonstrated regular self-directed use of the intervention over long periods of time. Participants adhered well to the electrical stimulation treatment plans consisting of both surface electrodes (Alon et al., 2002, Alon et al., 2003, Dos Santos-Fontes et al., 2013, Gabr et al., 2005, Hara et al., 2008, Kimberley et al., 2004, Page et al., 2015, Sullivan and Hedman, 2007, Sullivan et al., 2012) and implanted percutaneous electrodes (Burridge et al., 2011, Turk et al., 2008) and triggered by timed and cyclic stimulation (Adie et al., 2016, Alon et al., 2002, Dos Santos-Fontes et al., 2013, Sullivan et al., 2012); EMG (Gabr et al., 2005, Hara et al., 2008, Kimberley et al., 2004, Page et al., 2015); or closed-loop systems (Burridge et al., 2011, Sullivan et al., 2012, Turk et al., 2008).

Studies using constraint-induced movement therapy also reported participants being able to adhere to a large amount of unsupervised therapy practice ranging from 10 hours across two weeks (Smania et al., 2012) to 350 hours over a 10 week period (Page and Levine, 2007). Participants in this group were all more than two months post stroke.

In the interactive gaming group, adherence to the programme was generally poor. One study reported high attrition in the intervention versus the control group (Standen et al., 2017), whilst another indicated participant preference for fewer sessions of longer duration rather than daily sessions (Donoso Brown et al., 2014). When interactive gaming was used to support robotic and orthotic device interventions, participants also reported less than the prescribed amount of therapy practice (Nijenhuis et al., 2015, Nijenhuis et al., 2017, Sivan et al., 2014), which was not noted for studies in the same intervention category that included conventional task practice (Stinear et al., 2008, Wolf et al., 2015, Zondervan et al., 2015). Participants reported that the games "lacked complexity" (Sivan et al., 2014) and that "more attention towards motivational strategies is needed" (Burridge et al., 2017). An exception to this was interactive gaming involving the Nintendo Wii™ which may reflect the expertise behind the game development (Adie et al., 2016, Mouawad et al., 2011). Both studies found the Wii™ intervention to be well tolerated and beneficial for arm recovery, although one reported equivalent improvement through practice of selected activities from the Graded Repetitive Arm Supplementary Programme (Harris et al., 2009), which was more cost effective (Adie et al., 2016).

No technology

Details of intervention /device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice (hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Repetitive functional task practice two tasks chosen from a menu of daily activities. 20 repetitions of each task practised twice daily.	Brkic, 2016 UK	4 week programme of twice daily self-supervised practice. Twice-weekly therapy review of goals and tasks. Daily practice recorded on log sheets. Control group received usual care.	Pilot RCT (n = 24) <3 months	28	6	82%	Patients adhered well to twice daily practice over 4 weeks	Intervention was acceptable and led to achievement of goals but fatigue levels require monitoring
Graded repetitive arm supplementary programme (GRASP). Participants complete 1 hour a day of self-administered exercise programme from a manual.	Harris, 2009 USA	4 week program; 60minutes per day, 6 days a week. Daily practice recorded on log sheets. Weekly review from a therapist. Control group provided with education book on stroke recovery and general health.	RCT (n = 103) <3 months	24	2	92%	1 hour a day for 4 weeks was feasible	Intervention is feasible and offers a low-cost method of delivery for maximising time spent on arm recovery
Self-directed exercise programme with task board and paper and glass cups. Graded according to ability to carry out repetitive reach and grasp tasks.	Lee, 2013 Republic of Korea	10 week programme of 60 minutes unsupervised practise twice a week; Weekly 1 hr session with physiotherapist..	Before-after (n = 7) >12 months	20	10	67%	Twice weekly practice of programme was feasible	Self-directed exercise using a task board can improve function and reduce pain in the stroke arm.
3 hour self-directed practice consisting of 15 minutes self-mobilization exercises; 90 minutes unimanual task practise (bringing cup to mouth, stacking cups; reaching for water bottles; moving cutlery and coins; turning cards) and 40 minutes bimanual task practice (buttons; folding napkin and opening a bottle)	Natta, 2015 Benin	2 week programme; 3 hours practice per day for 5 days/week over 2 weeks. Telephone review every two days to monitor progress.	Before-after (n = 12)>12 months	30	2.25	93%	3 hours a day practice was feasible	Self-directed therapy is feasible and inexpensive and could increase the number of rehabilitation sessions to improve recovery
Progressive training programme of whole reach-to-grasp tasks and part practice activities aiming to achieve 100-300 repetitions per session.	Turton, 2016 UK	6 week programme. One hour self-directed practice per day. 14 x one hour therapy sessions over the six weeks. Daily practice recorded on log sheets. Control group received usual care.	RCT feasibility (n = 48) 3-6 months	42	14	75%	Participants achieved median 30 minutes self-practice per day	Home-based intensive task-specific rehabilitation is safe and feasible.

Interactive gaming

Details of intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice(hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Nintendo Wii sports™ Commercially available video game offering non-immersive virtual reality therapy.	Adie, 2016 UK	6 week programme. Self-directed exercise using the Nintendo Wii sport™games for 45 minutes per day in seated position. Weekly telephone review. Control group practised tailored arm exercises 45 minutes per day for 6 weeks	RCT (n = 240) <3 months	31.5	1.5	95%	Participants achieved a mean of 39 minutes practice per day	Wii™ based exercise was safe and well tolerated but improvements were not superior to less expensive alternatives.
	Mouawad 2011 Australia	2 week programme. Self-directed exercise using the Nintendo Wii sport™ for 30 mins increasing to 3 hours per day; additional 1 hr per day of supervised training.	Before-after (n = 7) >12 months	22	10	69%	Participants achieved a mean of 2.4 hours practice per day	Intervention led to improvements in motor function which also benefitted use of stroke arm in activities of daily living.
Neurogame Therapy system Surface EMG-controlled video games to target wrist activation. Surface electromyography signals from wrist flexors and extensors transmitted to computer and converted into movements to control the game.	Donosos, 2014 USA	4 week programme. 45 mins self-directed practice x 5 days a week for four weeks (or total of 15 hours). Intermittent support as required during the 4 weeks (estimated at 2 visits over the 4 weeks).	Repeated measures (n = 12) >12 months	15	1	94%	Five sessions weekly not feasible. Fewer sessions of longer duration may be more	Intervention benefitted muscle activation but limited changes in kinematic and activity level outcomes indicate need for additional functional component.
Virtual glove Hand-mounted unit with infra-red light emitting diodes mounted to fingertips. Nintendo Wiimotes on monitor tracks diodes to translate hand movements into 3D space. 3 games encourage reach and grasp, grasp and release and pronation / supination.	Standen, 2017 UK	8 week programme. Self-directed practice of 20 minutes maximum, 3 times a day. Weekly or fortnightly review visits offered. Control group received no input other than visits to collect outcome measures.	Pilot RCT (n = 29) 6-12 months	56	4	93%	Low recruitment and retention rates. Higher than expected levels of support required (median 6hrs 10 minutes of support per person).	Additional strategies required to boost recruitment and adequate resources to support participants with the technology.
Armeo®Senso Sensor-based virtual reality training session with touchscreen computer and wearable movement sensors to offer high dose repetitions via computer therapy games.	Wittman, 2015 Switzerland	6 week programme. As much practice as they chose playing virtual reality reaching game. No additional support was provided	Non-randomised feasibility study (n = 5)	17	0	100%	Average amount of time spent on playing was 16.8 hours over 6 weeks.	Intervention is viable option for home therapy
	Wittman, 2016 Switzerland	6 week programme. As much practice as they chose playing VR reaching game. No additional support was provided	Before-after (n = 11) >12 months	14	0	100%	Average daily time spent practising was 30 minutes for 4 days per week (mean 13.7 hours over 6 weeks).	IMU-based home therapy is safe and offers high dose of therapy

Electrical stimulation

Details of intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice (hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Handmaster™ system Neuroprosthses maintains wrist in 10-20 degree extension and delivers electrical stimulation through 5 surface electrodes to stimulate flexion / extension of fingers to grasp and release objects.	Alon, 2002 USA; Israel	3 week functional programme. 10 minutes increasing to 45mins self-directed practice twice daily.	Before-after study (n = 29) >12 months	37	2	95%	Good compliance with programme	Handmaster is safe and effective for improving hand function
	Alon, 2003 Sweden; Netherlands; Israel	5 week functional programme. 20mins daily increasing in the first 2 weeks up to 2hrs 45mins daily to be practiced for the remaining 3 weeks	Before-after (n = 77) >12 months	75	2	97%	High compliance supported use of FES of up to 2hrs 45 mins practice per day	5 week programme improved selected hand functions
Electrical stimulation using closed-loop control of micro stimulator implants to activate elbow extension, wrist extension, finger / thumb extension and thumb abduction when reaching and grasping.	Burridge, 2011 UK	12 week programme; 1-2 hours per day at home for 12 weeks plus x 3 review sessions by researcher (one every 4 weeks).	Before-after (n = 6) >12 months	72	1.5	98%	Participants achieved a mean of 59.5 days of unsupervised practice	Closed-loop stimulation improved function but subjects reported inconvenience using. A fully implanted wireless version would overcome this.
Reliefband® device to deliver repetitive peripheral nerve stimulation prior to motor training tasks. Bi-phasic square-wave electrical nerve stimulation delivered via surface electrodes built into style device at frequency of 31 Hz. 5 different levels of stimulation.	Dos Santos-Fontes, 2013 Brazil	4 week programme for 2 hours before motor training tasks. 2 blocks of training per day over 4 weeks. Therapy review at 7 days to ensure correct procedure and weekly review thereafter. Control group wore wristband on dorsal surface of wrist thick polyester barrier to prevent electrical stimulation to nerve	Pilot RCT (n = 20) >12 months	42	1.25	97%	High compliance with intervention reported	Intervention is safe and feasible leading to long-lasting enhancement of arm function.
Neuromove 900 – uses 3 surface electrodes to detect electromyography in affected muscles whilst practising extension exercises.Electrical stimulation delivered if muscle activity exceeds a preset threshold.	Gabr, 2005 USA	Twice daily use of 35 minutes over 8 week programme Control group 8 weeks home exercise programme for 35minutes per day.	Cross over RCT (n = 12) >12 months	65	0	100%	High compliance with intervention reported by completed patient diaries	Intervention is feasible and increased active wrist extension. No functional benefits were found.
Power-assisted closed-loop electromyographically triggered electrical stimulation system worn under clothes to induce greater muscle contraction than EMG signal detected. Targets supination/pronation, flexion/extension of digits, wrist and elbow; abduction/adduction of shoulder	Hara, 2008 Japan	5 month programme; 30 min self-directed programme 5 days a week gradually increasing to 1hr per day within the first 10 days. Thereafter 1hr per day 5 days a week for 5months.	RCT (n = 22) >12 months	106	15	88%	10 out of 12 participants were able to comply with the full five month programme	Intervention benefitted wrist and finger extension and shoulder flexion.

Electrical stimulation (continued)

Details of intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice (hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Automove Model AM 706 stimulator Electromyography triggered somatosensory stimulation to peripheral nerves to facilitate hand opening	Kimberley, 2003 USA	3 week programme of 6 hours a day over 10 days. Half the time participant triggered stimulated response through active effort, rest of time machine automatically stimulated muscle contraction. Control received same programme using sham device before cross-over	RCT crossover (n = 16) >12 months	60	0.75	99%	All participants achieved 60 hours typically through 3-6 hours every day or every other day.	Intervention self-administered in an intensive manner is feasible. Improvements lead to improvements in hand function.
Mentamove neuromuscular electrical stimulation device detects electrical signals in muscle group and activates muscle if EMG activity meets or exceeds preset threshold.	Page, 2015 USA	8 week programme of 1hr mental practice per day. Patients imagined carrying out 2 upper limb tasks without actually moving. Device detected if electrical signals sent to targeted muscle group met threshold and if so activated muscle;	pre-post case series design (n = 6) >12 months	56	2	97%	High compliance with intervention	Intervention appears to be feasible and benefitted arm impairment, dexterity and participation in activities.
Rehabilicare EMS +2 Muscle stimulator with Stimcare + electrodes.	Sullivan, 2007 USA	8 week programme of neuromuscular and sensory amplitude electrical stimulation during task-specific exercises for 15 minutes once or twice daily. Sensory stimulation 15 minutes twice daily for participants with sensory deficits.	Before-after (n = 10) >12 months	56	none reported	100%	Poor completion of log books but all participants completed the programme	Intervention is feasible and led to sensory and motor improvements.
Glove electrode with electrical stimulation delivered by EMPI 300 PV neuromuscular stimulator.	Sullivan, 2012 USA	4 week programme sensory electrical stimulation delivered during 10 task-specific arm exercises. Twice daily for 30 minutes 5 days a week. Control group followed same programme using a sham device.	RCT (n = 43) 6-12 months	20	none reported	100%	High compliance with the intervention	Intervention did not benefit task practice. Future studies should explore of more intensive practice leads and if stimulation is better before or during the task practice.
Radiofrequency microstimulator implanted in arm and forearm to activate elbow, wrist and finger extension and thumb abduction while performing functional tasks	Turk, 2008 UK	12 week programme; 12 weeks self-supervised practice of 1 hour per day 5 days a week. Weekly to fortnightly lab-based sessions with research therapist to adjust device.	Before-after (n = 7) >12 months	60	15	80%	High compliance with the intervention	Intervention was feasible and led to improvements. Personalising the intervention around the subjects led to higher motivation/compliance.

Constraint-induced movement therapy (CIMT)

Details of intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice (hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Task-related arm training delivered by therapist plus unilateral self-directed programme following shaping principles and based around activities of daily living. Constraint mitt worn for 4 hours. Daily log of time spent exercising.	Brunner, 2012 Norway	4 week programme; 4 hours a week supervised therapy as in/outpatient plus 2-3 hours a day self-directed functional programme. Mitt worn for 4 hours a day. Control group followed dose-matched programme of bimanual tasks practice	RCT (n = 30) <3 months	56	16	78%	Participants were able to achieve the required amount of self-directed practice and wore the mitt for a mean of 3.5 hours per day.	Intervention was as effective as bimanual training and therefore wearing a mitt may be unnecessary. Programmes should include bimanual tasks.
LifeCIT: Web-supported programme guiding participants through CIMT programme, daily targets set for constraint mitt wear time and time spent on exercises, computer-based therapy games and activities of daily living.	Burridge, 2017 UK	3 week programme 6 hours a day, 5 days a week for 21 days. Control group received usual care	Pilot RCT (n = 19) <3 months	90	0	100%	High compliance with intervention. Mitt worn for mean 4.8 hours per day for 13.6 / 15 days. Activities performed for mean 3.2 hours per day.	A web-supported programme of constraint-induced movement therapy can increase intensity and adherence.
Modified CIMT programme delivered via tele-rehabilitation.	Page, 2007 USA	10 week programme; 3 half hour therapy sessions per week delivered via tele-rehabilitation; mitt worn for 5 hours daily and participants recorded ADLs performed during this time	Before-after case series (n =4) >12mths	350	16	95%	Good adherence to the programme. Participants and therapists reported high satisfaction.	Delivery of constraint-induced movement therapy via the internet is feasible and inexpensive.
CIMT delivered via video-conferencing equipment	Pickett, 2007 USA	2 week programme; 6 hrs per day self-directed practice 5 days a week with 1.5hrs per day of tele-rehabilitation support from therapist (split across morning and afternoon)	Before-after case series (n = 2) >12 months	60	15	80%	Patients reported moderately high time demands for the intervention and difficulty reconciling times for therapy reviews.	Partial confirmation that intervention is effective. Need to streamline delivery with more portable equipment.
Modified CIMT consisting of daily outpatient session and self-directed practise of 30 household activities.	Smania, 2012 Italy	2 week programme. 1 hour individual treatment sessions as outpatient in morning and 1 hour self-directed household activities in afternoon 5 days a week for 2 weeks. Constraint splint worn for 12 hours per day. Control group received 1 hour therapy and 1 hour self-directed household tasks.	RCT (n = 66) 6-12 months	10	10	50%	Participants were able to adhere to the programme	Two hours of constraint induced movement therapy a day may be effective than conventional therapy.
Daily restraining of hand whilst carrying out intensive training activities based on participants activities of daily living. Training recorded in log sheets.	Tariah, 2010 Jordan	2 month programme, 2 hours a day, 7 days a week. Control group received dose matched neuro-developmental therapy.	RCT (n = 20) 6-12 months	120	none reported	100%	All participants adhered to the intervention.	The intervention was feasible and led to improvements in arm function.

Robotic and dynamic orthotic devices

Details of Intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*Self-directed practice (hours)*	*Supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
HandSOME (Hand spring operated movement enhancer) to extend fingers in grasp and release tasks and logs movement data.	Chen, 2017 USA	4 week programme; 90 minutes per day x 5 days per week.Graded unimanual and bimanual tasks e.g. fill water bottle, pick and place objects. Weekly therapy review.	Before-after (n=10) >12 months	30	2	94%	Practice ranged from 3 to 33 hours. 3 participants unable to don/doff device.	Gains after intervention were not sustained. Improvements to donning and doffing device needed.
Saebo Mobile Arm support (SaeboMAS) Gravity compensation of proximal arm with **Supervised Care and Rehabilitation Involving Personal Telerobotics (SCRIPT)** dynamic wrist / hand orthosis for passive extension of arm, wrist and hand task. Computer games with remote monitoring.	Nijenhuis, 2015 Netherlands; Italy; UK	6 week programme; 30 mins per day x 6 days per week. Weekly home visit of 15 minutes and daily remote monitoring of progress and training adjustments.	Feasibility study (n = 24) >12 months	18	1.5	92%	Mean of 1.75 hours per week of self-directed practice.	Intervention is feasible and improved function and quality of life but not dexterity.
	Nijenhuis, 2017 Netherlands	6 week programme; 30 mins per day x 6 days per week. Weekly home visit. Control group performed conventional home exercise programme.	Pilot RCT (n = 20) 6-12 months	18	1.5	92%	Mean of 2 hours per week of self-directed practice.	No benefit found and control group reported higher training duration.
Home-based computer assisted arm rehabilitation robotic device (hCAAR) Joystick handle linked to robotic arm to complete tasks on computer screen	Sivan, 2014 UK	8 week programme. 30 minutes a day 5 days a week; fortnightly therapist telephone call.	Feasibility study (n = 19) > 12 months	20	1	95%	Lower dose of practice than requested. Median 7.2 hours practice over the 8 weeks.	Intervention improved arm movement and function. Improvements could be made to the games.
Active-passive bilateral therapy (APBT) device to prime the motor system prior to tasks.	Stinear, 2008 New Zealand	1 month programme. 10-15 minutes APBT followed by 10 minutes of 2 repetitive tasks with wooden blocks x3 daily. Control group performed the same tasks without the priming with APBT.	RCT (n = 32) >12 months	30	none reported	100%	High compliance with intervention	Both groups benefitted from self-directed motor practice. Intervention group had additional neurophysiological changes to the motor cortex.
Hand mentor pro™Robotic active-assist device for forearm paired with video games to improve activity in wrist and fingers. Remote monitoring through tele-rehabilitation.	Wolf, 2015 USA	8 week programme. 2 hours practise with device plus one hour of functional activities 5 days a week. Weekly monitoring via telephone / email. Control group performed 2 hours traditional exercises and 1 hour functional activities.	RCT (n = 99) 3-6 months	120	2	98%	High compliance with intervention	Both groups benefitted from self-directed approach. Added benefit of Robot group was additional information for the therapist.
Robotic upper extremity repetitive therapy (RUPERT IV) Wearable robotic exoskeleton system assists shoulder/ arm / hand movements to reach for 3-D virtual targets.	Zhang, 2011 Switzerland	4 week programme. 45 minute sessions 1-2 times each weekday for 4 weeks. Weekly review visit from therapist.	Before-after (n = 2) >6 months	15	2	88%	Participants were able to complete the programme	Inconclusive results due to small sample size and wide variation between participants.
Resonating arm exerciser Mechanical device encourages shoulder and elbow flexion/extension to roll wheelchair back and forth.	Zondervan, 2014 USA	3 week programme of resonating arm exercises. 3 hours per week for 3 weeks. Weekly phone contact from therapist. Control group were given booklet of conventional exercises.	RCT cross-over (n = 17) >12 months	9	0.75	92%	High compliance with intervention. Participants able to complete about 10 hrs of self-directed practice	Home-based training was feasible and reduced impairment.

Details of intervention / device	*First Author, year, country*	*Study protocol*	*Study design Recruited (n=) Mean Time post stroke*	*No.of hours self-directed practice*	*No. of hours supervised practice (hours)*	*% self-directed practice*	*Adherence to amount of independent practice*	*Authors' conclusion*
Mirror therapy								
Mirror therapy Instruction booklet with photographs and video of exercises to follow.	Michielson, 2011 Netherlands	6 week program; 1 hour per day x 5 days a week for 6 weeks. Weekly 1 hour therapy review with therapist and telephone calls. Control group performed same programme but with direct view of both hands.	RCT (n = 40) >12 months	30	6	83%	High compliance with average of 30 hours of self-directed practice.	Improvements to motor function found. Further research into optimum practice intensity and duration required.
Tele-rehabilitation								
Task specific training programme presented on laptop screen. Equipment for modular tasks to support fine motor tasks, stereognosis, tactile discrimination and object manipulation. Guidance and support provided via video conferencing.	Langan, 2013 USA	6 week programme. 1 hour practice a day for 5 days a week. Daily monitoring via internet video conferencing reduced to once a week by final week.	Before-after (n = 7) >12 months	30	3.5	90%	Good adherence to the programme - over 90% compliance.	Tele-rehabilitation is viable and offers feedback based on one-to-one supervision or data acquired during training
SMART rehabilitation system – x2 motion sensors track arm movements and communicate information to computer interface via Bluetooth. Feedback on exercise performance provided to the wearer.	Mawson, 2011 UK	2 week programme of computer aided repetitive reaching exercises carried out daily.	Before-after study (n = 4) >6 months	7	none reported	100%	Good adherence to the programme	The SMART system may be a more cost-effective and effective method of delivering therapy.
Wearable devices								
Wrist-worn accelerometer with prompt alert function programmed to provide feedback to the wearer on their impaired arm activity levels. Therapy reviews offer opportunity to view activity data on computer interface and set activity targets for next few days.	Da Silva, 2018 UK	4 week repetitive task programme to encourage stroke arm use within activities of daily living whilst wearing the watch. Amount of practice based on individual baseline activity levels. Twice weekly therapy reviews to view data and task practice and to reset activity targets	Before-after study (n = 11) <1 month	Not reported in hours	8	n/a	Adherence was good	Feedback delivered by the accelerometer increased arm activity. Participants favoured hourly prompts with a low prompt threshold.

Table 2.1 Description of included studies

2.5 Results of Meta-analysis

2.5.1 Effects of Self-directed interventions on arm function / impairment

A total of 16 randomised studies were included in the analyses (Adie et al., 2016, Brkic et al., 2016, Brunner et al., 2012, Dos Santos-Fontes et al., 2013, Harris et al., 2009, Kimberley et al., 2004, Michielsen et al., 2011, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Stinear et al., 2008, Sullivan et al., 2012, Tariah et al., 2010, Turton et al., 2016, Wolf et al., 2015, Zondervan et al., 2015). Two studies were excluded due to insufficient methodological rigour or poor reporting quality (Gabr et al., 2005, Hara et al., 2008) and a third did not report on clinical outcomes (Burridge et al., 2017). None of the studies made a direct comparison between an intervention that was self-directed with the same intervention delivered under supervision of a therapist whilst all except three studies used a dose-matched control intervention.

Due to heterogeneity between the types of interventions and the range of outcome assessments employed, an overall treatment effect for self-directed interventions on arm function was not considered meaningful. Instead, as described below, data were analysed within each sub-group (Figure 2.2). Note that the study in the wearable devices group did not meet the criteria for inclusion in the meta-analysis.

Three studies (Brkic et al., 2016, Harris et al., 2009, Turton et al., 2016) in the No Technology group were included in the analysis, all of which measured arm function using the Action Research Arm Test (ARAT). For the two pilot randomised controlled trials (Brkic et al., 2016, Turton et al., 2016), the change in scores before and after the intervention were used in the analysis whilst the end scores were used for the randomised controlled trial (Harris et al., 2009). Analysis narrowly failed to show a statistically significant benefit of the intervention on arm function (n=169; mean difference (MD) 1.96, 95% confidence interval (CI) -0.99 to 4.92).

Within the interactive gaming group, two studies were considered suitable for analysis (Adie et al., 2016, Standen et al., 2017). The impact of self-directed interactive gaming programmes did not indicate a benefit for arm function (n=231; SMD 0.11, 95% CI -0.37 to 0.15).

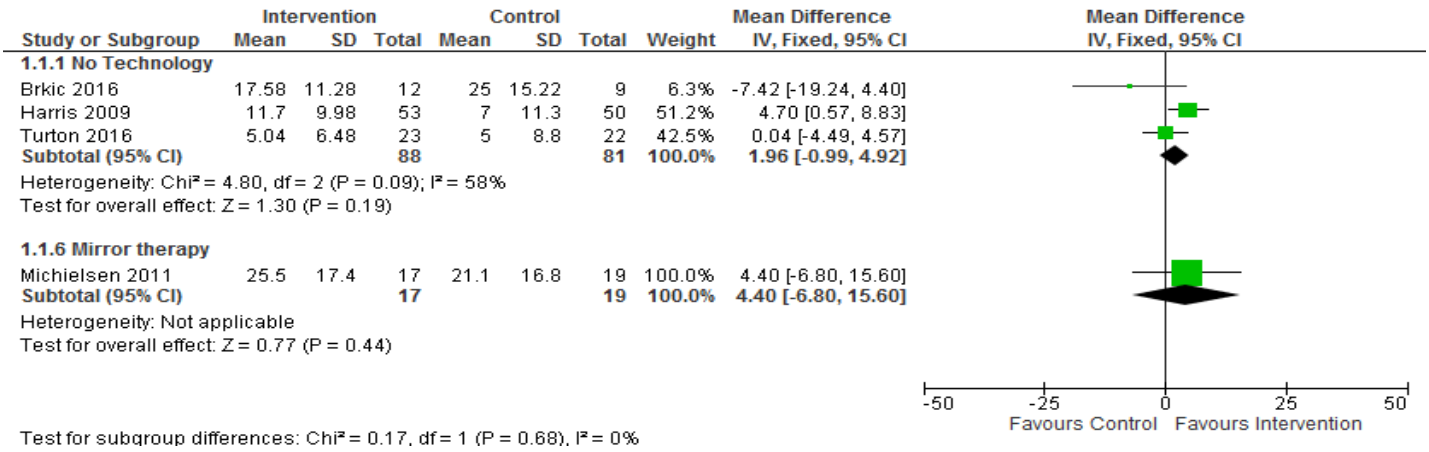
Suitable data were available for three studies (Dos Santos-Fontes et al., 2013, Sullivan et al., 2012, Kimberley et al., 2004) using electrical stimulation. The interventions in these studies all used surface electrodes and compared the intervention with a sham device. A mixture of outcome measures were used (Fugl-Meyer: end score (Sullivan et al., 2012), Jebsen Taylor test: change score (Dos Santos-Fontes et al., 2013) and Box and blocks: end score (Kimberley et al., 2004)) necessitating the use of a standardised mean difference (SMD). There was a statistically significant effect on arm function favouring the self-directed electrical stimulation intervention group (n=94; SMD 0.50, 95% CI 0.08 to 0.91).

Three of the studies in the constraint-induced movement therapy group were suitable for meta-analysis (Smania et al., 2012, Tariah et al., 2010, Brunner et al., 2012). Two of these measured changes in arm function using the Wolf Motor Function Test (one using change scores (Smania et al., 2012); and the other end score data (Tariah et al., 2010)) the remaining study used the ARAT (Brunner et al., 2012). The impact of self-directed constraint-induced movement therapy on arm function indicated a statistically significant effect in favour of the intervention group (n=105; SMD 0.39, 95% CI –0.00 to 0.78).

Four studies (Nijenhuis et al., 2017, Stinear et al., 2008, Wolf et al., 2015, Zondervan et al., 2015) were included in the robotic and orthotic devices group analysis. ARAT change data scores were used for two of the studies (Nijenhuis et al., 2017, Wolf et al., 2015) and Fugl-Meyer change data scores for the other two. The impact of these programmes did not indicate a statistically significant benefit of the intervention on either arm function (n=171; SMD -0.04, 95% CI -0.35 to 0.27).

Only one study (n=36) reported on the use of self-directed mirror therapy, showing no impact on the ARAT (n=36; MD 4.40, 95% CI -6.80 to 15.60).

Only one tele-rehabilitation study met the criteria for meta-analysis (Wolf et al., 2015) however, as tele-rehabilitation was not the intervention being tested but rather a means of delivering the therapy remotely, this study has been included in the robotic devices sub-group of the analysis.



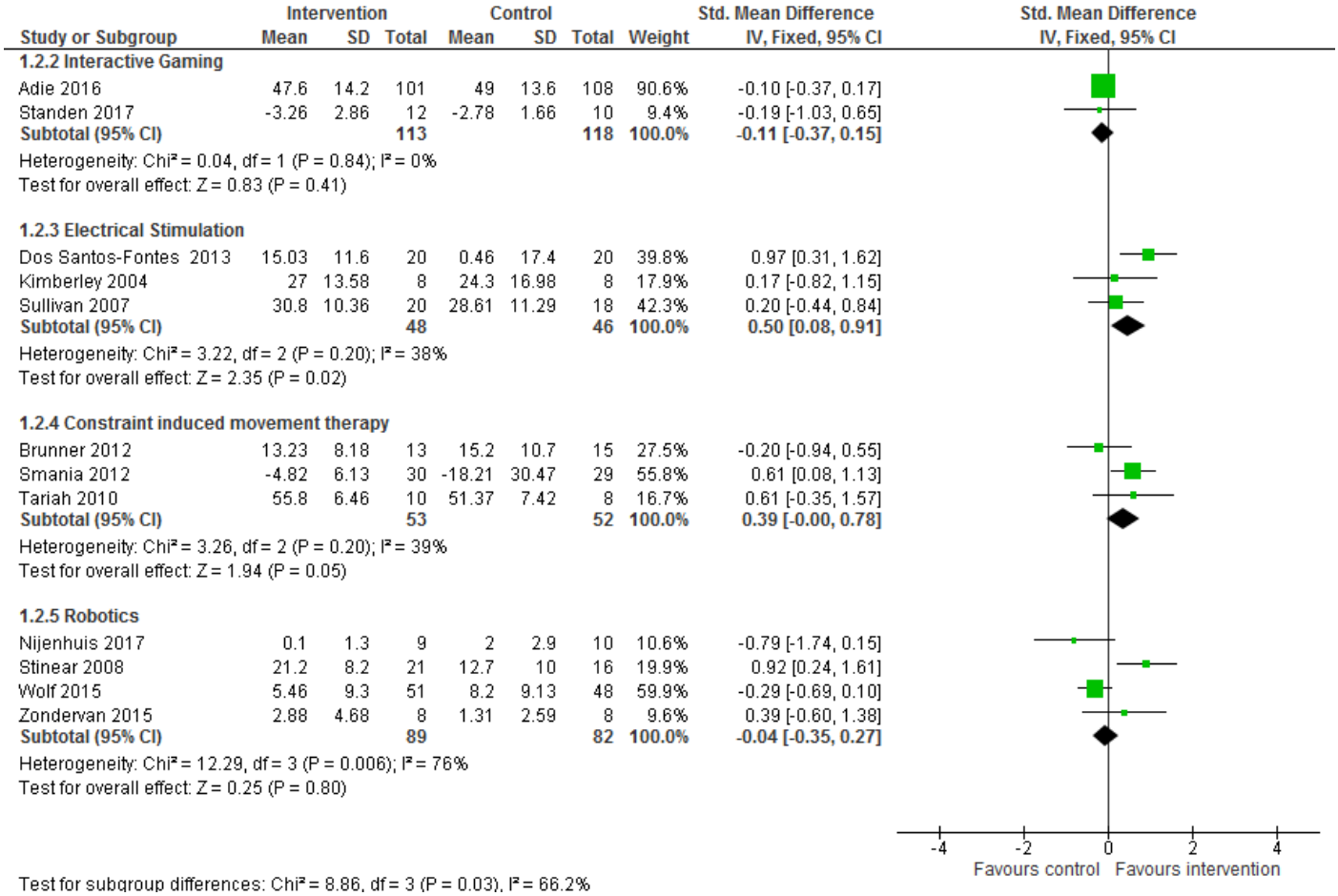


Figure 2.2 Treatment effect of self-directed intervention on arm function

2.5.2 Effects of interventions on independence and self-care activities.

The impact of the interventions on independent use of the arm use in daily activities was measured by eleven studies. Ten used the Motor Activity Log (Brunner et al., 2012, Harris et al., 2009, Kimberley et al., 2004, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Sullivan et al., 2012, Tariah et al., 2010, Turton et al., 2016, Zondervan et al., 2015) to obtain the participants' perceived use of their stroke arm in thirty daily activities and one provided a post-intervention score of the Nottingham Extended Activities of Daily Living scale (Brkic et al., 2016).

A pooled meta-analysis was carried out on studies reporting the motor activity log "amount of use" (Brunner et al., 2012, Harris et al., 2009, Kimberley et al., 2004, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Sullivan et al., 2012, Tariah et al., 2010, Turton et al., 2016) (**Figure 2.3**) and "quality of use" (Brunner et al., 2012, Harris et al., 2009, Kimberley et al., 2004, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Sullivan et al., 2012, Tariah et al., 2010, Turton et al., 2016, Zondervan et al., 2015) (Figure 2.4) scores. A statistically significant effect favouring the intervention group was demonstrated for both groups of scores: the amount of use (n = 348; MD 0.47, 95% CI 0.27 to 0.67) and the quality of use of the arm (n = 364 participants: MD 0.29, 95% CI 0.12 to 0.46). Analysis within the technology subgroups is described below.

Within the No Technology group, two studies (Harris et al., 2009, Turton et al., 2016) with 148 participants measured participation in daily activities using the motor activity log. Analysis demonstrated a statistically significant benefit of the intervention on amount of arm use (n=148; MD 0.60, 95% CI 0.07 to 1.13; P value = 0.03) and on the quality of arm movement (n=148; MD 0.52, 95% CI 0.03 to 1.00, P value = 0.04).

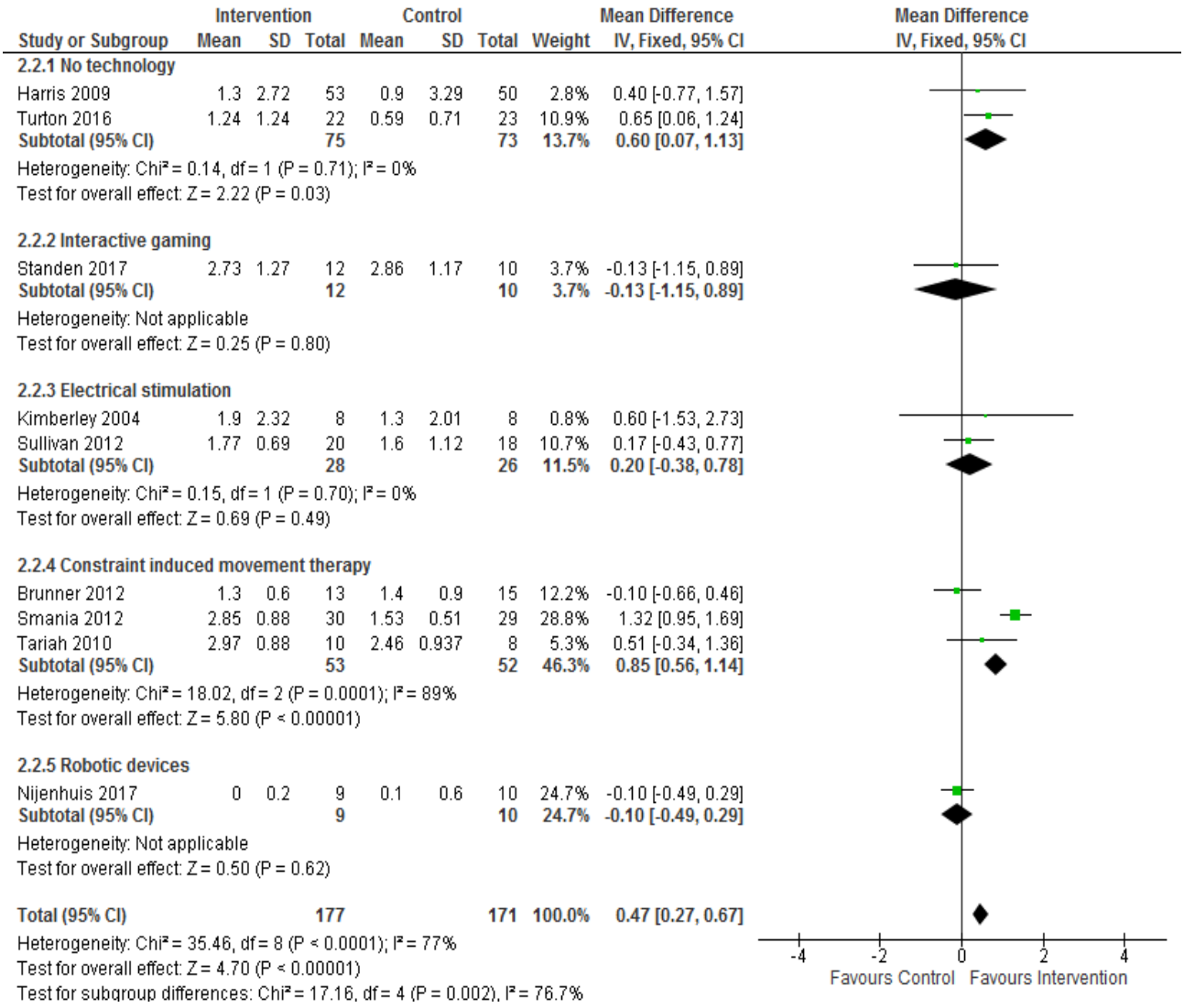


Figure 2.3 Treatment effect of self-directed interventions on perceived amount of use of the stroke arm

No benefit was found for the only included study (Standen et al., 2017) in the interactive gaming group (n=22; MD -0.13, 95% CI -1.15 to 0.8). However, the same study did show a benefit for the participants perceived quality of use of the stroke arm (n=22; MD 1.25, 95% CI 0.27 to 2.23).

Two studies (Kimberley et al., 2004, Sullivan et al., 2012) reported on the benefits of electrical stimulation on independence in daily activities however this was not

statistically significant: perceived amount of arm use (n=54; MD 0.20, 95% CI -0.38 to 0.78) and perceived quality of arm use (n=54; MD 0.21, 95% CI -0.37 to 0.79).

Data from three (Brunner et al., 2012, Smania et al., 2012, Tariah et al., 2010) pooled studies showed a statistically significant benefit of constraint-induced movement therapy on participants ability to carry out daily activities: perceived amount of arm movement (n=105; MD 0.85, 95% CI 0.56 to 1.1, P=<0.00001); perceived quality of arm movement (n=105; MD 0.75, 95% CI 0.46 to 1.03, P=<0.00001).

Only one study in the robotic and orthotic devices group measured the amount of use of the stroke arm (Nijenhuis et al., 2017) with no benefit found (n=19; MD -0.10, 95% CI -0.49 to 0.29). Two studies (Nijenhuis et al., 2017, Zondervan et al., 2015) measured the effect of robotic devices on the quality of use of arm but again no benefit was found (n=35; MD -0.25, 95% CI -0.51 to 0.02).

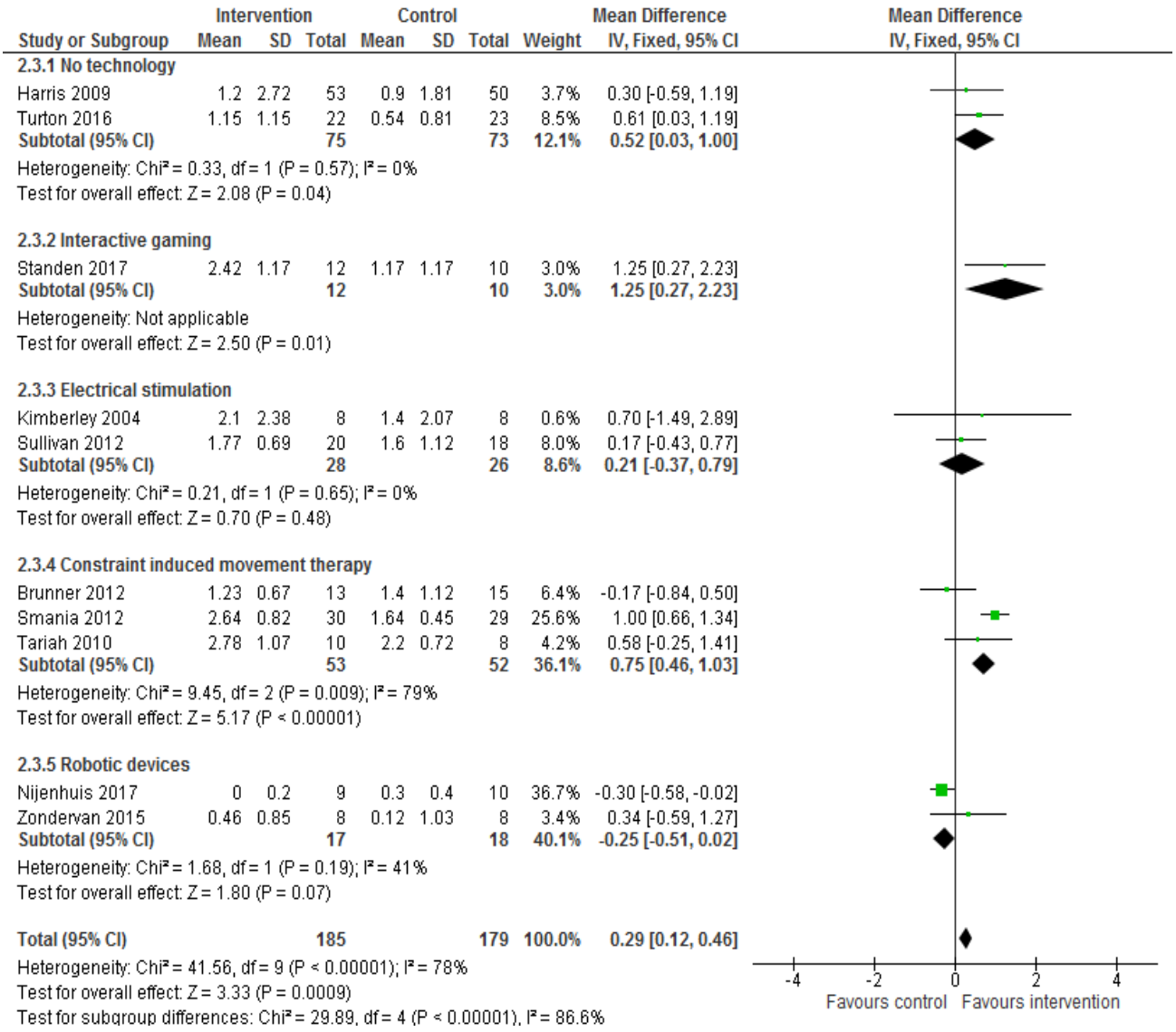


Figure 2.4 Treatment effect of self-directed interventions on perceived quality of use of the stroke arm

2.5.3 Effect of interventions according to time since stroke onset

All 16 studies were pooled by standardised mean difference to examine the influence of time since stroke onset (Figure 2.5). No benefit was found at < 3months; 3-6 months or 6 to 12 months post stroke. A statistically significant benefit on arm function was found for patients more than 12 months post stroke (n= 145; SMD 0.61, 95% CI 0.27 to 0.94). The studies included in the post 12 months category included electrical stimulation (n=2; participants = 56) (Dos Santos-Fontes et al., 2013, Kimberley et al., 2004), robotic devices (n=2; participants = 53) (Stinear et al., 2008,

Zondervan et al., 2015) and mirror therapy (n=1; participants = 36) (Michielsen et al., 2011).

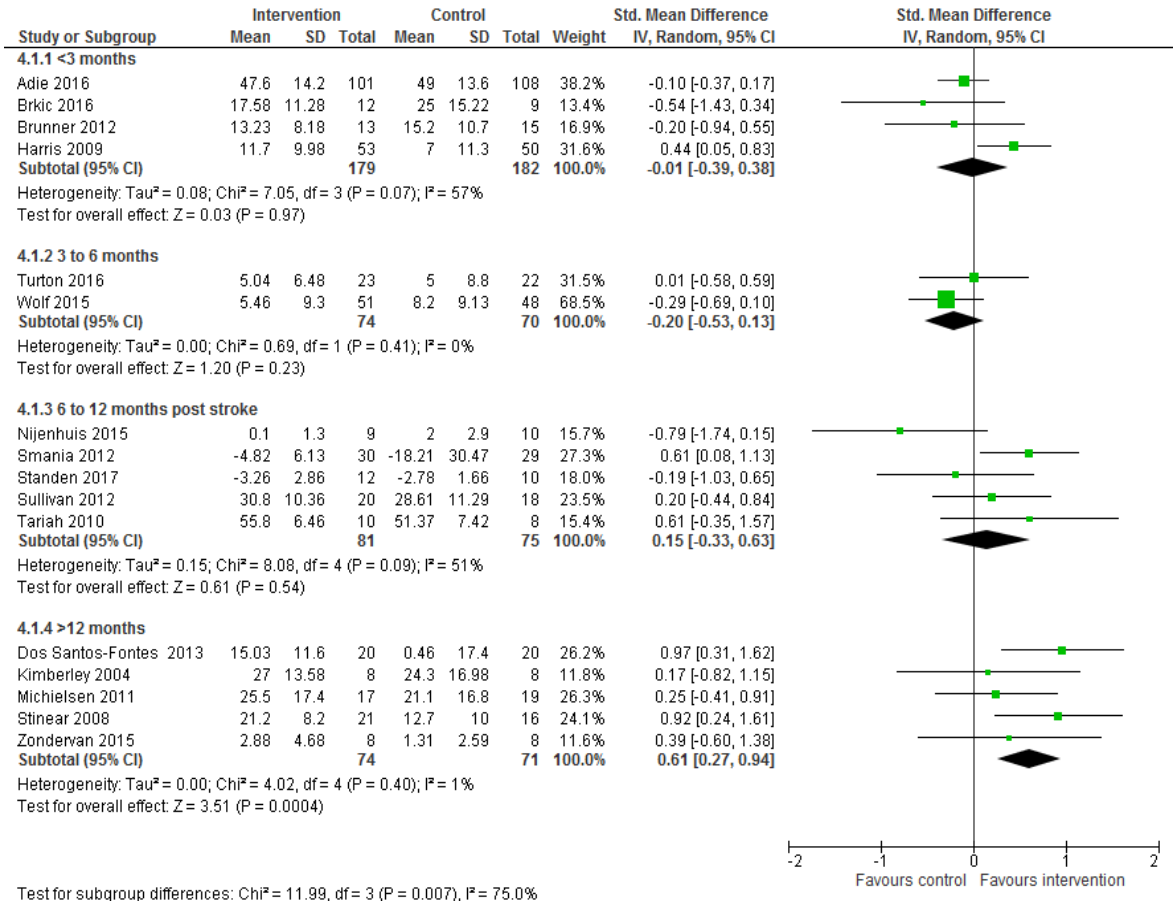


Figure 2.5 Effect of time since stroke on arm recovery

2.5.4 Effect of dose of interventions based on the amount of time spent in self-directed therapy

When all studies were pooled, there was no dose-response relationship found between the amount of time spent in self-directed practice and recovery (Figure 2.6).

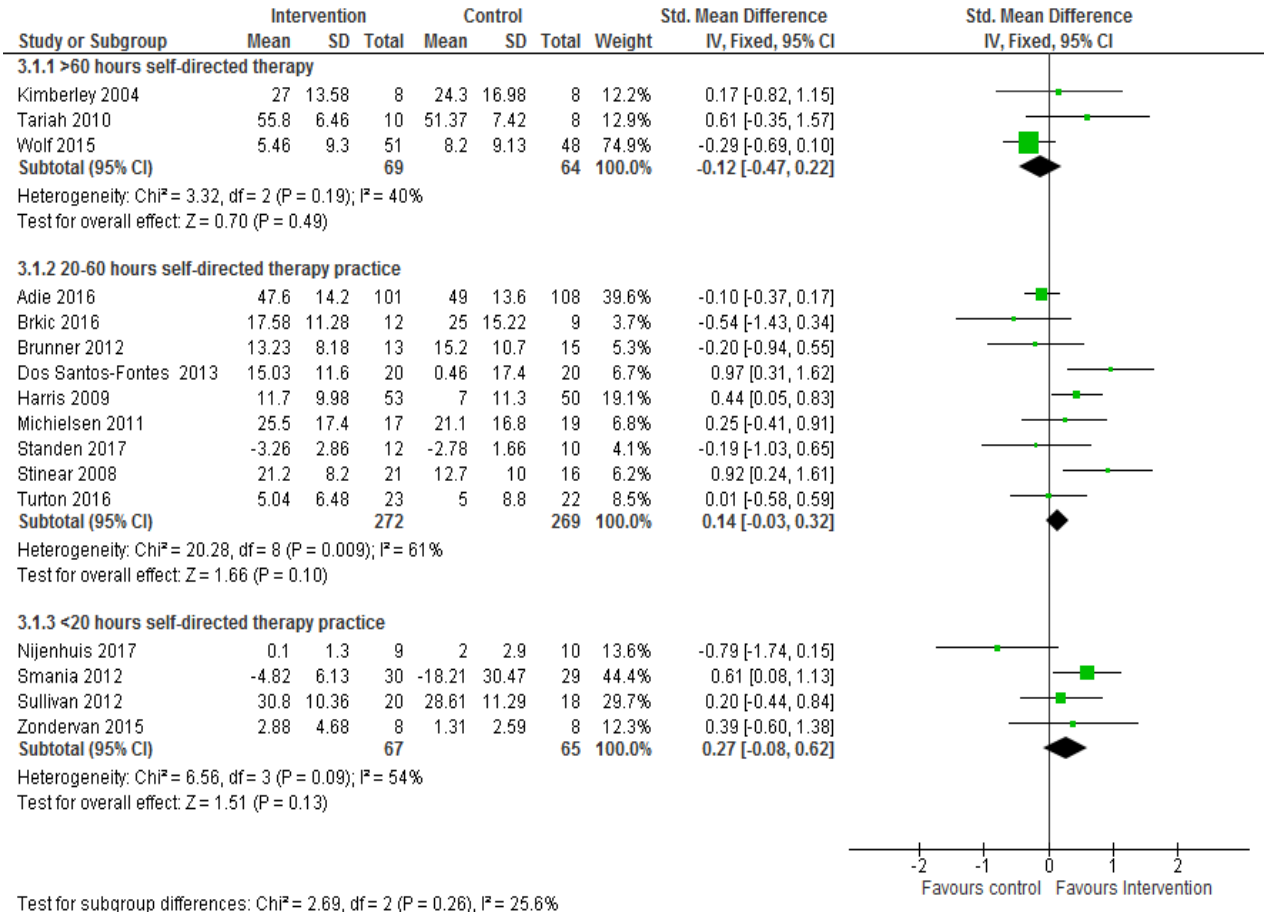


Figure 2.6: **Effect of dose of self-directed therapy on arm function**

Further sensitivity analysis was carried out using only data from the electrical stimulation and constraint-induced movement therapy groups (Figure 2.7) as these had been shown to benefit arm function / impairment. In this analysis only those studies that completed less than 20 hours self-directed therapy practice were found to give a statistically significant benefit relative to controls (n=97; SMD 0.44, 95% CI 0.04 to 0.85), although greater amounts of practice also showed a positive trend.

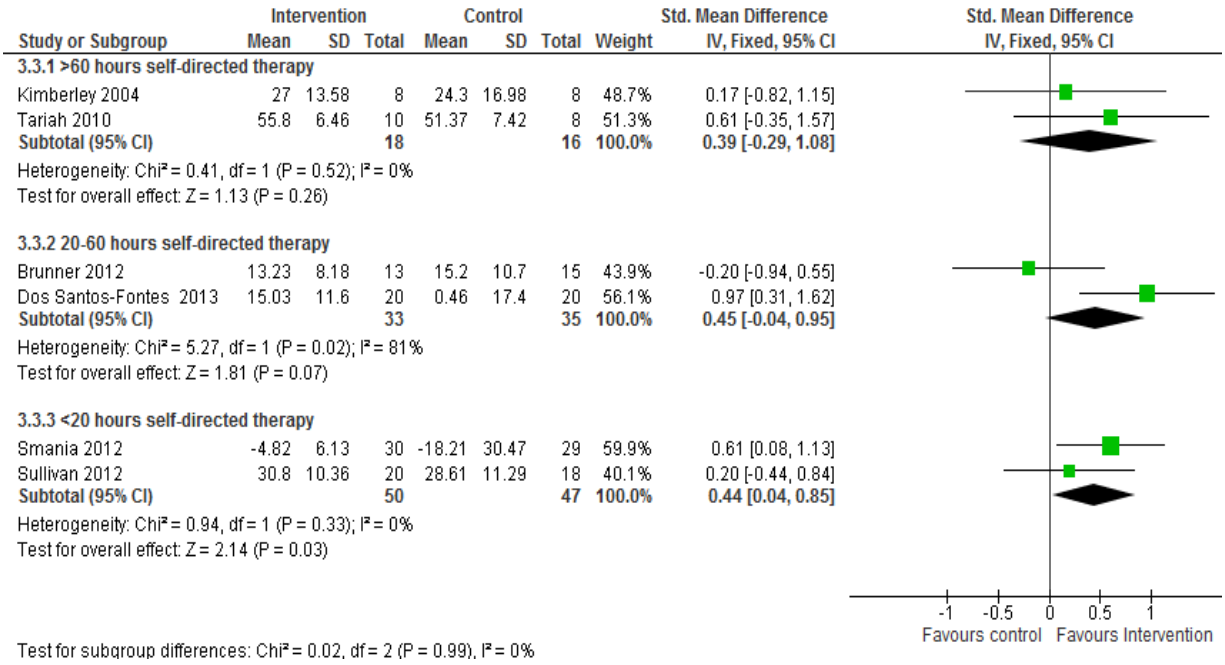


Figure 2.7 Effect of dose of self-directed therapy on arm function (CIMT and ES combined)

2.5.5 Risk of bias

A risk of bias assessment was carried out for all studies that followed a randomised trial design (Figure 2.8). Most studies used an appropriate form of randomisation that ran a low risk of biasing the study. Five were assessed as unclear and one study (Tariah et al., 2010) used an alternating numbers approach which runs a high risk of selection bias. Allocation concealment was adequate in 12 studies (Adie et al., 2016, Brkic et al., 2016, Brunner et al., 2012, Dos Santos-Fontes et al., 2013, Hara et al., 2008, Harris et al., 2009, Michielsen et al., 2011, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Turton et al., 2016, Wolf et al., 2015) whilst six were unclear due to the lack of information and one was considered to be of high risk of bias due to the method of randomisation used (Tariah et al., 2010).

Blinding of participants in rehabilitation studies is known to be challenging. We found that it was only attempted in the electrical stimulation studies where a sham device was used for the control group (Dos Santos-Fontes et al., 2013, Kimberley et al., 2004, Sullivan et al., 2012). This appeared to be successful in two studies

(Kimberley et al., 2004, Sullivan et al., 2012) whilst reduced compliance for the control group in a third study (Dos Santos-Fontes et al., 2013) may have been due to participants becoming unblinded. Successful blinding of outcome assessments was achieved for 13 studies (Brunner et al., 2012, Burridge et al., 2017, Dos Santos-Fontes et al., 2013, Gabr et al., 2005, Harris et al., 2009, Kimberley et al., 2004, Michielsen et al., 2011, Smania et al., 2012, Stinear et al., 2008, Sullivan et al., 2012, Tariah et al., 2010, Wolf et al., 2015, Zondervan et al., 2015). Two studies (Hara et al., 2008, Nijenhuis et al., 2017) did not attempt to blind outcome assessors and the remaining four studies (Adie et al., 2016, Brkic et al., 2016, Standen et al., 2017, Turton et al., 2016) reported being unsuccessful.

A further four studies were reported as high risk of bias due to high levels of attrition (>30%) (Dos Santos-Fontes et al., 2013, Standen et al., 2017), unclear reporting of which participants were contributing towards outcome data (Hara et al., 2008) and under reporting of details for outcomes (Gabr et al., 2005).

Figure 2.8 Risk of bias summary: review authors' judgements for each included RCT study.

2.6 Discussion

The evidence base for self-management programmes in stroke care is continuing to grow and supports added benefits of empowerment and self-efficacy that impact positively on the lives of people after stroke (Fryer et al., 2016). Specific aspects however are still largely under-explored (Wray et al., 2017) and little is known regarding the delivery of self-directed interventions. Whilst broader self-management programmes focus on developing the skills required to manage various aspects of an overarching condition (Wray et al., 2017), the studies in this review focus on being able to independently initiate and carry out discrete interventions for restoring arm function according to a pre-determined protocol.

The search strategy was broad and attempted to include all methods of self-direction, but may still have been restricted by whether authors had identified their intervention as “self-directed” and the search terms available. To aid this process non-randomised studies were included, but often these studies were small in size, settings were not well described and their poor quality excluded them from the analysis of effects. Overall heterogeneity was substantial in terms of the types of interventions studied, reporting of the amount of self-directed practice and the time post stroke of participants potentially limiting findings.

Of the 38 studies included, some were designed specifically as a self-directed arm intervention (Harris et al., 2009, Langan et al., 2013, Lee and Kim, 2013, Mawson, 2011, Niama Natta et al., 2015, Page and Levine, 2007, Pickett et al., 2007, Tariah et al., 2010), whilst other studies used self-direction as the only feasible mode of delivery. Although the principle underlying their application was similar (i.e. to encourage additional arm motor activity), the described technologies employed different mechanisms of action. A range of outcome measures were used across the studies making it difficult to make direct comparisons. As no studies were found comparing supervised and unsupervised delivery of the same intervention it is difficult to draw any firm conclusions regarding the efficacy of self-direction as a generic approach.

Thirteen of the 16 randomised studies compared the intervention group against a dose-matched control group (Adie et al., 2016, Brunner et al., 2012, Dos Santos-Fontes et al., 2013, Kimberley et al., 2004, Michielsen et al., 2011, Nijenhuis et al., 2017, Smania et al., 2012, Standen et al., 2017, Stinear et al., 2008, Sullivan et al., 2012, Tariah et al., 2010, Wolf et al., 2015, Zondervan et al., 2015) which resulted in both groups receiving the same increased dose of therapy. All except one (Tariah et al., 2010) of these also followed a self-directed programme. It could perhaps be suggested that both control and intervention groups benefitted from the increased dose, which may explain the small effect sizes between the groups.

There was no clear dose-response found amongst self-directed programmes, although this is confounded by difficulties in being able to accurately report how much practice was performed. Some interventions had built-in mechanisms for recording the amount of practice. Future technology that can accurately capture upper limb practice will greatly assist researchers as well as provide useful feedback to participants during the delivery of self-directed interventions.

Overall there was high compliance across the studies and an ability to follow a self-directed programme suggesting that stroke patients are willing and able to partake in this type of research intervention. This may partly reflect the inclusion criteria and selection strategies which identify the most able and enthusiastic volunteers, but the empowering nature of self-direction may also provide a clearer link between what patients are able to do themselves and the possibility of better recovery. High compliance and low attrition seemed to reflect a strong focus on practising tasks that were directly associated with daily activities for example through reach and grasp movements.

Interventions using computer games that were not directly related to functional tasks reported more cases of participants leaving studies, not completing the full amount of self-directed practice and difficulties with recruitment. Feedback from participants

suggested that the quality of the gaming experience and relevance to rehabilitation goals largely influenced their motivation to continue to engage with the intervention. Those that used commercially developed software with more engaging gameplay and graphics appeared to show better compliance for achieving the specified amount of therapy practice.

These may be important findings for developing interventions into effective self-directed programmes and for understanding how theories of self-management can support theories of motor recovery (Krakauer, 2006). Self-efficacy and motivation, have been well documented as key theoretical principles underpinning successful self-management (Korpershoek et al., 2011, Jones and Riazi, 2011). Similar virtues of motivating and engaging the player in video games have also been reported (Brown and Cairns, 2004). When designing rehabilitation interventions in general, it is important that the patient remains central to the process throughout (Wade, 2016). In the absence of a therapist to offer encouragement, it is perhaps even more essential that self-directed interventions have enough personal relevance and interest to keep the patient motivated and engaged with ongoing practice.

It is generally believed that early intervention will benefit motor recovery and a recent review supported this concept when using interventions employing assistive technology (Farmer et al., 2014). However, we found that improvements could still occur at a later stage particularly in relation to constraint-induced movement therapy and electrical stimulation. Although this may be explained by active recruitment of participants outside of early rehabilitation for some interventions, it could also be indicative that stroke survivor's readiness to engage in self-directed health programmes may be better later after stroke (Hibbard et al., 2004). Usual care at a later time period after stroke is unlikely to involve frequent sessions of supervised therapy, and so building up independence in self-management could run in parallel with acquiring independence in rehabilitation activities. It is recommended that future research in this area should consider time post-stroke and perhaps challenge traditional thinking about a narrow early time window with a maximal influence upon recovery (Pollock et al., 2014).

One major limitation was determining what constitutes a self-directed intervention and to what extent the therapy being described in each study was self-directed. The absence of a clear definition created difficulties in developing a robust search strategy and we were required to closely examine the description of each intervention against our own definition and inclusion criteria. Inclusion in this review was therefore largely reliant upon how clearly the authors described the self-directed component of the intervention and there may be other studies employing a self-directed approach that were not included because of the description provided.

This review highlights that there is a broad range of interventions described as incorporating a self-directed approach to rehabilitation of the arm after stroke. There were many known and unknown differences between the included studies and interventions, which may have more influence upon the results than the self-directed approach. Certain characteristics of self-directed interventions were identified that will aid future research in this area and support development of an accelerometer-based technology to promote independent practice through feedback. Amongst intervention subgroups, the most convincing benefit for improving use of the impaired arm in daily activities came from constraint-induced movement therapy and therapy programmes without any additional technology. These are all relatively low-cost and safe interventions, which through their use of repetitive functional task practice, support the principles of motor recovery described in Chapter 1.

Conclusion

This chapter has explored the range of self-directed interventions for the upper limb after stroke that exist including those with and without technology.

Constraint-induced movement therapy, electrical stimulation and no technology programmes appear to be the interventions that are most effective when delivered in a self-directed way. The key component that was common to these interventions and identified as a requirement for the WAVES intervention was the use of repetitive practice of functional tasks or part-tasks. Of these only CIMT reported a benefit for both improved arm function and using the impaired arm in daily activities highlighting

perhaps the added benefit that the behaviour change components of the transfer package offered.

Section 2: Development, testing and refinement of the intervention

Chapter 3. Development of the WAVES intervention

This chapter describes the development of the WAVES intervention in the context of the Medical Research Council (MRC) Framework for developing and evaluating complex interventions (Craig et al., 2008).

It begins with a section describing the development and evaluation of a complex intervention before describing the development of the WAVES intervention using the Template for Intervention Description and Replication (TIDieR) checklist as a framework (Hoffman et al., 2014) (Appendix C).

3.1 Aim

To describe the development of the WAVES self-directed therapy programme using guidance from the MRC and TIDieR as a framework.

3.2 Developing a complex intervention

The MRC describes a complex intervention as one that contains several interacting components (Campbell et al., 2000, Craig et al., 2008). Due to the complex nature of how the components that make up these interventions interact, they can be difficult to standardize and to subsequently evaluate.

The MRC describes cycles of intervention design and development with stages of testing and piloting the intervention. Interventions are constantly being refined and improved so the end of the development phase can be defined as being,

"…the point where it can reasonably be expected to have a worthwhile effect" (Craig et al., 2008)

To ensure that the intervention is supported by the best, most appropriate and up to date research evidence available, the evidence base supporting each component of the proposed intervention needs to be explored and built upon (Craig et al., 2008).

Five key principles of intervention development have been identified (O'Cathain et al., 2019). The first is that intervention development is a dynamic process which, whilst moving through a sequence of actions, will also move backwards and forwards between overlapping parts of the process. This may involve reviewing the evidence base or involving and working with stakeholders.

The second refers to using an iterative process whereby cycles of assessing, reviewing and refining versions of the intervention are carried out based on feedback from those using or receiving the intervention.

The third key principle suggests the need for developers to be creative in their approach to engaging stakeholders to participate in intervention development.

The final two key principles focus on the importance of being open to the possibility that the initially proposed intervention may not work or may need to be changed from that initially intended and that developers need to look ahead and plan for how the intervention will be fully evaluated at a later stage.

3.3 Behaviour change techniques to increase arm activity

In addition to the number of elements in the intervention, the level of complexity of the intervention varies according factors such as the range of possible outcomes for different population groups, the setting that the intervention will be delivered in or the number of behaviours required to both deliver and receive the intervention (Craig et

al., 2008). Encouraging stroke survivors to engage in greater arm activity in both hospital and at home required a change in routine behaviour. Managing the complexity of behaviour can be particularly difficult to influence with stroke survivors where the patient demographics can vary considerably depending on the severity of the stroke, other pre-morbid health conditions and the person's psychological readiness to engage in rehabilitation. Managing these factors during the development phase was fundamental to reduce the possibility of failure when evaluating the intervention at a later date (O'Cathain et al., 2019).

The COM-B behaviour change model (Michie et al., 2011) was used to identify potential behaviours that could be targeted to support implementation of the intervention. According to Michie et al (2011), three factors need to be present for any behaviour intervention to be successful; capability, opportunity and motivation (Michie et al., 2011). Capability considers whether a person has the necessary physical and cognitive attributes to make the behaviour possible. Opportunity is how conducive a person's physical and social environment is to make the behaviour possible and motivation is the conscious and sub-conscious thought processes that drive behaviour (Michie et al., 2011). In the case of the accelerometer wristband intervention, we were hoping to change behaviours that influenced independent therapy practise and use of the impaired arm.

Capability: To carry out prescribed exercises independently, participants needed to have the physical capability to use the impaired arm and the psychological or cognitive capability to make an appropriate response (i.e. to increase arm movement) to the feedback provided by the technology. The level of capability was expected to vary between participants requiring the intervention to be tailored for each individual.

Opportunity: Opportunities to increase arm use whether it be for repetitive task practice or using the arm in daily activities were expected to be dependent on both physical and social issues. Accessing a suitable therapy area and equipment to carry out exercises can be particularly difficult for stroke survivors who are less mobile or limited to the constraints of a ward environment. Traditionally, a therapist would

provide these opportunities by assisting patients to access an appropriate area with equipment to carry out a scheduled session. Consideration needed to be given to how participants would be able to set themselves up for therapy practice independently particularly if prompts could be received at any point during the day.

Having the social opportunities to use the impaired arm in daily activities were expected to be limited by factors such as the expectations set by the hospital that staff will provide meals and assist patient's in their ADLs; reluctance by family or carers to see someone they care for struggle when they could help them; and participants lacking the understanding and belief that increasing use of the impaired arm will aid long-term recovery particularly when they can manage the task better using their unimpaired side.

Motivation: Having the perception that the intervention might benefit arm recovery was key to ensuring that participants stayed motivated and adhered to the intervention. This could be affected by the participant's sense of control over their situation, their confidence in themselves to succeed and their emotional responses to either the stroke itself or their engagement in therapy. The impact of cognitive and perceptual impairment as a result of the stroke could further complicate and alter their perception of any given situation. It was intended that the wristband intervention would enhance motivation as the feedback received, particularly through data reports, would show progress over time that might not otherwise be perceived by the participant.

Linked to motivation, and an important factor which is often highlighted in behaviour change literature, is self-efficacy. Self-efficacy is derived from Bandura's model of social cognitive theory (Bandura, 1986) and refers to a person's belief in their own capabilities to successfully accomplish a task or goal. It has been found to have the greatest influence on both initiating and sustaining a behaviour change - if a person has the belief and expectation that they can achieve the desired outcome then they are more likely to engage in that behaviour (Bandura, 1986). Conversely however, if a person has a low sense of self-efficacy and lacks the expectation of achieving the

desired outcome they will lower their aspirations and are more likely to avoid that behaviour or put less effort into achieving their goals (Bandura, 1986).

According to Bandura, there are four performance-based processes that can influence and enhance self-efficacy based on the sources of information people use to judge their level of self-efficacy which overlap with aspects of subsequent behaviour change theory (Bandura, 1977):

1. Performance accomplishments: mastery experience is gained through positive experiences and accomplishments in a task or goal and is the most powerful source with which to enhance self-efficacy. Achievement of small personal goals is accumulative, building confidence over time rather than through a single one-off event.
2. Vicarious experience: this is gained by observing the behaviour of others and modelling their own behaviour on this. The effect of this source on efficacy expectations is weaker than mastery experience as it is dependent on inferences from social comparisons and may not reflect the person's own capabilities.
3. Verbal persuasion: People are led to believe that they can succeed by persuasion from a significant other - often a health professional.
4. Emotional arousal: self-efficacy can be influenced by physiological feedback and emotional feelings. Where an individual interprets a situation to evoke negative feelings for example pain on moving the arm, self-efficacy will be compromised and the situation may be avoided.

Although the wristband intervention was designed around evidence and principles from motor rehabilitation rather than primarily from a behaviour change perspective, it aimed to change behaviour in a manner consistent with these previous theoretical frameworks and concepts.

3.4 Development of the WAVES therapy programme

The initial 'pre-development' phase of the WAVES intervention began prior to submitting the study grant application and involved a small scale study to repurpose

technology that had previously been designed to reduce drooling in individuals with Parkinson's Disease (Holden et al., 2015). This work was led by specialist designers in the computer science department and consisted of an initial user-based design process exploring the acceptability and usability of delivering a vibration cue to prompt arm movements amongst stroke survivors with long-term arm weakness (Holden et al., 2015). The study supported the possibility that the wristband might be useful to used alongside existing therapy programmes by prompting an increase in therapy exercises but indicated that further design improvements were required to support longer term use (Holden et al., 2015).

As discussed in Chapter 1, motor recovery can be influenced by a number of key elements which can be supported through rehabilitation. Informed by published evidence, the National Clinical Guidelines for stroke suggest that interventions for arm recovery after stroke should focus on intensity and repetition, be task-specific and based around functional activities (Intercollegiate Stroke Working Party, 2016). As highlighted in Chapter 2, these same qualities were later found to benefit both arm function *and* independent use of the impaired arm in daily activities when applying a modified, self-directed approach to constraint-induced movement therapy (Da-Silva et al., 2018). Despite evidence that CIMT is effective however, key barriers to implementation have been identified (Viana and Teasell, 2012):

1. Poor generalisability - to be eligible for CIMT stroke survivors need to be able to transfer and stand for two minutes independently thus ruling out any patients who are non-mobile. They are also required to have a minimum of 10°extension at the wrist and of at least 2 digits and thumb abduction. Cognitive ability is scored at ≥24 on a Mini-mental State Examination. These patients would normally be described as falling into the mild to moderate severity of stroke ruling out those with a more severe stroke. It is estimated that just 10% of stroke survivors are eligible for CIMT (Kwakkel et al., 2015).
2. High resource intensity – the cost of providing up to six hours a day for five days a week over two weeks can be prohibitively costly to publically funded health services.

3. Therapist factors – therapists have found it difficult to adopt CIMT due to the time required to deliver it, difficulty in developing a daily protocol of six hours of massed practice and shaping and caseload pressures.
4. Patient factors – some people are reluctant to have their better hand constrained whilst others are not able to tolerate the intensity of the programme.
5. Protocol factors – studies have indicated that the constraint mitt itself may have little impact on outcomes with emphasis being on the high-intensity task-specific practice.

Previous research supported the feasibility of replacing feedback given by a therapist with that delivered by technology and that vibro-tactile feedback may be preferable (see Chapter 1). The WAVES study therefore aimed to examine the concept that provision of 'live' feedback on arm activity is feasible and could lead to increased awareness, movement and integration of the impaired arm into daily activities. This increase in arm use and activity would equate to an enhancement in therapy practice and thereby improve function in the arm. Further patient and public involvement was carried out by the computer science department through a series of workshops seeking the views of stroke survivors, their carers and therapists on the design of the wristband and ease of understanding the visual activity data. These workshops ran alongside development of the therapy intervention and informed the development of an initial prototype of the technology.

The initial WAVES intervention consisted of three components as shown in Figure 3.1, each with their own additional sub-components.

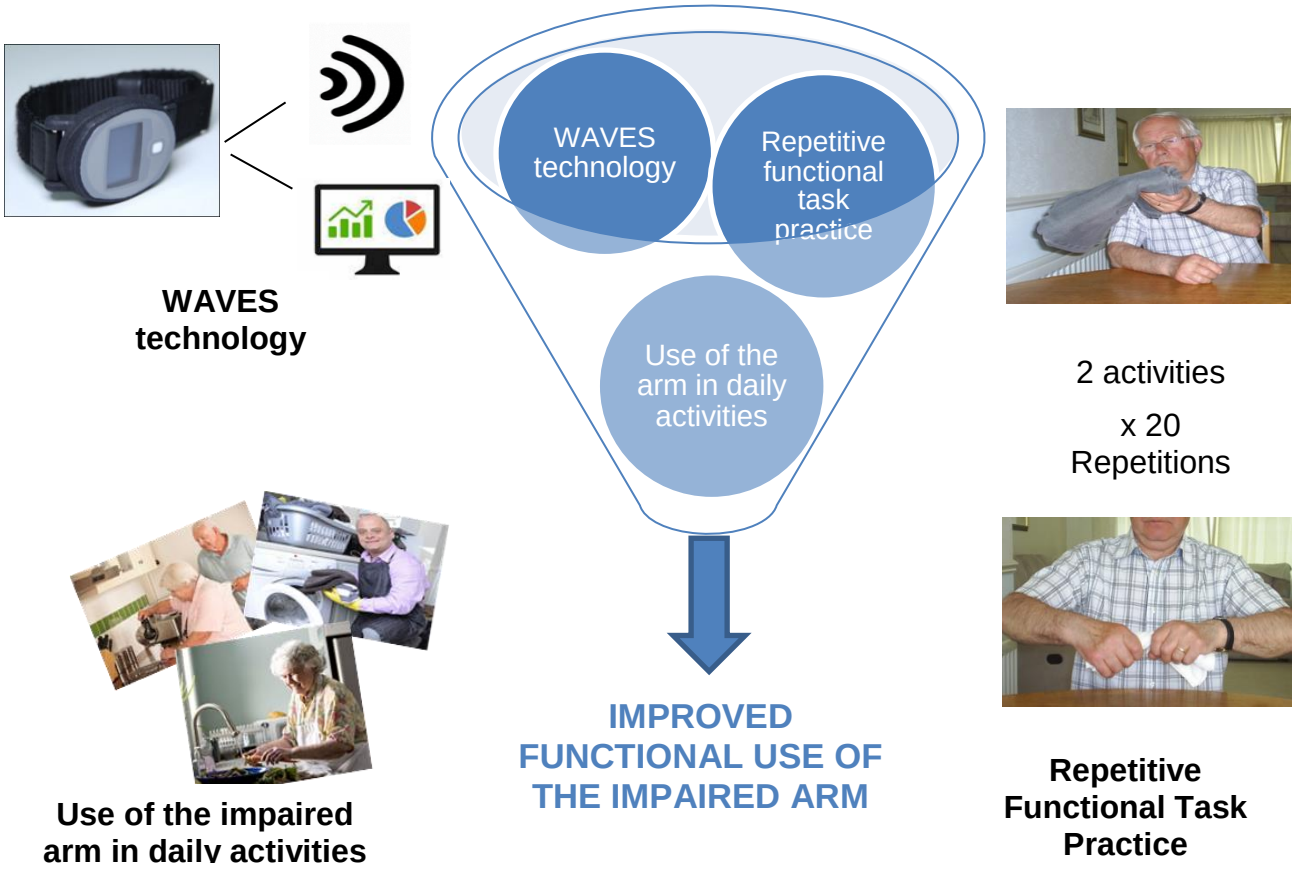


Figure 3.1 Component parts of the WAVES intervention

Based upon the process described by the MRC Framework for Complex Interventions, the logic model presented in Figure 3.2 illustrates the causal assumptions of these components to enhance arm recovery.

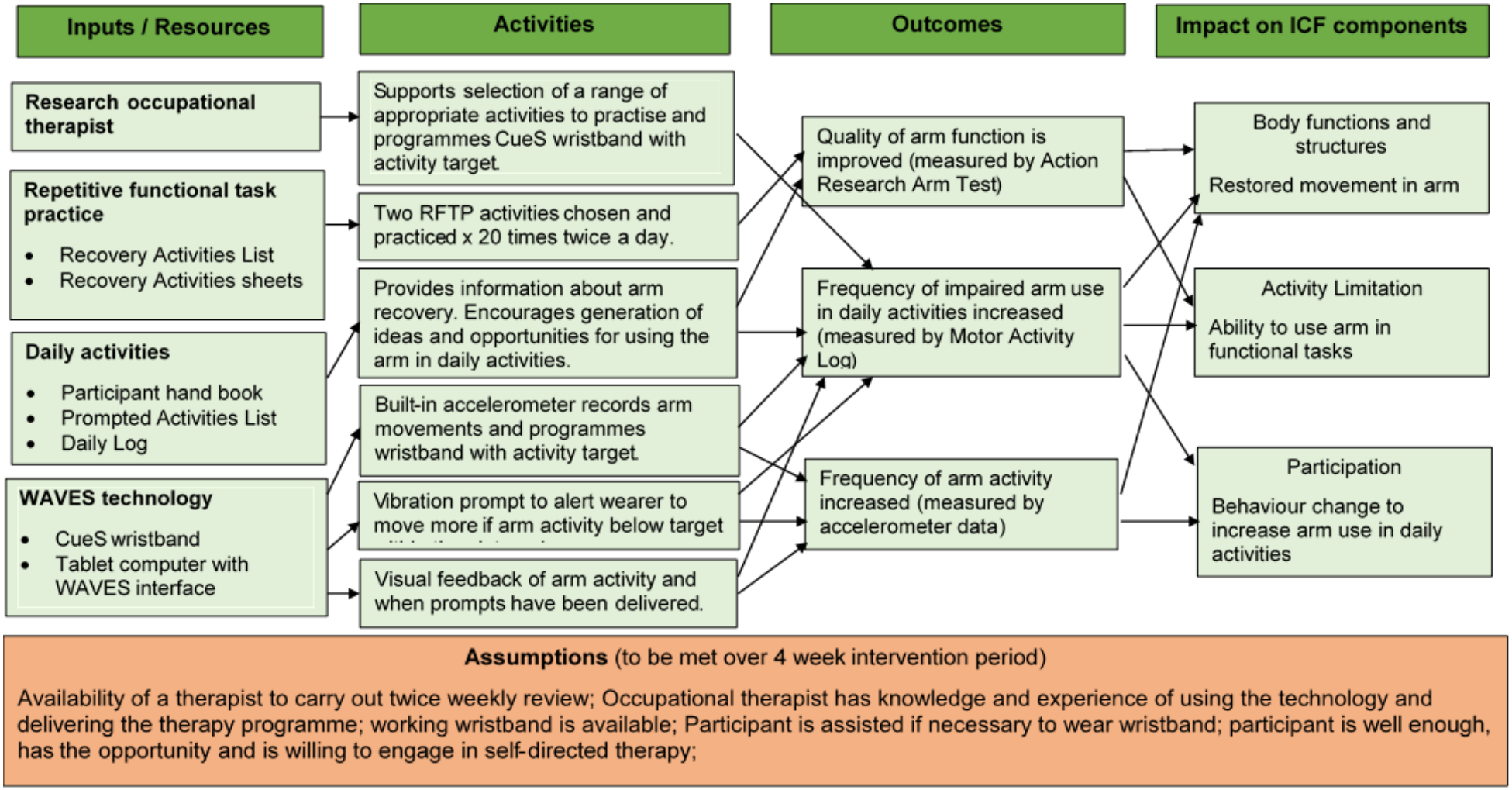


Figure 3.2 Logic model of WAVES intervention

Underpinning the activities in the logic model is the previously described concept of behaviour change. The Behaviour Change Technique (BCT) taxonomy identifies 93 consensually agreed behaviour change techniques that are used in behaviour change interventions (Michie et al., 2013). Using the BCT taxonomy as a framework, behaviours that were expected to further compound the complexity of the intervention were analysed and a number of behaviour change techniques identified from the BCT taxonomy to address each one. A summary of these behaviours and techniques are illustrated in Table 3.1.

Behaviour change techniques identified to support the intervention	
Goals and planning	**Comparison of behaviour**
Goal setting (behaviour) Problem solving Action planning Review behaviour goals	Demonstration of the behaviour
	Associations
	Prompts / cues Associative learning
Feedback and monitoring	**Repetition and substitution**
Feedback on behaviour Self-monitoring of behaviour Feedback on outcome(s) of behaviour	Behavioural practice / rehearsal Habit formation Overcorrection Generalisation of target behaviour Graded tasks
Shaping knowledge	**Reward and threat**
Instruction on how to perform the behaviour	Social reward
Natural consequences	**Self-belief**
Information about health consequences	Verbal persuasion about capability Focus on past success

Table 3.1 Behaviour change techniques to be used in the intervention

3.5 Describing the WAVES intervention as a complex intervention according to the TIDieR checklist

The Template for Intervention Description and Replication (TIDieR) checklist was developed as a systematic way for researchers to describe interventions in enough detail to allow them to be replicated (Appendix C). Using the TIDieR checklist, each component of the WAVES intervention (WAVES technology, encouraging use of the arm in ADLS and the repetitive functional task practice programme) is described below:

3.5.1 Brief name that describes the intervention

The title of the Stroke Association funded project was “WAVES” (Wristband Accelerometers with Vibrating alert to prompt Exercise after Stroke). This was adopted as the name of the whole intervention.

3.5.2 WHY (Rationale, theory, or goal of the elements essential to the intervention)

3.5.2.1 WAVES technology

The WAVES technology was the primary active and novel component of the intervention intended to increase intensity by promoting therapeutic use of the impaired arm (guided by a defined therapy programme) using two types of personalised feedback which sought to change behaviour.

Feedback facilitates modification and refinement of motor skills through the provision of information related to task performance and is associated with better outcomes (Subramanian et al., 2010). Feedback can help to promote a shift from explicit learning where a motor skill is learnt and executed through cognitive processes, to implicit learning where the motor skill becomes an automatic and unconscious movement that demands less cognitive attention. After a stroke intrinsic feedback, i.e. the sensory information such as proprioception, vision and touch provided following a movement, can be impaired necessitating provision of the feedback from an external source (Subramanian et al., 2010). Despite strong evidence to support the delivery of extrinsic feedback in motor recovery, the effectiveness of different aspects of feedback in stroke patients - such as frequency of delivery - remains

inconclusive (Harrison et al., 2018, Molier et al., 2010, Subramanian et al., 2010). There could be a number of reasons for this but it is likely that the varying degree of impairment between participants requires the delivery of feedback to be personalised based on individual need (Subramanian et al., 2010) and that the type of activity being encouraged should reflect pre-stroke arm use.

Extrinsic feedback is usually provided by a therapist either verbally, visually or by facilitating movements so the patient can feel the movement. Using technology such as robotics or virtual realities, similar types of feedback can be offered without the need for face-to-face contact with a health professional (Molier et al., 2010). These technologies open up opportunities to support patients with self-directed therapy practice outside of a clinical setting however, any benefit appears to be focused purely on impairment and less on functional use of the arm.

Despite investigation into the different types of feedback and how best to deliver it there is insufficient evidence to definitively suggest which type of feedback is most effective (Harrison et al., 2018, Molier et al., 2010, Subramanian et al., 2010). Combining tactile and visual feedback though appears to have a beneficial effect (Subramanian et al., 2010). In preliminary work for this project, stroke survivors expressed a preference for a vibro-tactile prompt over an auditory prompt as it is considered to be less obtrusive (Holden et al., 2015). Ensuring that prompting from the CueS wristband was unobtrusive was an important deciding factor in opting to use a vibro-tactile prompt with additional visual feedback in the WAVES intervention.

The CueS wristband, with integrated accelerometer, collected baseline activity data against which to measure progress and delivered vibro-tactile prompts to alert the wearer when activity levels fell below a pre-agreed threshold. This allowed the wearer to self-monitor the amount of arm use / therapy practise and to increase arm use whenever they received a prompt. Increased use of the impaired arm is important to prevent functional degradation and to enhance function (Kleim and Jones, 2008).

The WAVES computer interface provided visual feedback of activity when data was downloaded at a later date from the CueS wristband. Visual feedback of recent historic arm activity data was displayed on a computer screen matched against a 12 hour clock. When reviewed with the participant this supported therapeutic conversations around times of day when the impaired arm had been used and to enquire about what activities the participant had been involved in during that time. In this way the environment and daily activities were encouraged to be associated with arm recovery. Therapists would encourage participants and praise them on their achievement whilst supporting them to identify additional ways to increase arm activity during less active times in the day.

3.5.2.2 Use of the impaired arm in ADLs

Throughout the programme, participants were encouraged to involve the impaired arm in activities of daily living (ADLs) as much as possible to support increased impaired arm activity and promote integration of recovery to functional tasks. This was encouraged and agreed within the abilities and limitations of each participant.

A key element of any intervention is the application of the intervention within everyday practice (Craig et al., 2008) and the ultimate goal of arm rehabilitation is to restore and apply functional use of the impaired arm within everyday practice. It is well documented, that stroke survivors struggle to transfer the gains made in a clinical settings to normal daily routines (Moore et al., 2018, Waddell et al., 2017). If we consider this using the COM-B model, it would appear that ‘Capability’ can be influenced in the clinical setting but that the ‘opportunity’ and ‘motivation’ to engage in the same behaviours outside the clinic may be lacking. In developing the new intervention therefore, there needed to be some additional consideration given to understanding what motivates people to adapt their behaviour in order to apply the therapeutic skills back into function and how best to support a positive change in self-efficacy.

Based upon the previously described behaviour change theory, it seemed logical when developing the intervention, that if an element of the therapy practice was embedded in routine activities of daily living it would provide opportunities to master skills in a number of different tasks / situations. A qualitative study by Satink et al showed that practising every day activities supported self-management as stroke survivors interacted more with their environments and were rewarded by their ability to fulfil the same roles they had prior to the stroke (Satink et al., 2016). CIMT is another good example of an intervention showing the benefits of transferring the gains made from structured therapy practise to real life situations through its transfer package of behavioural techniques (Taub, 2012, Meharg and Kings, 2015).

Applying these same principles to the WAVES intervention, participants were encouraged to use the impaired arm as often as possible during pre-selected ADLs. The amount of practice and frequency of feedback supported the differing levels of arm impairment and ability shown by participants (Subramanian et al., 2010) by creating a personalised list of ADLs that the impaired arm could be involved in based upon typical activities carried out in day-to-day routines (Appendix D). These were called ‘prompted activities’ as they could be used to increase arm activity either in response to receiving a prompt or to avoid receiving a prompt.

Supported by the CueS technology, the prompted activities provided opportunities to incorporate the basic elements of motor recovery described by Kleim and Jones such as intensity, variability, repetition, specificity and salience within a training schedule proposed by Krakauer (Kleim and Jones, 2008, Krakauer, 2006). It was hoped that by supporting new learning in this way, it would be more likely to be retained over time and through regular rehearsal would become more automatic as is associated with implicit learning (Subramanian et al., 2010).

3.5.2.3 Repetitive functional task practice

A repetitive functional task programme was included to ensure that every participant had the opportunity to receive evidence based arm rehabilitation with a focus on participants chosen goals.

A pre-existing standardised therapy programme was adapted with the purpose encouraging repetitive practice of functional movements at a level of recovery for individual participants. This was the Repetitive Arm Functional Tasks After Stroke programme (RAFTAS) (Brkic et al., 2016) which had been previously developed as a self-directed RFTP programme within the local research group. Although RAFTAS had not been used in a large trial, the feasibility work showed that it was an acceptable and feasible method of providing RFTP in both inpatient and community NHS settings (Brkic et al., 2016). Other RFTP programmes were considered but there was no evidence that these would be superior in this context and no local experience in their delivery. The RAFTAS had the added benefit of integrating repetitive task practice around functional routines (Brkic et al., 2016).

3.5.3 WHAT Materials were used in the intervention

Materials used in the WAVES intervention included the WAVES technology (CueS wristband, laptop computer and software) and paper-based materials supporting the prompted activities and repetitive task practice programme. A full list of the essential materials needed to deliver the WAVES intervention can be found in Appendix E. The intervention materials and how they were developed specifically for WAVES will now be described.

3.5.3.1 WAVES technology content

The CueS wristband collects and monitors arm activity, delivers vibration prompts and provides activity data to be displayed on a computer interface (**Figure 3.3**). Enclosed in the wristband is a WAX9 accelerometer manufactured by Axivity (www.axivity.com) to record arm activity and a small built-in motor to deliver the vibro-tactile prompt (Holden et al., 2015). A standard micro-USB socket enables data download, programming and charging (3-7 days depending upon activity). Bespoke algorithms allow data to be displayed on the computer interface showing the amount of movement against time. A micro-processor in the device enables the wristband to be programmed with a target threshold or activity and to analyse incoming activity data against this target. If the average movement data coming into the device falls below a pre-set target, then a vibro-tactile prompt is delivered to alert the wearer.

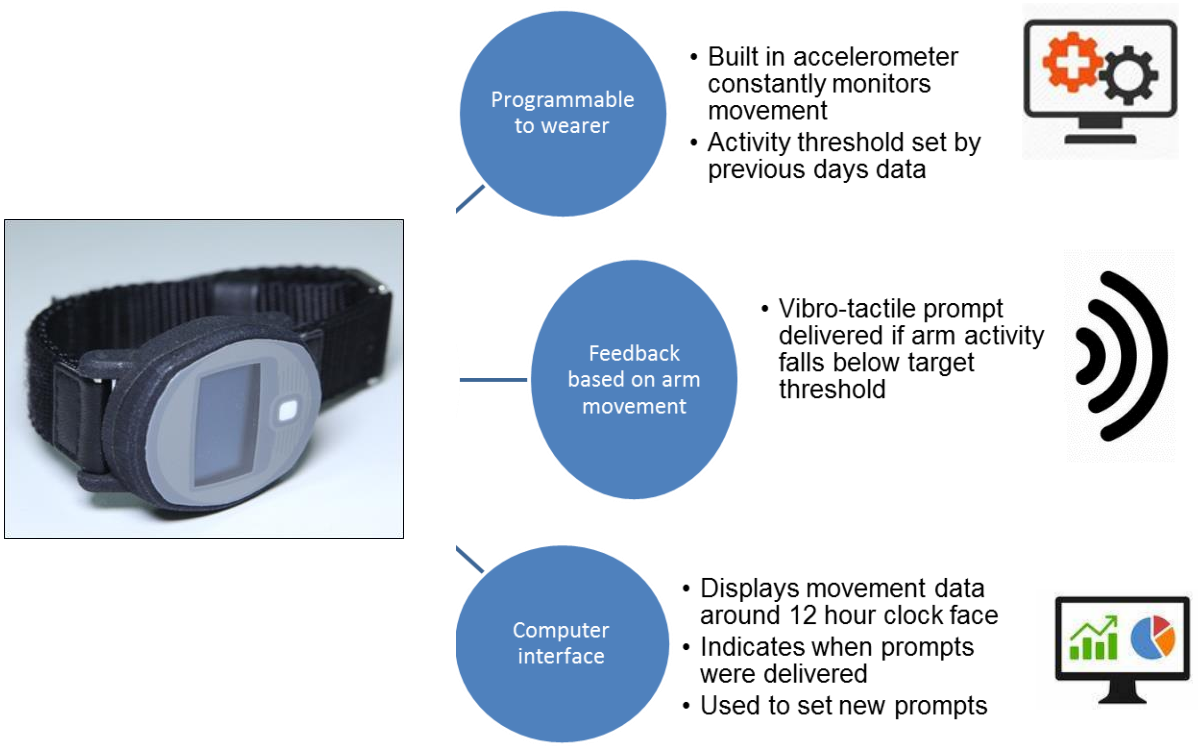
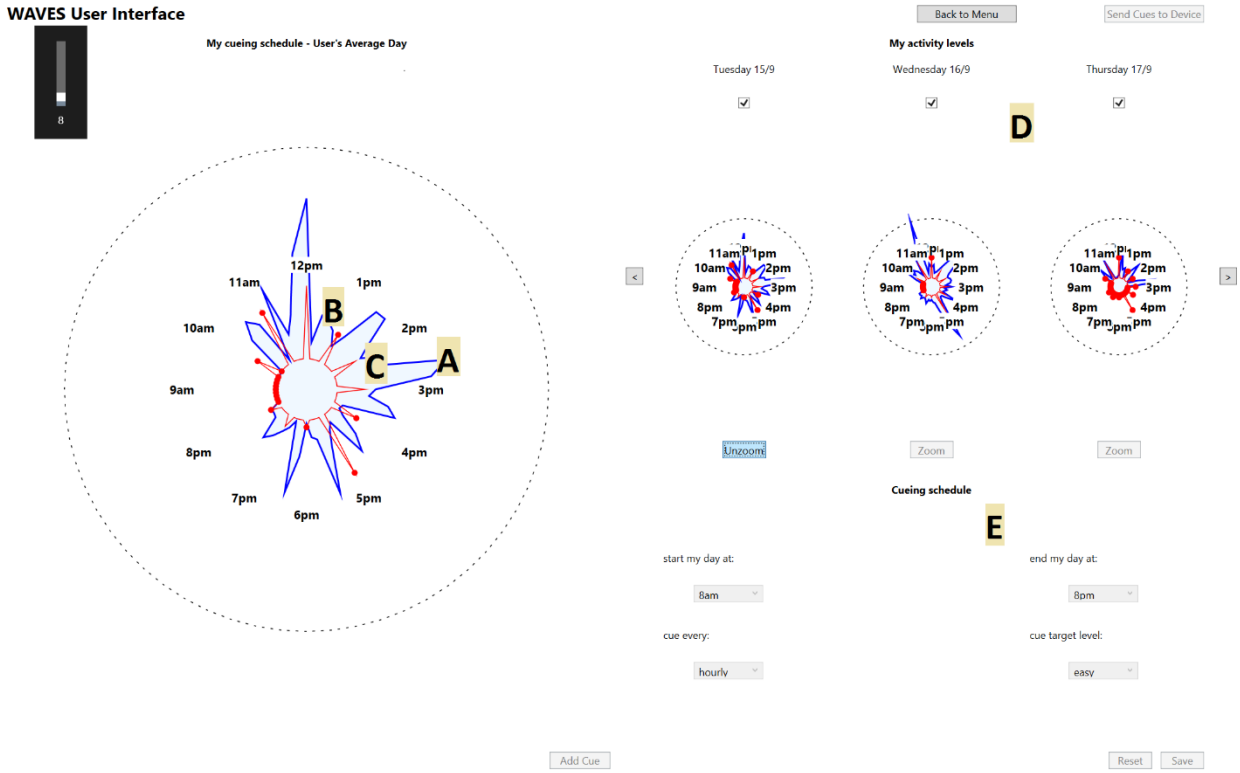


Figure 3.3 The WAVES intervention technology

Data collected by the CueS wristband was downloaded to the WAVES computer interface and visually displayed to participants to show how much the impaired arm had moved during the day and when prompts had been delivered. The interface had been designed by one of the WAVES co-applicants following consultation with stroke survivors and their carers and with health professionals working in stroke. Movement data for each day is displayed around a 12 hour clock face (Figure 3.4) by a blue shaded area. The intensity of movement is indicated by how far the shaded area extends out away from the centre of the clock face. Red dots indicate when a prompt had been delivered. This visual display supported patient-therapist conversations around how participants had used their impaired arm across the course of the day. Previous days' data were illustrated on smaller clock faces to the right of the screen and could be selected to assist with determining the next activity target.



Key: A – blue shaded area represents movement activity; B – red dots illustrate when a prompt was delivered; C – point of red line indicates activity threshold for that hour; D – shows history of last 3 days with option to scroll back to view earlier data; E – options to set the CueS prompting schedule, end time, maximum prompt frequency and prompt threshold

Figure 3.4 The WAVES computer interface display of movement data

The interface provided options to adjust the CueS prompt settings. A simple decision tree for setting Prompt thresholds and frequencies was developed to guide the study therapist and participants in determining adjustments to balance encouragement of greater activity against a risk of habituation (Appendix F). An intervention checklist was developed to guide the study therapist through each therapy session to ensure that all participants received a similar intervention process.

3.5.3.2 Prompted Activities List

Participants were provided with Participant Handbook which provided information on how to care for the arm after stroke and the benefits of increased therapy practice The prompted activities were recorded on a Prompted Activities List (Appendix D) in the participant handbook. These were additional activities to the twice daily repetitive task practice (see below) and created a personalised menu of activities for the participant to select from in order to increase arm movements within normal daily

routines e.g. stroking a household pet or watering plants. Prescribed repetitive task exercises including the two recovery activities could also be included on this list as a reminder to the participant to build practice into daily routines. The Prompted Activities could be used either in response to receiving a prompt or to increase arm activity in the hope that a prompt would be avoided.

The Prompted Activity List assigned an alphabetical letter to each activity. When a prompted activity had been carried out the corresponding letter was marked off on an 'alphabet wheel' printed onto a daily log sheet (Appendix G). The Alphabet wheel was an attempt to support participants with visual field deficits or neglect as it draws the eye towards the next letter in a way that a linear log would not. For participants who were unable to write due to the stroke affecting their dominant hand, the log sheet was designed to only require a mark in the box next to each letter.

3.5.3.3 Repetitive functional task practice (RFTP) programme content

The RFTP involved twice daily self-supervised repetitive practice of two selected multi-joint movements related to ADL (washing, dressing and eating/drinking) for 20 repetitions per day (80 repetitions per day in total)(Brkic et al., 2016). Patients had a twice weekly therapy review to consider selection of the next two movements from a menu graded according to complexity.

To reduce the amount of paper work involved for both therapists and patients and to ensure that the therapy programme complimented the CueS intervention, a modified version of the original RFTP programme was developed. The activity sheets were condensed and re-categorised into activity groups, for example, individual activities to reach and grasp differing objects were replaced with a general 'Pick and Place' activity group. Each group of activities were graded according to how much movement was required to complete them for example a 'pick and place' activity could consist of any of the following:

- weight bearing through the affected side while completing the task with the unimpaired arm
- reaching and touching an object with the impaired arm
- picking up an object with two hands
- picking up an object with just the impaired arm
- picking up and moving an object between different heights.

Each activity sheet provided examples of how to modify the activity to different objects in different situations. In this way the participants were encouraged to consider how one task practise could be generalised to different situations in order to promote self-management and true recovery (Kleim and Jones, 2008). Participants recorded their daily RFTP on these sheets (Appendix H).

3.5.4 WHAT Procedures were used

The WAVES intervention was a four week programme commencing the same day as patient consent and baseline assessment had been obtained. Details of the procedure pertaining to each separate component of the intervention are described below. A therapy schedule (see Appendix I) was used to describe the order of each of these procedures and so support the research therapist when delivering the therapy review sessions.

3.5.4.1 WAVES technology application

Participants were provided with a CueS wristband for the impaired arm and shown how to put it on and off. They were provided with a Patient handbook detailing information about how to care for the wristband and requested to wear the wristband from 8 o'clock in the morning until 8 o'clock at night.

At the start of each therapy review the CueS data was connected via USB cable to a laptop computer and the data downloaded to the WAVES interface. It could take 10-15 minutes to download the data and re-charge the battery, so the rest of the therapy review proceeded while this was happening.

From day seven the study therapist viewed the data collected by CueS with the participant. A discussion took place around periods of activity and inactivity with suggestions of ways participants could increase impaired arm use or spread activity more evenly across the day as necessary.

Participants were then guided by the study therapist to select a prompt threshold. When setting the target, participants could visualise the increase they had set compared to how much they had previously moved their arm. The expectation was to encourage limb activity which was in the upper half of the patient's individual range of ability without triggering too many prompts which could lead to habituation.

It was anticipated that at very low levels of function, the speed and amplitude of limb displacement might not be of sufficient magnitude to reliably distinguish purposeful arm activity from the data “noise” generated by walking or passive movement. This could lead to difficulties in setting and deploying a threshold reflecting arm movement. At high levels of function, the CueS threshold was expected to reach a ceiling level whereby it would not be possible for the person to be any more active. If participants reported at a review that prompts did not appear to be linked to activity levels, they were presented with options to change the threshold settings, switch to a time-dependent prompt (e.g. hourly), disable the prompt function temporarily or discontinue it for the remainder of the study and rely upon the interface movement data report alone to modify recovery activities. Decisions around these options were guided by the therapy decision tree (Appendix F) to inform the most appropriate changes to the threshold and frequency of the CueS prompt settings.

Once the CueS wristband had been programmed, the study therapist reminded participants that if they received a vibration prompt from the CueS wristband it was an indication that they had not used their impaired arm enough.

3.5.4.2 Prompted Activities List application

From day seven, the study therapist introduced the participant to the idea of the Prompted Activities and encouraged the participant to identify 5 to 10 activities that they could attempt to carry out using their impaired arm. The study therapist demonstrated how to complete the Prompted Activities List and how to record which prompted activities they had attempted on the daily log sheet (Appendix G). Participants were advised to choose an activity from the Prompted Activities List to increase arm use either to avoid receiving a prompt or in response to receiving a prompt. During future review sessions, participants were encouraged to keep adding to this list of activities as they improved.

3.5.4.3 Repetitive task practice programme application

Following baseline assessment and at the beginning of each therapy review, the study therapist completed a basic upper limb assessment to establish motor impairment and other neurological deficits that may impact on upper limb function. A

discussion then took place regarding upper limb rehabilitation needs and the participant selected two areas of arm recovery that were most important to them. A realistic functional goal for each area was set which could potentially be achieved within the four week therapy programme.

The study therapist used the 'recovery activity' list (see Appendix J) to select an appropriate 'recovery activity' for each functional goal. The research therapist used their clinical judgement to select activities which were most appropriate to the current upper limb functional level of the participant. A recovery activity that was a component of or worked towards a functional task could be set if it was more appropriate for participants with minimal movement in the arm. For example, an initial recovery activity to "touch your chest with your affected hand" may have been set for the goal 'to wash under my arm'. The study therapist provided the participant with a recovery activity sheet (Appendix K) and demonstrated the RFTP activities to ensure they were a suitable choice and that the participant would be able to practise independently.

The continuing relevance of activities was reviewed twice weekly (i.e. every 3-4 days) over the 4 week period by the study therapist. If a goal had been achieved, a new goal and recovery activity was chosen. If the goal had been too challenging the recovery activity or goal could be modified or a new goal chosen.

New Activity sheets were provided at each review session to correspond with the new recovery activity and the participant was reminded to practice them twice a day with up to 20 repetitions at each session.

3.5.5 The interactions between the WAVES components.

Figure 3.5 shows the interaction between the component parts of the CueS technology and arm movement.

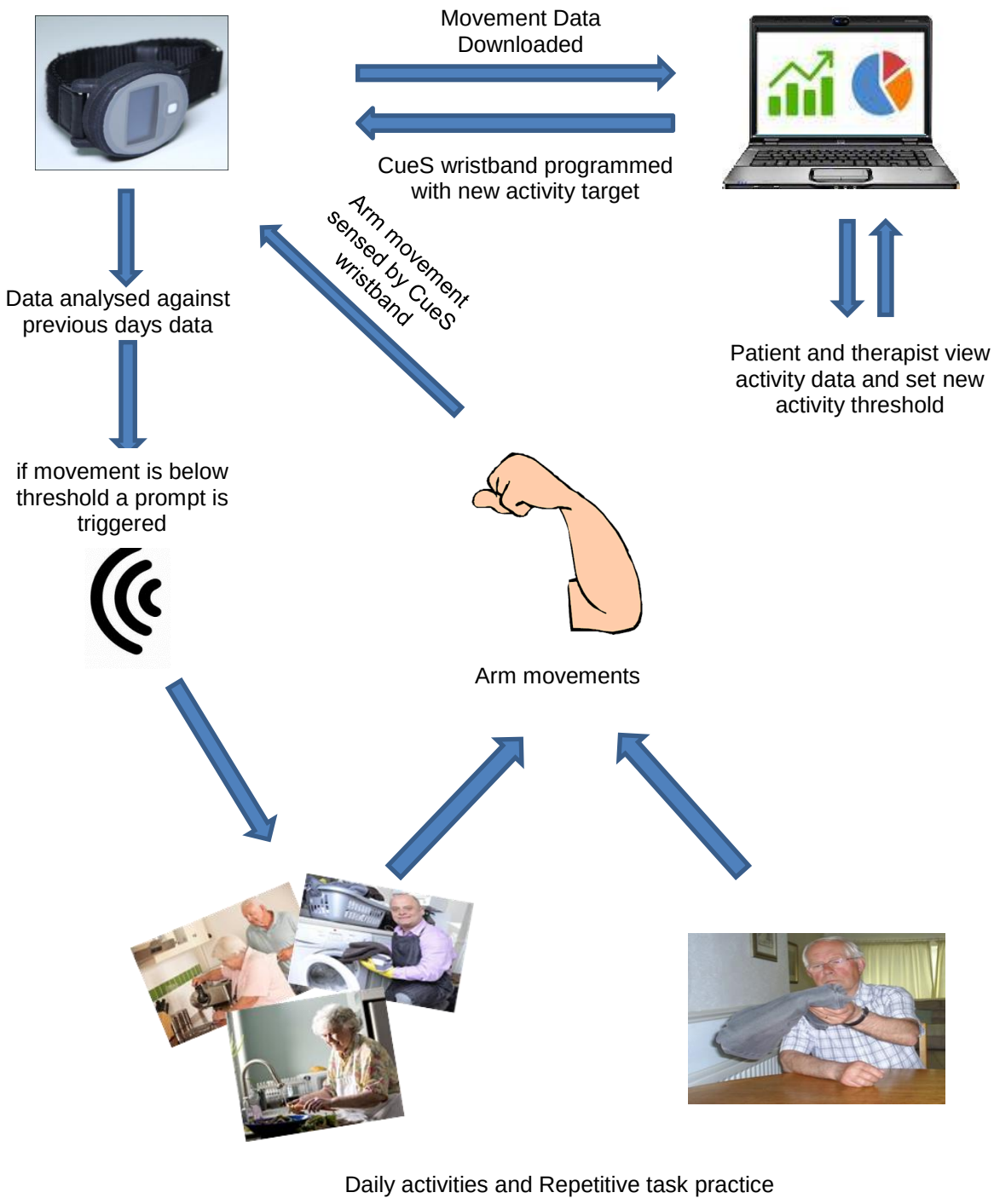


Figure 3.5 Interaction of component parts of the intervention

3.5.6 WHO would deliver the interventions and what behaviours / skills were required

The intervention was designed to be delivered by NHS therapists working across both hospital and community settings. Differences in the skill set of staff delivering the intervention was an additional factor to consider when developing how successfully the intervention would be implemented. There was an assumption that all therapists would be competent at rehabilitating the arm after stroke and have a reasonable level of information technology skills.

To assess the usability of the intervention by therapists, the study therapist (this author) was identified as the most appropriate person to set the patient up and support with the intervention at this stage because of their knowledge and expertise in the recovery of arm function after stroke whilst being competent and familiar in using the technology. As this was still the developmental stage of the intervention, the study therapist continued to work closely with the computer science department at the University at this stage to report any necessary adjustments required to the technology and to gather useful feedback from participants around any changes required to the therapy programme.

3.5.7 WHERE did the intervention occur

The WAVES intervention was intended to be used across both hospital and community settings each with the potential to either help or hinder the delivery and subsequent outcomes.

Participants were identified from two inpatient stroke services in the North East of England. There was an expectation most participants would be discharged home before completing the four week intervention. To accommodate this, the WAVES intervention was designed to be delivered across both hospital and community settings with the expectation that future use of the WAVES technology would be community based.

3.5.8 WHEN and HOW MUCH was required

This was a four week programme starting within 28 days of having a stroke. The CueS wristbands were worn for the duration of the four weeks allowing for seven cycles of therapy reviews. This was considered a sufficient length of time to test both the adjustment of the CueS wristband settings and examine for an effect on arm activity.

A baseline of arm activity was collected over the initial seven days of wear. This timescale of seven days was chosen to allow for variations in daily routines for example over a weekend. The prompted activities part of the intervention commenced at the end of the first week when the first prompts had been set. Participants were advised to do as much as they felt willing or able to do of the prompted activities which were tailored around each participant's ability and daily routines.

The RFTP programme consisted of twice daily practice of 2 recovery activities (20 repetitions each) and commenced on day one.

3.5.9 TAILORING the intervention

Through the nature of the intervention, each component of the intervention was designed so that it could be personalised to the needs and routines of individual participants.

The settings of the CueS wristband could be adjusted when programming the device to allow the programme to be suit the abilities of each participant. The frequency of the prompts could be adjusted between hourly, two hourly, three hourly or four hourly according to how often the participant wanted to be alerted. A range of settings were also available to adjust the prompt activity threshold. In the absence of any previous intervention of this type, these were set at 5%, 15%, 25% or 50% above the median of the previous 3 days activity to allow for a range of abilities between participants.

The therapy programme was designed to reflect individual patient needs through goal setting and choice of the prompted activities. The amount of practice was tailored according to how much the individual felt able to do.

3.5.10 MODIFICATIONS during the course of the study

The original procedure detailed above was modified following feedback from the first two participants. There was confusion between the RFTP introduced on day one and the subsequent introduction of the prompted activities list at day seven. To avoid confusion and integrate these two parts of the intervention more smoothly, the intervention was modified so that participants started the Prompted Activities from day one following identification of just 3 to 5 activities. These was in addition to the two RFTP exercises they had been given which encouraged participants to continue to practice these exercises even after a goal had been achieved and a new one set. In this way the intervention was always building on the skills already learnt.

Due to intermittent technical malfunction of the CueS wristbands, and in preparation for the forthcoming randomized controlled trial, the computer interface and prompt algorithm were modified and tested on the final two participants. Full details of these changes are explained in Chapter 7 following analysis of the feedback from participants.

3.5.11 PLANNED adherence and fidelity

A therapist hand book with a therapy schedule and decision tree were developed to ensure consistent delivery of the intervention as described in the study protocol. Local therapists and clinical network staff were provided with training to support recruitment into the study and encourage adherence for participants who were still inpatients.

Adherence to wearing the CueS wristband was recorded by the built-in accelerometers. In addition participants were asked at each therapy review if there had been any occasion when they had not worn the wristband and reasons why. Participants were asked to estimate how many times per day they had been

prompted and how they had responded when prompted e.g. carried out a prompted activity.

3.6 Conclusion

This chapter described the WAVES intervention for the initial stage of the MRC framework by using the TIDieR checklist. The MRC framework recommends a phased approach to testing the key components of the intervention, this will be described in subsequent chapters (Craig et al., 2008). In describing the concept of the intervention it is already evident that there would need to be careful examination of participants' ability to respond appropriately to any prompts received and the feasibility of combining an RFTP with prompted activities occurring throughout the day.

Chapter four describes the observational study carried out to evaluate the technical feasibility of the WAVES intervention components working together and obtains feedback from participants on the acceptability of being prompted by the CueS device and the daily therapy programme.

Chapter 4. Proof of concept study: Aims and methods

In the previous chapters, the theoretical basis of the WAVES intervention to enhance impaired arm activity was explored to justify the development and integration of each component part. The next phase of development following the Medical Research Council guidelines (Craig et al., 2008) was a proof of concept study to demonstrate the feasibility of the intervention and acceptability to stroke survivors. This was to allow the opportunity for individual components to be further developed if necessary.

This Chapter describes the aims and methods of a four-week proof of concept study with a small cohort of stroke patients. The results of this study are presented in subsequent chapters with final evaluation and refinement of the intervention in preparation for the pilot randomized controlled trial detailed in Section 3.

4.1 Aims

To explore the technical and clinical feasibility, early evidence of and intervention response and acceptability of the WAVES intervention.

Objectives

1. To describe the technical feasibility of collecting activity data using the CueS wristband and delivering a vibration prompt when arm activity fell below the prompt threshold;
2. To report how participants responded to prompts by examination of arm activity data;
3. To describe the views of participants regarding the acceptability of the WAVES intervention and how they informed further developments of the intervention.

4.2 Methods

4.2.1 Study Design

This was a prospective single arm intervention group observational study with thematic analysis of verbal feedback from participants. A summary of the study design is shown in Figure 4.1. The study was approved by the National Health Service Newcastle Central Research Ethics Committee (reference number 16/NEC/0063) and conducted according to international standards for Good Clinical Practice (NIHR, 2013).

4.2.2 Study population

Participants needed to be over the age of 18 years; have a new stroke-related upper limb motor deficit but with enough movement to lift their hand off their lap; be able to provide consent to participate in the study and be living within the catchment area of the local community services for each participating study centre.

Patients were excluded if they had pre-existing upper limb limitations (e.g. frozen shoulder) or could not comply with a structured therapy programme as a result of significant cognitive, communication or visual impairment.

4.2.3 Case ascertainment, recruitment and consent

Potential participants within four weeks of acute stroke were identified by local therapists and research staff from two inpatient stroke services in North East England.

Interested patients were provided with written information about the study (Appendix L) and the study therapist informed. The study therapist visited the patient in hospital to obtain written informed consent (Appendix M) and to carry out baseline assessments (Appendix N).

4.2.4 Baseline assessment

Baseline clinical data included demographics (gender; age; hand dominance; previous stroke and effects; pre-stroke dependency according to modified Rankin Score (van Swieten et al., 1988) and pre-stroke function according to Barthel Score (Wade and Collin, 1988)); stroke characteristics (aetiology, clinical subtype, severity according to National Institutes of Health Stroke Scale (Brott et al., 1989)).

Impaired arm function was measured using the Action Research Arm Test (ARAT)(Lyle, 1981b) and the Motricity Index (Demeurisse et al., 1980) at baseline and four weeks after starting the intervention.

The ARAT consists of 19 tasks related to grasp, grip, pinch and gross movement which are assigned a score of between 0-3 for each task. A score of zero indicates the participant was unable to perform any part of the test and a score of three would indicate that the test was performed normally. A total score is given of between 0 and 57.

Discomfort or pain in the impaired arm was measured using a 0-10 numerical visual analogue scale. Fatigue was also measured with a 0-10 numerical scale where zero represented no pain and 10 the worst pain.

4.2.5 Intervention

All participants commenced the four week intervention whilst still an inpatient on the stroke unit. They continued to receive usual clinical care from NHS therapists in addition to a twice weekly review from a single study therapist. Participants who were discharged from hospital during the study period were asked to continue the programme at home and subsequent review sessions took place in the participants' own homes.

Following baseline assessment the study therapist and participant discussed rehabilitation goals around washing, dressing and other personal care tasks. The study therapist supported the participant to identify two functional goals to work towards and then provided them with two relevant functional movements to practice (Brkic et al., 2016). Participants were encouraged to practise these movements independently twice daily for up to 20 repetitions of each and to record the practice on their recovery activity sheet. The ongoing relevance of these activities was reviewed at twice weekly review sessions (Appendix O). This formed the previously developed repetitive functional task practice programme by Brkic et al as described in Chapter 3.

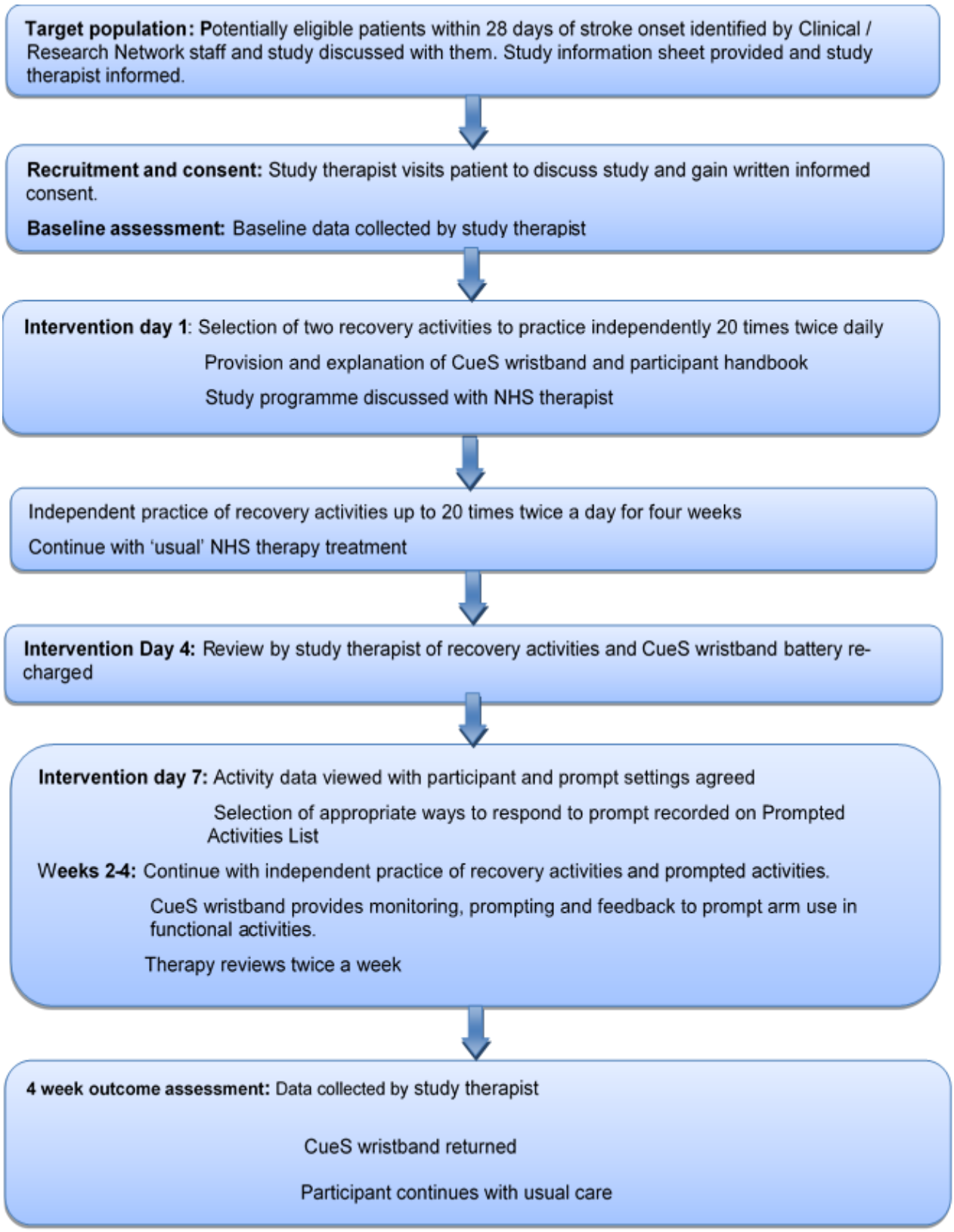


Figure 4.1 Study summary diagram

Participants were instructed to wear a CueS wristband on their impaired arm for 12 hours daily between the hours of 8am and 8pm. To personalise the intervention, the first week of CueS wristband wear was to collect baseline activity data only and no prompts were set. This baseline of the participants' upper limb activity levels was subsequently used to set the initial activity threshold and frequency of the prompts.

As described in Chapter 3, during the second therapy review session (day seven), the wristband was programmed to vibrate when arm activity levels dropped below an agreed threshold. The threshold was agreed with the participant and the frequency set based on their ability and motivation. If subsequently prompted, participants were instructed to increase impaired arm movements, by performing pre-selected activities from their prompted activities list or to practice one of the repetitive task practice exercises (Brkic et al., 2016). This self-directed practice was recorded by the participant on the patient held daily log sheet and expanded throughout the four week programme during twice weekly therapy reviews.

During the twice weekly review sessions with the study therapist, the CueS data were downloaded onto the WAVES portable computer interface and the impaired arm re-assessed. During these reviews, feedback was shared with the participant on the number of prompts they had received, whether this amount had been acceptable and how they had responded to the prompt i.e. by practising a given activity or if they chose to ignore the prompt. The therapist and participant then used the activity data to discuss progress and maintenance of an appropriate balance of activity practice and rest periods. To accommodate changes in motor performance, the new CueS wristband data accumulated since the previous review defined a new baseline activity pattern and prompt settings were agreed for the next 3 days. In order to encourage movement in the upper range of ability, prompt thresholds were set at 5%, 25% or 50% above the wearer's median hourly activity level according to individual preference.

4.2.6 Outcome Measures

Post-intervention outcome assessments at week 4 included: Action Research Arm Test (ARAT) (Lyle, 1981b) and the Motricity Index (Demeurisse et al., 1980) to measure upper limb motor function / impairment; visual analogue scales (1-10) to measure pain and fatigue and tri-axial accelerometer data to objectively measure impaired upper limb activity levels (Appendix P).

As part of the feasibility assessment, we estimated the proportion of time that the CueS device was worn out of the possible maximum hours. If there was a continuous period of 30 minutes or more during each fixed hourly interval when the device recorded an SVM value of zero, then this hour was labelled as “device not worn”. Although an SVM >0 may have been recorded for part of that hour, this definition was chosen to reflect the hourly timing of the prompt mechanism and provide a “count” of how many whole hours that the CueS wristband appeared to be in use. All processing and analysis of the accelerometer data was carried out by a member of the computer science department.

At the start of each therapy review, participants were asked for comments about the programme. They were encouraged to consider any good or bad points from their experiences. Participants’ responses to this question were recorded verbatim on the therapy review session forms (Appendix O).

As part of the wider project funded by the Stroke Association, participants were invited to take part in a semi-structured interview at the end of the four week intervention by a qualitative researcher who had not been involved in the clinical care of the patient or the therapy programme. The researcher was based in a separate school of the university and had experience of qualitative research in a healthcare setting. These interviews were audio-recorded and were intended to follow a topic guide developed by this PhD candidate focusing on the utility and acceptability of the rehabilitation programme. Unfortunately, the findings from these interviews could not be included in this thesis as the transcribed recordings were not made available and the results of this work remain unpublished to date. Understanding participant’s

experience of the intervention however, was an important part of the development phase and was expected to help identify potential barriers to wearing the wristband and adhering to the programme. In the absence of this data, participants experiences of the intervention obtained based on the feedback comments provided at the beginning of each therapy review.

4.2.7 Analysis

Quantitative data: Descriptive statistics were analysed using SPSS software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Nominal and ordinal data are reported as a number and a percentage. Continuous data are reported as mean and standard deviation (SD) or, where the distribution is skewed as median and interquartile range [IQR].

Accelerations detected by the CueS wristband were converted into Signal Vector Magnitude (SVM) which summarises the intensity of activity across three dimensions relative to "g" (9.8 m/s^2) per minute as a single value (Karantonis et al., 2006).

For each participant, Student's t-test was used to compare the mean SVM over 60 minutes before a prompt was delivered by the CueS wristband, with the mean SVM over 60 minutes after a prompt was delivered. This part of the data analysis was carried out by a member of the computer science department.

Feedback from participants: Thematic analysis was applied to comments collected during therapy review sessions. Common themes were identified related to the experience of wearing the CueS wristband and viewing the data report during therapy review sessions. To do this, all comments were organised by participant and therapy review sessions, read in close detail and any interesting or key things coded (Appendix Q). A list of themes was generated from these codes and each one assigned a number (Appendix R and S) before being reviewed and refined to draw out a more coherent list of common preliminary themes (Appendix S). The comments were then re-organised into final themes and summarised using anonymised representative quotes.

4.3 Results

The results are presented in two sections to reflect the study objectives. Chapter 5 reports the technical feasibility and clinical applicability of the WAVES intervention when delivered alongside usual NHS treatment. Chapter 6 describes patients' experiences of using the WAVES technology and the accompanying therapy programme. Chapter 7 summarises the findings and reports how these findings informed further development and refinement of the WAVES technology and study design in preparation for the Pilot RCT.

Chapter 5. Proof of concept study: quantitative results

This chapter reports on study objectives 1 and 2 and describes the technical and clinical feasibility of the WAVES intervention and how participants responded to receiving the prompts.

5.1 Baseline demographics and stroke characteristics

Gender	
Male/female (total number)	7/4 (11)
Age (years)(mean ± SD)	67 ± 11
Time since stroke onset (days) (mean ± SD)	13 ± 6
Stroke impaired side (R/L)	4/7
Stroke Type (total number)	
Infarct	7
Haemorrhage	2
Unknown	2
Stroke sub type (total number)	
TACS	3
PACS	2
LACS	3
POCS	3
Assessments (median [IQR])	
NIHSS (range 0-42: no symptoms – severe impairment)	4 [3,8]
ARAT (range 0-57: no function - normal function)	44 [26, 48]
Motricity (range 0-100: no movement – normal power)	78 [58, 84]
Fatigue NAS (range 0-10: not tired – extremely tired)	7 [5,8]
Pain NAS (range 0-10: no pain – worse pain ever)	3 [0,5]

Key: SD standard deviation; TACS total anterior circulation stroke; PACS partial anterior circulation stroke; LACS lacunar stroke; POCS posterior circulation stroke; IQR interquartile range; NIHSS National Institute for Health Stroke Scale; ARAT Action Research Arm Test; NAS numerical analogue scale

Table 5.1 Baseline Demographics

Table 5.1 shows the summary baseline demographics and stroke characteristics of participants.

A total of eleven patients were recruited from across the two sites. Individual patient characteristics at baseline and after four weeks are shown in Table 5.2. The median increase in ARAT scores was 9.5 [n=10, IQR 2.8, 17.3]. There was no notable increase in pain or fatigue and no adverse events reported.

Participant	*Clinical stroke classification*	*Dominant hand affected?*	*ARAT‖ baseline*	*ARAT‖ 4wks*	*Motricity score baseline*	*Motricity score 4wks*	*Pain NRS# baseline*	*Pain NRS# 4wks*	*Fatigue NRS# baseline*	*Fatigue NRS# 4wks*
P1	LACS	N	48	57	84	91	0	0	8	5
P2	POCS	N	48	57	96	96	0	0	6	5
P3	TACS*	Y	3	4	10	29	4	4	6	4
P4	PACS†	Y	45	55	62	71	0	0	8	6
P5	TACS*	N	44	57	77	92	3	0	7	6
P6	POCS‡	N	40	57	78	77	6	3	8	5
P7	POCS‡	N	8	11	56	70	0	0	5	6
P8	LACS§	N	26	56	62	92	6	0	8	4
P9	LACS§	N	39	57	93	92	5	4	5	6
P10	PACS	N	49	51	72	84	4	0	9	5

Total Anterior Circulatory Stroke;** ***†Partial Anterior Circulatory Stroke; ‡Posterior circulatory Stroke; §Lacunar Syndrome; ‖Action Research Arm Test; #Numerical Rating Scale

Table 5.2 Clinical outcomes and pain and fatigue scores for individual participants

5.2 Objective 1: To describe the technical feasibility of collecting activity data using the CueS wristband and delivering a vibration prompt when arm activity fell below the prompt threshold.

Participants wore the CueS wristband for an average of 299 out of a maximum of 336 hours (89%). One person withdrew prior to commencing the intervention and therefore no outcome data are available. Of the ten participants who completed the four-week programme, three people's CueS wristband data were corrupted due to technical failures indicating the CueS wristband and interface required further adjustments. The first two participants (who were recruited in parallel), lost data due to a CueS wristband coding error. This resulted in random deletion of data and no prompts delivered despite changing the settings at each review. The reason for this only became apparent following a detailed review of their raw data and the code was corrected. Data for these two participants and clinical outcomes were not included in the analysis due to uncertainties about how well the data reflected the full 4 week programme and whether there were unrecognised times when a prompt could have been delivered.

For the last participant, the data interface software had been modified based upon user feedback, with the intention of displaying the activity data in a style that could further facilitate prompt setting decisions. It became apparent however during its use that the interface was not displaying the most recent activity on the same time axis as the previously downloaded data. Due to the geographical location of the patient relative to the research team it was not possible to correct this before the end of the 4 week programme. As the prompt setting process had been corrupted, this patient's data was not included in the results as the impact of prompts would not have reflected the same protocol used with the other participants.

5.3 Objective 2: To report how participants responded to prompts by examination of arm activity data.

The study group received at total of 1,288 prompts from the wristband, an overall median of 4 [IQR 3.7] per day. Prompting schedules and responses for each participant are shown in Table 5.3. With the exception of the first prompt schedule

which was set by the study therapist, all settings were determined by the participant based on their experiences and preferences for being prompted. When agreeing prompt settings at therapy review sessions, participants mostly chose minimum intervals of hourly (96% reviews) rather than 2, 3 or 4 hourly. There was also a clear preference for the target reviews threshold to be set at the lowest setting i.e. 5% above the previous median baseline activity (75%).

	Prompt setting Week 2 : review 1			*Prompt setting Week 2 : review 2*			*Prompt setting Week 3 : review 1*			*Prompt setting Week 3 : review 2*			*Prompt setting Week 4 : review 1*			*Median number of prompts / day*		*Influence of CueS prompt on arm activity*			
Participant	Prompt Frequency	Prompt Threshold	Participant reported prompts	Prompt Frequency	Prompt Threshold	Participant reported prompts	Prompt Frequency	Prompt Threshold	Participant reported prompts	Prompt Frequency	Prompt Threshold	Participant reported prompts	Prompt Frequency	Prompt Threshold	Participant reported prompts	Reported by participants	Recorded by CueS device	Overall mean activity [95%CI] 1 hour pre-prompt (g)	Overall mean activity [95%CI] 1 hour post-prompt (g)	% change in activity 1 hour post-prompt	p-value
3	3	Easy	2	1	Easy	3	1	Easy	3	1	Med.	3	1	Med.	4	3	4	0.31 [0.26-0.36]	0.38 [0.32-0.43]	+23	0.04
4	4	Easy	0	1	Easy	2	1	Easy	4	1	Hard	6	1	Easy	2	1	4	0.78 [0.59-0.98]	0.94 [0.74-1.14]	+20	0.18
5	1	Easy	3	1	Easy	1	1	Med.	0	1	Med.	2	1	Easy	n/a	2	5	1.22 [0.99-1.45]	1.37 [1.14-1.60]	+12	0.11
6	2	Easy	2	1	Easy	2	1	Easy	2	1	Med.	2	2	Easy	2	2	3	1.58 [1.32-1.83]	2.03 [1.73-2.33]	+29	0.01
7	3	Easy	0	1	Easy	1	1	Easy	0	1	Easy	0	1	Hard	0	0	1	0.13 [0.11-0.14]	0.15 [0.12-0.18]	+20	0.19
8	1	Med.	4	1	Med.	6	1	Easy	4	1	Easy	4	1	Easy	5	4	7	0.42 [0.36-0.48]	0.52 [0.45-0.59]	+23	0.01
9	1	Hard	3	1	Easy	0	1	Easy	4	1	Easy	5	1	Easy	5	4	11	0.88 [0.81-0.95]	0.98 [0.87-1.08]	+11	0.05

Key: Frequency in hours e.g. 1= hourly, 2 = 2 hourly, 3 = 3 hourly and 4 = 4 hourly
Prompt Threshold levels: Easy = 105%; Med. = 125% and Hard = 150% of previous activity

Table 5.3 Participant selected prompting schedule

Data from participants 1, 2 and 10 has been omitted due to accelerometer data contamination

The median number of prompts ranged from 1 to 11 per day. In the hour following a prompt there were increases in mean activity levels from 11% to 29% compared to the previous hour, with an average SVM increase across all recorded prompts (n=1288) of 19.8%. Figure 5.1 shows the average distribution of activity per minute of the impaired limb across all participants in the hour before and after delivery of a prompt. The increase appears greatest in the second half of the hour afterwards, increasing only slightly in the half hour directly after a prompt, and then further increasing to between 31 and 60 minutes. This delayed increase could suggest a change in behaviour to avoid a further prompt rather than simply an immediate response to the device. A visible increase in arm activity could be seen across the four-week programme when the data was viewed on the WAVES interface (see Appendix T for examples).

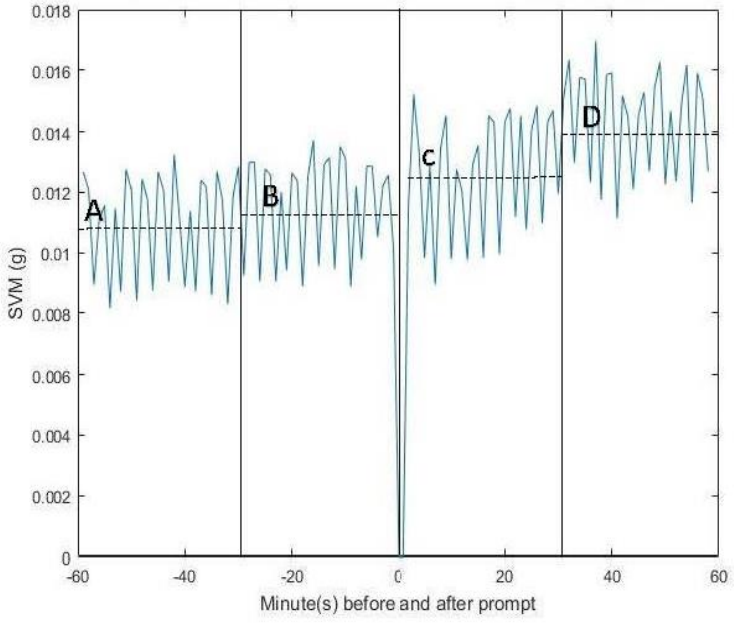


Figure 5.1 Distribution of SVM in minutes before and after prompt[2].

Vertical solid lines represent 30 minute time intervals. Dashed horizontal lines reflect the mean SVM/minute as follows: (A) mean SVM/min -60 to -30 min before a prompt = 0.0109, (B) mean SVM/min -30 to 1 min before a prompt = 0.0111, (C) mean SVM/min +1min to 30 min after a prompt = 0.0125 and (D) mean SVM/min +31 to +60 min after a prompt. Note that data ±1 min of a prompt were not included in the analysis to avoid possible SVM contamination by the CueS motor vibration. SVM: signal vector magnitude.

[2] Data collated by a fellow member of the WAVES team and PhD student from the computer science department

5.4 Discussion

Although technical failures were experienced, the results support application of the WAVES intervention to prompt upper limb activity throughout the day. Participants adhered well to the programme according to the proportion of hours of CueS wear and responses to prompts.

It is important to acknowledge that this was an un-blinded observational study on a small number of volunteers by a single study therapist. As participants were within 4 weeks of stroke onset, arm power and function would be expected to improve anyway and so this cannot be ascribed to the intervention. It was not possible to assess the reliability of application of the technology as there was only one study therapist, who was already involved in the development of the intervention.

The study showed that patients with a range of motor impairments were able to respond to the prompts and adapted the CueS settings according to their own needs. For example, one participant (P3) with very little functional movement in their affected arm and sensory inattention, requested frequent prompts at a medium rather than low setting as this was more likely to ensure regular prompts to use their arm. Others, such as P5 and P6, with better movements showed a preference for a low prompt threshold and wanted to increase use of the arm to try to avoid being prompted. Three participants (P3, P5 & P7) had been observed to have a notable sensory inattention to their impaired side and, although this was not formally assessed, anecdotally two of these participants were noted to become more aware of the impaired side.

Most participants showed a preference for an hourly prompt with prompt thresholds set at 5% above the median baseline activity level. When settings were raised to

above 25% it was immediately followed with a drop back to the lowest setting indicating that options for setting the threshold may need to be revised.

The devices used in this proof of concept study were prototypes, with three failures due to software errors, so some improvements were also required to improve reliability and quality assurance.

It is important to acknowledge at this stage that the CueS wristband is sensitive to changes in general movement but it cannot distinguish between purposeful and automatic arm movements, such as arm swing whilst walking. The accelerometer data may therefore need to be interpreted cautiously (Hayward et al., 2016). Previous studies have found that data from wrist worn accelerometers correlate well with longitudinal arm function changes (Bailey and Lang, 2013) and the consistent nature of daily activity routines amongst community dwelling stroke patients provides some reassurance that data variability reflects arm movement patterns, especially in the context of a structured therapy programme (Tieges et al., 2015). However, no conclusion can be drawn from the proof of concept study that the changes in activity data did definitely represent purposeful arm use during ADL or activity practice. The visual display of the data around a 12 hour clock allowed for some validation through discussions with participants about whether a specific data pattern represented changes in arm movement or not based upon their reported activities at the time e.g. making lunch, grocery shopping etc (see example in Appendix U).

5.5 Conclusion

This chapter has shown that participants were able to adhere to the WAVES intervention over a 4-week period and there is evidence to suggest a short-term increase in arm activity in response to prompts from the CueS wristband. Improvements were now required to ensure device reliability and further adjustments to the prompting mechanism.

The next chapter describes the responses from participants in the study on their experiences of wearing the CueS wristband, viewing the data activity reports and following the therapy programme.

Chapter 6. Proof of concept study: participant feedback

6.1 Objective 3: To describe the views of participants regarding the acceptability of the WAVES intervention and how they informed further developments of the intervention.

All 10 stroke survivors who took part in the study provided feedback on their experiences of using the WAVES intervention. Although technical complications for participants 1, 2 and 10 rendered their accelerometer data inadmissible, their experiences of receiving prompts as well as undergoing the therapy programme were still useful and were included in analysis of the qualitative data.

Comments collected during each therapy review session indicated five themes reflecting different aspects of the intervention. These themes were: the design of the wristband, receiving prompts; viewing the activity data; the repetitive task practice exercises and participants' views on the intensity of the programme. Each theme is discussed below with comments from participants where relevant

6.2 Theme one: Design of the CueS wristband

Three sub-themes emerged regarding the design of the CueS wristband (Table 6.1).

The first related to the design of the strap with a number of participants early on in the study reporting that it felt awkward to wear and that the Velcro strap would catch on clothing. An alternative latex watch strap with a standard buckle catch was tried with participants P9, P10 and P11 which appeared better although one participant (P9) still found it difficult to put on and reported that the latex stuck to their skin.

Sub-theme: Design of watch strap
P1 The watch catches on my sleeve though
P2 I needed assistance with putting the watch on
P4 Better that the watch does not have any information on the screen (in order) to focus on exercises rather than the watch
P6 the Velcro straps have clicked a pair of my trousers
P8 watch feels awkward
P9 The rubber on the watch is sticking
P9 Difficult to put on and off therefore I'm not taking it off.
Sub-theme: CueS wristband not waterproof
P2 It's not waterproof, you don't get all the data due to this
P2 missing important times like when using my hand in the shower
P3 Sometimes I forget to put it on and lose opportunities like when in shower. Would be better if you didn't need to take it off
Sub-theme: Strength of vibration
P2 watch should be louder as I don't hear if I'm asleep.
P6 I woke up with a shock on one occasion when the prompts went off while asleep
P8 If the vibration was stronger it would feel better
P8 I can feel the watch buzzing
P8 Sometimes I can't feel it or hear it when other people do

Table 6.1 Theme 1: Participants' comments on the design of the CueS wristband with prompt mechanism

Another common concern was that the CueS wristband was not water resistant and therefore could not be worn in the shower or while washing dishes. As the wristband was still in the development stage, the technology itself was enclosed in a plastic casing which was not fully water resistant. It was anticipated that this could be improved at a later date if the device was found to be useful clinically. Participants were disappointed that by removing the wristband to shower / do other activities involving water, these achievements were not being recognised or acknowledged through the data, “It’s not waterproof, you don’t get all the data due to this ” and “It’s good but missing important times like when using my hand in the shower” (P2).

Participants also expressed concern that by taking the watch off there was a risk of them forgetting to put it back on:

“Sometimes I forget to put it on and lose opportunities … would be better if you didn’t need to take it off” (P3)

These comments indicated that participants felt a sense of pride and ownership in the activity they had accumulated and an eagerness to receive acknowledgment of all their activity when the therapist viewed the data.

A few participants commented on the strength of the vibro-tactile prompt. A vibro-tactile prompt had been chosen over an auditory prompt to reflect previous literature (Fong et al., 2013, Lawrie et al., 2018) which suggested that prompts from wearable devices should be as unobtrusive as possible. Ensuring that the vibration prompt was strong enough to be felt but not so strong as to be intrusive (particularly when participants might be resting) was an important aspect of the design. One participant appeared to fluctuate in their ability to feel the prompt stating at one review “if the vibration was stronger it would feel better” (P8) but at another “I can feel the watch buzzing” (P8). This same participant was aware that there were times when they themselves were unaware of the prompt while others in the room could hear the

wristband vibrating “Sometimes I can’t feel it or hear it when other people do”. These comments may be a reflection of some of the additional cognitive and perceptual deficits that some stroke survivors experience. Another participant described being startled when woken up by the vibration prompt “I woke with a shock on one occasion when the prompts went off while asleep. It hasn’t bothered me on any previous occasions though” (P6).

Finding an optimum level of vibration strength may be difficult due to the complexity of stroke and different people’s needs. Attention to external stimuli can be affected by stroke and fluctuate depending upon factors such as fatigue or distraction from other stimuli. Increasing the strength of the vibration needs to be done with caution as it also increases the volume of the prompt which could impact on privacy. With the recent surge in popularity of commercial activity trackers (Lynch et al., 2018), wearing a prompting device such as the CueS wristband might be viewed less as a medical device and more as a normal lifestyle accessory.

6.3 Theme two: Experience of receiving the vibro-tactile prompt

A number of comments were made regarding participants’ experiences of receiving a prompt (Table 6.2). Many of these described the prompts as a useful way to increase awareness and activity of the impaired arm,

“It made me more aware to exercise my arm … it stimulates and reminds you to do things” (P1).

“…bringing attention to my stroke side. I’ve become more aware of the need to use both hands in activities” (P5).

“Prompts are really helpful to remind me to use my arm” (P3)

P1 It reminds me to check the time as it vibrates every hour. It made me more aware to exercise my arm
P1 It stimulates and reminds you to do things
P1 Its good that it motivates you
P3 good because it reminds you to do something when it beeps
P3 Prompts have been good to remind me to use my arm
P3 Prompts are really helpful to remember to move the arm
P5 it's reminding me to do the exercises
P5 I feel I've done much better than if I hadn't had the watch…
P5 its up to me when and how much to do but it reminds me if I've not done enough
P5 bringing attention to my stroke side. I've become more aware of the need to use both hands in activities
P6 It's encouraging but I felt a bit despondent on one occasion when I got prompted despite a very busy morning
P6 I find it buzzes even though I know I have done the work. I always know its there to remind me"
P6 I woke up with a shock on one occasion when the prompts went off while asleep. It hasn't bothered me on previous occasions though.
P8 If the vibration was stronger it would feel better
P8 I can feel the watch buzzing
P8 I get sick of prompts going off on days when I'm tired. It's made me think to use my hand more though
P8 Sometimes I can't feel it or hear it when other people do
P10 Its helping to remind me to use my arm…Its vibrating all the time every 15-20 minutes

Table 6.2 Theme 2: Participants' experience of receiving the vibro-tactile feedback

“It’s helping to remind me to use my arm” (P10).

Comments alluded to feeling motivated by the prompts to do more, “it’s good that it motivates you” (P1) and giving some control over how much arm exercise they did, “It’s up to me how much to do but it reminds me if I’ve not done enough” (P8).

There was a sense that at times participants felt ambivalent towards the prompt particularly when they were feeling tired, “I get sick of prompts going off on days when I’m tired. It’s made me think to use my hand more though” (P8). One participant commented, “I find it buzzes even though I know I have done the work. I always know it’s there to remind me” (P6) and on another occasion, “It’s encouraging but I felt a bit despondent on one occasion when I got a prompt despite a very busy morning” (P6).

This participant had mild impairment and the visual display of their activity data showed that they had, indeed, been prompted despite high amounts of arm activity. In designing the algorithms behind the prompting mechanisms, there had been some anticipation that a ceiling effect may come into play when participants reached a point where their impaired arm was being used towards the maximum of their ability. Although this participant was able to rationalise for herself that the prompt was incorrect, it raised the question of what impact negative feedback could have and how this could be minimised. It highlighted the need for an additional “neutral” threshold setting to reinforce rather than increase current activity.

6.4 Theme three: Experience of viewing the activity data

As the study therapist delivering the intervention, I was able to observe how well participants engaged with the visual display of their activity during the therapy review sessions. The data enabled participants to participate fully in conversations around their daily routines and use of the impaired arm. Despite this, only a couple of people

commented on the visual reports when asked about the intervention in general (Table 6.3).

P6 Knowing that I can see what my arm has been doing motivates me to do more
P6 It's fascinating – like seeing the feedback on screen and being able to relate it to what I've done.
P6 I can see how far my hand has come.
P6 within a day and a half I can see progress which is encouraging
P7 Difficult to see and understand the interface
P7 it's good that movements are being recorded

Table 6.3 Theme 3: Participants' experience of the visual data

It is unclear whether this was an indication that participants put more onus on the prompting mechanism and valued the prompts more than viewing the data or if it was simply a reflection that participants were responding to the aspects of the intervention that they had done independently. As there was only one study therapist delivering the intervention it was not possible to consider variations in emphasis which could have impacted on interpretation of the data and consequent response to the programme.

One person reported the visual display to be particularly useful, "Knowing that I can see what my arm has been doing motivates me to do more" (P6) and "It's fascinating – like seeing the feedback on screen and being able to relate it to what I've done. I can see how far my hand has come … within a day and a half I can see progress which is encouraging" (P6). Another participant (P7) however, found the visual display difficult to see and understand suggesting the need for therapy support to interpret the data.

6.5 Theme four: Participant experiences of the therapy programme

Comments about the therapy programme were generally positive with participants appreciating the opportunity to receive additional therapy for the arm.

P1 I don't like filling in the sheets
P1 I like to write down in my own diary what I've done
P2 I like how you record my practice (referring to alphabet wheel on daily log sheet)
P2 Activities were a good challenge.
P3 found weight bearing activities good – I can feel the muscles on top of my arm
P3 good to have extra input for my arm as NHS therapists mainly focusing on legs
P4 Managing exercises well
P4 It's good
P4 I think I'm managing well with everything
P4 programme was better than I thought it would be
P5 Repetitive tasks may have been too much
P5 Good to have something to do outside therapy time
P5 Helps focus on things.
P6 it stretches me but within a day and a half I can see progress which is encouraging
P7 Its quite hard. Need somebody there to keep me right
P7 I feel better for doing the exercises – make me feel like I want to do more
P8 Managing well and I feel like I'm improving
P8 Finding repetitive tasks useful now and would like more.P9 It's fine, slight cramp after doing the nut and bolt exercise

Table 6.4 Theme 4: Participants' experience of the therapy programme

“good to have extra input for my arm as NHS therapist is mainly focusing on legs” (P3). As the review in chapter 2 indicated, the idea of self-directed therapy exercises to practice outside of formal therapy was also well received, “good to have something to do outside therapy time” (P5).

and,

“the programme was better than I thought it would be” (P4)

People found the repetitive task exercises to be achievable which motivated them to continue with the programme, “I feel better for doing the exercises - makes me feel like I want to do more” (P7), “It stretches me but … I can see progress which is encouraging” (P6) and “Activities were a good challenge” (P2)

Overall, the content of the therapy programme was found to be beneficial to recovery “found weight bearing activities good – I can feel the muscles on top of my arm” (P3) and “…managing well and I feel like I’m improving” (P8) and “I think I’m managing well with everything” (P4).

Some participants, however, reported that they found the programme challenging with several comments indicating that at times it was difficult,

“Its quite hard, I need somebody there to keep me right” (P7)

and,

“Repetitive tasks may have been too much” (P5).

Despite these challenges participants indicated that what motivated them to carry on was being able to see that they were progressing “managing well and I feel like I’m improving” (P8), “I feel better for doing the exercises – makes me feel like I want to do more” (P7); “It stretches me but within a day and a half I can see progress which

is encouraging" (P6) and "finding repetitive tasks useful now and would like more"(P8).

There were mixed comments about completing the daily log sheets with one participant preferring to use her own diary to write things down and another commenting that they liked using the alphabet wheel to cross off the daily exercises, "I like how you record my practice" (P2).

6.6 Theme five: Intensity of the programme

Perhaps not surprisingly, the majority of comments from participants referred to the intensity of the programme. These included comments about both the therapy exercises and the prompting mechanism to further increase activity. As noted above there was a mixture of comments with participants inferring that despite finding the programme difficult at times, they were aware that this intensity was important and were rewarded by seeing improvements in their arm. With frequent reference to the prompts "reminding" them of their impaired arm, participants appeared to appreciate the benefit of the wristband in supporting them to carry out their exercises.

One participant acknowledged that other aspects of the stroke also impacted on how well they engaged in the rehabilitation programme, "Difficult sometimes to keep a focus on things due to other things going on and emotional impact of stroke" (P5)

P1 It made me more aware to exercise my arm

P2 It helps you to do extra movement

P2 it motivates you to use your arm

P2 Activities were a good challenge

P3 reminding me to do the exercises

P3 it reminds you to do something when it beeps

P3 Prompts have been good to remind me to use my arm

P3 good to have extra input for my arm as NHS therapists mainly focusing on legs

P3 Prompts are really helpful to remember to move the arm

P5 Good to have something to do outside therapy time

P5 I've become more aware of the need to use both hands in activities

P5 Good but think I naturally push myself too hard with arm activity

P5 it's up to me when and how much to do but it reminds me if I've not done enough

P5 Difficult sometimes to keep a focus on things due to other things going on and the emotional impact of stroke

P5 Repetitive tasks may have been too much

P6 I find it buzzes even though I know I have done the work

P6 on one occasion when I got prompted despite a very busy morning

P6 It's interesting because it stretches me but within a day and a half I can see progress

P6 motivates me to do more

P6 It makes you think and work hard

P7 It's quite hard. Need somebody there to keep me right

P7 I feel better for doing the exercises - makes me feel like I want to do more
P8 Its benefitted me as made me do more
P8 Its made me remember to use my hand more
P8 I get sick of prompts going off on days when I'm tired. It's made me think to use my hand more though so achieving more
P8 Finding repetitive tasks useful now and would like more.
P9 It's fine, slight cramp after doing the nut and bolt exercise
P10 Its helping to remind me to use my arm
P10 Its vibrating all the time every 15-20 minutes

Table 6.5 Theme 5: Intensity of the programme

6.7 Discussion

Participants reported that the intervention was acceptable and had reminded and motivated them to use their impaired arm more. Whilst some found the intensity of the additional therapy practice to be challenging, there was an acknowledgement that this was necessary. Comments that they could see the improvements they were making seemed to encourage them to continue with the programme.

Some improvements suggested by participants were to improve the style of the wristband to be less bulky with a different style strap and for it be waterproof.

Changes to the prompting mechanism were identified to include an option to set the prompt threshold at a constant level for when participants reach a peak in their recovery. It was also suggested that the strength of the prompt itself may need to be a bit stronger to ensure that all participants are aware when a prompt is triggered.

The therapy programme was generally well received although there were a few suggestions that the RFTP component might be too much. It was unclear if this was referring to the exercises themselves or trying to fit in the additional prescribed exercises and the list of prompted activities on top of NHS usual care. As described later, the structure of the therapy programme was therefore reviewed prior to the NHS therapists delivering it in the pilot RCT.

Most participants liked the visual representation of data displayed around a clock face as it was a simple and clear representation of what they had done across the day. The option to compare recent activity data with the previous week or the beginning of the programme was gratifying for participants as they could clearly see any progress they had made. Having an objective visualisation of activity also provided affirmation for those participants who reported receiving prompts despite having used their impaired arm. Some improvements to the display were identified to ensure that participants with impaired vision could see the data clearly.

6.8 Summary

This Chapter has reported on the acceptability of the WAVES intervention from the participants' perspectives. Areas for further development of the intervention were identified which will be discussed in more detail in the next chapter.

Chapter 7. Refining the WAVES intervention

As described in Chapter 3, a number of components to the WAVES intervention added to its complexity. The proof of concept study tested whether each component into of the WAVES intervention could be integrated into arm rehabilitation and whether there was a response to prompts. Each component was reviewed for their initial acceptability and practicality before a pilot feasibility trial (Collins et al., 2005).

This chapter will describe the revisions made to each component of the WAVES intervention resulting from the proof of concept study. This is not a formal research evaluation of the technology, but describes how information and views collected shaped the intervention for the next stage.

7.1 Aim

To describe refinements made to the WAVES intervention in preparation for a pilot randomised controlled trial based upon multiple sources of information including:

- Direct contact between the candidate and patients during the intervention delivery
- Review of the proof of concept data by the study investigators
- Discussion with the technology development team

7.2 Refining the complexity of the intervention

7.2.1 Removal of the repetitive task practice component

The results of the first study indicated that the intervention may be useful in supporting enhanced use of the impaired arm. However, feedback from some participants indicated that the additional RFTP exercises were challenging without a therapist being present to support them. The investigator team also had concerns about the training demands of the intervention on NHS therapists who would need to familiarise themselves with the technology alongside delivering a new therapy

programme. It was expected that the NHS therapists delivering the WAVES intervention would also be providing usual care which, if adhering to the national guidelines, should already include some functional repetitive task practice (Intercollegiate Stroke Working Party, 2016). The addition of a formal research RFTP component of the intervention could therefore be an unnecessary complication of the intervention and interfere with the main objective of motivating general increased arm use. For this reason, after discussion between the study investigators, the formal RFTP component was replaced with training of NHS therapists in how to deliver repetitive functional task practise leaving the new intervention to focus on just the WAVES technology and integrating use of the impaired arm in daily activities (Figure 7.1).

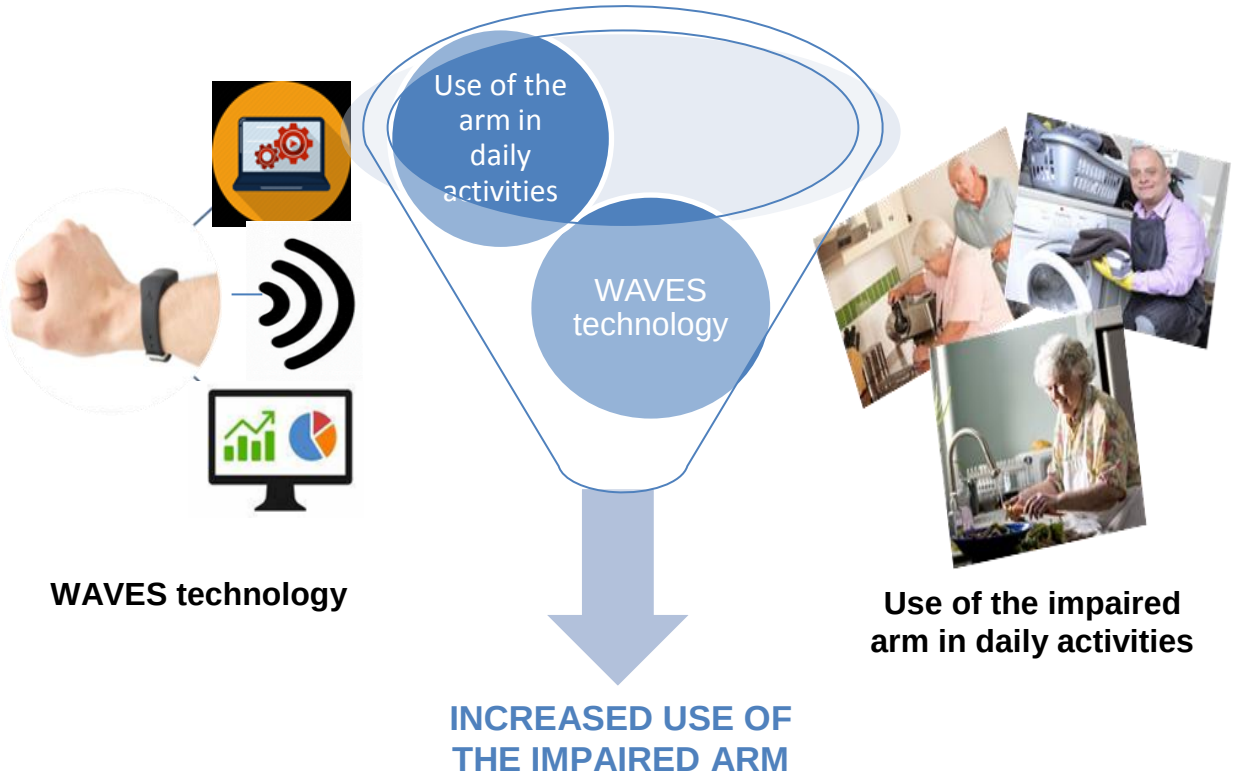


Figure 7.1 Revised WAVES intervention

A revised logics model is detail below in Figure 7.2 highlighting the causal effects of the revised components.

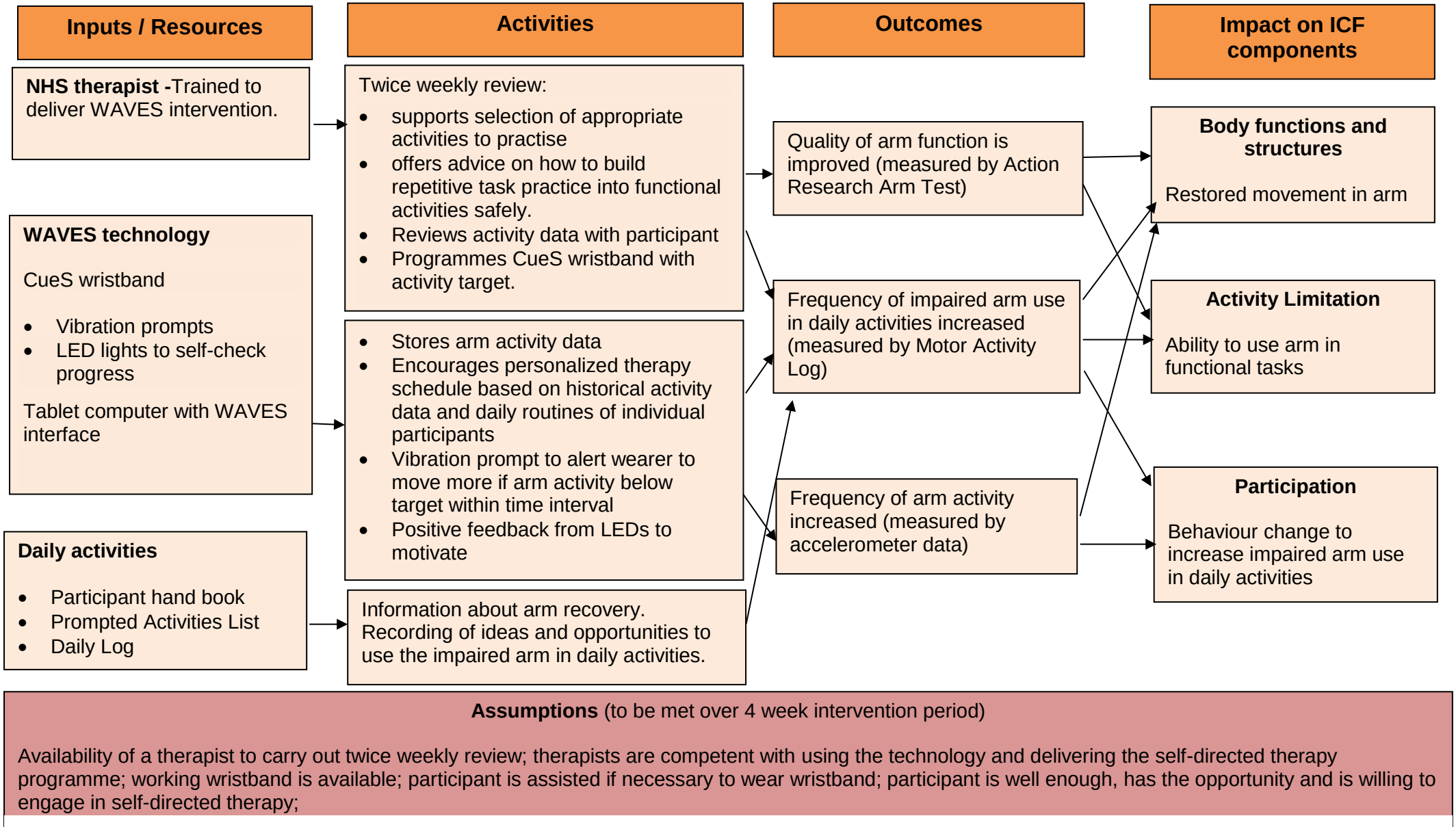


Figure 7.2 Revised Logics model

7.3 Modifications to the WAVES technology

7.3.1 Modifications to the design of the CueS wristband

To make it less conspicuous, the wristband was re-designed to be smaller and more in keeping with the design of commercial activity trackers. In anticipation of it becoming waterproof in the future the fabric strap was replaced with a silicone one and the Velcro in favour of a standard buckle fastening (Figure 7.3). As it was still a prototype, the device within the wristband was still not fully watertight so participants continued to be advised to avoid getting it wet.

Figure 7.3 New CueS wristband

7.3.2 Modifications to the vibro-tactile prompt

Whilst delivering the intervention, it had been apparent that some participants had used the timed nature of the prompting mechanism to anticipate a prompt being due and would do a short burst of increased arm activity to avoid receiving a prompt. As the intention was to integrate use of the arm into daily routines, there was concern amongst the investigators that this approach was not helpful. It was also difficult for participants to know if they had moved enough to meet their threshold target until the hour was up and they either received or did not receive a prompt. Consequently, the feedback from the prompt could be perceived negatively as it was highlighting a

‘missed’ target rather than rewarding and celebrating the successes of what they had achieved.

Following discussions with members of the WAVES team from the computer science department, changes were made to improve wearer understanding of their progress towards the hourly target and reduce anticipation. The first change was to alter the timing of when a prompt was delivered so that activity needed to be maintained across the whole of the time interval between prompts. Based on a new algorithm, arm activity was monitored every minute rather than at hourly intervals. This made it more difficult for participants to anticipate a prompt based on time and was intended to encourage arm use across the whole of the time interval between prompts.

The new algorithm calculated when to deliver a vibration prompt by summarising the amount of movement at the end of every minute and adding it to the current history of movement. An average would be taken over the recent history (a sliding 120 minute window) to calculate the amount of incoming activity on a minute by minute basis. In this way a ‘moving average’ was created on a sliding window scale. A prompt would only be delivered if the average incoming activity was below the historical activity threshold level for that minute *and* the minimum prompt interval had elapsed since the last prompt. As the wristband was constantly reviewing the data, the average incoming activity could drop back below the threshold at any point if the wearer didn’t keep topping up their activity levels.

7.3.3 Addition of LED lights to wristband

To support and encourage participants to monitor their own progress in between data download at therapy reviews, coloured light emitting diodes (LED), similar to those on commercial activity trackers, were added to the wristband. When activated by tapping the watch face, the lights would indicate know how much of their activity quota they had achieved (Figure 7.4).

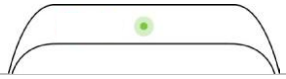
	No target set for this time of day.
	Working towards 1/3 of the target.
	Achieved at least 1/3 of the target and working towards 2/3.
	Achieved at least 2/3 of the target and working towards the full amount.
	Achieved the target.
	Exceeded the target by 5% or more.

Figure 7.4 LED lights showing activity progress

7.3.4 Modifications to prompt settings

The prompt threshold, was based on a percentage increase in the median amount of activity for each minute, as determined by the three previous days of data. To allow for patients who had already progressed to maximal recovery, an additional setting of 0% or 'no change' was added to the prompt settings. Based on the results of the previous study, the percentage by which to increase activity was reduced from 10%, 25% and 50% to 0%, 5%, 10% and 20% above the current median baseline.

The time intervals for receiving prompts were kept the same with an additional half-hourly interval for participants who might wish to receive more frequent prompts.

7.3.5 Modifications to the computer interface

A complete redesign of the computer interface was required to facilitate clinician interpretation of the data and flexible programming of the wristbands. Data continued to be displayed around a clock face, but when programming the device, a separate clock face showed the proposed threshold against the new activity baseline. The threshold could be manually adjusted if the participant indicated a need to be more or less active at set times of the day, for example if they routinely had a nap in the afternoon.

Movement data was still displayed around a 12 hour clock face (Figure 7.5) with movement activity illustrated by the blue shaded area. The threshold target was represented by a solid green line and the average incoming activity by a magenta dashed line. When the incoming data crossed or fell within the green line a vibration prompt was delivered as indicated by an orange dot providing the minimum time interval had elapsed since the previous prompts. Previous days were illustrated on smaller clock faces at the top of the screen and could be scrolled through and selected for use in calculating the new baseline.

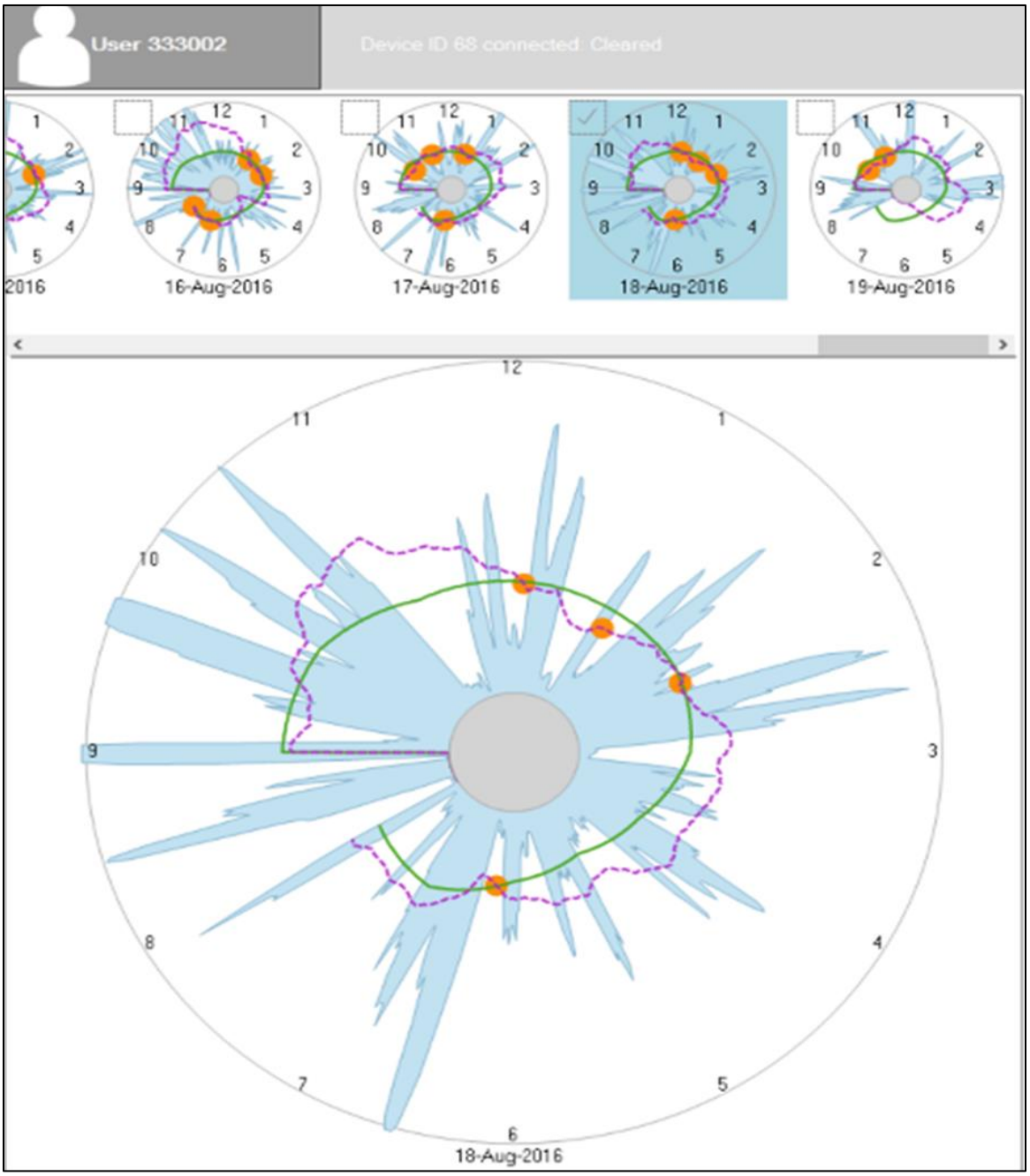


Figure 7.5 The WAVES computer interface display of movement data

7.4 Use of the impaired arm in ADLs

Although the RFTP content was reduced, participants were still encouraged to identify activities where they were able to use the impaired arm and to practice these as often as possible. These activities were logged on a list and when practised were recorded on a daily log sheet. Recommended therapy exercises could be included in the Daily Activities List but, where participants had sufficient hand function, they were encouraged to identify opportunities to use the impaired arm in functional daily activities. Depending on the level of impairment, this could range from positioning the impaired arm while the more functional arm carried out the task, to the impaired arm being fully involved in tasks. Additional information in a Therapy Handbook provided advice on how to incorporate repetitive task practise into these activities e.g. grasp and release exercise when sorting laundry.

In this way the Daily Activities List served to create a personalised menu of therapeutic activities for each participant to select from in order to increase impaired arm movements within normal daily routines. Completed tasks were marked off on a daily log sheet.

7.5 Supporting materials

7.5.1 Participant handbooks

A user handbook was developed with instructions for care and use of the CueS wristband and how to respond when a prompt was delivered. The handbook included the Daily Activities List and daily log sheets to record which activities had been practised.

7.5.2 Training materials

Training materials were developed to support therapists in delivering the intervention. These consisted of a therapy handbook with full study protocol and step-by-step instructions on how to conduct the therapy programme (Appendix V). A separate CueS manual was developed for therapists outlining how to care for the CueS wristband, charge the battery, programme the wristband, download data and interpret

the visual display of data (Appendix W). Laminated flowcharts from the handbook were provided as a quick guide to support therapists in programming and downloading the data from the wristbands.

The original decision tree for setting Prompt thresholds and frequencies was included in the therapy handbook to guide the study therapist and participants with adjusting the new prompt settings.

7.5.3 Modifications to the Procedures used

The WAVES intervention continued to be delivered as a four week programme. Details of the procedure pertaining to each separate component of the intervention are described below. A therapy schedule in the WAVES therapy manual, described each procedure for delivering the therapy review sessions (Appendix V, page 12)

As before, participants were instructed to wear a CueS wristband on the impaired arm for the duration of the four week period between the hours of 8 o'clock in the morning until 8 o'clock at night.

Rather than waiting a week before programming the wristbands, prompts were set at the first therapy review session around day 3 or 4. This was in part due to the expectation that daily routines were unlikely to vary considerably across a seven day week for stroke survivors and also to maximise the number of opportunities to adjust the threshold settings across the duration of the study. While data were downloading and batteries recharging, daily log sheets were reviewed and arm movements re-assessed by a therapist. Additional activities were identified and added to the Daily Activities List for future practice.

Participants viewed their data with the therapist to agree prompt settings to programme the wristband with before continuing with the programme. They were advised to choose an activity from the Daily Activities List if they received a prompt

and to tap the wristband if they wanted to monitor their progress towards reaching their activity threshold

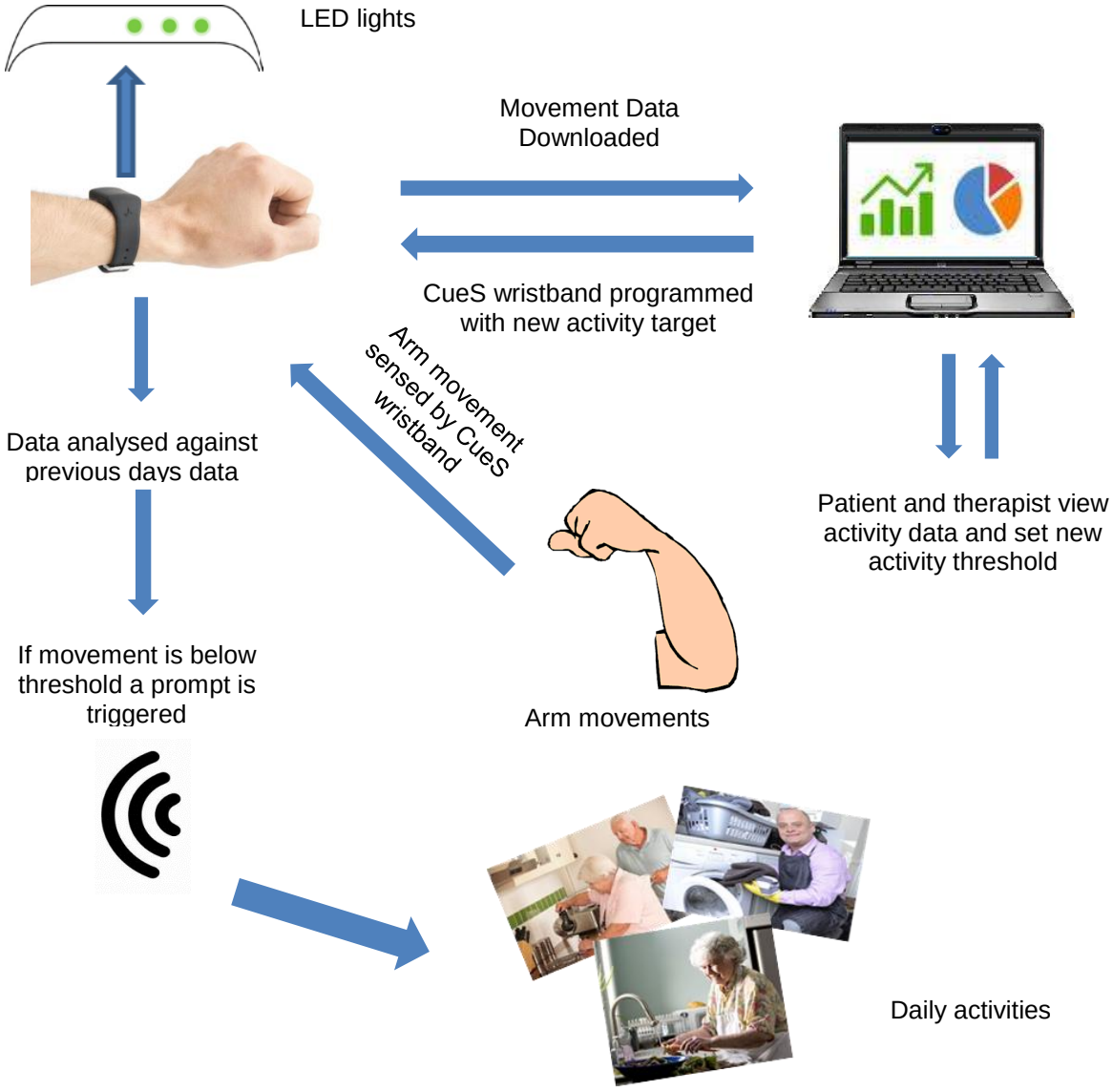


Figure 7.6 Interaction of component parts of the WAVES intervention after modifications.

7.6 Conclusion

This chapter has discussed the modifications made to the WAVES intervention in anticipation of the pilot RCT. In making these modifications, consideration was given to the findings of the first study as well as delivery of the intervention in an inpatient and community setting by NHS therapists who may lack a research background.

This chapter concludes Section 2 which has described the development process of the WAVES intervention. Section 3 will further evaluate the feasibility of the modified intervention when used in a pilot multi-site randomised controlled trial.

Section 3: Piloting the feasibility of the intervention to inform further evaluation in a multi-site randomised controlled trial.

Chapter 8. Wristband Accelerometers to motiVate Exercise after Stroke (WAVES) Pilot RCT: Aims and objectives

Prior to fully evaluating a complex intervention, the Medical Research Council recommend examination of the procedures to be used to ensure that they are acceptable, demonstration that recruitment is feasible and collection of information to calculate a sample size for the future trial (Craig et al., 2008).

Until recently the terms feasibility and pilot have often been used synonymously to describe a preparatory study undertaken to inform whether a future full-scale study would be viable (Thabane et al., 2010).While the MRC definition does not really help to clearly distinguish between the two (Craig et al., 2008), consensus has been reached to suggest that 'feasibility' is an umbrella term to describe all studies that aim to ask if a future trial can be done (Eldridge et al., 2016). Feasibility studies have specific and clearly defined objectives that need to be achieved in order to progress to the next stage. Pilot studies have been described as a subset of feasibility studies which still include the same feasibility objectives but represent a smaller scale version of the future definitive study thereby allowing the opportunity to assess the feasibility of specific parts of the process of conducting the trial (Eldridge et al., 2016, National Institute for Health Research, 2019, Thabane et al., 2010).

The proof of concept study described in Chapter 4 had already provided some evidence that patients are able and willing to respond to activity related feedback with increased movement of the impaired arm. In preparation for further testing of the intervention, adaptations to improve acceptability and potentially increase efficacy were made. This next study was designed as a miniature version of a future RCT and included objectives around trial processes such as recruitment, randomisation, blinding, follow-up and safety reporting across a number of different study sites. For these reasons, the study is described as a 'pilot' randomised controlled trial. It is entitled: Wristband Accelerometers to motiVate Exercise after Stroke (WAVES).

8.1 Trial aims

- To assess the feasibility of a multi-centre, observer blind, randomised controlled trial of the WAVES intervention to prompt independent practice of functional activity of the arm during rehabilitation after stroke.
- To report the objective measurement of changes in affected arm activity using clinical outcomes and accelerometer data during and after the WAVES programme.
- To explore individual response in affected arm activity and upper limb clinical outcomes during the intervention and control programmes

8.2 Study objectives

8.2.1 Trial feasibility objectives

1) To determine whether it is possible to enrol one patient per month from each study centre.

2) To report the attrition of participants in control and intervention groups.

3) To report adherence to the WAVES intervention.

4) To report the frequency of usual rehabilitation care received by control and intervention groups within the study intervention period.

5) To report the success of outcome assessor blinding to participant group allocation.

6) To report serious adverse events in control and intervention groups during the study.

7) To report completeness and summary statistics of data to inform the design of a future multi-centre RCT including a sample size calculation.

8.2.2 Objective measurement of changes in affected arm activity

8) To report the change in activity and function of the affected arm during and after the self-directed arm rehabilitation program (with and without prompts);

9) To report the short term effect of a vibration prompt on arm activity.

8.2.3 Exploration of individual response to the intervention

10) To identify individual participants who had a general increase in arm activity

11) To identify individual participants who increased use of the impaired arm when carrying out daily activities.

12) To identify which participants had an increase in arm function.

13) To describe possible reasons why some participants did not show an increased use of the impaired arm in daily activities.

Chapter 9. Wristband Accelerometers to motiVate Exercise after Stroke (WAVES) Pilot RCT: Methods

9.1 Aim

The following chapter describes the methods used to carry out a multi-centred pilot randomised controlled trial of the WAVES intervention to promote greater arm use after stroke.

9.2 Method

9.2.1 Study design

This was a pragmatic parallel group randomised controlled trial with blinded outcome assessment. Participants were randomised to:

Group 1 (Control group): WAVES intervention with non-prompting CueS wristband in addition to usual care

Group 2 (Intervention group): WAVES intervention with prompting CueS wristband in addition to usual care.

A summary of the overall study design is presented in Figure 9.1.

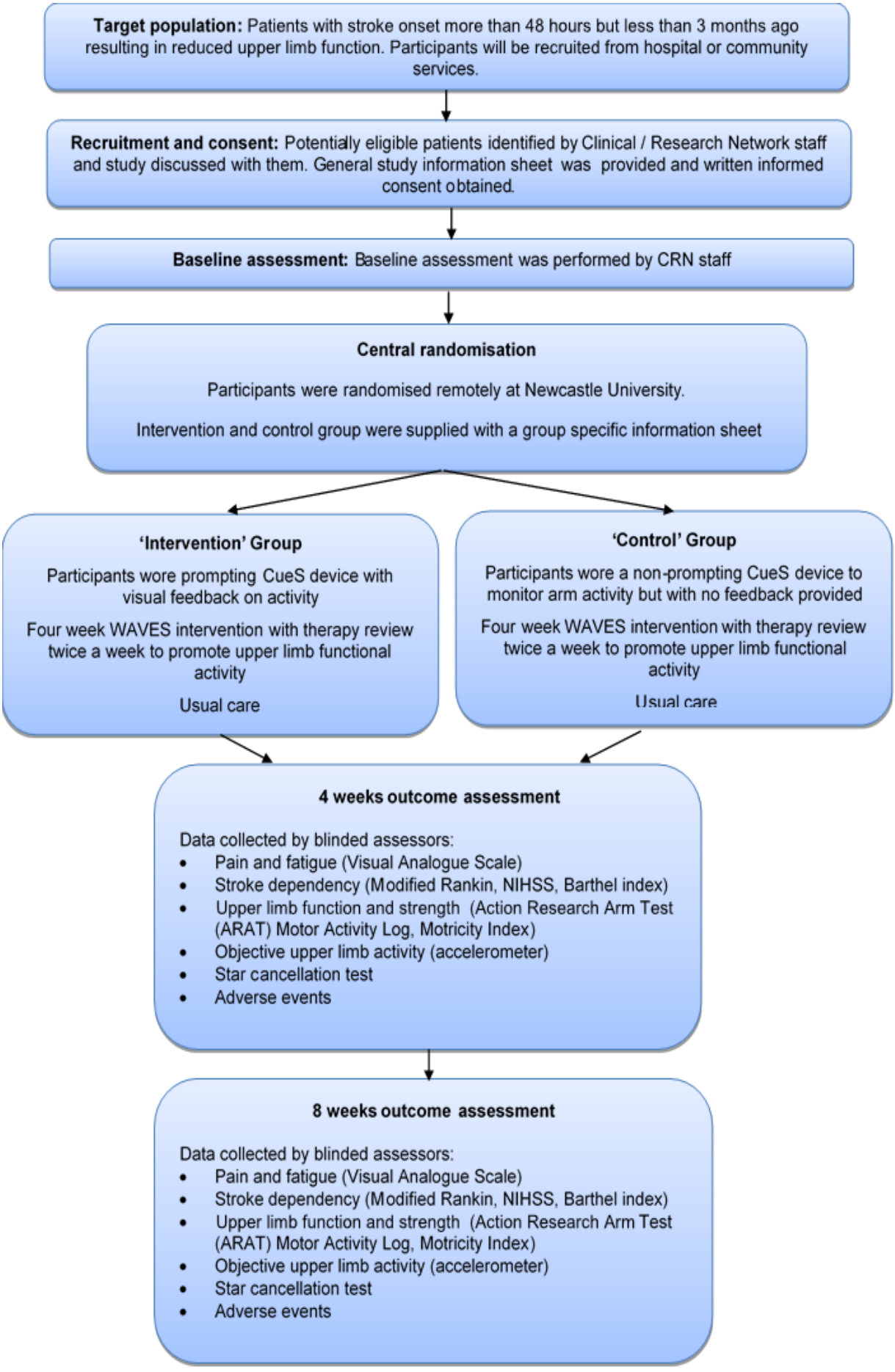


Figure 9.1 Study summary

9.2.2 Study setting

Patients between 24 hours and three months post stroke were identified by occupational therapists, physiotherapists and local research support staff from four stroke services in North East England (Northumbria Healthcare NHS Foundation Trust, Gateshead Health NHS Foundation Trust, Newcastle upon Tyne NHS Foundation Trust and North Tees and Hartlepool NHS Foundation Trust). All study sites provided both in-patient and community therapy services and therefore the intervention was designed to be delivered by occupational therapists and physiotherapists on the stroke unit, in the community or both, depending on when participants were recruited and the stage they were at in their rehabilitation.

9.2.3 Study population

9.2.3.1 Inclusion criteria

Adults with any stroke subtype who fulfilled the following criteria were eligible:

- Age ≥ 18 years.
- Over 48 hours but less than three months post stroke onset.
- New reduced upper limb function on one side.
- Able to provide informed consent to participate in the study.
- Living within the community services catchment area of a participating study centre.
- Receiving at least twice weekly NHS therapy review which is planned to continue for four weeks from the start of the intervention period (in order to enable delivery of the therapy programme).

9.2.3.2 Exclusion criteria

Patients were excluded if in the opinion of the treating therapist they:

- had severely reduced upper limb function resulting in the inability to lift the affected hand off the lap when sitting.

- were likely to be unable to follow the programme due to significant cognitive impairment or communication difficulties.

- had any other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain that could inhibit participation in the programme.

- had a diagnosis likely to interfere with rehabilitation e.g. registered blind, severe visual problems as a result of stroke, palliative treatment approach being provided.

- were unable to sense either the Cues wristband vibratory prompts or visual display.

9.2.4 Sample size

A formal sample size calculation was not undertaken as this was a pilot study. Based upon recruitment rates in previous trials (Rodgers et al., 2003, Church et al., 2006) it was predicted that 60 patients could be enrolled at a rate of one patient per study centre, per month over a period of 15 months.

9.2.5 Case ascertainment, recruitment and consent

Potentially eligible participants were identified and provided with a general patient information sheet which described the therapy programme and wristband activity monitoring function but did not describe the differences in CueS wristband feedback between the intervention and control groups (Appendix X). Written consent was obtained by research support staff. To estimate a crude identification rate, clinical registry data from one site (A) was used to calculate the number of stroke admissions with an upper limb impairment who did not have significant dysphasia, and so might have been eligible for enrolment.

Recruitment activity at each site was monitored prospectively against the target. Only simple strategies for achieving adequate participant enrolment were put in place (e.g. training sessions for new staff).

9.2.6 Baseline assessment

A baseline assessment was performed by the research support staff following patient consent to study participation (Appendix Y). The following data was collected: date of stroke; first ever or recurrent stroke; stroke type (e.g. infarct, haemorrhage); hand dominance; National Institutes of Health Stroke Scale (NIHSS) (Brott et al., 1989); pre and post-stroke Barthel score (Wade and Collin, 1988); upper limb pain and overall fatigue (measured by a numerical visual analogue scale, 0-10); upper limb function (measured by the Action Research Arm Test) (Lyle, 1981a); real world upper limb activity (measured by the Motor Activity Log (Uswatte et al., 2006b)); upper limb strength (measured by the Motricity Index) (Demeurisse et al., 1980) and unilateral spatial neglect (measured by the star cancellation test (Halligan et al., 1990)).

9.2.7 Randomisation

Randomisation was conducted after completion of the baseline assessment. A member of the NHS therapy team contacted the co-ordinating centre at Newcastle University Stroke Research group via a central telephone service to request randomisation. Participants were stratified according to study centre and randomised by an independent online database to intervention (Group 2) and control group (Group 1) on a 1:1 ratio.

9.2.8 Study intervention (WAVES intervention)

Once randomised, participants were provided with a CueS wristband to wear every day over the four week programme and a therapy handbook. NHS occupational therapists and physiotherapists who were providing usual NHS therapy, guided participants to choose appropriate activities that they could safely practice using the impaired arm. Additional advice was provided on how to build in repetitive practice of these tasks or part tasks. Participants recorded the activities on the ‘Daily Activities List’ in their Therapy Handbook and kept a record of which ones they had practised on the daily log sheet. Participant Handbooks were returned to local research support staff at the end of the intervention period and the data entered onto an online database.

For the first three days of the programme, the CueS wristband recorded impaired arm movement but no prompts were delivered. From day three, twice weekly therapy

review sessions were conducted by NHS therapists to download the activity data and recharge the battery. Participants in the intervention group viewed the visual display of their activity data with their NHS therapist and discussed their progress. If activity levels were consistently low at certain times of the day, therapists suggested ways to incorporate additional arm activity e.g. using the impaired arm to turn pages of a magazine, using television controls, eat finger foods. Conversely, if excessive activity in the morning was resulting in fatigue, advice was offered around pacing activities across the whole day.

The previous three days' data were used as a baseline to guide and inform each new prompt threshold. As previously described, once programmed, the wristband monitored activity and alerted participants by a gentle vibration if activity levels fell below the agreed target within the minimal prompt frequency time period. If prompted by the wristband, the wearer was encouraged to increase activity by selecting an activity from their daily activities list or alternatively just trying to engage their arm more in routine activities at the time. In addition, participants monitored their own progress throughout the day by tapping the watch to trigger LED lights indicating how close they were to meeting their activity target for that hour.

9.2.9 Study control intervention

The control group received the same arm therapy programme as the intervention group however the wristband they were provided with was a non-prompting CueS wristband. These wristbands were the same as those worn by the intervention participants but all alert functions were deactivated so that although activity data were still collected no feedback via prompts, visual LED display of pictorial display of data were available. As such, control participants had no additional feedback to support them in remembering to use their arm throughout the day. Therapists visited patients twice weekly to recharge the wristbands and review the choice of practice activities in the same manner as the intervention group in order to promote attention matching.

9.2.10 Training of NHS therapists and clinical research staff

All NHS staff involved in the study were required to undergo training provided by the study therapist. For NHS therapists, this consisted of a two hour training programme

covering how to programme the wristbands, identifying appropriate activities to practice, advising participants on how to build repetitive task practice activities from whole or part tasks and how to conduct the study according to Good Clinical Practice guidelines. A therapy handbook was provided with full study protocol and step-by-step instructions on how to conduct the therapy programme including a CueS programming decision tree to ensure consistent delivery of the intervention as described in the study protocol. Comprehensive flow charts for each stage of the study were also made available (Appendix Z). Additional training was offered throughout the recruitment period as an extra support and to allow new members of staff to be involved.

Clinical research staff, attended a one-hour training session covering how to conduct the baseline and outcome assessments and how to programme the standard accelerometers to record arm activity at four and eight weeks. Action Research Arm Test kits were provided to each study site with an instruction booklet for each assessment.

Outcomes were assessed at four weeks (+/- 3 days) and eight weeks (+/- 5 days) following day one of the therapy programme. Assessments were undertaken by research support staff who were blinded to participant group allocation. Clinical outcomes included: stroke dependency (measured by the Modified Rankin Scale[15], Barthel Activities of Daily Living Index (Wade and Collin, 1988)); pain and fatigue (measured by a numerical visual analogue scale, 0-10); upper limb function (measured by the Action Research Arm Test (Lyle, 1981b)); real world upper limb activity (measured by the Motor Activity Log (Uswatte et al., 2006b)); arm strength (measured by the Motricity Index (Demeurisse et al., 1980)); and unilateral spatial neglect (measured by the Star Cancellation Test (Halligan et al., 1990)).

A standard accelerometer was given to each participant at the week 4 and week 8 outcome assessment and used to capture impaired arm activity across three days. The participants returned these by post in a pre-paid envelope.

9.2.11 Preparing the accelerometer data for analysis

Raw accelerometer data for each of the three axis were converted into ActiGraph counts in one second epochs and combined into a single vector magnitude using the formula ($\sqrt{(x^2 + y^2} + z^2$) for one minute epochs (Brond et al., 2017). Only data collected between the hours of 8am to 8pm were used in the analysis.

To ensure that data represented time when the participants were wearing the wristbands, non-wear time intervals were removed (defined as an interval where accelerometer counts per minute were all at zero for more than 60 consecutive minutes)(Masse et al., 2005). Wear time data were then split into active and inactive minutes, with inactive minutes defined by a count of zero (Bailey and Lang, 2013, Tryon and Williams, 1996). For each participant, the proportion of time that the impaired arm was active was calculated. The amount of activity at each time point (baseline, week 4 and week 8) was quantified as the average number of counts per minute across each three day period.

To report on the immediate effect of a prompt (objective 9), the number of CPM in the hour after a prompt were compared with the number in the hour before a prompt.

9.2.12 Outcome definitions

To report any changes in impaired arm activity and function during and after the programme (Objective 8), three consecutive days of wristband activity recordings were compared between the groups at baseline (first 3 days of wear), the end of the intervention (week 4) and after a futher 4 weeks without a wristband (week 8).

To report on individual participants' response to the study programme (objectives 10 to 13), participants were defined as responders or non-responders based on the following assumptions:

Increase in impaired arm activity: Arm activity was measured in CPM. In the absence of a minimal clinically important difference (MCID) score for the CPM,

participants who achieved at least a 10% increase above their baseline CPM were considered to be a responder.

Increase in use of the impaired arm in ADLs: Use of the impaired arm was measured using the Motor Activity Log (amount of use) scale. Participants were considered to have responded with an increase in using their impaired arm in daily activities if they had increased their Motor Activity Log score by the MCID of 1 point (Lang et al., 2008).

Increase in impaired arm function: Impaired arm function was measured using the ARAT. Participants were considered to have responded with an increase in arm function based on the MCID increase on ARAT of over 12 points (Lang et al., 2008). As the maximum score on the ARAT is 57, participants would need to have a baseline score of <45 to be able to achieve a positive response.

Non-responders: were participants who did not respond with a MCID in the amount of use of the impaired arm in ADLs. Potential reasons why these participants did not improve their arm use is explored further using data collected about pain; fatigue; and serious adverse events.

9.2.13 Blinding of outcome assessors

The intention was that both patients and outcome assessors would be blinded to treatment group. Group allocation concealment was managed using an independent online database and randomisation initiated only by the treating therapist to ensure outcome assessors collecting study data remained blinded to group allocation. Therapists delivering the intervention were instructed not to inform patients if they were in the 'intervention' or the 'control' group but to refer to the groups as Group 1 (control) and Group 2 (intervention). Two different versions of the participant handbook were developed to accommodate the different randomisation group. Participants randomised to the intervention group received a Group 2 Participant Handbook (Appendix AA) and CueS wristband with the prompting and visual feedback. Those in the control group were provided with a Group 1 Participant Handbook (Appendix AB) and a non-prompting CueS wristband which still recorded activity but did not provide feedback.

Outcome assessments were performed by local research support staff who were blinded to treatment allocation. After each assessment, the researcher was asked to record whether they had unintentionally become aware of treatment allocation. To prevent participants from inadvertently disclosing their group allocation to outcome assessors, they were requested not to discuss their experiences of wearing the wristband during these assessments.

9.2.14 Study withdrawal

Participants were free to stop the therapy programme or withdraw altogether from the study at any time without giving a reason. If a patient decided to stop the therapy programme, the data already collected was included in the analysis unless consent was specifically withdrawn and their permission was sought to continue with the outcome assessments.

9.2.15 Recording and reporting of adverse events

The safety of the intervention was assessed by monitoring and examining any adverse events that occurred during the study. An adverse event was “any untoward medical occurrence”. No associated adverse events had been anticipated from the WAVES technology itself. Increases in pain and fatigue had been identified as potential adverse events that could occur from increased exertion on specific joints. We therefore specifically enquired about the presence of pain in the affected upper limb and overall fatigue.

All adverse events were recorded for the duration of each participant’s involvement in the study but only Serious Adverse Events were specifically reported. A Serious Adverse Event was defined as any event that “resulted in death; was life-threatening; resulted in in-patient hospitalisation or prolonging of existing hospitalisation; resulted in persistent significant disability or incapacity” (NIHR, 2013) or was otherwise considered medically significant by the investigator. Recording took place during the outcome assessments by inclusion of the following question: “Are there any new

medical problems since the last study assessment?" Events considered to be SAEs were documented onto a separate study SAE form (Appendix AC) and reported to the study centre.

9.2.16 Data management

Data were recorded locally on study specific documents and transferred to the coordinating centre via an industry-standard secure online database, using a pseudo-anonymised study identification code to link individual participants with their local health records. All paper copies of study documents were retained at local sites where they are being stored securely for five years in line with sponsor policy. The online database was encrypted and only accessible via individual passwords.

9.2.17 Data monitoring

Interim safety and efficacy data were not formally reviewed against pre-determined criteria for stopping early as this study was a pilot study. Safety data were prospectively reviewed at monthly project management meetings with the chief investigator. The well-being of individual participants were also closely monitored by clinicians who were still treating patients within their local clinical service.

9.2.18 Data analysis

Descriptive statistics were calculated using SPSS software (IBM Corp., Released 2013, IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY). Nominal and ordinal data are reported as a number and percentage. Continuous variables are reported as mean and standard deviation (SD) except where the distribution was skewed, in which case they are reported as median and interquartile range [IQR].

Shapiro-wilk test was used to determine if the accelerometer data was normally distributed. As data was not normally distributed, non-parametric testing was used to compare the groups.

To determine if there had been a benefit of receiving regular prompts, Mann-Whitney U test was used in between-group comparisons of median CPM for each group at baseline, 4 weeks and 8 weeks. Statistical significance was again set at p value < 0.05.

To report the immediate effect of receiving a prompt on arm activity, the difference between the total number of counts per minute in the hour preceding a prompt and the total number of counts per minute in the hour following a prompt was calculated and compared using the Wilcoxon signed rank test (set at p value <0.05).

9.3 Conclusion

This chapter has described the methodology applied to conduct the pilot randomised controlled trial of the WAVES intervention. The results of the trial are presented and discussed across the next three chapters with Chapter 10 reporting on the results of the feasibility objectives, Chapter 11 reports the changes in affected arm activity and the effect of the vibration prompts and Chapter 12 describes the individual responses to the intervention. A brief summary is given of each set of results at the end of the relevant chapters and a more in-depth discussion of the findings are presented in Chapter 13.

Chapter 10. Wristband Accelerometers to motivate Exercise after Stroke (WAVES) Pilot RCT: Feasibility results

This chapter describes the results of the feasibility objectives (1 to 7) from the WAVES pilot RCT as outlined in Chapter 8.

10.1 Aim

To report on the feasibility of a multi-centre observer blind, randomised controlled trial of the WAVES intervention to prompt independent practice of functional arm activity of the arm during rehabilitation after stroke. Results will be described in line with study objectives (see Chapter 8).

10.2 Objective 1: To determine whether it is possible to enrol one patient per month from each study centre

Thirty-three participants were recruited and randomised to control (Group 1, n=19) or intervention (Group 2, n= 14). This fell short of the anticipated 60 participants but there were periods of time when sites achieved the target of recruiting one participant per site per month (Table 10.1). The average recruitment rate per site was 0.6 per month. Sites B and C reported difficulties with recruitment which were largely around the limited availability of local research support staff to recruit participants and NHS therapists to review participants every three-four days.

DATE	Site A		Site B		Site C		Site D			Total	
	Predicted	Actual	Predicted	Actual	Predicted	Actual	Predicted	Actual	Predicted	Actual	% Predicted
May-16	1	1							1	1	100
Jun-16	1	0			1	0			2	0	0
Jul-16	1	0	1	2	1	1			3	3	100
Aug-16	1	2	1	0	1	1			3	3	100
Sep-16	1	1	1	0	1	0	1	1	4	2	50
Oct-16	1	1	1	1	1	0	1	1	4	3	75
Nov-16	1	0	1	0	1	1	1	0	4	1	25
Dec-16	1	1	1	1	1	0	1	0	4	2	50
Jan-17	1	2	1	1	1	1	1	0	4	4	100
Feb-17	1	0	1	1	1	1	1	2	4	4	100
Mar-17	1	1	1	0	1	1	1	0	4	2	50
Apr-17	1	0	1	0	1	0	1	1	4	1	25
May-17	1	0	1	1	1	1	1	1	4	3	75
Jun-17	1	1	1	0	1	0	1	1	4	2	50
Jul-17	1	1	1	0			1	1	3	2	67
Aug-17	1	0	1	0			1	0	3	0	0
Sep-17	1	0	1	0			1	0	3	0	0
Total	17	11	15	7	13	7	13	8	45	33	73
		= site closed to recruitment									

Table 10.1 Recruitment rates for each study site

Recruitment was delayed for sites B, C and D due to delays with the study set up and Site C closed early due to research support staffing issues. Based on the time when each study site was open, the maximum number of patients recruited would have been 45 rather than the anticipated 60. It was disappointing to only recruit 33 (73%) of this number however it was sufficient to inform the main objectives.

A total of 1270 stroke patients were admitted across the four sites during the recruitment period. Based on clinical registry data from site A, approximately 46.2% were admitted with an upper limb impairment which was reduced to 36.8% when those with significant dysphasia were removed. Further reduction due to the additional exclusion criteria (see Chapter 9) cannot be assessed as there was no formal screening log, but it is likely that there were many more patients suitable than were approached about the study.

The overall distribution of participants in relation to the study is shown below (Figure 10.1).

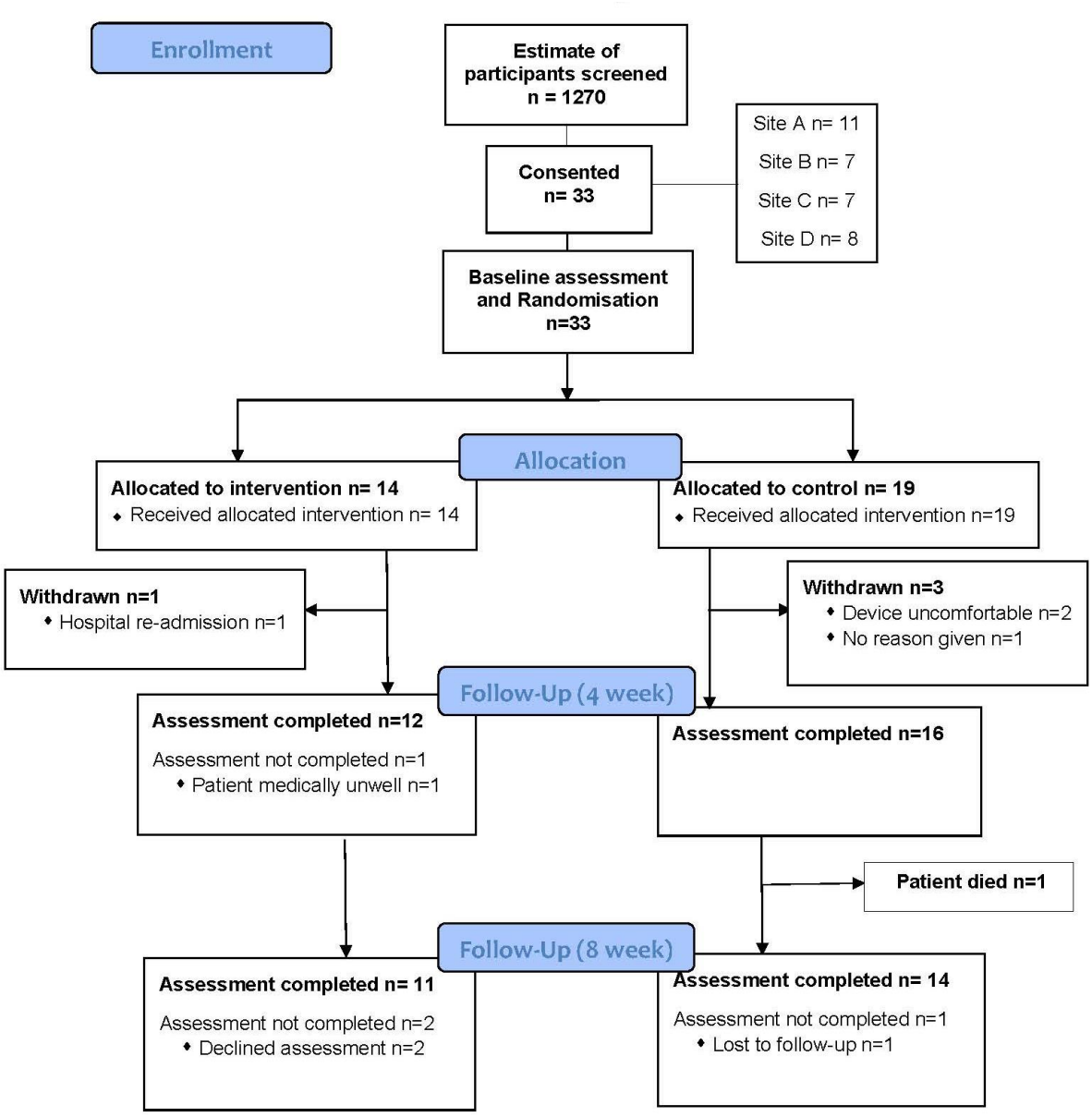


Figure 10.1 Consort flow diagram

	Intervention group N=14	Control Group N=19
Gender		
Male n (%)	6 (43%)	7 (37%)
Female n (%)	8 (57%)	12 (63%)
Age		
Median (IQR) years	73 [65-80]	69 [61-80]
Pre-stroke Barthel		
Range 0-20	20 [20-20]	20 [20-20]
Stroke type		
Infarct	13	18
Haemorrhage	1	1
Missing	0	0
Stroke sub-type n (%)		
TACS	4 (28.6%)	5 (26.3%)
PACS	4 (28.6%	5 (26.3%)
LACS	5 (35.7%)	7 (36.8%)
POCS	1 (7.1%)	1 (5.2%)
Uncertain	0 (0%)	1 (5.2%)
First ever stroke	12	15
Time from stroke to consent		
Median (IQR) days	27 [13-48]	26 [18-33]
NIHSS score		
Median (IQR)	4 [3-5]	5 [3-7]
Range 0-42: no symptoms – severe impairment		
Modified Rankin Scale		
0	0	0
1	0	0
2	3	6
3	6	8
4	5	5
Range 0-5: no symptoms – severe disability		
Barthel Index	15 [10-18]	12 [10-16]
Pain numeric rating scale		
Range 0-10: no pain – worst pain ever	0 [0-3]	0 [0-4]
Fatigue numeric rating scale		
Range 0-10: Not tired at all – extremely tired	6 [5-7]	7 [5-9]
Motricity Index (impaired arm)		
Median (IQR)	77 [54-84]	51 [38-70]
Range 0-100: No movement – Normal power		
ARAT		
Median (IQR)	37 [16-46]	15 [2-35]
Star cancellation		
Median (IQR)	53 [51-54]	52 [48-54]
Number scoring ≤44	0	3
Missing	1	1
Range 0-54: ≤44 indicates spatial neglect		
Motor Activity Log		
Amount of use Median (IQR)	1.4 [0.5-2.6]	0.3 [0.1-1.2]
Missing	0	1
How well Median (IQR)	1.5 [0.7-2.4]	0.3 [0.1-1.0]
Missing	0	1
Range 0-5: Not used – Normal movements		

Table 10.2 Baseline characteristics of participants

The baseline characteristics of participants in each randomisation group are shown above in Table 10.2. Baseline characteristics indicated that stroke severity was similar across groups although there was an obvious disparity between the groups for arm function. Participants were mostly female (61%) and had an average age of 71 years (SD 63, 80). Time since stroke ranged from 5 to 89 days with a median of 26 days [IQR: 16, 45]. Prior to the stroke, all participants had been functioning independently with a median pre-stroke Barthel Index score of 20 [IQR: 20, 20].

10.3 Objective 2: To report the attrition of participants in control and intervention groups.

Four participants withdrew from the study during the intervention phase: one from the intervention group at 15 days due to re-admission to hospital with a serious illness (cause unrelated to the study intervention), and three from the control group. Two of the control group participants reported discomfort from the wristband as the reason for withdrawing after one day and eight days, and the third, at five days, did not give a reason. Between the four and eight week outcome assessments, one participant from the control group died which, again, was unrelated to the study (Figure 10.1).

10.4 Objective 3: To report adherence to the WAVES intervention

Adherence to the intervention was measured based on how compliant participants were with wearing the wristband, therapists adherence to providing twice weekly therapy reviews, adherence to reviewing and changing the prompt settings and adherence to recording therapy practice on the daily log sheets.

10.4.1 Adherence to wearing the CueS wristbands

Participants' adherence to wearing the CueS wristbands is shown in **Table 10.3**. The median number of days that CueS wristbands were worn by the control group was 18.5[IQR: 8.0 - 23.5] and 25.0[IQR: 21.8 - 28.0] for the intervention group. A number of technical issues with the devices meant that for 134 days (15.7%) a working

wristband was not available. Reasons for this included malfunctions related to battery recharging and software bugs within the device.

	Number of days CueS wristband worn			
	Days data collection due	Days without working wristband	Days working wristband not worn	Days working wristband worn
Intervention N=14	389	21	1	367
Control N=19	462	113	6	343
Total number of days	851	134	7	710

Table 10.3 Adherence to wearing CueS wristband

Only seven days of data were lost due to participants not wearing the wristband when a working one was available meaning that they were worn for 710 /717 days (99%). On the days when a wristband was worn, they were worn for 79% of the recommended time per day between the hours of 8am and 8pm. The accelerometer data showed that some participants did not don the wristband until later in the morning which impacted on their overall wear time. This may have been out of their control if they required assistance.

10.4.2 Adherence to reviewing the data and adjusting the prompt settings

The number of NHS therapy review sessions participants received was a median of 7.5 [IQR:6.8-8.0] for the intervention group and 6.0 [IQR:4.3-8.0] for control group. Reasons for receiving less than the anticipated seven reviews were largely related to staffing issues such as part-time NHS therapists being unable to commit to two sessions per week.

NHS therapists reviewed activity data with the intervention participants and asked how they had responded to receiving a prompt. Participants reported practising the activities from their Daily Activities List (43% of responses), practising their own self-chosen activity at the time (38% of responses) or ignoring the prompt (17% of responses).

Table 10.4 shows the settings participants chose when adjusting the frequency of the prompt delivery. A clear preference was indicated across the group for hourly prompt settings. The total number of prompts received across the study was 2273 with a median of 8 [IQR: 6-10] prompts being delivered to each participant per day.

Study Id	Review 1	Review 2	Review 3	Review 4	Review 5	Review 6	Review 7	Review 8
1								
2								
3								
4								
5								
6								
7								
8								
9								
11								
12								
13								
14								

Key: = ½ hourly = hourly = 2 hourly

Table 10.4 Choices made of frequency of prompts

A wider range of options were selected when participants set the prompt threshold levels (Table 10.5).

Study Id	ARAT	Review 1	Review 2	Review 3	Review 4	Review 5	Review 6	Review 7	Review 8
1	0								
2	3								
3	4								
4	20								
5	20								
6	25								
7	35								
8	38								
9	39								
11	43								
12	56								
13	57								
14	57								

Key: = neutral (0%) = low (5%) = medium (10%) = high (20%)
= missing data

Table 10.5 Preferences for prompt settings

The preferred option, selected 35 / 67 times (52%), was to set the target at 10% above the median baseline activity level. The lowest setting (5% above baseline) was selected 18 times (27%) and the neutral and high settings seven times each (10%).

10.4.3 Adherence to recording which activities had been practised

Participants recorded which activities from their Daily Activities List they had practised in their daily logs. For the intervention group a median of 8 [IQR: 6, 11] different activities were practised each day with a maximum of 20 and a minimum of 1 practised on some days. For the control group a median of 10 [IQR: 6-14] activities were practised with a maximum of 24 and minimum of 1. Figure 10.2 shows the median number of different types of activities practised each day increased across the four week intervention period for each group. The control group (Group 1)

showed a greater number of different activities being practised towards the middle and end of the intervention period.

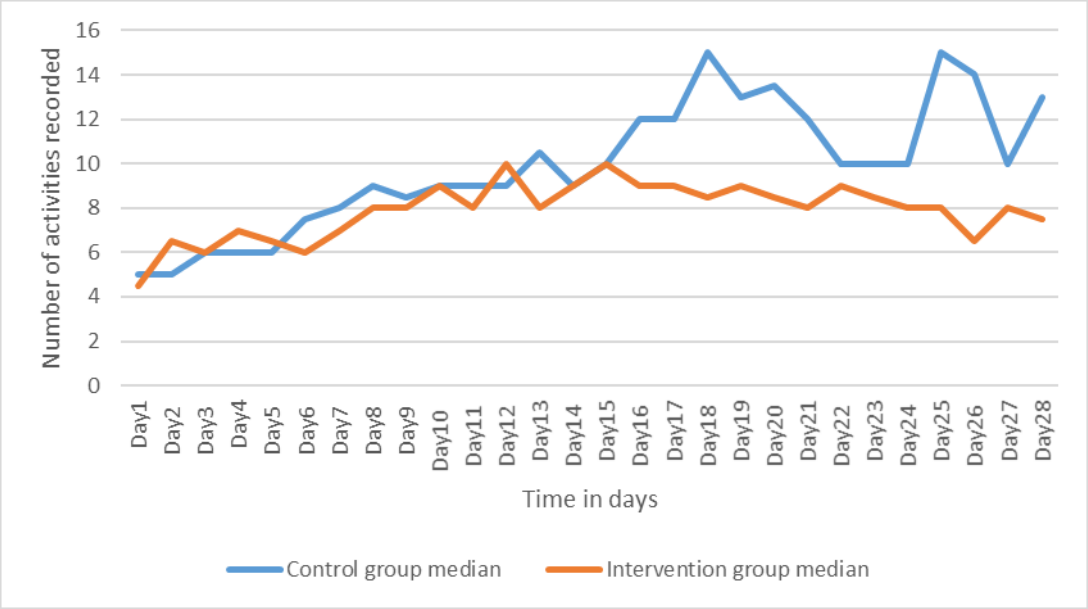


Figure 10.2 Median number of practiced activities recorded on daily log sheets

10.5 Objective 4: To report the number of usual rehabilitation care sessions received by control and intervention within the study intervention period

Twenty-two participants recorded their usual care sessions on the daily log sheets (n= 11 from each group). Both groups received a similar number of usual care sessions, the Control group recorded a median of 10 (IQR: 6, 16) per patient across a median of 27 days (IQR: 24, 28). The intervention group recorded a median of 9 sessions (IQR: 3, 21) across a median of 27 days (IQR: 24, 29). Four participants did not record their usual care sessions, and five participants did not return their handbooks.

10.6 Objective 5: To report the success of outcome assessor blinding to participant group allocation

Outcome assessors remained blinded to group allocation for 27 / 28 participants up to the four week outcome assessments (96%). On the one occasion that an outcome assessor became un-blinded, this was due to the participant discussing their experience of receiving the prompts.

10.7 Objective 6: To report serious adverse events in control and intervention groups during the study

Adverse events were recorded on the therapy review forms by the therapist at each therapy review and by the outcome assessors at four and eight weeks. Patients were asked if there had been any new medical problems since the last review and were scored on their level of pain in the arm and general fatigue

By the end of the study eight serious adverse events had been recorded (Table 10.6). None of these were related to the study and only one led to the patient withdrawing from the study early.

Study ID	Randomisation group	Seriousness criteria	Brief description of event	Outcome
1	Intervention	Inpatient hospitalisation	Urinary tract infection	Complete recovery
30	Control	Inpatient hospitalisation	Inflammation of RIG site	Complete recovery
18	Control	Inpatient hospitalisation	Possible further stroke	Recovered with sequelae
3	Intervention	Inpatient hospitalisation	Possible further stroke	Complete recovery
24	Control	Inpatient hospitalisation	Pulmonary embolism	Recovered with sequelae
10	Intervention	Inpatient hospitalisation	NSTEMI	Death
28	Control	Inpatient hospitalisation	TIA	Complete recovery
27	Control	Patient died	unknown	Death

Table 10.6 Serious adverse events reported during the study

There were no concerns that the intervention had caused an increase in pain or fatigue although, as will be discussed in Chapter 11, both pain and fatigue may have

had a bearing on who responded to the intervention. Table 10.7 and Table 10.8 show which participants reported pain at any point in the study and their reasons. It appears from the comments made that research support staff may have deviated slightly, at times recording general pain rather than arm specific pain. There were also a number of participants whose pain was due to a pre-existing condition which should perhaps should have excluded those participants from the study although this may not have been known to staff at the time of recruitment.

Intervention Group

Study ID	Baseline	Four weeks	Comments	Eight weeks	
12	0	1	Patient didn't give a reason	0	
8	0	0		2	Slight pain/ache occasionally in arm
1	5			7	migraine this morning, pain relief taken, migraine improving
13	2	5	left shoulder & left leg pain, has had this prior to stroke, although does feel it is worse - has arthritis	4.5	left hand & left shoulder pain PMH arthritis, thinks the pain is worse since stroke
2	0	0		3	ache when moving left arm or after exercising
3	5	0			
14	0	6	Left arm heavy and aching between shoulder and elbow.	5	Still has ache in left shoulder
11	0	2	Pain in wrist	0	
6	0	8	Painful shoulders from pre-existing condition	0	
9	8	0		0	

Table 10.7 Intervention group participants' score of pain at baseline, four and eight weeks

Control Group

Study ID	Baseline	Four weeks	Comments	Eight weeks	
32	0	8	Long standing issue but none in the arm		
26	0	8	Pain in right arm and right side of her neck. Currently taking paracetamol. GP reviewing.	10	Still experiencing shoulder and arm pain. Physio to review this. ?frozen shoulder.
23	0	8	Flare up of pre-existing fibromyalgia	8	Left hand & wrist painful, worse than pre stroke.
17	0	10	Pain in her left shoulder - severe at times	10	left shoulder & upper arm pain
18	4	6	Pain top of left shoulder	4	One episode of pain following 1st physiotherapy session since second stroke.
24	0	2	Pain experienced during physiotherapy without analgesia	5	Fluctuating pain, no definite trigger, physiotherapy, in bed, analgesia from GP
27	7	7.5	Pain all of time. Not getting any worse		
31	0	0		5	Back and leg pain, present before stroke onset
15	8	0		9	patient had a mechanical fall and has soft tissue damage to right side of body causing discomfort
28	0	0		4	old back problem causing back pain to left side
19	5	0		1	Occasional shoulder ache if left arm over exercised
16	4	8	Stiffness in upper arm	8	Patient gets pain in upper arm if over exercises

Table 10.8 Control group participants' score of pain at baseline, four and eight weeks

10.8 Objective 7: To report completeness and summary statistics of data to inform the design of a future multi-centre RCT

Clinical outcome measures with completeness of clinical outcome data are shown in Table 10.9. Excluding patients who had withdrawn or died, outcome assessments were completed for 28 / 29 participants at four weeks and 25 / 28 participants at eight weeks. Two participants (one from each group) were unable to complete the baseline Star Cancellation Test due to an inability to understand the instructions. The four week NIHSS score was missing for one participant due to assessor error. One participant was bedbound and too unwell to sit up to complete the four week ARAT. One participant declined the Motor Activity Log at four weeks and the same participant declined the ARAT at both four weeks and eight weeks.

	Intervention 4 weeks N=12	Control 4 weeks N=16	Intervention 8 weeks N=11	Control 8 weeks N=14
NIHSS score				
Median (IQR)	2 [1-4]	4 [1-5]	1 [1-3]	3 [1-4]
Missing	0	1	0	0
Range 0-42: no symptoms – severe impairment				
Modified Rankin Scale				
0	1	0	0	0
1	0	0	1	2
2	6	6	5	2
3	3	8	3	10
4	2	2	1	0
Range 0-5: no symptoms – severe disability				
Barthel Index				
Median [IQR]	19 [16-19]	17 [12-19]	19 [17-20]	15 [15-18]
Missing	0	0	0	0
Pain numeric rating scale				
Median [IQR]	0 [0-4]	1 [0-8]	0 [0-5]	5 [0-8]
Missing	0	0	0	0
Range 0-10: no pain – worst pain ever				
Fatigue numeric rating scale				
Median [IQR]	5 [2-5]	5 [5-8]	5 [2-5]	7 [5-8]
Missing	0	0	0	0
Range 0-10: Not tired at all – extremely tired				
Motricity Index (impaired arm)				
Median (IQR)	92 [77-100]	79 [54-88]	93 [77-100]	75 [50-93]
Missing	0	0	0	0
Range 0-100: No movement – Normal power				
ARAT				
Median (IQR)	57 [29-57]	35[15-56]	57 [37-57]	31 [21-55]
Missing	0	2	0	1
Star cancellation				
Median (IQR)	54 [53-54]	53 [51-54]	54 [51-54]	54 [51-54]
Number scoring ≤44	0	2	1	1
Missing	0	0	0	2
Range 0-54: ≤44 indicates spatial neglect				
Motor Activity Log				
Amount of Use Median (IQR)	3.8 [1.9-4.5]	1.1 [0.3-2.9]	4.2 [2.1-4.3]	1.2 [0.7-2.9]
Missing	0	1	0	0
How well Median (IQR)	3.4 [1.6-3.9]	1.3 [0.3-2.2]	3.6 [2.1-3.9]	1.3 [0.5-2.8]
Missing	0	1	0	0
Range 0-5: Not used – Normal movements				

Table 10.9 Summary statistics for clinical outcomes and data completeness

Completeness of outcome accelerometer data collected is shown in Table 10.10. All returned wristbands had a complete data set of three days of wristband wear. At the four week outcome, one participant declined to wear a device and one device was lost as the participant had died. Two further devices were not returned (intervention group n= 1). At week eight, the same participant as in week four declined to wear a device and two were not returned. All of the devices that were not returned were for participants from study site C.

	Number of days CueS data collected	**Number of days of outcome data collected**	
	Baseline to week 4	Week 4	Week 8
Intervention N=14	367	33 / 36	33 / 33
Control N=19	343	39 / 48	33 / 42
Total number of days	710	72 / 84	66 / 72

Table 10.10 Completeness of accelerometer data

It was possible to estimate the size of a future clinical efficacy study from the results of the pilot RCT[3]. As the intervention purpose is to increase arm use (participation) rather than impairment / function, the Motor Activity Log (Amount of Use Scale) is recommended as the primary outcome measure. Based on a previously reported minimal detectable change of 1 point (Chen et al., 2012) and data from this study (a standard deviation between baseline and eight weeks of 1.2 points), 108 participants would be required to detect a clinically important effect (p=0.05) with a power of 90% in a two-arm trial with attrition of 12%.

[3] Sample size calculation provided by University based statistician

10.9 Conclusion

This chapter has reported on the feasibility of conducting a multi-centre, observer blind, randomised controlled trial of the CueS wristband to prompt independent practice of functional activity of the impaired arm and found that this would be possible during rehabilitation early after stroke. There was a high level of adherence and no evidence of safety concerns. Recruitment rates may be improved by further development of the technology to include interfaces which can be used and interpreted without additional therapist involvement.

The next chapter reports on the clinical outcomes from the pilot RCT and analysis of the accelerometer data including data to show the immediate effect of receiving a vibration prompt and the longer term effects of the intervention up to the eight week outcome.

Chapter 11. Wristband Accelerometers to motivate Exercise after Stroke (WAVES) Pilot RCT: Clinical outcomes and accelerometer results

Chapter 10 reported the results of the feasibility objectives and concluded that with sufficient support from research and clinical staff, a larger efficacy trial of wristband activity monitoring and feedback would be feasible. The purpose of this chapter is to report on changes in impaired arm activity both during and after the intervention interval.

11.1 Aim

To report changes in activity of affected arm using clinical outcomes and accelerometer data during and after the WAVES programme.

11.2 Objective 8: To report the change in activity and function of the affected arm during and after the self-directed arm rehabilitation program (with and without prompts)

Accelerometer data from all 33 participants (14 intervention and 19 control) in the pilot randomised controlled trial were included in the between-group comparisons of changes in arm activity.

A total of 233, 166 minutes of valid accelerometer data were collected (control n = 125, 210 and intervention n = 107, 956) of which 101, 625 were ‘active’ minutes (control n = 50, 967 and intervention n= 50, 658) once non-wear and inactivity data had been removed.

Table 11.1 shows the median number of counts per minute and clinical scores for each group at baseline and the four and eight week outcomes. The ARAT scores in Table 11.1 show the randomisation disparity between the groups at baseline which is also reflected by the amount of CueS counts per minute (CPM). This pattern

		Baseline[a]	*P* value[b]	4 Weeks[a]	*P* value[b]	8 Weeks[a]	*P* Value[b]
Amount of arm activity (CPM)	Intervention	N=14 777 [499, 1298]	0.08	N=11 916 [617, 1675]	0.06	N=11 1317 [656, 1395]	0.01
	Control	N=17 562 [404, 714]		N=13 574 [516, 891]		N=11 536 [317, 836]	
Amount of arm function (ARAT score)	Intervention	N=14 37 [16, 46]	0.07	N=12 57 [29, 57]	0.08	N=11 57 [37, 57]	0.12
	Control	N=19 15 [2, 35]		N=14 35[15, 56]		N=13 31 [21, 55]	
Amount of arm use in ADLs (MAL score)	Intervention	N=14 1.4 [0.5, 2.6]	0.04	N=12 3.8 [1.9, 4.5]	0.03	N=11 4.2 [2.1, 4.3]	0.04
	Control	N=19 0.3 [0.1, 1.2]		N=15 1.1 [0.3, 2.9]		N=14 1.2 [0.7, 2.9]	

Abbreviations: CPM, counts per minute; ARAT, Action Research Arm Test; ADLs, Activities of Daily Living; MAL, Motor Activity Log
[a]Values are median [interquartile range]
[b]Between group differences of median CPM

Table 11.1 Counts per minute, amount of arm function and amount of arm use for each group at each time-point

remained the same at four weeks with both groups showing a marginal increase in activity. By follow-up at eight weeks however, the activity CPM for the control group had dropped back to below that seen at baseline, whilst the intervention group CPM had continued to increase (Figure 11.1). This resulted in a statistically significant difference in CPM between the groups (p=0.01) at eight weeks (Table 11.1 Counts per minute, amount of arm function and amount of arm use for each group at each time-point).

Arm function and the amount participants were using the impaired arm, as measured by the ARAT and Motor Activity Log respectively, also indicated a pattern of increase for both groups up to the four week outcome, which again continued up to the eight week outcome for the intervention group but not for the control group. Statistical comparison has not been performed due to the small volume of data.

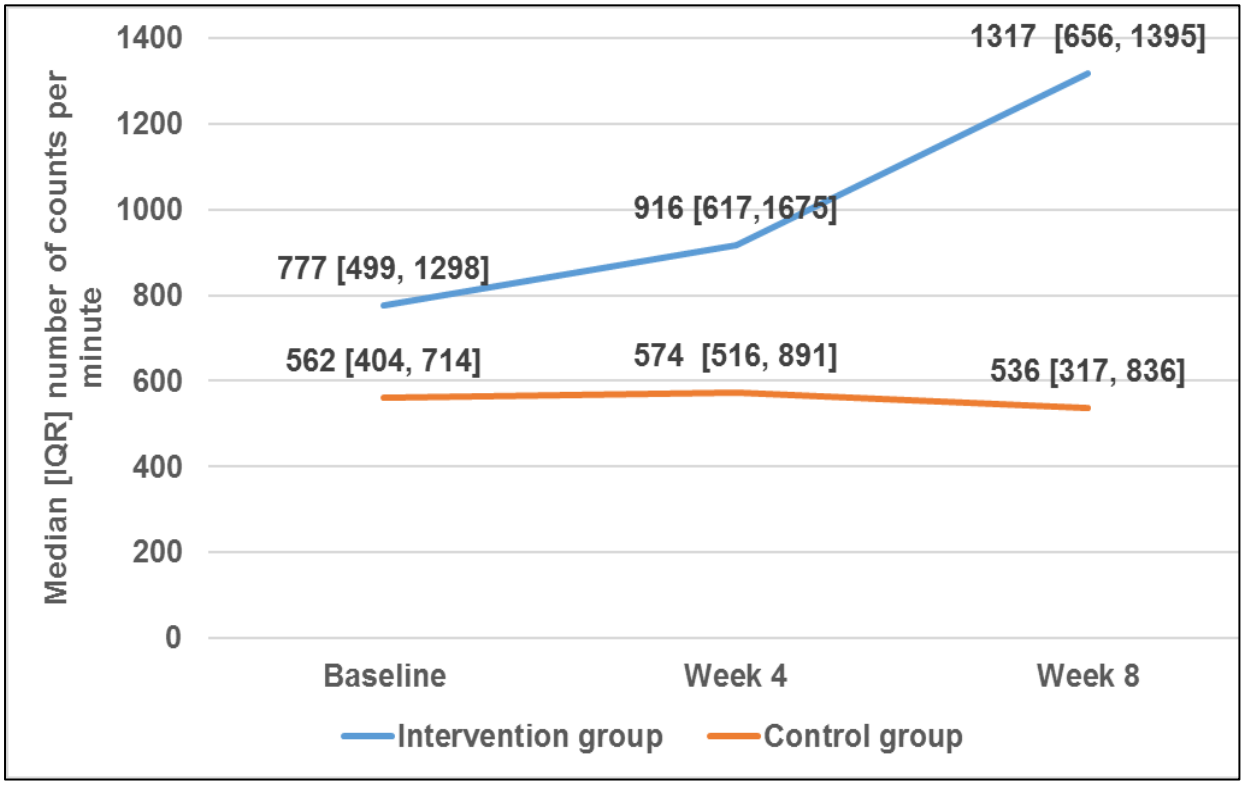


Figure 11.1 Number of counts per minute between groups

11.3 Objective 9: To report the immediate effect of a vibration prompt on arm activity

Data from the 14 intervention participants were included in examination of the immediate effect of vibration prompts on arm activity.

A total of 2135 vibration prompts were delivered to the participants in the intervention group (median of 8 [IQR: 6-10] per participant per day). Fifty-seven percent (n=1216) of these were followed by an increase in CPM of any amount during the subsequent hour. There was a 16.8% increase ($p \leq 0.001$) in the total number of CPM in the hour after a prompt (103 704 134) compared to the total in the hour preceding a prompt (88 777 026).

11.4 Summary of results

In this chapter, we have shown that over half of the prompts delivered led to a measurable increase in activity during the hour after a prompt and that there was a sustained increase in activity over the eight weeks of follow up. Further research is required, but this type of intervention may have the potential to support patients by prompting an increase in arm use required for recovery and aiding the transition of newly acquired motor skills back into daily activities. This will be discussed in more detail in Chapter 13.

The next chapter examines how individual participants responded to the intervention in relation to their use of the impaired arm in daily activities. It will consider, in particular, whether there is any evidence of change in arm function during and after the intervention period which could indicate that the WAVES intervention was changing behaviour.

Chapter 12. Wristband Accelerometers to motivate Exercise after Stroke (WAVES) Pilot RCT: results of individual responses to the intervention

The previous chapters focused on the feasibility of a multi-site RCT and investigated between group comparisons to indicate whether the intervention might be influencing activity and recovery. The results reported in Chapter 11, appear to support the notion that regular prompting would remind participants to use their impaired arm more and it would be expected that this might lead to an increase in arm function. This chapter takes an exploratory approach to consider how individual participants responded to the intervention in an attempt to better understand the potential impact on arm recovery.

12.1 Aims

To explore how individual participants responded to the intervention and whether any pattern exists between an increase in CPM and increased use of the impaired arm in daily activities.

Using data from the feasibility study, Table 12.1 shows each participants' scores on the number of counts per minute (arm activity), Motor Activity Log (arm use) and Action Research Arm Test (arm function) at baseline, four weeks and eight weeks.

Intervention group

Participant	Baseline			Week 4			Week 8		
	CPM	MAL	ARAT	CPM	MAL	ARAT	CPM	MAL	ARAT
P1	467	0.0	0	-	-	-	608	0.2	15
P2	846	0.1	3	730	0.4	4	757	0.2	4
P3	343	0.2	4	272	0.8	25	-	-	-
P4	517	0.6	20	916	3.9	38	1317	4.8	57
P5	572	2.7	20	-	5.0	57	-	-	-
P6	1257	1.0	25	1675	1.8	26	1395	2.5	37
P7	494	3.3	35	617	3.9	46	656	4.3	43
P8	2678	1.6	38	2187	4.3	57	1869	4.2	57
P9	723	2.5	39	747	3.6	57	896	3.7	44
P10	500	3.5	43	-	-	-	-	-	-
P11	953	2.5	43	1614	3.5	57	1342	4.2	57
P12	1420	1.8	56	1647	4.6	57	1826	4.8	57
P13	831	1.0	57	538	2.1	57	641	2.1	57
P14	2008	1.3	57	1702	4.5	57	1354	4.2	57
Control group									
Participant	Baseline			Week 4			Week 8		
	CPM	MAL	ARAT	CPM	MAL	ARAT	CPM	MAL	ARAT
P15	435	0.0	0	412	1.1	35	395	1.1	31
P16	439	0.0	0	409	0.3	13	317	0.9	42
P17	784	0.0	0	514	0.2	0	288	0.0	0
P18	499	0.5	1	871	2.8	38	150	0.1	0
P19	562	0.1	2	518	0.6	15	428	1.0	22
P20	605	0.0	3	-	-	-	-	-	-
P21	344	0.1	5	-	0.4	15	-	0.1	20
P22	258	0.9	6	-	-	-	-	-	-
P23	374	0.2	9	536	0.2	19	712	1.0	23
P24	592	0.2	15	518	0.3	30	836	1.5	55
P25	644	0.2	15	656	2.1	50	695	2.3	55
P26	478	0.7	22	574	2.9	34	536	1.3	29
P27	288	0.3	28	-	-	-	-	-	-
P28	-	0.0	35	-	2.5	56	-	2.8	57
P29	1136	4.0	39	1557	5.0	57	1344	4.1	45
P30	612	1.8	45	912	-	-	-	3.0	-
P31	1217	2.0	45	834	5.0	57	1040	5.0	57
P32	1092	1.2	52	1141	3.1		-	-	-

Abbreviations: ARAT Action research arm test; MAL Motor activity log (amount of use); CPM number of active counts per minute.

Reasons for missing data: P1 hospital admission at 4 week outcome; P3 declined 8 week outcome assessment; P5 declined 8 week outcome assessment and watch not returned for week 4 accelerometer data; P10 withdrew early; P20 withdrew early; P21 declined to wear watch for outcome assessments; P22 withdrew early; P27 unable to complete 4 week outcome as bedbound and died before week 8 outcome assessment; P28 accelerometer data lost by site; P30 declined to compete ARAT at 4 and 8 week outcome assessment and MAL at 4 week outcome assessment; P32 withdrew early;

Table 12.1Table of results (sorted in ascending order of baseline ARAT score)

As described in Chapter 9, participants were defined as responders or non-responders based on the following assumptions:

Increase in impaired arm activity: In the absence of a minimal clinically important difference (MCID) score for the CPM, participants who achieved a token increase of 10% of their baseline CPM were considered a responder in arm activity.

Increase in use of the impaired arm in ADLs: Participants were considered to have responded with an increase in using their impaired arm in daily activities if they had increased their Motor Activity Log (amount of use) score by the MCID of 1 point (Lang et al., 2008).

Increase in impaired arm function: Participants were considered to have responded with an increase in arm function based on the MCID increase of over 12 points on the ARAT (Lang et al., 2008). As the maximum score on the ARAT is 57, participants would need to have a baseline score of <45 in order to be able to record them as a positive response.

Non-responders: were participants who did not respond with a MCID in use of the impaired arm in ADLs. Potential reasons why these participants did not improve their arm use is explored further using data collected about pain; fatigue; and serious adverse events.

The data for each participant in Table 12.1 were used to apply these rules and responders (green) or non-responders (red) for increased arm activity, increased arm use and increased arm function illustrated in Table 12.2. Participants who scored ≥45 on baseline ARAT are indicated in orange (inconclusive) as it would not be possible for them to indicate the MCID.

		Responders at 4 weeks			Responders at 8 weeks		
	Baseline ARAT	Increased arm activity (CPM)	Increased arm use (MAL)	Increased arm function (ARAT)	Increased arm activity (CPM)	Increased arm use (MAL)	Increased arm function (ARAT)
Intervention Group							
P1	0	-	-	-	✓	x	✓
P2	3	x	x	x	x	x	x
P3	4	x	x	✓	-	-	-
P4	20	✓	✓	✓	✓	✓	✓
P5	20	-	✓	✓	-	-	-
P6	25	✓	x	x	✓	✓	✓
P7	35	✓	x	x	✓	✓	x
P8	38	x	✓	✓	x	✓	✓
P9	39	x	✓	✓	✓	✓	x
P10	43	-	-	-	-	-	-
P11	43	✓	✓	✓	✓	✓	✓
P12	56	✓	✓	56	✓	✓	57
P13	57	x	✓	57	x	✓	57
P14	57	x	✓	57	x	✓	57
Control Group							
P15	0	x	✓	✓	x	✓	✓
P16	0	x	x	✓	x	x	✓
P17	0	x	x	x	x	x	x
P18	1	✓	✓	✓	x	x	x
P19	2	x	x	✓	x	x	✓
P20	3	-	-	-	-	-	-
P21	5	-	x	x	-	x	✓
P22	6	-	-	-	-	-	-
P23	9	✓	x	x	✓	x	✓
P24	15	x	x	✓	✓	✓	✓
P25	15	x	✓	✓	x	✓	✓
P26	22	✓	✓	✓	✓	x	x
P27	28	-	-	-	-	-	-
P28	35	-	✓	✓	-	✓	✓
P29	39	✓	✓	✓	✓	x	x
P30	45	✓	-	-	-	✓	-
P31	45	x	✓	✓	-	✓	✓
P32	52	x	✓	x	-	-	-

Key: Responder:

Non-responder:

Inconclusive:

Table 12.2 Responders and non-responders in each group

12.1.1 Objective 10: To identify individual participants who had a general increase in arm activity indicated by a 10% in CPM.

Table 12.2 shows that by four weeks there was a similar proportion of participants who had increased their general arm activity in the intervention (5/14) and control (6/18) groups. Despite the apparent disparity in arm function between the groups at baseline, this did not appear to influence who did or did not increase arm activity and there is no obvious pattern to be seen between arm activity and arm function as may have been expected.

By the eight week outcome, the intervention group included more people responding with an increase in general arm activity but there was considerable missing data in the control group and this may not be a genuine observation.

Of the 10 participants (5 in each intervention group) who showed an increase in arm activity by four weeks, 6 (3 in each group) also indicated a benefit in the amount they were using their arm in ADLs. Of these, none in the control group maintained the increase in arm use up to the 8 weeks point whilst the 3 from the intervention group all did. A further 2 went on to show a benefit by the eight week point. Overall by eight weeks, only 1 participant from the control group had increased general arm activity *and* use of the impaired arm in daily activities in contrast to 6 in the intervention group.

12.1.2 Objective 11: To identify individual participants who increased use of the impaired arm when carrying out daily activities indicated by reaching a MCID of 1 point on the MAL.

In the intervention group 8 out of 12 participants showed an increased use of the impaired arm in daily activities by the end of the four week period according to the definition of response. Two of the non-responders at this point continued to improve and showed an increase by eight weeks. At the end of the study, 10 out of 12 intervention participants were showing a positive response to arm use in daily activities.

In the study control a similar number of participants to the intervention group (8 out of 10) had shown improvement by the four week outcome. By eight weeks, one more continued to improve up to the responder status however 3 previous responders failed to maintain their arm use resulting in only 6 out of 14 showing an increased use of their impaired arm in daily activities by the end of the study.

Of the all the participants in the study who showed an increase in the amount of use of the impaired arm in ADLs, only about half mirrored this with an increase in overall arm activity. Conversely, all except one (8 in each randomisation group) had an increase in arm function. This was maintained at eight weeks for all except one participant (P9) for whom, despite increases in general arm activity and use of the arm in daily activities, arm function decreased back to below the MCID.

12.1.3 Objective 12: To identify which participants had an increase in arm function indicated by reaching the MCID of 12 points on the ARAT.

Across the whole study group, 19 participants (intervention n= 9) either increased their arm function by more than 12 points or reached the ceiling score of 57 points by the end of the intervention period. Most of these participants also increased use of the impaired arm in daily activities by the four week outcome (n = 15/19; intervention n=8; control n= 7).

By eight weeks, intervention participants continued to show increased arm function and arm use but in the control group, three participants at week eight did not maintain the improvement in both arm function and arm use that had been observed at week four (P18. P26 and P29). There were 2 new responders for improved arm function but these were not shown to improve their arm use (P21 and P23). There were also 2 responders (P16 and P 19) who despite maintaining their arm function improvement at four weeks until the eight week outcome, did not show any improvement in arm use.

By the end of the study, 8 participants in the intervention group responded with an increase in arm function or reached the ceiling score 57 points and of these 7 also showed an improvement in arm use. In the control group, 9 participants showed an improvement in arm function but only five also increased their arm use.

12.1.4 Objective 13: To describe possible reasons why some participants did not show an increased use of the impaired arm in daily activities

Table 12.3 shows which participants did not increase use of the impaired arm in daily activities i.e. non-responders. There were four in the intervention group at four weeks and two at eight weeks. In the control group there were six non-responders at four weeks and this increased to eight by the eight week outcome. The comments related to possible reasons for this based on the information available regarding SAEs and pain or fatigue. Only two participants (P2 and P29) had no clear reason for not improving the use of the impaired arm. One of these, from the control group had responded well with improved arm use at four weeks but did not maintain it up to the eight week time-point. For the other participant, the baseline, four week and eight week ARAT scores indicated that there was no change in the arm which may suggest that for this participant, there was just no potential for change.

Intervention group non-responders (arm use)					
4 weeks					
	Baseline ARAT	Arm use	Arm function	Arm activity	Comments
2	3	x	x	x	No changes in arm strength or function
3	4	x	✓	x	Further stroke
6	25	x	x	✓	Shoulder pain from pre-existing condition 8 /10
7	35	x	x	✓	Increase in MAL did not reach MCID until 8 week outcome
8 weeks					
1	0	x	✓	✓	Admitted to hospital with urinary tract infection during intervention period
2	3	x	x	x	No changes in arm strength or function

Control group non- responders (arm use)					
4 weeks					
	Baseline ARAT	Arm use	Arm function	Arm activity	Comments
16	0	x	✓	x	Arm pain 8 /10 worsened by exercise, fatigue 9/10.
17	0	x	x	x	Shoulder pain reported and rated 10 / 10
19	2	x	✓	x	Fatigue scored at 8 / 10 at weeks 4 and 8
21	5	x	x	-	Scored 10/10 for fatigue
23	9	x	x	✓	Arm pain scored at 8 / 10. Pre-existing condition of fibromyalgia
24	15	x	✓	x	Pulmonary embolism. Fluctuating pain managed by analgesia and physio. Nursed in bed.
8 weeks					
16	0	x	✓	x	Continued to experience high pain and fatigue
17	0	x	x	x	Continued to experience shoulder pain
18	1	x	x	x	Further stroke affecting arm, leg and speech
19	2	x	✓	x	Continued to experience fatigue
	5	x	✓	-	Fatigue rated at 9.5 / 10
23	9	x	✓	✓	Continued to experience joint pain at wrist
26	22	x	x	✓	Shoulder pain reported at 8/10 and multiple falls
29	39	x	x	✓	Arm function deteriorated – no clear reason

Table 12.3 Possible reasons for not showing an increase in arm use

12.2 Results summary

This chapter shows that, according to stated response definitions, there was no obvious difference between randomisation groups in terms of the number of participants who responded with an increase in arm activity, arm use or arm function during the first four weeks. By eight weeks, there was still no difference between the groups in terms of how many participants had increased their arm function, but the intervention group had more participants meeting the response definition for both increased general arm activity and use of the arm in daily activities.

These results will be discussed in more detail in the next chapter which provides an overall summary of the results of the Pilot RCT and discusses the strengths and weakness of the trial.

Chapter 13. Wristband Accelerometers to motivate Exercise after Stroke (WAVES) Pilot RCT: Discussion

13.1 Summary of overall findings from the WAVES pilot RCT

The results of the feasibility objectives suggest that a multi-centre, observer blind, randomised controlled trial of a wristband accelerometer specifically designed to encourage independent practice of functional activity of the impaired arm after stroke is possible, although difficulty recruiting the pre-specified number of participants would need to be addressed prior to a larger clinical trial of efficacy.

Clinical outcomes and the accelerometer data both showed that arm activity increased for the intervention group whilst they were wearing the wristbands, and continued to increase further over the follow-up period, despite the wristbands having been removed. In contrast, the control group only made marginal increases in activity during the intervention period which reduced to below baseline activity over the follow-up period. The number of participants was small and these observations may have been due to the unequal baseline arm function following randomisation, but they are consistent with the intended purpose of the intervention to promote greater general use of the affected arm.

Intervention participants responded with a significant increase in arm activity in the hour after being alerted by the vibration prompt, suggesting a direct mechanism which may have contributed to the longer term benefits of greater impaired arm use.

During the four week programme the number of participants showing improvement between the groups was similar. However by eight weeks, all but two participants in the intervention group had continued to improve showing a minimal clinically important difference on the Motor Activity Log and indicating that they were using the impaired arm more in daily activities. In contrast, less than half of the control participants showed improvement on the MAL.

13.2 Discussion of overall findings

As this was a feasibility study, the inclusion criteria were broad to gain experience from a wide range of patients and the study relied upon local staff to identify potential participants. Service support limitations prevented a screening log from being recorded and the number of potential participants was estimated instead. This was a weakness of the study as, whilst clinicians can be best qualified to select appropriate participants for research, their professional relationship with the patient and personal views about the intervention can influence their decision on whether or not an individual might “benefit” (Thomas et al., 2015).

The overall recruitment was 3% of the estimated number of potential participants which despite being less than planned, is in line with similar studies (Brkic et al., 2016, Turton and Fraser, 1990). Although not consistently reached each month, the agreed target rate of one participant per month was achieved by sites on multiple occasions. Recruitment fluctuated due to the availability of local research support staff for identification of participants and NHS therapists for providing twice-weekly reviews. The time commitment from therapists for performing study reviews and data download was estimated at 15 minutes twice a week to be done within usual care sessions. However, difficulties were reported in providing twice weekly sessions, particularly once patients had been discharged from hospital when travel time to participants’ homes became an additional time factor. Furthermore, regular upper limb therapy at some sites would normally have been delivered by support staff/assistants. The requirement to deliver the study intervention by a qualified therapist would have impacted on the workload for that therapist.

The immediate increase in arm activity following a vibration prompt was a new and relevant finding which could have significant implications for arm recovery and rehabilitation. Increased dose of therapy has been associated with better outcomes (Lohse et al., 2014) and the frequency of prompts being delivered during this study provided opportunities to increase the dose through regular episodes of therapeutic

practice built around daily routines. More than half of the prompts delivered were followed by an increase in arm activity over the subsequent hour suggesting the potential for a meaningful increase in activity from the intervention. Prompts that did not elicit an immediate activity response still had the potential to increase awareness of the impaired arm. Whether or not this amount of increased activity is sufficient to elicit a long term behaviour change will need further investigation, but our finding that the intervention group continued to increase arm activity beyond the treatment period is encouraging.

At the end of the four-week therapy programme, both groups had shown longitudinal improvements in both arm function and amount of impaired arm use in daily activities. The benefits of task specific training and opportunity to practice functional activities are well documented and recommended as current best practice (Intercollegiate Stroke Working Party, 2016, Pollock et al., 2014) so it would perhaps have been expected that both groups benefitted from the additional therapy input.

The results suggest that there is not a simple relationship between the intervention and outcomes. The initial expectation when designing the study was that feedback from the WAVES technology would encourage an increase in arm activity which, supported by the Daily Activities List, would lead to an increase in using the impaired arm in daily activities and consequently better arm function. Whilst the group difference shows a near statistical difference in favour of the intervention group for CPM by four weeks, the results for individual participants showed similar proportions in the control and intervention group did not increase their CPM. Of the participants who *did* increase their CPM by four weeks, there was no indication at this point, that this was mirrored by an increase in either arm function or use of the impaired arm in daily activities.

A clearer pattern emerged for participants who showed an increase in arm use measured by the Motor Activity Log. All such responders in the intervention group maintained these benefits up to the eight week point with an additional two participants moving into responder status. By the end of the study only two out of

eleven participants in the intervention group had not responded with an increase in arm use and both of these had very limited arm function (ARAT scores of 15 and 4 points). In the control group three participants who by four weeks had responded with an increased use of the arm had reverted back to non-responder status leaving just 6 responders out of a possible 14 to have increased use of the impaired arm in daily activities.

The majority of participants in the intervention group who responded with an increase in arm use were also noted to have responded with an increase in arm function and vice versa. In contrast, only about half of the participants in the control group who responded with increased arm function also showed an increase in arm use. This supports previous literature acknowledging an apparent lack of integration of the impaired arm in daily routines even when there have been significant improvements in arm function (Doman et al., 2016, Rand and Eng, 2012, Waddell et al., 2017). That the intervention participants appeared to have shown parallel improvements in arm function and arm use is encouraging and requires further investigation.

Viewed retrospectively, our intervention included integration of a number of specific strategies which reflect those associated with a longer term behaviour change approach, i.e. setting activity goals, regular therapist review, providing visual feedback comparing to baseline and participants being able to self-monitor their progress by tapping on the wristband and see their data displayed on the interface (Michie et al., 2011). It could be hypothesised that, rather than the benefit of the prompts simply increasing short-term arm activity, they supported a more lasting change in behaviour. It may be that the regular and frequent prompting delivered by the CueS wristbands, has influenced participants' awareness to habitually use their impaired arm in tasks, particularly if this was at times when they were already engaged in activity. A recent review of habit forming behaviours, defined a habit as:

> "a process whereby a cue automatically triggers an impulse to act based on cue-action associations learned through repeated performance" (Gardner, 2015)

Habits are considered to be contextually triggered by the environment. The regular prompting of arm movements, in the context of being engaged in a particular activity, may have formed an association whereby the activity itself or the environment then became a cue to use the impaired arm. This might explain the continued improvements for the intervention group noted at the eight week assessments.

A novel feature of the WAVES technology enabled therapists and participants to tailor the prompting mechanism to support the wide variability in each stroke patients' abilities and preferences. As noted in the proof of concept study, participants consistently showed a preference for choosing a regular hourly prompting schedule. However, when setting the threshold they opted for a slightly higher target of activity than previously, choosing the "medium" level of 10% above their new baseline activity level for each hour. The preference shown for this slightly higher setting appears to have resulted in a higher number of prompts being delivered to patients, with some being prompted every hour. This could be an indication that the threshold was set too high for prompt avoidance, but it may be an indication that patients preferred receiving more frequent reminders. This may be important for the impact of the intervention because repetition helps to form new behaviours and habits (Gardner et al., 2019). A frequent prompt reminder did not appear to deter continuing wear, and there was often documentation of an activity response.

The more frequent delivery of prompts may also have encouraged a therapy schedule with frequent, shorter doses of therapy practice aligned with recommendations by other authors (Bernhardt et al., 2016, Krakauer, 2006). In this way the intervention group may have naturally distributed their practice across the day by integrating arm use into whatever activity was appropriate when the wristband prompted them rather than consciously setting aside time to work through the Daily Activities List. This would be an important area for future research into the mechanism of the intervention.

It was noted in Chapter 9 that the control group recorded practising more activities than the intervention group on their log sheets. Without feedback from the wristbands, the focus of the study for the control group would have been practising the daily activities on their list. In the absence of reminders from the wristband or feedback on their progress from the activity reports, participants in this group may have reverted to the more traditional approach of setting aside time each day to practise and record their activities rather than integrating therapy practice into their daily routine. Once the therapy programme was removed at the end of the four week intervention period, the activities list would have been removed which may explain why their arm activity dropped between weeks four and eight.

Encouraging frequent use of the impaired arm in normal daily routines potentially opens up opportunities to increase the type of practice that involves variability of the task, random task practice and distributed practice – all of which are well documented for improving motor learning (Krakauer, 2006, Kleim and Jones, 2008). Further evaluation of the benefits of receiving frequent feedback whilst also considering the possibility of participants habituating to prompts would be an area for further consideration in a future study.

13.2.1 Strengths

A key strength of the intervention was the development by a multi-disciplinary team with direct patient engagement. The team consisted of experts in interaction design, ubiquitous computing and clinical stroke research. The CueS wristband and WAVES interface functions were developed iteratively based upon patient feedback. A key difficulty in rehabilitation research is the blinding of participants to group allocation. Control participants were given a non-prompting CueS wristband to wear reduce the possibility that they might behave differently and the use of a two stage information process which avoided the possibility of the control group participants having any expectations that prompts could occur. The outcome assessments (clinical and activity data) were performed by research staff who were informed of individual participant group allocations.

The high retention of participants particularly in the intervention group was encouraging, and the study intervention appears to have been well tolerated with no increase in pain or fatigue associated with the technology. Only one participant who was receiving the prompting feedback withdrew and this was for reasons unrelated to the intervention itself. It is important to note that three participants withdrew from the control group early after recruitment. This level of loss of primary outcome data would need to be factored into a later clinical trial.

13.2.2 Limitations

The study also had a number of limitations. The original aims and objectives of the pilot study were focused around feasibility. As such, the sample size was small and not powered to determine clinical efficacy of the prompting mechanism. It was not possible to stratify participants based on level of arm impairment and as mentioned previously, the disparity in the baseline ARAT scores meant that the intervention group had better arm function at the start of the study and more potential for improvement (Stinear et al., 2017b). Further difficulties in interpreting the ARAT outcomes occurred from some participants already meeting the maximum score of 57 at baseline therefore being unable to show further improvements on this scale. A cut-off score on the ARAT was specifically avoided to include participants with good arm function but who were at risk of poor integration of the arm during daily activities because of other impairments.

Despite the advantage at baseline for the intervention group, it is important to note that the CPM difference between both groups increased, including some participants with very limited movement at baseline. For this reason the Motor Activity Log was selected as the primary outcome in the power calculation for a future trial, as it focuses on arm use rather than impairment.

The decision to select patients within the first three months of stroke was a pragmatic decision made to ensure that participants were still in regular contact with therapists to support them with the clinical aspects of the study. However, this limits the

generalizability of the trial to those who have been living with an arm impairment after stroke for longer. Furthermore, all participants were recruited from stroke services in the North East of England with little variation between service deliveries

Future research should also consider optimal timing of the intervention, and the requirement for therapist supervision. Previous trials of self-directed interventions have shown that there are benefits beyond the early rehabilitation stage (Da-Silva et al., 2018) and it is possible that stroke survivors may benefit more from using wearable monitors to encourage self-directed activity at a later stage. There is often a reduction in usual care as the rate of arm motor function improvement slows down and this may be the point when patients have more time, energy and ability to take on more responsibility for their recovery. This approach is also likely to improve study recruitment as guaranteed continuity of clinical care would not be needed. A longer period of use with a matching follow up interval would also be required to consider habituation and sustainability (Harrison et al., 2018).

13.3 Conclusion

This chapter has discussed the results of the pilot RCT and concludes that the results support the feasibility of a future multi-centre randomised controlled trial of the WAVES intervention. Over half of the prompts delivered led to an increase in impaired arm activity and use of the arm in daily activities. Both these increases continued for the intervention group even after the wristbands had been removed indicating that the WAVES intervention may have the potential to support the transition of newly acquired motor skills back into daily activities.

The next chapter summarises this thesis and discusses the application of the WAVES intervention during future research.

Chapter 14. Discussion

14.1 Summary of thesis findings

Frequent practice of functionally orientated upper limb movements has the potential to improve recovery after stroke (Pollock et al., 2014) but current evidence based approaches rely upon an increase in direct contact therapy time which can be difficult to provide (Kwakkel et al., 2015). This thesis has described the development and clinical application of a self-directed intervention (the WAVES intervention) using feedback from a novel form of technology to increase functional use of the impaired arm after stroke.

The Medical Research Council (MRC) framework for the development and evaluation of complex interventions was used to guide the process. Part 1, explored the current evidence base and theories around arm recovery after stroke. The systematic review of self-directed interventions in Chapter 2 reviewed evidence supportive of stroke survivors being able to engage in high levels of independent therapy practice outside of formal therapy sessions over a sustained period of time. The greatest benefits were shown for interventions involving the practice of functional tasks. The use of technology, whilst beneficial for arm impairment, was less beneficial for improving functional use of the arm in daily tasks except in the case of constraint induced movement therapy where restraining the unimpaired arm with a mitt was found to benefit both arm function and arm use. The WAVES intervention was developed based on these findings and established behaviour change theory before being further refined in preparation for the pilot RCT described in Section 3.

The principal findings of the RCT indicated that a self-directed intervention using the WAVES technology to prompt arm movement was acceptable to stroke patients in the first three months after a stroke and that a multi-centre parallel group RCT of the intervention would be feasible with modifications to improve recruitment.

Changes in arm use and arm function were greater for the intervention group and continued to improve past the study intervention phase. This was a good indication that the intervention had the potential to increase impaired arm use in daily activities and warrants further evaluation as an acceptable approach to positively change behaviour during stroke rehabilitation.

Setting activity parameters based on historic activity data and providing feedback to support attainment of these parameters is a new concept. The variability in how individuals responded to the intervention presented in Chapter 12 highlighted a number of further areas that could be explored to help better understand the trajectory of arm recovery after stroke. Programmable accelerometers enable accurate recording of activity and devices like the CueS wristband may offer an alternative method of prescribing dose as a percentage of previous activity rather than a unit of time spent on task or a number repetitions. The individualised prompting schedule that the WAVES technology offers also allows for optimal training therapy schedules to be tailored around the individual's daily routine thus encouraging normal use of the impaired arm.

14.2 Technology and self-directed interventions

Technology is being increasingly utilised in stroke rehabilitation to support practice outside of therapy sessions to enhance the dose of therapy (Farmer et al., 2014), and use positive feedback to encourage behaviour change and promote self-efficacy. Qualitative studies indicate that patients and therapists understand the need to enhance rehabilitation through self-directed practice and are keen to consider the use of technology to support this (Demain et al., 2013). The review in Chapter 2 supported that stroke survivors did indeed engage and adhere well to self-directed practice both with and without the use of technology. The review indicated that some self-directed interventions, particularly those using interactive gaming and robotic devices, were less popular with patients as they lacked relevance and did not translate well to functional activities.

A recent review of assistive technologies for arm recovery after stroke restricted the definition of technologies to those that were either a “mechanical or electrical device used in a functional task-oriented training session” (Farmer et al., 2014). Studies included robotics, transcranial magnetic stimulation, electrical stimulation, biofeedback, virtual reality, stochastic resonance and constraint induced movement therapy. The review, which was not restricted to self-directed modes of delivery, supported the findings in Chapter 2 that patients continue to benefit from treatment late after stroke although greater benefits were found when treatment started early after stroke. The effect size when starting treatment in the first 6 weeks post-stroke ranged between -0.14 to 2.43 compared with -0.39 to 0.88 in the chronic phase (Farmer et al., 2014). The exception to this was high-intensity CIMT which resulted in less improvement in motor function than standard CIMT or traditional therapy (Dromerick et al., 2009). The review concluded that whilst assistive technology can assist in improving recovery of the arm the benefits were small compared to routine treatments and rarely translated to functional improvements or increased activity at the participation level (Farmer et al., 2014).

This dissonance between the functional capability of the affected arm and how much the person actual uses the arm in daily activities is an area that is starting to gain more attention (Doman et al., 2016, Rand and Eng, 2012, Waddell et al., 2017, Waddell et al., 2019). As motor recovery requires the restoration of motor movements, upper limb interventions tend to focus on reducing impairments at the body functions and structure level and improving the person’s ability to execute an activity (World Health Organisation, 2002). There is an overall assumption that this will lead to improvements in participation (i.e. using the arm outside of the clinic setting) (Waddell et al., 2019). However, success is often measured with outcomes designed to measure impairment or functional capacity of the arm – not performance. Self-rated assessments such as the Motor Activity Log have been useful in capturing patients perceptions of how much they use their arm outside of the clinic setting although they are limited in how much information they provide, relying on good recall and awareness of impaired arm use and being prone to bias.

A number of interesting observations were made in Chapter 2 between the types of technology used in self-directed interventions and the manner in which they were used. Technology had often been developed to address an impairment based problem or need. For example, electrical stimulation to stimulate a muscle contraction or robotic devices to mechanically move the arm. Whilst these approaches have been found to be effective and can achieve high levels of precise repetitions without direct therapist supervision (Demain et al., 2013), the gains made from these devices in training single specific joint movements as opposed to more complex movements, have not been found to translate well into everyday tasks (Timmermans et al., 2009, Rodgers et al., 2019). The WAVES technology differed to these technologies in its focus on targeting sustained behaviour change for greater participation .i.e. use of the arm in real world settings, with changes to impairment or activity limitation being secondary outcomes. As different patients have different impairments, to achieve this aim the WAVES technology allowed a 'dose' of intervention to be determined by setting targets of activity across each day based on past performance rather than a given number of repetitions or time spent on task.

In Chapter 2, the interventions found to be most useful in supporting self-directed practice were electrical stimulation and CIMT. Whilst electrical stimulation was noted to benefit arm function, again these did not translate well into actual use of the arm in daily activities (Da-Silva et al., 2018). Indeed, the only form of technology that benefitted both arm function and arm use was the mitt used in constraint induced movement therapy interventions. It could be argued that the mitt differed from the other forms of technology in that it took a more behavioural approach by restricting use of the unimpaired arm in order to *force* impaired arm use, rather than *assisting* impaired arm movements. In many ways the therapy aspect of CIMT was more akin to those in the 'no technology' group in that the therapy practice involved repetitive task practice of functionally orientated tasks. However, despite evidence to support CIMT, there are several barriers to its implementation and generalizability as discussed in Chapter 3. The WAVES intervention addressed these barriers by widening the criteria so that it could be used by a wider cohort of stroke survivor including those who are immobile and with severe arm impairment. It was delivered as a self-directed intervention thus encouraging routine behaviour change and reducing the amount of face-to-face contact with a therapist considerably from six

hours a day for five days over two weeks to just one session twice weekly over four weeks; participants were actively involved in developing their treatment plans and fitting therapy practise in around their daily routines negating the need to fit in additional therapy sessions; the CueS wristband replaced the mitt making it more acceptable to participants and enabling them to practise activities that require both hands.

Similar to the transfer package in CIMT, it supported active involvement of the impaired arm through the integration of therapeutic practice of activities into daily routines. The accurate feedback on impaired arm activity across different times of the day provided by the WAVES interface, allowed therapists to target their advice on what to practice and when. For example, if activity was low due to the wearer spending long periods of time in front of the television, they might suggest using the stroke hand to eat finger foods, drink from a cup, use TV controls whilst watching TV. This had the potential of creating habit forming behaviours for example through building associations with the act of sitting watching TV and using the impaired arm. It also opened up opportunities for conversations about when activity levels were highest or lowest in order to monitor if this was an appropriate change in activity e.g. a drop in activity when resting or due to forgetting to use the arm.

The strength of the WAVES technology therefore appears to be the ‘live’ use of feedback to promote arm use and integration of the impaired arm into daily routines. The prompting mechanism provided a schedule of frequent bursts of therapy practice and the opportunity to generalise skills to a variety of tasks and situations which would be expected to support motor learning (Krakauer, 2006). Improvements in impairment and function may have been a secondary outcome of the intervention due to the increase in the amount of arm use. However considering that participants were still early after stroke, spontaneous recovery and usual care therapy will also have contributed to this.

14.3 Accelerometers to provide feedback within rehabilitation

Prior to the start of this project, there appeared to be a lack of any clinical trials using wristband accelerometers to support arm rehabilitation after stroke (Noorkoiv et al., 2014). Emerging research indicates that wearable devices are becoming recognized as a means of not only monitoring activity but also providing feedback to the wearer (Lawrie et al., 2018, Wang et al., 2017). There has been a recent surge in the use of commercially available activity trackers to support and deliver feedback on physical activity and other health needs to the wearer (Lynch et al., 2018). These devices, however, have been designed for a normal healthy population and are not appropriate for use with stroke patients. Despite a growth in the literature on wearable devices to support rehabilitation, very few of these have been clinically evaluated with most articles reporting on technical and usability evaluation in place of clinical outcomes (Wang et al., 2017). The lack of literature available regarding the use of accelerometers to provide feedback to stroke patients highlights the novelty of the WAVES intervention.

Since the review by Noorkoiv (Noorkoiv et al., 2014) two studies have reported on the use of accelerometers to provide activity feedback to stroke patients although one of these was measuring general activity rather than arm activity (Lawrie et al., 2018, Whitford et al., 2018). A third study reported on the use of a wrist-band actometer to deliver vibro-tactile cueing to reduce unilateral neglect (Fong et al., 2013). Further details on these studies were outlined in Chapter 1 and in this chapter they will be discussed in relation to how they compare to the WAVES intervention.

There was high compliance from participants to wear the CueS wristband which supports the findings of the studies by Whitford et al and Fong et al (Fong et al., 2013, Whitford et al., 2018) but had not been found in the study by Lawrie et al using a smartwatch (Lawrie et al., 2018). The use of a smartwatch with visual display on the watch face to indicate arm activity, had a high drop-out rate of 22% and reported the need for frequent reminders from staff to wear the watch. As discussed in Chapter 2, patients engage and adhere more effectively to therapy programmes when they are involved in meaningful practice. A strength of the WAVES study was

the involvement of patients and carers at the design stage of developing the WAVES technology and the use of multi-modal feedback to support and enhance a therapy programme that was tailored around patient goals and daily routines. There is no indication that participants in the smartwatch study were given any guidance on how to increase their activity (Dong et al., 2018) and so the lack of relevance required to motivate participants to fully engage with the programme may have been a factor.

In contrast to providing minimal guidance on methods to increase activity, in the study by Fong et al on cueing to reduce unilateral neglect, participants were told to carry out specified arm movements when cued and to move their arms as much as possible during the wearing period (Fong et al., 2013). Despite the intervention being intended for unilateral neglect, the intervention group showed a statistically significant improvement in hand movements (Fong et al., 2013). Even though only one arm movement was given to participants, the overall number of repetitions generated over the 3 hour period (5 repetitions every 5 minutes) appears to have been sufficient to elicit a change.

The study by Whitford et al followed a similar behavioural approach to the WAVES study in their use of visual activity reports (Whitford et al., 2018). These were carried out twice a week to raise awareness on arm use and to encourage the participants to reflect and evaluate for themselves ways to increase use of the impaired arm. The main difference to the WAVES study was that the feedback consisted of different types of scientific graphs containing a lot of information on the amount of use of each arm, the amount of two-hand use, the intensity of activity and progress. Feedback from stroke survivors in designing the WAVES interface indicated that stroke survivors would struggle to understand this format of data and that too much information would be confusing. To support understanding and reinforce the feedback, questions were asked and a ‘teach back’ approach used in the Whitford study but it is unclear how successful this method was. Participants’ views generally on wearing the accelerometers were similar to those reported by the WAVES participants with an overall impression that they found the feedback useful and motivating. There was a keenness to have feedback every day to enable a better understanding of how to improve. However this was reported as participants wanting

to know “how fast they would need to move to improve the graphs” rather than how to increase use of the arm in daily activities in order to improve function (Whitford et al., 2018). This finding implies that potentially participants had not fully understood the purpose of the feedback.

The common theme throughout the studies discussed above and the WAVES intervention was the delivery of feedback to enhance activity without the need for additional therapy input. The type of feedback differed between studies with those receiving vibro-tactile cues seeming to do better than those relying on visual feedback alone. Participants however, did report they liked the visual feedback and appreciated having the opportunity to look back over historic data.

A protocol paper recently published of an ongoing multi-centre randomized controlled trial (Held et al., 2018) described a very similar intervention and study design to the WAVES study. The intervention involves a wrist worn tracking device (ARYS-me) with a built-in accelerometer which, like the CueS wristband, delivers a vibro-tactile prompt to patients when activity falls below a set threshold. The technology uses Bluetooth to download activity to a smartphone application so that participants can view their progress at any time. Gamification of the activity data illustrates progress on a ‘Tree of Recovery’ and rewards activity with ‘diamonds’ to be used to grow the tree.

Unlike the CueS wristbands which have a target matched to the same time of the previous days, the ARYS device has a linear target calculated across the whole day (between 8am and 10pm) and assumes a steady amount of arm activity across this period of time. This could be problematic as stroke survivors typically are more active between the hours of 10am and 1pm and show a steady decline in activity as the day progresses (Tieges et al., 2015). This could mean that participants hit their activity targets too early in the day to benefit from the prompting mechanism which was something that was considered and avoided during the development of the CueS wristband. The mode of delivery of this intervention is moving more towards supported self-management with only one set-up session and a weekly phone-call, in

comparison to the WAVES intervention where there was greater therapist support. It will be interesting to determine if stroke patients need more support with this type of device, or if it can be more self-managed.

14.4 The WAVES technology

Over the course of the development phase the WAVES intervention evolved from being a complex intervention to prompt repetitive functional task practice exercises to one that could support any therapy programme with an emphasis on integrating arm exercises and practice into functional tasks. The individual components of the intervention and how they map onto behaviour change concepts are described in the MRC Framework logic model Figure 7.2 and Table 3.1.

That both groups improved during the study intervention phase, is perhaps a reflection of the timing of the intervention (early after stroke when spontaneous neurological changes are occurring) and an indication that self-directed practice of functional activities in itself was beneficial. However, only those receiving personalised feedback from the WAVES technology continued to improve indicating a potential benefit from the intervention.

Whilst personalised feedback from both the CueS wristband and corresponding interface allowed the intervention to be tailored to each participant's abilities, the relative value of each of these mechanisms of feedback is unclear and will now be discussed.

14.4.1 Tailoring the feedback

The prompting schedule of WAVES was based on participants agreeing how frequently they were willing to be prompted and how much to increase the activity threshold based on historic data of the wearer. Unlike other studies that used a fixed threshold increase (Held et al., 2018, Lawrie et al., 2018), participants had a choice

of four prompt thresholds settings of 0%, 5%, 10% or 20%. Participants in the pilot RCT did not make many adjustments to the settings showing a strong preference for a 10% increase with hourly prompting. This was one of the higher settings and consequently produced regular prompting for most participants. Whilst having a choice of settings may be useful for some patients, this work demonstrates that a fixed 10% increase would be acceptable and preferable to the lower threshold of 3% and 5% used by other devices (Held et al., 2018, Lawrie et al., 2018). A CueS device with a fixed setting would reduce the complexity of the mechanism making it less costly to develop and more straightforward for patients to use independently of a therapist.

The timing and delivery of feedback from the wristband and interface differed considerably. For example prompting from the wristband was delivered hourly and enabled monitoring of activity at any time via the LED lights, while the interface could only be viewed twice a week. Previous studies using concurrent vibro-tactile feedback, indicate that this may be more effective but a better understanding of the benefits of each of these would enable further development of the technology to support self-directed arm therapy practice.

14.4.2 Is integration more important than dose?

A unique characteristic of the WAVES intervention was the interaction between the prompting mechanism and increasing impaired arm use integrated into a normal routine. The topic of ‘dose’ has dominated stroke rehabilitation journals over recent years with a general consensus that more therapy practice is better (French et al., 2016, Kwakkel, 2006, Pollock et al., 2014) but with no actual agreement about how much is considered to be optimal and concerns that high doses early after stroke could lead to worse outcomes (Bernhardt et al., 2016, Dromerick et al., 2009). As dose tends to be measured by either the number of repetitions or the amount of time spent on task (Kwakkel, 2006) studies examining the effects of dose tend to involve sessions of massed practice (Han et al., 2013, Lang et al., 2016, Winstein et al., 2016). However, these results often contradict each other for example the recommendation of more than 17 hours therapy practice (French et al., 2016) was negated in a study by Han and colleagues where 20 hours was found to have no effect whilst 30 and 60 hours did. The increase in this study consisted of extending

the period of training time from one hour a day, five-days a week across two weeks to the same amount across three and five weeks. Other studies such as some of the modified forms of CIMT have adjusted the daily amount of time spent training for example reducing training time from 6 hours to 3 hours a day and found that this reduction in training produced similar results (Corbetta et al., 2015).

High intensity CIMT (three hours per day) early after stroke was found to result in worse outcomes at three months than standard CIMT or usual care (Dromerick et al., 2009) whilst one hour per day (sometimes split into two thirty minute sessions) has been found to be beneficial (Kwakkel et al., 2016). Possible explanations were that the higher dose of practice interfered with neuroplasticity causing enlargement of the lesion or excitotoxicity (Dromerick et al., 2009). However there was no evidence to support these explanations leaving the authors to consider if the outcomes were in fact a result of a different training schedule (Dromerick et al., 2009). Krakauer proposed the benefits of having frequent blocks of practice broken up with longer rest periods (distributed practice) over massed or 'blocked' practice (Krakauer, 2006). The increased time spent in practice therefore for the high intensity CIMT group may have resulted in fewer rest periods at a time when the brain was vulnerable to change.

A similar effect was found when patients were given an enhanced dose of out-of-bed mobilisation activity early after stroke (Bernhardt et al., 2016). Dose response analysis from this study found that increasing the *amount* of time-out-of-bed resulted in less favourable odds of a positive outcome whilst increasing the *frequency* of time-out-bed significantly improved the odds.

The results found in the WAVES pilot RCT support these emerging ideas around delivering frequent, shorter bouts of therapy practice. The prompting mechanism of the CueS wristband encourages regular integration of impaired arm practice into daily routines and in doing so creates a therapy schedule that prompts frequent practice of relevant functional activities. It is perhaps unfortunate that the methods used to create the count per minute value didn't allow for a summed number of active minutes per day. This would have enabled some comparison of dose between other

studies, however, the ‘dose’ of the WAVES intervention was based on a percentage increase of previous activity spread across a twelve hour period. Future research could investigate dose as a number of bouts of activity distributed across the day and consider the ideal length and frequency of each bout of practice needed and optimal periods of rest between practice (Krakauer, 2006). However, future research also needs to examine the circumstances under which greater positive change in behaviour and self-efficacy for upper limb rehabilitation can be achieved, with application of theoretical frameworks to maximize longer term impact,

14.5 Limitations of the intervention

There were a number of limitations of the intervention which warrant further discussion.

It is important to acknowledge that whilst we know from the accelerometers how active the impaired arm was, we don’t know what they were actually doing to increase activity. Although all activities were recorded we only requested the number of different activities practiced each day to be reported back to the study centre. As such we are unclear about what these activities consisted of, how frequently they were practiced or what was recorded on the lists of daily activities. It was also unclear how much the therapists were supporting participants and if an unconscious therapy bias could have influenced the results. The control group reported practicing more activities than the intervention group which could be as a result of the therapists giving them more exercises to practice or it could have resulted from the randomisation groups behaving differently. For example, the intervention group may have paid less attention to the activity list and focused more on practicing activities when prompted by the wristband whilst the control group may have set aside a block of time each day to practice all activities on their list.

14.5.1 Activity units

The decision to convert the accelerometer data into a 'count' value came from initial concerns that the data would lack clinical meaning to patients, therapists and even researchers who were unfamiliar with the field of accelerometry. The interface had been designed to illustrate peaks and troughs in activity levels across the day which were simple enough for therapists and patients to understand. The difficulty then was being able to convey what the data outcomes meant in terms of measuring change. Converting the data into a 'count' value had been used before as a more acceptable approach but may lead to blunting of any signal within the data (Hayward et al., 2016).

Comparing accelerometer data between studies, can be difficult due to different brands of accelerometers being used each with their own processes to generate activity counts (Hayward et al., 2016). Actigraph is one of the most commonly used accelerometers in stroke research (Hayward et al., 2016) and so a process to convert Axivity data from the CueS into Actigraph equivalent counts was used (Brond et al., 2017). It was hoped that using this method would enable comparison between the WAVES data and that of other studies. In converting the data into counts however, the raw data which had been collected in 1 second epochs were summed into 1 minute epochs. Epoch length has been found to affect results of activity in free-living environments (Arya et al., 2012) and whilst a one minute epoch made analysing the data more manageable, some precision may have been lost. For example, non-active time was defined if there was value of zero counts in a minute. If only a few seconds of movement were recorded it would therefore indicate that the arm had been active for the whole of that minute even though there was more time spent inactive. It was not possible therefore to compare the amount of time that participants moved their arms with other studies.

Despite the conversion to counts, it can still be difficult to understand fully what the data means. There is an assumption that an increase in CPM will reflect improvement in arm function, and this may be the case if the arm is being used more frequently. However, improvements could occur due to a number of factors such as: an increase in range of movement; speed of movements and opportunity to use the

hand, all of which may be reflected differently in the accelerometer data. For example, as movements improve they may become smaller or more refined which could result in a lower CPM demonstrating improvement, however movements may also be quicker resulting in a potential increase in CPM. In the absence of any 'normative' stroke data for comparison, the use of clinical outcomes continue to be a necessity for reporting effects on arm use. Application of the accelerometer data may be more useful in defining the prompting algorithms.

14.5.2 Unilateral or bilateral activity monitoring

As participants only wore an accelerometer on their impaired arm it is unclear how much the data reflects changes in impaired arm movement over more general movements such as arm swing when walking. Previous investigators have measured change in the ratio of use between the impaired and unimpaired arms with bilateral accelerometers but there is no standardisation of data collection and interpretation (Hayward et al., 2016, Uswatte et al., 2006a). In addition, due to the pragmatic and self-directed nature of the intervention, the WAVES technology was designed to be as user friendly as possible. Consultation with stroke survivors had indicated that wearing two devices over a four week period would be cumbersome and pose particular difficulties around using the impaired arm to don the wristband. This was likely to impact on compliance to wearing the wristbands. Based upon previous studies, we assumed that due to the sedentary nature of stroke patients, diurnal walking activity would only change gradually thus limiting contamination of the data by walking (Tieges et al., 2015), and that gains in mobility would be likely to reflect increasing opportunities for arm use (Kwakkel et al., 1999).

14.6 Future research

The WAVES pilot RCT and earlier studies support the use of 'live' feedback from wristband accelerometers to encourage self-directed activity (Da-Silva et al., 2019, Fong et al., 2013, Lawrie et al., 2018, Whitford et al., 2018). From the limited data available, stroke patients appear to respond better to vibro-tactile feedback although there may be additional benefits of providing visual data reports. Patients have been found to respond well to self-directed therapy practice and as the WAVES intervention has evolved away slightly from supporting a prescribed therapy

programme to supporting patients at the participation level, there may be less need to have therapist oversight. The evaluation of feedback delivered by the ARYS-Me wristband described above is expected to be completed later this year and should provide further insight into how well stroke survivors manage using the phone app and without the support of regular therapy reviews.

It is recommended that future studies include additional activity recordings, such as accelerometer data from the unimpaired arm and/or leg, to confirm the relationship between prompts, functional arm use and walking. For example, a wristband worn on both wrists at least during baseline and outcome assessment periods in order to measure change in the ration of use of both arms.

A comparison between the provision of vibro-tactile prompts only, visual data reports only and a combination of both would be useful to better understand the mechanism of the WAVES technology.

14.7 Conclusion

This thesis aimed to develop and investigate a self-directed intervention using live feedback to promote functional use of the impaired arm after stroke. The results from the pilot RCT support the feasibility of a future multi-site RCT and indicate that there may be a sustained benefit of the intervention supporting integration of impaired arm use back into normal daily activities. The mechanism behind the feedback and implications for long-term behaviour change remain unclear and indicate a need to reconsider how we provide effective doses of therapy for the upper limb after stroke.

Appendices

Appendix A.Timeline of project processes undertaken

		Timescale
Pre-project phase: planning development process and applying for funding 1. Literature review of accelerometer measurement of upper limb use after stroke 2. Establishment of project team and applicants 3. Development of project protocol detailing processes to be undertaken 4. Recruitment of research therapist (this author) to develop new therapy intervention and co-ordinate study.	Study applicants	Jan 14 to Dec 15
Phase A: User-centred design process of wristband accelerometer with feedback functions and data report interface 3 Design Workshops University ethics approval Workshop design Recruit patients and clinicians for workshops Carry out 1st and 2nd set of workshops Design software interface 3rd and final workshop with patients / clinicians	CSD CSD CSD RDS CSD / RDS CSD CSD	Jan 15 to Jun 15
Phase B: Development and testing of Stroke-specific therapeutic protocol 1. Develop Therapy Intervention Literature review	RDS RDS	Jan 2015 to Mar 2015

Develop therapy programme	RDS	
Write protocol	RDS	
Write manual for therapist to deliver programme	RDS	
Develop documents to record therapy received	RDS	
Develop training package for site therapists	RDS	
2. Contact x2 sites to take required for part in study	RDS	Mar 2015 Apr 2015
3. Prepare documents required for REC 4. NHS ethics and R&D approval for chosen sites	RDS/CP	Apr/May 2015
5. Carry out training sessions with site therapists	RDS	Jun 2015 - Feb 2016
6. Study therapist to carry out therapy programme with x12 participants	RDS	
7. Ongoing refinement of CueS data analysis and interface	CSD	
8. Patient interviews by qualitative researcher	CSD	
9. Systematic review of self-directed therapy programmes for arm rehabilitation	RDS	Jan 2016 to Jun 2017
Phase C: Refinement of Baseline thresholds, data report interface and study materials		
Initial thresholds set for subgroups	CSD	Oct 15 to Jan 16
CueS and computer interface finalised	CSD	
Supply of CueS and computers	CSD	Jan 16 to May 16
Final analysis of combined data from Phase B	RDS	
Final version of outcome assessments	RDS	
Acquisition of assessment tools	RDS	
Phase D: Pilot randomised controlled trial of the intervention		
1. Adapt study protocol for pilot RCT		
Development of manual and study materials for NHS therapists	RDS	Jan 2016 to Apr 2016
Data analysis programme	RDS / CP	

2. Ethics application, site set-up and staff training		
Contact CTOs and therapists of x4 study sites	RDS	Jan 2016 to Mar 2016
NHS ethics and R&D approval for chosen sites	RDS	
Training sessions for therapists	RDS	Apr to Sep 2016
Development of web-based data entry tool	RDS	
Training sessions for therapists	RDS	
Adverse event reporting set up	RDS	
3. NHS therapists to carry out programme with x60 participants	NHS/RDS	May 2016 to Sep 2017
4 week re-assessments	CTN	
8 week re-assessments	CTN	
4. Analysis of data and write up results	RDS / CP	Sep 2017 to Sep 2018
Key: RDS Ruth Da Silva (this author); CP Chris Price (main applicant); CSD Computer science department; NHS (National Health Service therapists); CTN Clinical Trails Network staff based at NHS sites.		

Appendix B. Medline Search Terms

1. Stroke/rh, th [Rehabilitation, Therapy]
2. exp upper extremity/ or exp arm/ or exp axilla/ or exp elbow/ or exp forearm/ or exp hand/ or exp shoulder/
3. 1 and 2
4. self-administer*.mp.
5. self-care.mp.
6. self-direct*.mp.
7. self-manag*.mp.
8. self-supervised.mp.
9. home-based.mp.
10. thera*.mp.
11. practise.mp.
12. extra.mp.
13. supplement*.mp.
14. enhanced.mp.
15. physical therapy.mp.
16. physiotherapy.mp.
17. exercise therapy.mp.
18. occupational therapy.mp.
19. 4 or 5 or 6 or 7 or 8 or 9 or 11 or 12 or 13 or 14
20. 10 or 15 or 16 or 17 or 18
21. 3 and 19 and 20

Appendix C. TiDier checklist

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.		
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		

TIDieR checklist

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.		
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.		

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

Appendix D. Prompted Activities List

DP-WAVES Study	Participant Number ☐ ☐ ☐	Date: _____

PROMPTED ACTIVITIES LIST

One of the best ways to ensure the therapy programme is effective and really works for you is by planning and choosing the right sort of activities to practice when you get a prompt.

Use this form to make a list of some of the activities you could carry out using your arm throughout the course of the day. If the CueS wristband senses that you have not moved your arm as much as on previous days, it will gently vibrate to remind you to do one of these activities if you can. This will be in addition to the 2 recovery activities set with your therapist.

By planning the things you will practice before you start the programme you will feel more in control of the effort you are putting into your rehabilitation. You have the choice to move onto another activity as you wish.

Remember: you don't *have* to do an activity when prompted by the CueS wristband.

Take some time to think about the sort of things you would be willing to try to do with your arm when prompted by the CueS wristband. It may help to think through your normal weekly routine, hour by hour.

e.g. with my arm I would like to try to practice

- turning the pages of the newspaper over
- drying up the plates
- feeding myself toast
- holding an apple while I eat it
- stroking the dog

When prompted to use my arm I would like to practise:	
A	
B	
C	
D	
E	
F	
G	
H	

Appendix E. Forms and Materials required

DP-WAVES Programme Planner

(for use by study therapist)

The following forms and equipment will be required to ensure that the initial therapy assessment session runs smoothly:

Forms and equipment needed for initial assessment and generation of an individualised programme	Tick
Patient information sheet	
Study Consent Form	
Baseline Assessment Form	
Therapy File - Initial Therapy Session Recording Form - Recovery Activity List - Recovery Activity sheets	
Patient Handbook File (patients) - Patient handbook - Daily Log Sheets - Prompted Activities List - Appointment Record Sheet	
Equipment - ARAT kit - Cues Wristbands	

The following forms and equipment will be required to ensure that the therapy review sessions runs smoothly:

Forms and equipment needed for therapy review sessions	Tick
Laptop / tablet	
Therapy File - Therapy review forms - Recovery Activity List - Recovery Activity sheets	

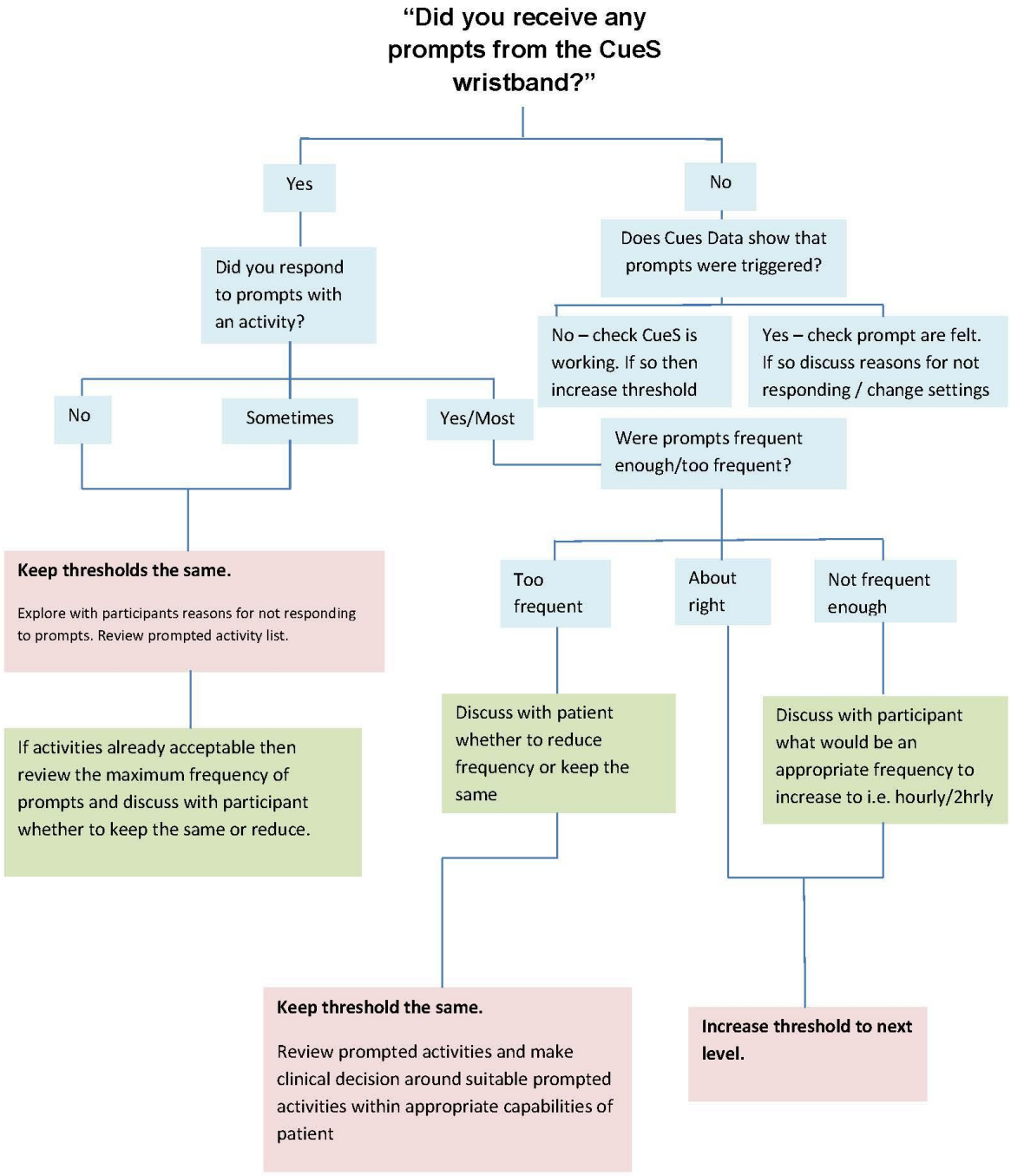
DP-WAVES Programme Planner

(for use by study therapist)

The following forms and equipment will be required to ensure that the final therapy review session runs smoothly:

Forms and equipment needed for final therapy review	Tick
Laptop / tablet	
Therapy File - Therapy final review form - Recovery Activity List - Recovery Activity sheets - 4 week assessment forms	
Equipment Needed - ARAT kit	

Appendix F. Prompt decision tree



Appendix G. Daily Log of prompted activity with alphabet wheel

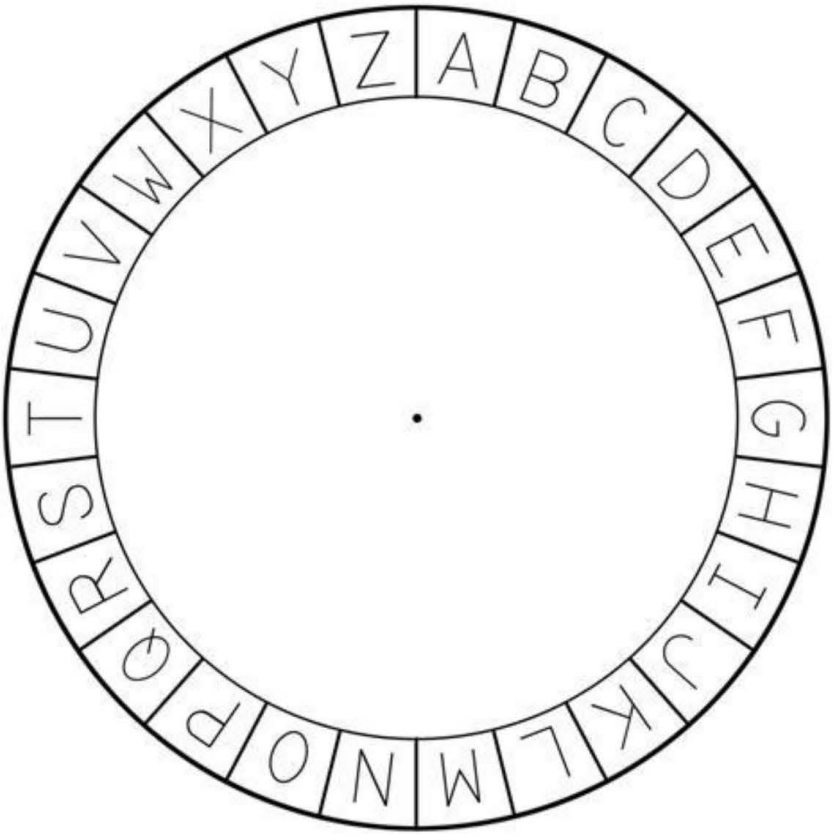
DP-WAVES Study	Participant Number ☐ ☐ ☐	Date: _____

Record of Prompted Activities

With the therapist, use your Prompted Activities sheet to generate ideas around possible activities you could carry out when prompted by the CueS wristband. Cross out or circle the letter which corresponds with the activity you practised.

Remember: you don't *have* to do an activity when prompted by the CueS and you don't need to *wait* for the prompt before practising an activity.

Today I practised the following activities:



Appendix H. Repetitive task practice log sheet

DP-WAVES Study	Participant Number ☐☐☐	Date: _____

Daily Log Sheet

With the help of your therapist choose two recovery activities from the handbook. Try to practise each activity up to 20 times twice a day and record below how many you manage.

Activity One is: _____

_____

Activity Card Number: ☐☐:☐☐ (for optional activities code: OA plus number)

Please indicate the number of repetitions of activity completed (to the nearest amount):

Morning: 5 ☐ 10 ☐ 15 ☐ 20 ☐

Afternoon: 5 ☐ 10 ☐ 15 ☐ 20 ☐

Approximate time of activity	Morning: Afternoon:	None done today ☐
Comments regarding the activity		

Activity Two is: _____

_____

Activity Card Number: ☐☐:☐☐

Please indicate the number of repetitions of activity completed:

Morning: 5 ☐ 10 ☐ 15 ☐ 20 ☐

Afternoon: 5 ☐ 10 ☐ 15 ☐ 20 ☐

Approximate time of activity	Morning: Afternoon:	None done today ☐
Comments regarding the activity		

Appendix I. Programme planner

DP-WAVES Programme Planner

(for use by study therapist)

1. Participant initial assessment and generation of an individualised therapy programme The first therapy session will take approximately 90 minutes.	Tick & Date
1) Completion of the consent process ➢ Appointment made by CTO for study therapist to come and explain therapy programme in detail including exactly what a participant would be required to do if agreeing to take part in the programme. ➢ Answer any questions a potential participant has about the study or programme. ➢ Obtain written consent on the study consent form.	
2) Upper limb assessment and goal setting ➢ study therapist completes Baseline Assessment ➢ A discussion will then take place regarding upper limb rehabilitation needs. ➢ The study therapist will assist the participant to select two needs that are most important to them and set a realistic functional goal for each which can be potentially achieved within the four week therapy programme.	
3) Provision and explanation of CueS wristband ➢ The study therapist will provide the participant with a CueS wristband for each wrist and ensure that the participant can manage to put it on and off. ➢ Participants will be informed to wear the wristband from waking up until going to bed at night but that it can be removed overnight.	
4) Selection and demonstration of recovery activities ➢ The study therapist will select an appropriate 'recovery activity' for each functional goal from the 'recovery activity' list ➢ The study therapist will explain and demonstrate the selected activities to ensure they are a suitable choice and that the participant will be able to practise independently. ➢ Study therapist will video record participant practising chosen activities	
5) Advise on how to carry out the recovery activities: ➢ The study therapist will advise on: ○ twice daily activity practise for seven days each week for four weeks. ○ up to 20 repetitions of each activity at each session. ○ recovery activity practice in a seated position unless otherwise stated (for safety)	
6) Provision and explanation of the participant handbook ➢ Provide participant with a study participant handbook. ➢ Demonstrate how to use handbook and explain the sections on using the CueS wristband, stroke recovery and care of the upper limb which are included. ➢ Demonstrate how to record activity practise on the daily log sheets	
7) Arrange next appointment ➢ Arrange therapy review for 3-4 days time	

Appendix J. Recovery activities

Recovery activity list

A list of recovery activities has been created for each functional category of daily living (washing, dressing, eating/drinking and optional).

There are a wide range of activities available in each category which are ordered into three levels of ability. Ability levels are indicated by the activity code e.g. W1 is a level one washing activity and D3 would be a level 3 dressing activity.

Levels were generated based on the ARAT categories as detailed below and are used as a guide to select an appropriate activity for the study participant. For example, a level 1 activity is appropriate for a participant with severe upper limb functional impairment.

Level 1	Gross upper limb movement only required. No hand dexterity / grip available. Activities often involve simple gross movements or 'propping'/weight bearing through the **affected** side and completing the activity with the **unaffected** side.
Level 2	Return of some activity in shoulder / elbow / wrist. Minimal hand dexterity / grip required for some of the activities. The **affected** side is more actively involved in the activity / may complete a simple activity independently. Some activities are more complex and require more complex mental processing.
Level 3	Good return of shoulder / elbow / wrist activity and dexterity / grip. The **affected** side undertakes the activity independently or leads the activity if the activity is bimanual. Some activities are complex and require greater mental processing.

Please choose a recovery activity from the relevant category which works toward the goal set for the patient. Try to encourage the patient to think of goals related to different aspects of their daily routine. This will hopefully allow for practise throughout the course of the day.

Once the activity has been chosen, provide the patient with the relevant activity sheet for that activity and enter details onto the daily activity log sheet.

Make it clear on the activity log sheet if activity should be completed in sitting or standing and which hand should be involved in the activity.

Patients should be provided with 2 recovery activities to practise twice a day.

'Pick and Place' Activities

Pick and Place activities are graded from weight bearing through affected side to completing full activity with affected arm. They can be used within each category of washing, dressing or eating/drinking simply by changing the object. They work well with other activities within each subgroup e.g. pick and place sponge as pre-requisite for washing body parts. Any objects can be used to fit in with patient's individual goals.

P1:01 **Weight bear through affected side**
Sit in front of a table to complete this task. Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side. Move objects from one side of the table to the other.

P1:02 **Reach and Touch an Object**
Sit in front of a table to complete this task. Start with your hand resting on the table. Reach towards an object using the **affected** hand. Touch the object, then return to the start position.

P2:01 **Pick and Place Object using two hands**
Sit in front of a table to complete this task. Move objects from one side of the table to the other **using both hands together**.

P2:02 **Pick and Place Object using Affected Hand**
Sit in front of a table to complete this task. Move an object from one side of the table to the other using the **affected** hand.

P2:03 **Pick and Place Object at differing Heights**
Sit/stand next to two surfaces of different heights (for example a table and a bed side cabinet or kitchen cupboard and work top). Move an object from one surface to another using the **affected** hand (remain seated).

Suggested Pick and Place Objects

Washing
- Tooth brush
- Tooth paste
- Hair brush / comb
- Deodorant
- Wash bag

Dressing/Grooming
- Item of clothing (e.g. socks, top, trousers etc)
- Glasses
- Hearing aid

Pick up slippers from the floor and move to the opposite side of your feet.

Eating/drinking
- Coffee / tea cup (empty)
- Water glass or beaker (empty)
- Drinks bottle (empty)
- Bowl (empty)
- Plate (empty)
- Knife or fork
- Coffee / tea cup (half full)
- Water glass or beaker (half full)
- Drinks bottle (half full)
- Bowl (with food)
- Plate (with food)
- Knife or fork
- Plate (empty, lift and reach)
- Plate (with food, lift and reach)

Washing Activities

W1:01 **Touch or rub body part using the affected hand**

Wrist
Hand
Knee (right or left)
Chest (midline)
Chin
Mouth
Nose
Eye (right or left)
Face (right or left cheek)
Ear (right or left)
Shoulder (right or left)
Under arm
Back of waistband
Forehead
Head (top of)
Head (back of)
Ankle

W2:01 **Open affected hand (to allow for cleaning) touch with the unaffected hand.**

W2:02 **Pick and Place sponge/flannel/towel**

W3:01 **Wash body part using a sponge, flannel, tissue or towel**.

Wrist
Hand
Knee (right or left)
Chest (midline)
Chin
Mouth
Nose
Eye (right or left)
Face (right or left cheek)
Ear (right or left)
Shoulder (right or left)
Under arm
Back of waistband
Forehead
Head (top of)
Head (back of)
Ankle

Washing Activities

W1.03 <u>Remove and replace item from washbag</u>
Hold / support the wash bag with the **affected/ unaffected** hand and take objects out / put them back inside using the other hand. Lifting one object out of the wash bag and placing it on to the table = 1 repetition. Picking one object up off the table and placing one object back into the wash bag = 1 repetition.

W1.04 Hold / support the wash bag with the **affected/ unaffected** hand – fasten then Unfasten the wash bag = 1 repetition.

W2.03 <u>Hold and position deodorant</u>
Pick up the deodorant with the **affected/ unaffected** hand and position under the opposite arm. Return the deodorant back to the table = 1 repetition.

W2.04 Ring out wash cloth / flannel **using both hands**, and then place back on the table = 1 repetition.

W2.05 Hold the deodorant with **affected/unaffected** hand and take the lid off / replace with the opposite hand. Taking the lid off the deodorant then replacing the lid = 1 repetition.

W2.06 Hold the shampoo bottle with the **affected/unaffected** hand and take the lid off / put It back on with the **opposite** hand = 1 repetition.

W2.07 Hold a tube of toothpaste with the **affected/unaffected** hand and take the lid off / put It back on with **unaffected/affected** hand = 1 repetition.

Dressing / Grooming Activities

D1:01 **Adjust item of clothing (whilst wearing it).**
Prop / weight bear through the **affected** side and complete the activity with the **unaffected** side:

Adjust top
Adjust glasses
Adjust hearing aid
Adjust collar
Adjust slipper
Adjust waistband

D2:01 **Adjust item of clothing (whilst wearing it) using both hands**.
Please select the appropriate object from the following list to practice the activity:

Adjust top
Adjust glasses
Adjust hearing aid
Adjust collar
Adjust slipper
Adjust waistband

D2:02 **Touch the following with the objects listed (use the affected hand to complete the activity):**

Ear (hearing aid)
Face (glasses)
Top of Head (hair brush / comb)
Back of head (hair brush / comb)
Brush hair (using both hands)

D2:03 **Put on the following item then take it off (practise part of this activity which is most appropriate to the participant).**

Top
Glasses
Hearing aid
Slippers
Trousers
Skirt

D3:01 Fasten then unfasten clothing using both hands = 2 repetitions.

D3:02 Brush hair using the **affected** hand

D3:03 Pull sleeve of **unaffected** side down using **affected** hand, then push the sleeve up again = 2 repetitions

Eating and Drinking Activities

Hand to Mouth Activities:

F2:01 Use both hand to bring cup/ fork or spoon to mouth and touch lips

F2:02 Use affected hand to bring cup/fork or spoon to mouth and touch lips

Adjust amount of liquid in cup or food on fork/spoon

Bimanual activities:

F1.03 Sit in front of a table to complete this task. Prop / weight bear through the **affected** side or hold cup with affected hand and complete the activity with the **unaffected** side. Perform stirring motion with **unaffected** side (no fluid inside cup).

F2.03 Support beaker with **affected/unaffected** hand and pour water into it from a Jug/ other cup held in opposite hand.

F3.01 Support drink of coffee / tea with the **unaffected** hand and stir with **affected** hand.

F3.04 Pick up a knife and fork, hold in position and place back down on the table = 1 repetition

F3.05 Pick up a piece of food using a knife and fork and put it back down = 1 repetition.

F3.06 Cut up food (1 slice = 1 repetition

Other/Optional Activity List

The following activities are suggestions to assist with selection of an 'optional' activity to work towards the 'optional goal' selected.

An activity can be chosen from this list or a different activity can be practised to work towards the 'optional activity' goal.

Self care

1. Personal care

- Open **affected** hand / position to enable nail cutting
- Stand using the **affected** arm to stabilise (e.g. at the sink)
- Shave- bimanual
- Brush teeth using toothbrush (bimanual / **affected** hand as able)
- Apply cream to face / body
- Use both hands to scoop up water from the sink to wash face
- Apply make-up
- Apply / remove resting splint
- Apply / remove wrist watch
- Handle medication

2. Functional mobility

- Arrange bed clothes
- Open doors with **affected** hand
- Turn a key in the door using the **affected** hand

3. Community management

- Hold / manipulate money
- Practise sitting to standing then standing to sitting with a hand on each arm of the chair, pushing through both hands.

Productivity

- Stabilise paper with **affected** side and write with **unaffected**
- 'Pick and place' pen
- 'Pick and place' book
- Stabilise paper with **unaffected** side and write with **affected** side.

Leisure

1. Quiet recreation

- Stabilise book with **affected** side and turn pages with **unaffected** side
- Stabilise magazine / newspaper with **affected** side and turn pages with **unaffected** side
- 'Pick and place' magazine
- Stabilise magazine / newspaper with **unaffected** side and turn pages with **affected** side
- Stabilise book with **unaffected** side and turn pages with **affected** side
- Art and craft activities

2. Active recreation

- Use of an MP3 player / iPod / laptop
- Holding / manipulating playing cards
- Use of TV control

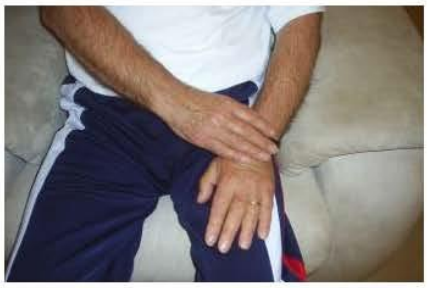
3. Socialising

- 'Pick and place' mobile phone
- Pick up and hold mobile phone in dialling position then place back on the table
- Telephone use (land line)
- Using an mobile phone (lifting phone up to the ear)
- Using a key pad / key board

Appendix K. Example of Activity sheet

Washing Activity

W1.01: Touch or rub body part using your affected hand



1. Start with your **affected** hand either on the arm of the chair or by your side.
2. Touch/ rub your ……..…… (insert body part) using your affected hand.
3. Return to the start position.

Appendix L Patient information sheet

INSERT NHS SITE LOGO

Developing a Programme for Wrist worn Accelerometers with Vibrating-alert to prompt Exercises after Stroke Study (DP-WAVES Study)

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide whether you would like to take part we would like you to understand why the research is being done and what it would involve for you.

It is important to take time to read this information sheet. One of our research team will go through the study with you and answer any questions that you have. This will take about 30 minutes.

Please feel free to talk to others about the study if you wish. Please ask us about anything that is unclear to you or if you would like any further information.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask us if you are unsure about anything.

Part 1

What is the purpose of the study?
Loss of arm function affects up to 85% of people who have recently had a stroke. and is reported to be one of the most distressing long term effects. Often people feel that rehabilitation does not focus enough on arm recovery.

Recent research has suggested that recovery may be improved by practising activities many times. Patients are being encouraged to carry out additional activities by themselves to increase the amount of practise. However remembering to carry out these activities and using the affected arm throughout the day can still be difficult.

Computer researchers and designers at Newcastle University have developed a wristwatch device called "CueS wristband" that reminds people who have had a stroke to move their affected arm more often. The CueS wristband has been specifically designed to monitor arm movement and can be programmed so that it vibrates gently to remind the wearer to carry out therapy activities to the best possible level.

The aim of this research study is to see how well the CueS wristband can be used alongside a structured therapy programme to remind patients to carry out activities. The programme can then be adjusted according to the views of patients.

If patients tell us that the CueS wristband is acceptable and might be useful, we plan to carry out a much larger study to decide whether it is beneficial for improving arm recovery after stroke.

This study is being led by a medical consultant and researcher (Dr Christopher Price) and senior occupational therapist (Ruth Da Silva) who work in the NHS and are part of the Stroke Research Group at Newcastle University. It is funded by The Stroke Association, a national charity aiming to improve the care and safety of stroke patients.

Why have I been invited to take part?
You have been invited to take part as you recently had a stroke which has caused problems with your arm. One of the health care professionals involved in your care has suggested that you might be suitable to take part.

Do I have to take part?
No, the decision is entirely up to you. We will describe the study and go through this information sheet. If you agree to take part, we will ask you to sign a consent form. You do not need to give a reason if you don't want to take part

What will happen to me if I take part?
You will take part in a therapy programme for four weeks which aims to improve the use of your stroke arm in normal everyday activities. This will be under the supervision of an NHS therapist and the study therapist (Ruth Da Silva) who is a senior occupational therapist experienced in treating patients with stroke. You will be given a CueS wristband to wear on each wrist during this four week period.

Ruth Da Silva will firstly complete an assessment. This will involve collecting some medical details about your stroke and examining how it has affected the movement of your arm. There are no extra scans or blood tests. With Ruth, you will be asked to select two arm movement "recovery activities" from a handbook of exercises. We will ask if we can make a brief video film when you practice these movements at the first assessment to help understand the information collected by the CueS wristbands. The video will focus on your arm movements and will not show your face. There will be no other filming during the study.

We will ask you to practice two recovery activities on your own twice a day and record what you did on a simple log sheet. The CueS wristbands will constantly monitor how much you are using your arms but can be removed at any time.

During the therapy programme, you will be reviewed twice per week by Ruth. She will discuss your goals and activities which will be adjusted according to your progress and how you are finding the practice. During the review Ruth will download the data collected by the CueS wristband on your stroke arm and you will be able to see a report about how much movement there has been during the previous days. This may help to decide upon what activities to do next.

After the first week, if you forget to use your arm or have not used it as much as you have in previous days, the CueS wristband will vibrate gently to remind you to carry out more activity. During each review Ruth will discuss with you what you would do if you received a vibration prompt and will reset the CueS wristband for how often it should prompt you. If you do not want to receive a prompt then the wristband can be turned off by tapping the front. You can choose what to do if a prompt is received and it is your choice whether you practise more movements.

The CueS wristband on your other (normal) side will not vibrate and will simply record movement for the four weeks. Both wristbands are waterproof and can be removed like a watch. Ruth will check you are able to do this or have some help available.

At the end of the 4 week therapy programme you will be invited to take part in an interview to find out what you thought about the therapy programme and the CueS wristband. The interview will be with a researcher employed by Newcastle University who is not directly involved in the care of patients. The discussion will be audio-recorded so we have an accurate record of your views and experiences. You can still take part if you have communication problems, but we would ask your permission first to discuss with your speech therapist how to make the interview easier.

Expenses and payments.
There are no payments for participation in this study. If you need to travel to any additional appointments just for the study, your travel expenses can be reimbursed.

What will I have to do?
If you agree to take part in the study you will be asked to wear a CueS wristband device on each wrist during the day and to practise your recovery activities twice each day for four weeks or more often if you receive a CueS prompt. You will also be

asked to complete a daily log sheet to record your practice and to tell us what you think about this type of therapy in an interview at the end of the four weeks.

What are the possible advantages of taking part?
Research has suggested that arm recovery is faster when extra treatment is given within the first few weeks or months after stroke. In this study, the arm therapy is extra on top of the stroke rehabilitation you would receive. This could possibly speed up how quickly you can use your arm again. Having this programme to practise at this early time after stroke will hopefully make the most of the potential to recover.

Research has also suggested that people who have had a stroke are helped most by practising everyday activities regularly. These are the types of activities we are using in this study (the 'recovery activities'). You may find it beneficial to have control of the type of activities you are doing and receive feedback from the CueS wristband.

It is hoped that the results from this study may help us develop a much larger study that could improve treatments for people who have had a stroke in the future

What are the possible risks of taking part?
It is common for people to feel tired after a stroke. Taking part in the study and doing the extra therapy could be tiring. There is a chance that you may feel too tired from practising the study programme to work on your usual therapy. If this happens then you need to tell your therapist and the study programme will be altered or stopped.

You may notice some discomfort in your arm when practising the programme but this should be no greater than the discomfort you may feel during your 'usual' therapy.

If the CueS prompts occur too often then you may find this frustrating. It will be possible to turn the CueS wristband off or remove it, and the study therapist will adjust when prompts can occur according to your preferences.

If the information in Part 1 has interested you and you are considering participation, please read Part 2 before making any decision.

Part 2

What happens if I change my mind about taking part in the study?
You are free to withdraw from the study at any point without giving a reason. If you agree to participate, but later decide that you no longer wish to take part in this study, please contact a member of the study team using the details at the end of this leaflet. It will not affect the care that you receive whether or not you decide to be involved at any point. Information collected about you will be used by the research team unless you specifically withdraw your permission for this.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to Ruth or a member of the research team at the address below. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanisms are available to you through your local hospital. You can contact the Patient Advisory Liaison Service:

[local contact details for PALS to be added to local version PIS]

What information will you collect about me?
We will need to take some medical information from you and simple measurements of your stroke arm. We would also like to make one short video recording when you first practice your recovery activities. This is so we can ensure that the CueS wristband is providing accurate information about your arm movements.

At the end of the programme we would like to make an audio recording of an interview with you so that we can describe your views and compare with other patients.

Will my taking part in this study be kept confidential?

All personal data and information that is collected about you during the course of the research will be regarded as strictly confidential. Your privacy will be protected at all times. Your identity will not be known by anyone other than the people directly involved in the study. None of your personal details will be stored alongside your recordings and you will be given a study code number so that your information will be protected. Any recordings of you will be stored securely at Newcastle University and will not be used for any other reason apart from the study.

Paper records containing information we have collected about you for the study will be kept in locked filing cabinets in secure rooms. Your information will also be placed on secure computers at Newcastle University. In accordance with research regulations, at the end of the study, the records containing your study data will be retained for 5 years in a secure archive. After 5 years, your study data will be destroyed.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from Northumbria Healthcare NHS Foundation Trust (the study sponsor) and your local hospital trust to check that the study is being conducted to the correct standards. All your study records and

your rights to them will be protected in accordance with the UK data protection laws. You will not be identified by name or context in any report or publications arising from this research. Any feedback comments you give us will be anonymous.

Involvement of the General Practitioner/Family doctor (GP)
With your permission, we will inform your GP if you decide to participate in the study.

What happens if I become unable to make decisions about carrying on with the research study?
If you become unwell during the study and are no longer able to make decisions about carrying on with the project, you will be withdrawn from the study. We will keep and use the information you provided when you were able to make decisions.

What will happen to the results of the research study?
The results will be shared at research meetings and published in medical journals. A report will be submitted to the Stroke Association, who are funding the research. You will not be identified in any report or publication. We will send a summary of the results to all participants once the study has been completed. A copy of the final report will also be available to participants upon request.

Who is organising and funding the research?
The study is being organised by Newcastle University and Northumbria Healthcare NHS Foundation Trust. It is funded by The Stroke Association. There is no payment to healthcare staff or the hospital for patients who are included in the study.

Who has reviewed the study?
All research in the NHS is reviewed and approved by an independent group of people to protect your interests, called a Research Ethics Committee. The study was reviewed by stroke experts on behalf of the Stroke Association.

If you require further information about the study please contact:

Ruth Da Silva
Research Occupational Therapist
Stroke Research Group
3 – 4 Claremont Terrace
Newcastle University
NE2 4AE
Telephone (0191) 2083842

Thank you for taking the time to read this information sheet.

Appendix M. Written consent form

DP-WAVES Study		Patient initials		Participant Number		Consent Form

Developing a Programme for Wrist worn Accelerometers with Vibrating-alert to prompt Exercises after Stroke Study (DP-WAVES Study)

Please initial box

1 I confirm that I have read and understood the patient information sheet dated 3rd March 2015 for this study and have had the opportunity to ask questions. ☐

2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and with no impact on my treatment. ☐

3 I understand that sections of my medical notes may be looked at by responsible individuals with permission from the study sponsor (Northumbria Healthcare NHS Foundation Trust) where it is relevant to my taking part in research. ☐

4 I understand that part of the initial assessment will be video recorded and this recording will be temporarily held securely at Newcastle University before deletion. ☐

5 I understand that I will be asked for an interview after the study and an audio recording will be temporarily held securely at Newcastle University before deletion. ☐

6 I understand that if I withdraw from the study, data already collected about me will contribute to the study unless I specifically withdraw consent for this. ☐

7 I agree for my general practitioner to be informed of my participation in this study. ☐

8 I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of person taking consent	Date	Signature

If a patient is able to give informed consent but unable to sign this consent form (e.g. because of weakness of the dominant hand following stroke), consent should be confirmed orally in the presence of a witness.

Name of witness	Date	Signature

(Original for research site file, copies for participant and hospital notes.)

Newcastle University

Consent Form (DP-WAVES) Version 1.0 3rd March 2015

NHS SITE LOGO

Appendix N. Baseline assessment form

Developing a Programme to use Wrist worn Accelerometers with Vibrating-alert for Exercises after Stroke (DP-WAVES) study

Baseline Assessment

Version 1: February 2015

Patient Study Number:	
Assessment Date:	☐☐/☐☐/☐☐☐☐
Assessor Name (print name):	
Assessor Contact Number:	

Chief Investigator: Dr Christopher Price

Address: Stroke Research Group, Institute for Neuro Science, Newcastle University, 3-4 Claremont Terrace, Newcastle NE2 4AE

Telephone: 0191 208 3842

Fax: 0191 208 5540

GENERAL INSTRUCTIONS

The baseline assessment form should only be completed by members of staff who have received training about the study.

Please write clearly using a black ballpoint pen.

Always make sure that the "YES/NO" square box answers are completed with a tick.

Errors

If an error needs to be rectified after the forms have been completed:

1. Draw a single line through the error, do not obscure the original entry
2. Enter the correct data beside
3. Initial and date the change and add a comment if necessary
4. Never use correction fluids.

Missing Data

Please do not leave blank boxes where a response is expected.

If data is missing the following should apply:

1. **ND** (for not done) should be entered into the field for all tests and examinations which should have been carried out but were omitted.
2. **NA** (for not applicable) should be entered into the field for missing data if a question does not apply to a patient status.
3. **NK** (for not known) should be entered when historical information, such as dates of onset of medical conditions is not known/not available.

Time

Please use the 24 hour clock eg: 15:30 (and not 3.30pm).

Dates

Please record a date as follows: DD/MM/YYYY.
If part of a date is unknown, please complete the corresponding boxes with NK.

Patient Identification

Please complete the header of all pages with the patient's study number.

Outcome measurements

Please complete outcome measures for both sides of the body if indicated.

SECTION 1: INFORMED CONSENT

1. Has the patient given written informed consent to take part in the study?

Yes ☐ Date of consent: ☐☐/☐☐/☐☐☐☐

No ☐ The patient **MUST NOT** be included in the study until consent has been obtained.

SECTION 2: CONFIRMATION OF STUDY ELIGIBILITY

	No	Yes
1. Is the patient aged ≥ 18 years?	☐	☐
2. Is the patient within 28 days of stroke onset?	☐	☐
3. Does the patient have new reduced upper limb function due to acute stroke but with retained ability to lift the affected hand off their lap?	☐	☐
4. Is the patient capable of undertaking the therapy programme and adhering to the study protocol?	☐	☐
5. Does the patient live within the community services catchment area of a participating study centre?	☐	☐

The answer must be YES to all of questions 1 – 5. If the answer is NO to any of questions 1 - 5, the patient is NOT eligible to participate in the DP-WAVES study. If the answer is NO to any question, please do NOT continue with this baseline assessment form.

	No	Yes
6. Does the patient have any other significant upper limb impairment (e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain) that will inhibit participation in the programme?	☐	☐
7. Does the participant have a diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care?	☐	☐

The answer must be NO to all of questions 6 - 7. If the answer is YES to any of questions 6 - 7, the patient is NOT eligible to participate in the DP-WAVES study. If the answer is YES to any question, please do NOT continue with this baseline assessment form.

SECTION 3: PATIENT DETAILS

1. Sex Male ☐ Female ☐

2. Age _____ years

SECTION 4: STROKE DETAILS

1. Please record date of current stroke: ☐☐/☐☐/☐☐☐☐

2. Side of body affected by current stroke: Right ☐ Left ☐ Both ☐

3. Hand dominance (main one if ambidextrous): Right ☐ Left ☐

4. Current stroke aetiology

Ischaemic ☐
Intracerebral haemorrhage ☐

5. **Stroke subtype (of current stroke)**

Total Anterior Circulation Stroke (TACS) ☐
Partial Anterior Circulation Stroke (PACS) ☐
Lacunar Stroke (LACS) ☐
Posterior Circulation Stroke (POCS) ☐
Uncertain ☐

6. Was this a first ever stroke? No ☐ Yes ☐

7. If no, did the patient have any residual neurological deficit due to previous stroke(s)? No ☐ Yes ☐

8. Please describe the neurological deficit and severity of deficit from previous stroke(s):

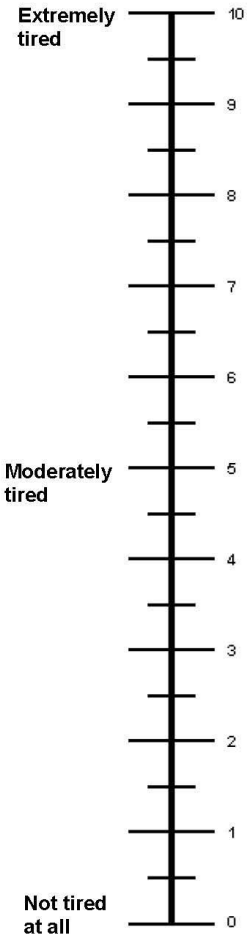
_____

_____

FATIGUE VISUAL ANALOGE SCALE

In general, how **tired** has the participant felt since having their stroke?

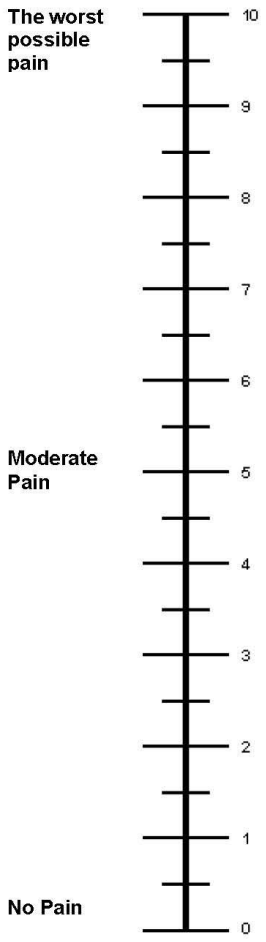
Please explain the Visual Analogue Scale (VAS) to the participant and ask the participant to select a score. Mark their score on the VAS below:



PAIN VISUAL ANALOGE SCALE

Since their stroke has the participant had any **pain** in their arm?

Please explain the Visual Analogue Scale (VAS) to the participant and ask the participant to select a score. Mark their score on the VAS below:



PRE-STROKE DEPENDENCY: Modified Rankin Scale

Please ask the patient which **ONE** statement below best describes them **BEFORE** the current stroke:

Tick ***one box***.

0 No symptoms at all..... ☐

1 No significant disabling symptoms..... ☐

2 Slight disability but does not require substantial help from other person, can walk ..... ☐

3 Moderately severe disability, requires substantial help from other person, can walk..... ☐

4 Moderately severe disability, requires substantial help from other person, unable to walk ..... ☐

5 Severe disability, bedbound..... ☐

6 Dead..... ☐

9 Unknown..... ☐

PRE-STROKE BARTHEL ACTIVITIES OF DAILY LIVING INDEX

For each question below, please ask the patient which answer best describes them **BEFORE THEIR STROKE** and tick the box.

Function	Description	Score	
Bowels	Incontinent (or needs to be given enema)	0	
	Occasional accidence (once a week)	1	
	Continent	2	
Bladder	Incontinent, or catheterised and unable to manage	0	
	Occasional accident (max. once per 24 hours)	1	
	Continent (for over 7 days)	2	
Grooming	Needs help with personal care:	0	
	Independent face/hair/teeth/shaving (implements provided)	1	
Toilet Use	Dependent	0	
	Needs some help but can do some things alone	1	
	Independent (on and off, dressing, wiping)	2	
Feeding	Unable	0	
	Needs help in cutting, spreading butter etc.	1	
	Independent (food provided in reach)	2	
Transfer	Unable - no sitting balance	0	
	Major help (1 or 2 people, physical), can sit	1	
	Minor help (verbal or physical)	2	
	Independent	3	
Mobility	Immobile	0	
	Wheelchair independent, including corners etc.	1	
	Walks with help of one person (verbal or physical)	2	
	Independent (but may use aid e.g. stick)	3	
Dressing	Dependent	0	
	Needs help but can do about half unaided	1	
	Independent (including buttons, zips, laces etc.)	2	
Stairs	Unable	0	
	Needs help (verbal, physical, carrying aid)	1	
	Independent up and down	2	
Bathing	Dependent	0	
	Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)	1	
Total (0-20)			

CURRENT HEALTH AND UPPER LIMB ABILITY

National Institutes of Health Stroke Scale (NIHSS) on admission

1a. Level of consciousness	0	Alert		
	1	Not alert, but arousable with minimal stimulation		
	2	Not alert, requires repeated stimulation to attend		
	3	Coma		
1b. LOC questions Ask month now and age	0	Answers both correctly		
	1	Answers one correctly		
	2	Both incorrect		
1c. LOC commands Ask to open/close eyes and form/release fist	0	Obeys both correctly		
	1	Obeys one correctly		
	2	Both incorrect		
2. Best gaze	0	Normal		
	1	Partial gaze palsy		
	2	Forced gaze palsy		
3. Visual field testing	0	No visual field loss		
	1	Partial hemianopia		
	2	Complete hemianopia		
	3	Bilateral hemianopia (blind, incl. cortical blindness)		
4. Facial palsy	0	Normal symmetrical movement		
	1	Minor paralysis (flattened nasolabial fold, asymmetry on smiling)		
	2	Partial paralysis (total or near total paralysis of lower face)		
	3	Complete paralysis of one or both sides (in the upper and lower face)		
5. Motor function arm	0	Normal (extends for 10 sec without drift)		
	1	Drift	Right	
	2	Some effort against gravity		
	3	No effort against gravity		
	4	No movement	Left	
		Untestable (limb amputated)		
6. Motor function leg	0	Normal (holds leg for 5 sec without drift)		
	1	Drift	Right	
	2	Some effort against gravity		
	3	No effort against gravity		
	4	No movement	Left	
		Untestable (limb amputated)		
7. Limb ataxia	0	No ataxia		
	1	Present in one limb		
	2	Present in two limbs		
8. Sensory	0	Normal		
	1	Mild to moderate decrease in sensation		
	2	Sever to total sensory loss		
9. Best language	0	No aphasia		
	1	Mild to moderate aphasia		
	2	Severe aphasia		
	3	Mute		
10. Dysarthria	0	Normal articulation		
	1	Mild to moderate slurring of words		
	2	Near unintelligible or unable to speak		
		Intubated or other physical barrier		
11. Inattention	0	Normal		
	1	Inattention or extinction to bilateral simultaneous stimulation		
	2	Sever hemi-inattention or hemi-inattention to more than one modality		
		Total Score:		

Motricity Index

Arm (in sitting position)
A. Pinch grip; 2.5cm cube between thumb and forefinger
B. Elbow flexion; from 90 degrees, voluntary contraction/movement
C. Shoulder abduction; from against chest

A. Pinch grip

0	No movement
11	Beginnings of prehension (any movement of finger or thumb)
19	Grips cube, but unable to hold against gravity
22	Grips cube, held against gravity, but not against weak pull
26	Grips cube against pull, but weaker than other side
33	Normal pinch grip

Score R arm ☐ Score L arm ☐

B. Elbow flexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

C. Shoulder abduction

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

Leg (in sitting position)
D. Ankle dorsiflexion; from plantar flexed position
E. Knee extension; from 90 degrees, voluntary contraction/movement
F. Hip flexion; usually from 90 degrees

D. Ankle dorsiflexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

E. Knee extension

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

F. Hip flexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

Arm score = (1) + (2) + (3) + 1 (to make 100)
Leg scores = (4) + (5) + (6) + 1 (to make 100)

TOTAL RIGHT ARM ☐ **TOTAL LEFT ARM** ☐

TOTAL RIGHT LEG ☐ **TOTAL LEFT LEG** ☐

Side score = (ARM + LEG)/2

RIGHT SIDE ☐ **LEFT SIDE** ☐

Action Research Arm Test (ARAT)

Instructions - There are four subtests: grasp, grip, pinch and gross movement. If a subject passes the first task in each subtest then they score top marks and move onto the next subtest. If a subject fails the first and the second task in a subtest, then they score zero overall for that subtest and move onto the next**. The patient must be able to sit unaided in order to attempt the test**. If not, the patient scores 0.

Score 0 = cannot perform any part of the test **1 = performs test partially**
2 = completes test, but takes abnormally long time or has great difficulty **3 = performs test normally**

Ask patient to **demonstrate** using the least impaired arm first:

a) Grasp

1. 10cm cube (if score = 3 then total = 18 & go to *Grip*)
2. 2.5cm cube (if Grasp score = 0 so far then Grasp total = 0 & go to *Grip*)
3. 5cm cube
4. 7.5cm cube
5. cricket ball
6. stone

Grasp total:

b) Grip

1. Pour water glass to glass (if score = 3 then total = 12 & go to *Pinch*)
2. 2.25cm tube (if Grip score = 0 so far then Grip total = 0 & go to *Pinch*)
3. 1cm tube
4. washer over bolt

Grip total:

c) Pinch

1. 6mm bearing 3rd finger & thumb (if score = 3 then total = 18 & go to *Gross*)
2. marble index & thumb (if Pinch score = 0 so far then Pinch total = 0 & go to *Gross*)
3. 6mm bearing 2nd finger & thumb
4. 6mm bearing 1st finger & thumb
5. marble 2nd finger & thumb
6. marble 3rd finger & thumb

Pinch total:

d) Gross

1. Place hand behind head (if score = 3 then total = 9 & finish)
2. Place hand on top of head
3. Hand to mouth

Gross total:

ARAT Total

The Action Research arm Test (ARAT) is the primary outcome measure for this study.

1. Has the ARAT been completed? Yes ☐ No ☐

2. If the participant was unable to complete the ARAT, please document the reason why:

_____

_____

If ARAT was completed please indicate the level of severity of the arm impairment:

3-19 (severe)	20-30 (moderate)	30-56 (mild)
☐	☐	☐

Baseline assessment is now complete, please continue to the goal setting form to identify two recovery activities for the participant to work towards.

Upper limb rehabilitation needs identified following discussion:

Washing _____

_____

_____

Dressing _____

_____

_____

Eating/drinking (if appropriate)_____

_____

_____

Other _____

_____

_____

Goals and recovery activities selected:

Goal 1. (W, D, E/D, O – please circle) _____

_____

Recovery activity: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

Goal 2 (W, D, E/D, O – please circle) _____

_____

Recovery activity: (please detail the activity and document the number from the 'Recovery activity list)'.

_____

_____

1. Demonstrate and practice the activities with the participant and ensure they are confident to undertake their programme without therapist supervision.
2. Place the appropriate activity sheets into the relevant sections of the participant's handbook.
3. Ensure the participant has Daily Activity Log sheets until next therapy review.
4. Demonstrate how to complete the activity log sheets.
5. Remind the participant to practice each activity up to 20 times, twice per day.
6. Discuss prompted activities to be used as a response to CueS response.
7. Set date of next therapy session = _____
8. Please document the date and time of the next therapy session in the participant's handbook.

To complete recruitment process please inform the participant that a researcher will be in touch in three weeks to organise a date and time for the informal interview assessment.

Following the initial recruitment session please:

1. Contact the study **qualitative researcher** to inform them of participant recruitment.
2. Complete 'Patient Study Number' details on the front sheet of this form and on each page header of this form.
3. Complete 'Patient Study Number' details on the participant's copy of the 'Patient Information Sheet'.
4. Complete the GP letter and post to the participant's GP.
5. Photocopy this completed 'Baseline Assessment & Randomisation Record'. Please place the original in the study investigator site file and keep a copy at Newcastle University.
6. Complete the 'DP-WAVES study sheet' and place in the patient's medical notes with a copy of the PIS and completed consent form.
7. Add the participant's contact details and study number to the 'link document' located in the usual care folder.
8. Liaise with the patient's usual care therapist regarding recruitment and how to support patient in wearing and caring for the wrist band.

Appendix O. Therapy review form

DP-WAVES Study	Participant Number ☐ ☐ ☐	Therapy Review Session

Therapy review session ( )

Participant Number ☐ ☐ ☐

Participant's comments about the programme (good and bad points):

_____

_____

_____

Any Adverse Events (ask the participant "Are there any new medical problems since the last review appointment?"):

No ☐ Yes ☐ If yes refer to decision tree for safety reporting

Review of CueS wristband (ask participant "Have there been any days when you have not worn the CueS?")

No ☐ Yes ☐

Please collect the participant's activity log sheets from the participant's handbook.

DP-WAVES Study	Participant Number ☐ ☐ ☐	Therapy Review Session

Upper limb reassessment

- Selective movement
- Passive range of movement
- Muscle tone
- Compensations
- Associated reactions
- Sensation
- Proprioception
- Coordination
- Pain

Shoulder	
Elbow	
Wrist	
Hand	

Inattention / other comments: _____

_____

_____

DP-WAVES Study	Participant Number ☐ ☐ ☐	Therapy Review Session

Review of goals achieved / progress made?

Goal 1: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

New goal set?

Yes ☐ No ☐

New goal set (if appropriate):

_____

Goal 2: _____

_____

Goal achieved? Yes ☐ No ☐ Partially ☐

New goal set?

Yes ☐ No ☐

New goal set (if appropriate):

_____

DP-WAVES Study	Participant Number ☐ ☐ ☐	Therapy Review Session

Review of CueS data and responses to prompts

Use therapy decision tree to review frequency/threshold of prompts set

Frequency of prompts – current setting:

1 hourly ☐ 2 hourly ☐ 3 hourly ☐ 4 hourly ☐

Current threshold set at ☐ percentile.

Did patient feel prompts: Yes ☐ No ☐

1. Did participants respond to the prompts felt? (explore if patient responded to or ignored prompts and how/why)

   Yes ☐ **No** ☐ **sometimes** ☐ **N/A** ☐

2. Approximately how many prompts per day did the patient feel? ☐

3. Was this number too many? ☐ Not enough? ☐ About right? ☐

4. How did participant respond to prompts?

   Recovery Activity ☐ Prompted Activity ☐ Other self-selected activity ☐

Does the frequency of prompts need to be changed:

Yes ☐ **No** ☐

If yes what will new frequency be set at:

1 hourly ☐ 2 hourly ☐ 3 hourly ☐ 4 hourly ☐

Does the threshold need to be changed?

Yes ☐ No ☐

If yes what will new threshold be set at: ☐ percentile

DP-WAVES Study	Participant Number ☐ ☐ ☐	Therapy Review Session

Please:

1. Demonstrate and practice the activities with the participant and ensure they are confident to undertake their programme without therapist supervision.
2. Place the appropriate activity sheets into the relevant sections of the participant's handbook.
3. Ensure the participant has Daily Activity Log sheets until next therapy review.
4. Demonstrate how to complete the activity log sheets.
5. Remind the participant to practice each activity up to 20 times, twice per day.
6. Review CueS data and discuss activity levels with participant
7. Use Therapy Decision tree to agree new thresholds and frequency of prompts to be set .
8. Discuss prompted activities to be used as a response to CueS response.
9. Set date of next therapy session = _____
10. Please document the date and time of the next therapy session in the participant's handbook.

Therapist Name (print) _____

Signature _____ Date _____

Appendix P. Four week assessment

Developing a Programme to use Wrist worn Accelerometers with Vibrating-alert for Exercises after Stroke (DP-WAVES) study

Four Week Assessment

Version 1: FEB 2015

Patient study number:	
Assessment Date:	☐☐/☐☐/☐☐☐☐
Assessor Name (print name):	
Assessor Contact Number:	

Chief Investigator: Dr Christopher Price

Address: Stroke Research Group, Institute of Neuroscience, Newcastle University, 3-4 Claremont Terrace, Newcastle NE2 4AE

Telephone: 0191 208 3842

Fax: 0191 222 5540

GENERAL INSTRUCTIONS

The outcome assessment form should only be completed by members of staff who have received training about the DP-WAVES study.

Please write clearly using a black ballpoint pen.

Always make sure that the "YES/NO" square box answers are completed with a tick.

Errors

If an error needs to be rectified after the forms have been completed:

1. Draw a single line through the error, do not obscure the original entry
2. Enter the correct data beside
3. Initial and date the change and add a comment if necessary
4. Never use correction fluids.

Missing Data

Please do not leave blank boxes where a response is expected.

If data is missing the following should apply:

1. **ND** (for not done) should be entered into the field for all tests and examinations which should have been carried out but were omitted.
2. **NA** (for not applicable) should be entered into the field for missing data if a question does not apply to a patient status.
3. **NK** (for not known) should be entered when historical information, such as dates of onset of medical conditions is not known/not available.

Time

Please use the 24 hour clock eg: 15:30 (and not 3.30pm).

Dates

Please record a date as follows: DD/MM/YYYY.
If part of a date is unknown, please complete the corresponding boxes with NK.

Patient Identification

Please complete the header of all pages with the patient's study number.

Objective measurements

Please complete outcome measures for both sides of the body if indicated.

SECTION 1: ADVERSE EVENTS

1. In the last month (since the study baseline assessment), has the participant suffered from any new medical problems?

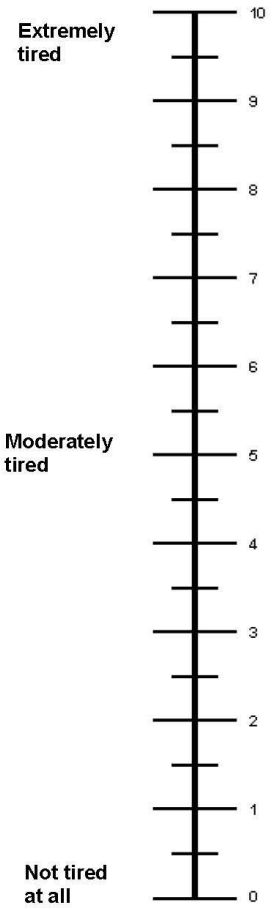
Yes ☐ No ☐

If yes, please provide details: _____

_____

_____

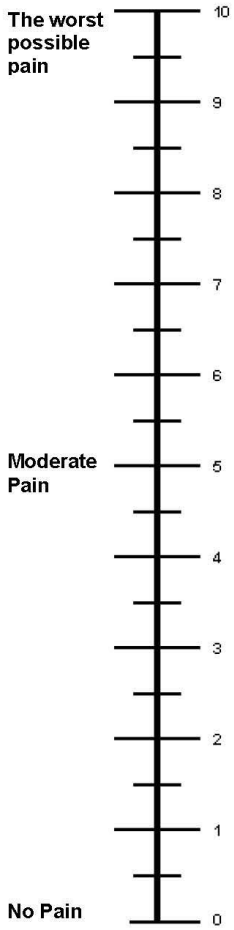
2. In the last month (since the study baseline assessment), in general, how **tired** has the participant felt? Please explain the Visual Analogue Scale (VAS) to the participant and ask the participant to select a score. Mark their score on the VAS below:



3. In the last month (since the study baseline assessment), has the participant had any **pain** in their arm affected by their stroke?

Yes ☐ No ☐

Please explain the Visual Analogue Scale (VAS) to the participant and ask the participant to select a score. Mark their score on the VAS below:



If Yes, please provide details: _____

_____

_____

4. Could the answers to any of the questions 1- 3 be considered as a **serious adverse event?**

NB: A serious adverse event is 'an untoward occurrence that:-

- Results in death.
- Is life-threatening.
- Requires hospitalisation, or prolongation of existing hospitalisation.
- Results in persistent or significant disability or incapacity.
- Consists of a congenital anomaly or birth defect.
- Is otherwise considered medically significant by the investigator'.

Yes ☐ No ☐

If Yes, you must complete the relevant documentation.

5. Participant's current status:

Inpatient ☐

Discharged but still under community therapy ☐

Discharged from all therapy ☐

BARTHEL ACTIVITIES OF DAILY LIVING INDEX

For each question below, please ask the patient which answer best describes them CURRENTLY and tick the box. They should be asked to report what they have actually done in the last week or so, not what they think they could do, ought to do or would like to do.

Function	Description	Score	
Bowels	Incontinent (or needs to be given enema) Occasional accidence (once a week) Continent	0 1 2	☐
Bladder	Incontinent, or catheterised and unable to manage Occasional accident (max. once per 24 hours) Continent (for over 7 days)	0 1 2	☐
Grooming	Needs help with personal care: Independent face/hair/teeth/shaving (implements provided)	0 1	☐
Toilet Use	Dependent Needs some help but can do some things alone Independent (on and off, dressing, wiping)	0 1 2	☐
Feeding	Unable Needs help in cutting, spreading butter etc. Independent (food provided in reach)	0 1 2	☐
Transfer	Unable - no sitting balance Major help (1 or 2 people, physical), can sit Minor help (verbal or physical) Independent	0 1 2 3	☐
Mobility	Immobile Wheelchair independent, including corners etc. Walks with help of one person (verbal or physical) Independent (but may use aid e.g. stick)	0 1 2 3	☐
Dressing	Dependent Needs help but can do about half unaided Independent (including buttons, zips, laces etc.)	0 1 2	☐
Stairs	Unable Needs help (verbal, physical, carrying aid) Independent up and down	0 1 2	☐
Bathing	Dependent Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)	0 1	☐
Total (0-20)			☐

Motricity Index

Arm (in sitting position)

A. Pinch grip; 2.5cm cube between thumb and forefinger
B. Elbow flexion; from 90 degrees, voluntary contraction/movement
C. Shoulder abduction; from against chest

A. Pinch grip

0	No movement
11	Beginnings of prehension (any movement of finger or thumb)
19	Grips cube, but unable to hold against gravity
22	Grips cube, held against gravity, but not against weak pull
26	Grips cube against pull, but weaker than other side
33	Normal pinch grip

Score R arm ☐ Score L arm ☐

B. Elbow flexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

C. Shoulder abduction

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

Leg (in sitting position)
D. Ankle dorsiflexion; from plantar flexed position
E. Knee extension; from 90 degrees, voluntary contraction/movement
F. Hip flexion; usually from 90 degrees

D. Ankle dorsiflexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

E. Knee extension

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

F. Hip flexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R leg ☐ Score L leg ☐

Arm score = (1) + (2) + (3) + 1 (to make 100)
Leg scores = (4) + (5) + (6) + 1 (to make 100)

TOTAL RIGHT ARM ☐ **TOTAL LEFT ARM** ☐

TOTAL RIGHT LEG ☐ **TOTAL LEFT LEG** ☐

Side score = (ARM + LEG)/2

RIGHT SIDE ☐ **LEFT SIDE** ☐

Action Research Arm Test (ARAT)

Instructions - There are four subtests: grasp, grip, pinch and gross movement. If a subject passes the first task in each subtest then they score top marks and move onto the next subtest. If a subject fails the first and the second task in a subtest, then they score zero overall for that subtest and move onto the next. The patient must be able to sit unaided in order to attempt the test. If not, the patient scores 0.

Score **0 = cannot perform any part of the test** **1 = performs test partially**
2 = completes test, but takes abnormally long time or has great difficulty **3 = performs test normally**

Ask participant to demonstrate using their least impaired arm first:

a) Grasp

1. 10cm cube (if score = 3 then total = 18 & go to *Grip*) ☐
2. 2.5cm cube (if Grasp score = 0 so far then Grasp total = 0 & go to *Grip*) ☐
3. 5cm cube ☐
4. 7.5cm cube ☐
5. cricket ball ☐
6. stone ☐

Grasp total: ☐

b) Grip

1. Pour water glass to glass (if score = 3 then total = 12 & go to *Pinch*) ☐
2. 2.25cm tube (if Grip score = 0 so far then Grip total = 0 & go to *Pinch*) ☐
3. 1cm tube ☐
4. washer over bolt ☐

Grip total: ☐

c) Pinch

1. 6mm bearing 3rd finger & thumb (if score = 3 then total = 18 & go to *Gross*) ☐
2. marble index & thumb (if Pinch score = 0 so far then Pinch total = 0 & go to *Gross*) ☐
3. 6mm bearing 2nd finger & thumb ☐
4. 6mm bearing 1st finger & thumb ☐
5. marble 2nd finger & thumb ☐
6. marble 3rd finger & thumb ☐

Pinch total: ☐

d) Gross

1. Place hand behind head (if score = 3 then total = 9 & finish) ☐
2. Place hand on top of head ☐
3. Hand to mouth ☐

Gross total: ☐

ARAT Total ☐

MOTOR ACTIVITY LOG (MAL) SCORE SHEET

"The purpose of this test is to examine how much and how well you use your more-affected arm. You will use two separate rating scales to describe how much and how well you use your weaker arm while you are doing specific activities. Please note that you can give half ratings if that best describes your performance of the activity in question. If for some reason, you do not perform these tasks, we will try to determine why. We will first discuss how much you do each of the activities with your weaker arm and then we will discuss how well you do them when using your weaker arm. It is important that you realize that these questions are about what you actually do – not what you think you may be able to do with your weaker arm. There are no right or wrong answers; simply select the ratings you believe best describes what you do. Please understand that I must follow a script with this procedure. Do you have any questions?"

"Considering your activities during the past week, did you use your weaker arm to … (state the activity)?"
If no, then ask why and direct the participant to the list of possible reasons why the arm was not used.
If yes, use the codes at the bottom of the score sheet to categorize the participant's response.

List of motor Activities	Amount	How Well	If no, why? (use code and give Comments)
Turn on a light with a light switch	☐	☐	☐
Open Drawer	☐	☐	☐
Remove an item of clothing from a drawer	☐	☐	☐
Pick up phone	☐	☐	☐
Wipe off a kitchen counter or other surface	☐	☐	☐
Get out of a car (just sit to stand movement)	☐	☐	☐
Open refrigerator	☐	☐	☐
Open a door by turning a door knob/handle	☐	☐	☐
Use a TV remote control	☐	☐	☐
Wash your hands	☐	☐	☐
Turning water on/off with tap	☐	☐	☐
Dry your hands	☐	☐	☐
Put on your socks	☐	☐	☐
Take off your socks	☐	☐	☐
Put on your shoes	☐	☐	☐
Take off your shoes	☐	☐	☐
Get up from a chair with armrests	☐	☐	☐

MOTOR ACTIVITY LOG (MAL) SCORE SHEET

List of motor Activities	Amount	How Well	If no, why? (use code and give Comments)
Pull chair away from table before sitting down	☐	☐	☐ _____
Pull chair toward table after sitting down	☐	☐	☐ _____
Pick up a glass, bottle, drinking cup or can	☐	☐	☐ _____
Brush your teeth	☐	☐	☐ _____
Put on makeup / shaving cream on face	☐	☐	☐ _____
Use a key to unlock a door	☐	☐	☐ _____
Write on paper (if non-writing hand N/A)	☐	☐	☐ _____
Carry an object in your hand	☐	☐	☐ _____
Use a fork or spoon for eating	☐	☐	☐ _____
Comb your hair	☐	☐	☐ _____
Pick up a cup by a handle	☐	☐	☐ _____
Button a shirt	☐	☐	☐ _____
Eat half a sandwich or finger	☐	☐	☐ _____
Total Score	_____	_____	
Average Score (Total score divided by 30)	_____	_____	

AMOUNT SCALE

0 **Not Used** Did not use my weaker arm

0.5

1 **Very Rarely** Occassionally used my weaker arm, but only very rarely

1.5

2 **Rarely** Sometimes used my weaker arm but most of the time with my stronger arm

2.5

3 **Half Pre-stroke** Used my weaker arm about half as much as before the stroke

3.5

4 **¾ Pre-stroke** Used my weaker arm almost as much as before the stroke

4.5

5 **Same as pre-stroke** Used my weaker arm as often as before the stroke

HOW WELL SCALE

0 **Never** Weaker arm was not used at all for that activity

0.5

1 **Very Poor** the weaker arm was moved during that activity but was not helpful

1.5

2 **Poor** the weaker arm was of some use but needed some help from the stronger arm or moved very slowly or with difficulty

2.5

3 **Fair** The weaker arm was used for the purpose indicated but movements were slow or were made with only some effort

3.5

4 **Almost Normal** The movements made by the weaker arm were almost normal, but were not quite as fast or accurate as normal

4.5

5 **Normal** The ability to use the weaker arm for that activity was as good as before the stroke.

POSSIBLE REASONS FOR NOT USING THE WEAKER ARM FOR THE ACTIVITY

If participant has not used their stroke arm in a particular activity please discuss with them the reason for this and select one of the possible reasons below:

Reason A. "I used the unaffected arm entirely."

Reason B. "Someone else did it for me"

Reason C. "I never do that activity, with or without help from someone else because it is impossible." For example, combing hair for people who are bald.

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

Reason E. "That is an activity that I normally did only with my dominant hand before the stroke, and continue to do with my dominant hand."

The Action Research arm Test (ARAT) is the primary outcome measure for this study.

1. Has the ARAT been completed? Yes ☐ No ☐

2. If the participant was unable to complete the ARAT, please document the reason why:

_____

_____

If ARAT was completed please indicate the level of severity of the arm impairment:

3-19 (severe)	20-30 (moderate)	30-56 (mild)
☐	☐	☐

The four week assessment is complete.

Assessor:

1. Please inform the study participant that a member of the research team will contact them to arrange the qualitative interview.
2. Please give all completed outcome assessment documentation to the CTO staff member.

CTO staff:

1. Please photocopy this completed outcome assessment form.
2. Place the original in the Investigator site file.
3. Please send the copy to Ruth Da Silva at Newcastle University.

Thank you for your contribution to the DP-WAVES study

Contact for further information:

If you have any queries or require further information about the DP-WAVES study please contact:

Ruth Da Silva
Stroke Research Group
Newcastle University
3-4 Claremont Road,
Newcastle upon Tyne,
NE2 4AE

Tel: 0191 2083842

Email: ruth.da-silva@ncl.ac.uk

Appendix Q. Initial coding of comments

Participant	Comments from participants of good and bad points of the programme	Initial coding of comments
P1	<u>Review session 1:1</u> *Frustrated as I expected it to prompt* Review session 2:1 *Well I'm still wondering why it hasn't vibrated yet* (patient reminded that CueS hadn't been set to prompt in first week but would prompt after today.) <u>Review session 2:2</u> *fed up because I can't feel the prompts* (watch malfunctioning and so no prompts received) <u>Review 3:1</u> *Shhhh … no comment* (watch still not delivering prompts)	Confusion caused as prompts not set until session 2:2 Confusion caused as prompts not set until session 2:2 Frustration caused by watch malfunction Frustration caused by watch malfunction

	Review 4:1 *It reminds me to check the time as it vibrates every hour. It made me more aware to exercise my arm but I don't like filling in the sheets* Final Review *It stimulates and reminds you to do things. I like to write down in my own diary what I've done – that helps too. The watch catches on my sleeve though.*	Prompts useful as a memory aide to orientate patient to time. Daily log sheets not liked Prompt reminds patient to move more Patient prefers own diary to log sheets Watch catching on clothing
P3	Review session 1:1 *fine - no problems* Review session 2:1 *found weight bearing activities good – I can feel the muscles on top of my arm* Review session 2:2 Good to have extra input for my arm as NHS therapists mainly focusing on legs	RFTP exercise good – feeling the benefit Benefitting from the RFTP

	Review session 3:1 *it's reminding me to do the exercises. Sometimes I forget to put it on and lose opportunities like when in shower. Would be better if you didn't need to take it off* Review session 3:2 *good because it reminds you to do something when it beeps* Review session 4:1 *Prompts have been good to remind me to use my arm. No bad parts* Final Review *prompts are really helpful to remember to move the arm*	Prompts benefitting arm use Disappointed that not everything is captured Better if you could wear it all the time Prompts reminding to increase activity Prompts reminding to increase activity Prompts reminding to increase activity
P4	Review session 1:1 *Managing exercises well but CueS device malfunction and so no data recorded*	RFTP ok CueS malfunction

	Review session 2:1 *Its good, I try to get more done in the morning as tired by the afternoon* Review session 2:2 Patient commented that he preferred that the watch does not have any information on the screen as he wants to focus on exercises rather than the watch Battery not holding its charge so some missing data Review session 3:1 *I think I'm managing well with everything* Watch battery not holding its charge – participant provided with charger to use over night. Review session 3:2 No comments given Review session 4:1	RTP good Patient experiencing fatigue Watch design liked for not having any additional information Keen that technology does not distract from exercises CueS malfunction – battery life CueS malfunction – battery life

	No comments given as patient did not wear for two days due to forgetting to put on and then being unwell. <u>Final Review</u> *programme was better than I thought it would be. I just need to work on my writing.*	Patient not adhering to wearing device – could be related to previous cueS malfunction? Benefitted from RTP
P7	<u>Review session 1:1</u> *Its quite hard. Need somebody there to keep me right* <u>Review session 2:1</u> No comments given as patient had been unwell <u>Review session 2:2</u> *I feel better for doing the exercises - makes me feel like I want to do more* <u>Review session 3:1</u> *It's good – I'm getting used to the idea of controlling my left arm. Difficult to see and understand the interface*[*]	Finding RTP difficult without help Feeling benefit from RTP – motivating Feeling the benefit from programme. Finds the interface difficult to see / understand

	Review session 3:2 No comments given due to watch malfunction Review session 4:1 *it's good that movements are being recorded. I feel I'm not getting enough session (*from NHS physiotherapist) Final Review *I'm thinking to use my arm more.*	CueS malfunction Likes that activity is recorded Increased arm activity
P9	Review session 1:2 No comments given Review session 2:1 *useful, prompts keep you aware* Review session 2:2 *The rubber on the watch is sticking*	Prompts raising awareness of arm Watch sticking

	<u>Review session 3:1</u> *It's fine, difficult to put on and off therefore I'm not taking it off.* N.B. Skin was a little itchy under watch <u>Review session 3:2</u> *It's fine* <u>Review session 4:1</u> *It's fine, slight cramp after doing the nut and bolt exercise* <u>Final review</u> *It was all fine except for the watch strap irritated skin and it was difficult to remove watch strap*	Watch difficult to put on/off unimpaired arm Skin irritation when left on RFTP causing cramps Watch uncomfortable and difficult to put on / off
P10	<u>Review session 1:1</u> No comments <u>Review session 2:1</u> *had an off weekend so I haven't done a lot of activity*	Not engaged in much activity

	Review session 2:2 *nee bother – it's been good* Review session 3:1 *Alright* Review session 3:2 *no problems* Review session 4:1 *Its helping to remind me to use my arm* Final review session *Its vibrating all the time every 15-20 minutes. In kitchen doing dishes green lights full and still going off*	Programme good Increase in arm activity Prompting at inappropriate times Prompts too much Green lights not reflecting prompt response
P2	Review session 1:2 *I needed assistance with putting the watch on – the watch on my good hand is more difficult than the Velcro*	Difficulty putting watch on / off unimpaired arm Velcro strap easier than clasp

	<u>Review session 2:1</u> *I'm finding it fine - no problems. Bit difficult fitting it into hospital routines as not up until 11am* <u>Review session 2:2</u> *It helps you to do extra movement* <u>Review session 3:1</u> *It's not waterproof, you don't get all the data due to this* <u>Review session 3:2</u> *watch should be louder as I don't hear if I'm asleep. It's good to remind me about my arm though and I like how you record my practice* (referring to alphabet wheel on daily log sheet) <u>Review session 4:1</u> *It's good but missing important times like when using my hand in the shower*	Hospital routines interfere with RTP Increases arm movement Disappointed that not everything is captured Prompt vibration not strong enough Increase in arm activity Daily log sheets useful Disappointed that not everything is captured

	Final review *Its good that it motivates you to use your arm. Activities were a good challenge. There were no bad points except that my right hand has not progressed so well* (both hands effected by ataxic movements)	Increase in arm activity RTP good and challenging Disappointed not made more recovery
P5	Review session 1:1 *Good to have something to do outside therapy time* Review session 2:1 *Good but think I naturally push myself too hard with arm activity* Review session 2:2 *Beneficial as it focuses you on doing something and its up to me when and how much to do but it reminds me if I've not done enough* Review session 3:1 *All good, bringing attention to my stroke side. I've become more aware of the need to use both hands in activities*	Keen to have self-directed exercises Ambivalence around being motivated to do more but finding it hard Feels has some control over how much to do Benefit of being reminded to move more Prompts raise awareness of stroke side Positive effect on inattention Increase in impaired arm use

	Review session 3:2 *Difficult sometimes to keep a focus on things due to other things going on and emotional impact of stroke* Review session 4:1 *Good all the way. Helps focus on things. Repetitive tasks may have been too much*	Finding the rehab difficult and hard work. Acknowledging all the other areas of recovery aside of the arm Prompts have helped to keep focus but RTP too much
P6	Review session 1:1 *It's interesting because it stretches me but within a day and a half I can see progress which is encouraging* Review session 2:1 *It makes you think. Knowing that I can see what my arm has been doing motivates me to do more* Review session 2:2 *It makes you think and work hard*	Finding it hard work but seeing the benefit of the RTP programme Encouraging Seeing the data increases motivation Increases motivation to increase arm activity

	<u>Review session 3:1</u> *It's encouraging but I felt a bit despondent on one occasion when I got prompted despite a very busy morning* <u>Review session 3:2</u> *the Velcro straps have clicked a pair of my trousers.It's fascinating – like seeing the feedback on screen and being able to relate it to what I've done. I can see how far my hand has come.* <u>Review session 4:1</u> *I find it buzzes even though I know I have done the work. I always know its there to remind me"* <u>Final Review</u> *I woke up with a shock on one occasion when the prompts went off while asleep. It hasn't bothered me on any previous occasions though.*	Disappointed when prompted despite using arm Patients perception of amount of use may not match that of the accelerometer Design of Velcro strap catching on trousers Likes visualising data on interface Interface makes sense and can relate to what has been done during the day. Interface allows participant to see progress Is being prompted even though the arm has been active. Reassured that it will remind to use the arm Vibration prompt too strong and woke patient up on one occassion
P8	<u>Review session 1:1</u> *Managing well and I feel like I'm improving*	RTP benefiting recovery

	Review session 2:1 *watch feels awkward* Review session 2:2 *"I'm finding it alright. Finding repetitive tasks useful now and would like more. If the vibration was stronger it would feel better* Review session 3:1 *I can feel the watch buzzing* Review session 3:2 *I get sick of prompts going off on days when I'm tired. Its made me think to use my hand more though so achieving more* Review session 4:1 *Its benefitted me as made me do more. Sometimes I can't feel it or hear it when other people do* Final review *Its made me remember to use my hand more. I feel I've done much better than if I hadn't had the watch.*	Design of watch awkward RTP useful Prompt vibration not strong enough Prompt vibration strong enough Too many prompts Patient fatigued Increase in activity Aware that sometimes prompt vibration not strong enough Conscious that other people might be bothered by the prompt Increase in arm activity Benefit to recovery

Appendix R. Numbered list of initial coding from participants comments

1. CueS wristband malfunction
2. Daily log sheets
3. Response to prompts
4. Design of the CueS wristband
5. Repetitive task programme
6. Recording of arm movements
7. Experience of wearing the watch
8. Intensity of the programme
9. Viewing of the data
10. Wearing the watch on the unimpaired arm
11. The strength of the vibration prompt
12. Negative feelings when prompt my not be justified
13. Other
14. Increase in arm movements
15. Missed data due to watch not being waterproof
16. Feelings / emotional response to the programme
17. Participant having control over what they did
18. Benefit of being reminded to move arm

Appendix S. Codes applied to initial comments

Participant	Comments from participants of good and bad points of the programme	Initial coding of comments	Code
P1	<u>Review session 1:1</u> *frustrated as I expected it to prompt* <u>Review session 2:1</u> *Well I'm still wondering why it hasn't vibrated yet* (patient reminded that CueS hadn't been set to prompt in first week but would prompt after today. <u>Review session 2:2</u> *fed up because I can't feel the prompts* (watch malfunctioning and so no prompts received) <u>Review 3:1</u> *Shhhh … no comment* (watch still not delivering prompts) <u>Review 3:2</u>	Confusion caused as prompts not set until session 2:2 Confusion caused as prompts not set until session 2:2 Frustration caused by watch malfunction Frustration caused by watch malfunction	13 13 1, 16 1, 16

	Review 4:1 *It reminds me to check the time as it vibrates every hour. It made me more aware to exercise my arm but I don't like filling in the sheets* Final Review *It stimulates and reminds you to do things. I like to write down in my own diary what I've done – that helps too. The watch catches on my sleeve though.*	Prompts useful as a memory aide to orientate patient to time. Increase in activity Daily log sheets not liked Prompt reminds patient to move more Patient prefers own diary to log sheets Watch catching on clothing	3, 14, 18 2 3, 14,18 2 4
P3	Review session 1:1 *fine - no problems* Review session 2:1 *found weight bearing activities good – I can feel the muscles on top of my arm*	RFT exercise good – feeling the benefit	5, 16

	<u>Review session 2:2</u> *good to have extra input for my arm as NHS therapists mainly focusing on legs* <u>Review session 3:1</u> *it's reminding me to do the exercises. Sometimes I forget to put it on and lose opportunities like when in shower. Would be better if you didn't need to take it off* <u>Review session 3:2</u> *good because it reminds you to do something when it beeps* <u>Review session 4:1</u> *Prompts have been good to remind me to use my arm. No bad parts* <u>Final Review</u> *Prompts are really helpful to remember to move the arm*	Benefitting from the RFTP Prompts benefitting arm use Disappointed that not everything is captured Better if you could wear it all the time Prompts reminding to increase activity Prompts reminding to increase activity Prompts reminding to increase activity	16, 5 3, 18 4, 15 4 3, 14, 18 3, 14, 18 3,14, 18

P4	<u>Review session 1:1</u> *Managing exercises well but CueS device malfunction and so no data recorded* <u>Review session 2:1</u> *Its good, I try to get more done in the morning as tired by the afternoon* <u>Review session 2:2</u> Patient preferred that the watch does not have any information on the screen as he wants to focus on exercises rather than the watch Battery not holding its charge so some missing data <u>Review session 3:1</u> *I think I'm managing well with everything* Watch battery not holding its charge – participant provided with charger to use over night.	RTP ok CueS malfunction RFTP good Patient experiencing fatigue Watch design liked for not having any additional information Keen that technology does not distract from exercises CueS malfunction – battery life CueS malfunction – battery life	5 1, 4 5, 14 8, 16, 13 4 4 4, 1 5 4, 1

	Review session 3:2 No comments given Review session 4:1 No comments given as patient did not wear for two days due to forgetting to put on and then being unwell. Final Review *programme was better than I thought it would be. I just need to work on my writing.*	Patient not adhering to wearing device – could be related to previous cueS malfunction? Benefitted from RTP	16, 1, 18 5
P7	Review session 1:1 *Its quite hard. Need somebody there to keep me right* Review session 2:1 No comments given as patient had been unwell Review session 2:2 *I feel better for doing the exercises - makes me feel like I want to do more*	Finding RTP difficult without help Feeling benefit from RTP – motivating	5 5, 16, 14

	Review session 3:1 *It's good – I'm getting used to the idea of controlling my left arm. Difficult to see and understand the interface*[*] Review session 3:2 No comments given due to watch malfunction Review session 4:1 *it's good that movements are being recorded. I feel I'm not getting enough sessions (*from NHS physiotherapist) Final Review *I'm thinking to use my arm more.*	Feeling the benefit from programme. Finds the interface difficult to see / understand CueS malfunction Likes that activity is recorded Increased arm activity	5 9 1 4, 9, 16, 8 14, 8
P9	Review session 1:2 No comments given Review session 2:1 *useful, prompts keep you aware*	Prompts raising awareness of arm	14

	Review session 2:2 *The rubber on the watch is sticking* Review session 3:1 *It's fine, difficult to put on and off therefore I'm not taking it off.* N.B. Skin was a little itchy under watch Review session 3:2 *It's fine* Review session 4:1 *It's fine, slight cramp after doing the nut and bolt exercise* Final review *It was all fine except for the watch strap irritated skin and it was difficult to remove watch strap*	Watch strap sticking Watch difficult to put on/off unimpaired arm Skin irritation when left on RTP causing cramps Watch uncomfortable and difficult to put on / off	4 4, 10 5, 8 5, 10

P10	<u>Review session 1:1</u> <u>Review session 2:1</u> *had an off weekend so I haven't done a lot of activity* <u>Review session 2:2</u> *nee bother – it's been good* <u>Review session 3:1</u> *Alright* <u>Review session 3:2</u> *no problems* <u>Review session 4:1</u> *Its helping to remind me to use my arm* <u>Final review session</u> *Its vibrating all the time every 15-20 minutes. In kitchen doing dishes green lights full and still going off*	Not engaged in much activity Programme good Increase in arm activity Prompting at inappropriate times Prompts too much Green lights not reflecting prompt response	13, 18 5 3, 14, 18 3, 4, 12, 16, 1 4 4

P2	<u>Review session 1:2</u> *I needed assistance with putting the watch on – the watch on my good hand is more difficult than the Velcro* <u>Review session 2:1</u> *I'm finding it fine - no problems. Bit difficult fitting it into hospital routines as not up until 11am* <u>Review session 2:2</u> *It helps you to do extra movement* <u>Review session 3:1</u> *It's not waterproof, you don't get all the data due to this* <u>Review session 3:2</u> *watch should be louder as I don't hear if I'm asleep. It's good to remind me about my arm though and I like how you record my practice* (referring to alphabet wheel on daily log sheet)	Difficulty putting watch on / off unimpaired arm Velcro strap easier than clasp Hospital routines interfere with RTP Increases arm movement Disappointed that not everything is captured Prompt vibration not strong enough Increase in arm activity Daily log sheets useful	4, 10 4 13 14, 8 4, 15, 16 4, 18, 11 18, 6, 2

	Review session 4:1 *It's good but missing important times like when using my hand in the shower* Final review *Its good that it motivates you to use your arm. Activities were a good challenge. There were no bad points except that my right hand has not progressed so well* (both hands effected by ataxic movements)	Disappointed that not everything is captured Increase in arm activity RTP good and challenging Disappointed not made more recovery	15, 16, 4 16, 14 5 16
P5	Review session 1:1 *Good to have something to do outside therapy time* Review session 2:1 *Good but think I naturally push myself too hard with arm activity* Review session 2:2 *Beneficial as it focuses you on doing something and its up to me when and how much to do but it reminds me if I've not done enough*	Keen to have self-directed exercises Ambivalence around being motivated to do more but finding it hard Feels has some control over how much to do Benefit of being reminded to move more	8, 13, 5 16, 8, 5, 5, 17, 18, 8

	<u>Review session 3:1</u> *All good, bringing attention to my stroke side. I've become more aware of the need to use both hands in activities* <u>Review session 3:2</u> *Difficult sometimes to keep a focus on things due to other things going on and emotional impact of stroke* <u>Review session 4:1</u> *Good all the way. Helps focus on things. Repetitive tasks may have been too much*	Prompts raise awareness of stroke side Positive effect on inattention Increase in impaired arm use Finding the rehab difficult and hard work. Acknowledging all the other areas of recovery aside of the arm RTP too much	13, 14 13 14 8, 16, 13 5, 8
P6	<u>Review session 1:1</u> *It's interesting because it stretches me but within a day and a half I can see progress which is encouraging* <u>Review session 2:1</u> *It makes you think. Knowing that I can see what my arm has been doing motivates me to do more*	Finding it hard work but seeing the benefit of the RTP programme Encouraging Seeing the data increases motivation	8, 5, 16 16, 9, 8, 17

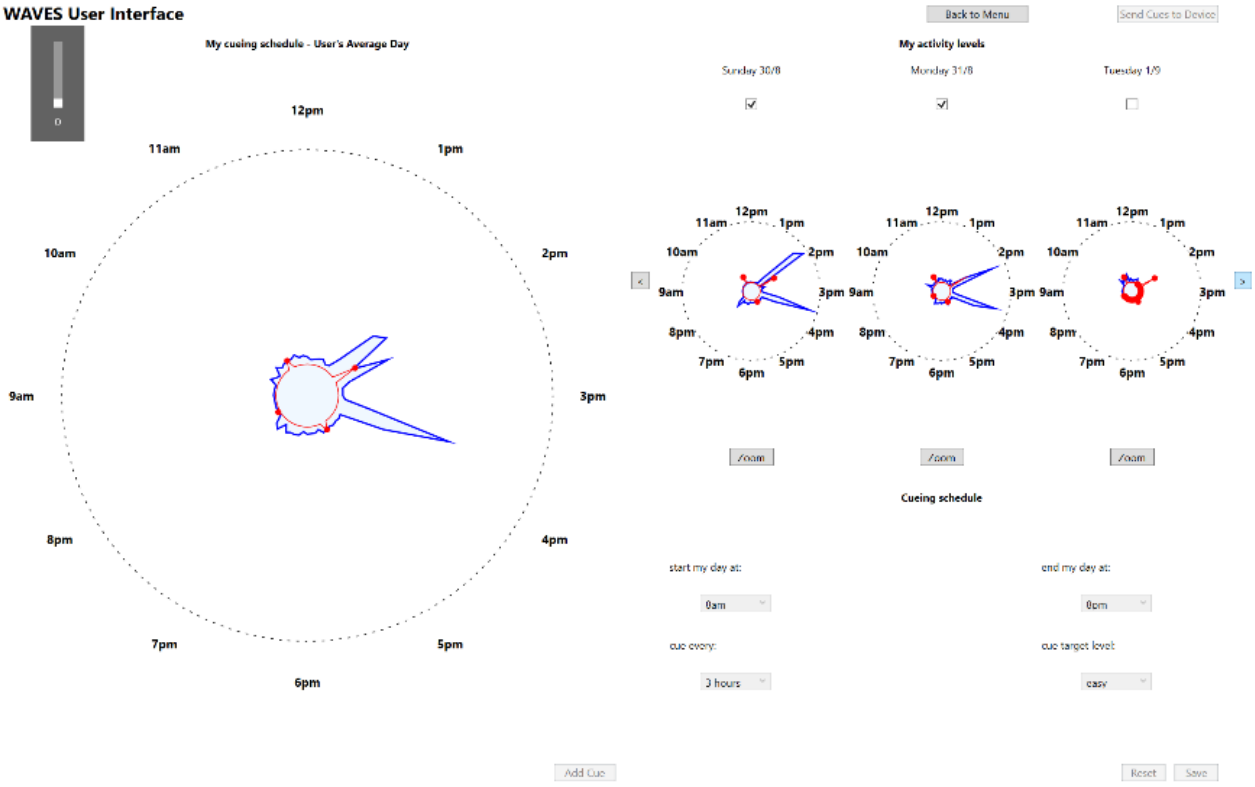
	Review session 2:2 *It makes you think and work hard* Review session 3:1 *It's encouraging but I felt a bit despondent on one occasion when I got prompted despite a very busy morning* Review session 3:2 *the Velcro straps have clicked a pair of my trousers.It's fascinating – like seeing the feedback on screen and being able to relate it to what I've done. I can see how far my hand has come.* Review session 4:1 *I find it buzzes even though I know I have done the work. I always know its there to remind me"*	Increases motivation to increase arm activity Disappointed when prompted despite using arm Patients perception of amount of use may not match that of the accelerometer Design of Velcro strap catching on trousers Likes visualising data on interface Interface makes sense and can relate to what has been done during the day. Interface allows participant to see progress being prompted even though the arm has been active. Reassured that it will remind to use the arm	16, 8, 17 16, 17, 3, 4, 12, 4, 9, 9, 17, 16, 16, 12, 3 3, 16

	Final Review *I woke up with a shock on one occasion when the prompts went off while asleep. It hasn't bothered me on any previous occasions though.*	Vibration prompt too strong and woke patient up on one occassion	4, 11,
P8	Review session 1:1 *Managing well and I feel like I'm improving* Review session 2:1 *watch feels awkward* Review session 2:2 *"I'm finding it alright. Finding repetitive tasks useful now and would like more. If the vibration was stronger it would feel better* Review session 3:1 *I can feel the watch buzzing*	RTP benefiting recovery Design of watch awkward RTP useful Keen to increase intensity Prompt vibration not strong enough Prompt vibration strong enough	5, 4 5 8 11,4, 3 11, 4, 3

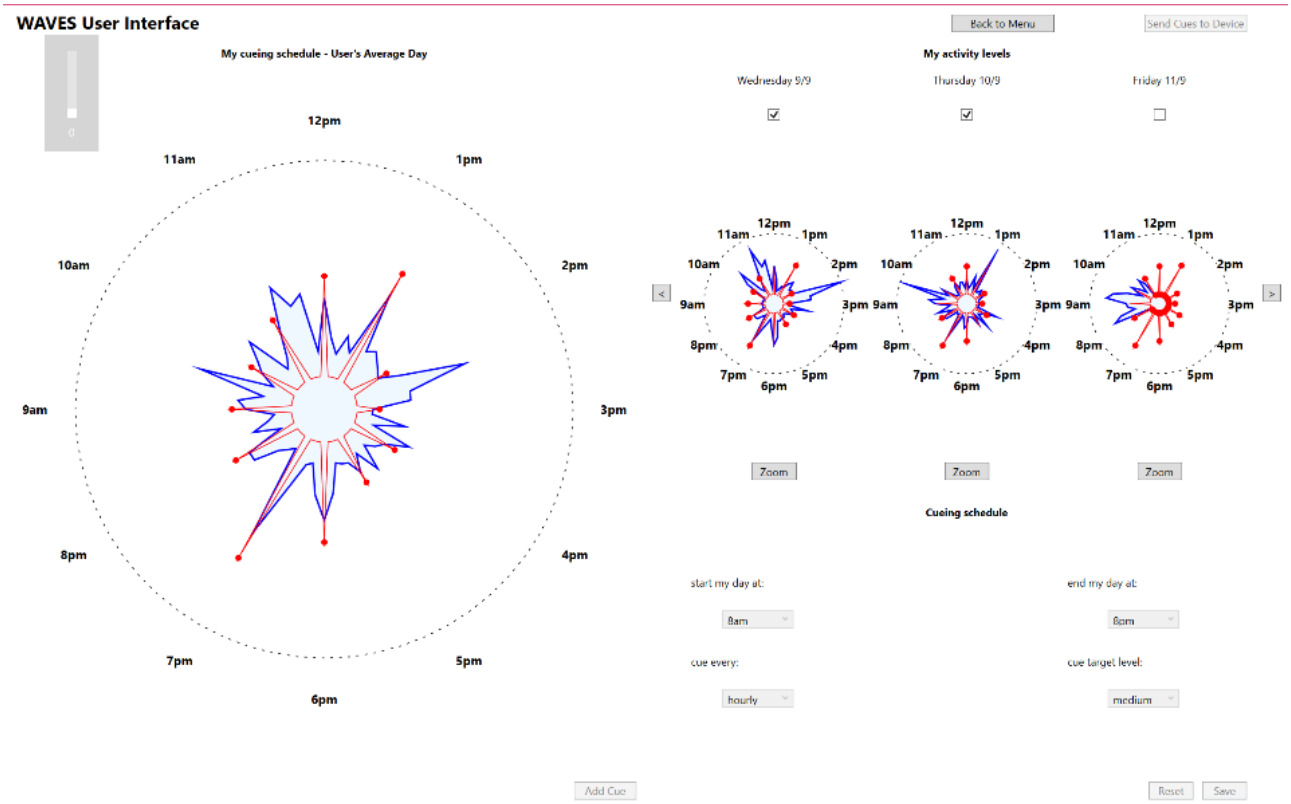
	Review session 3:2 *I get sick of prompts going off on days when I'm tired. Its made me think to use my hand more though so achieving more* Review session 4:1 *Its benefitted me as made me do more. Sometimes I can't feel it or hear it when other people do* Final review *Its made me remember to use my hand more. I feel I've done much better than if I hadn't had the watch.*	Too many prompts Patient fatigued Increased arm activity and feeling pleased that achieving more as a result Increase in activity Aware that sometimes prompt vibration not strong enough Concerned that other people might be bothered by the prompt Increase in arm activity Benefit to recovery	8, 3, 16 14, 16, 3 14, 16 4, 11, 16 14, 18, 16

Appendix T. Example of activity data from baseline to four weeks

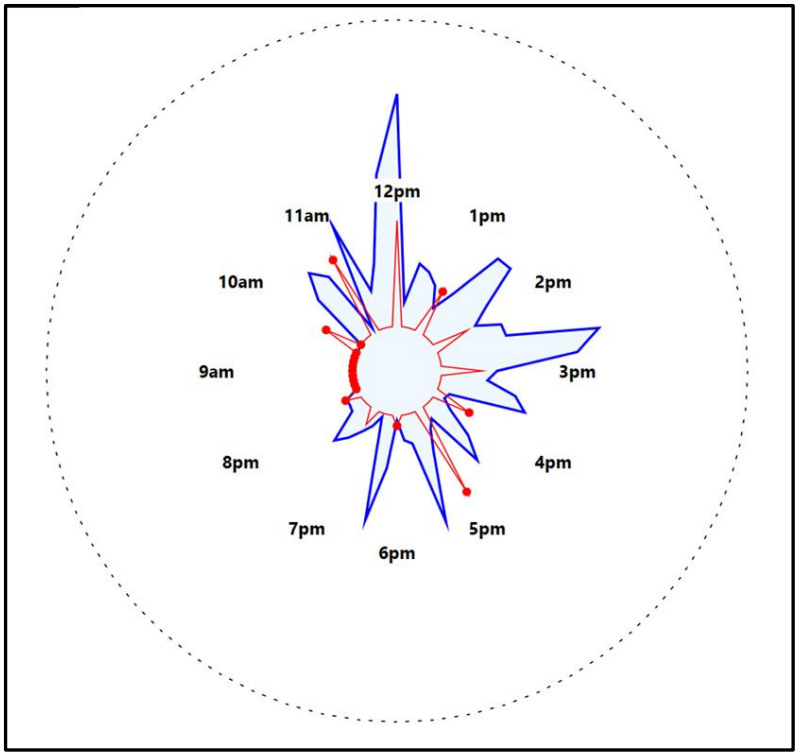
Participant 3: Baseline activity data



Particpant 3: Four weeks activity data



Appendix U. Example of one day's activity data



- Patient put watch on around 10am after carer had been
- Patient used hand to eat breakfast
- 11 am got ready to go out
- Around 11:30 patient routinely got taxi to the High Street and returned about 1pm
- Did exercises in the afternoon
- 5:30 carer came to change for bed

Appendix V. Therapy Manual

Wristband Accelerometers to motiVate arm Exercise after Stroke

(WAVES Study)

Therapy Manual

Please do not hesitate to contact Ruth Da Silva at the Newcastle University Stroke Research Group if you have any queries on:

Tel: 0191 2083842

Email: Ruth.Da-Silva@ncl.ac.uk

Contents

Background to the research project

Loss of upper limb function affects up to 85% of patients with acute stroke [1]. Patients report that it is one of the most distressing long term consequences of stroke and rehabilitation pays insufficient attention to the upper limb. Severity of impairment and rates of recovery vary considerably. Overall only 5-20% of stroke patients with an initial upper limb impairment fully regain function, and 30-66% have no function at six months [2]. In contrast, 80% of patients are eventually able to walk again [3]. Stroke patients who are unable to use their upper limb, even if ambulant, may require a prolonged inpatient stay and long term support from their families, friends and social services.

To improve arm function, theories of neuroplasticity and motor learning support a personalised therapy approach based on frequent rehearsal of functional tasks [4]. More time spent practising skills is expected to result in improved functional recovery with a suggested dosage of at least 20 hours of practice over a 4 week period [5] [6]. To provide effective repetitive functional task practice without additional resources, patients are being encouraged to initiate frequent activity themselves [7]. This approach enhances rehabilitation within current funding constraints as well as empowering patients and carers to be more involved in the recovery process.

Large pragmatic studies are still required to demonstrate whether patients can independently sustain a therapeutic level of activity which results in functional benefits. Qualitative studies indicate that patients and therapists wish to embrace technology to support high intensity upper limb rehabilitation, but barriers include impractical designs, lack of integration into individual therapy programmes and insufficient evidence for cost-effectiveness [8, 9]. Robot-assisted approaches can safely achieve high levels of precise repetitions without direct therapist supervision but studies have been small and the high cost prohibits home therapy. There is a need to develop affordable portable technology which promotes personalised self-supported upper limb rehabilitation activities whether patients are in hospital or at home.

The Cues wristband

The CueS wristband is a programmable wrist worn cueing device incorporating an accelerometer, miniature motor to cause vibration and simple LED display. Accelerometers are small electronic components that detect changes in the direction and velocity of movement. The CueS wristband (pictured below) was developed specifically for people with stroke, with previously established technology, by the Open Lab research group at Newcastle University. Inside the soft silicone wristband is an exchangeable sensor (the Axivity WAX9 Inertial Measurement Unit) which constantly measures and records arm movement [10]. Should the quantity of movement over a chosen time interval fall below a predetermined threshold, the wearer is prompted by a gentle vibrating-alert and can choose whether to generally increase their impaired limb activity during the next monitoring interval or to undertake specific additional activities (see p. 9 'therapy programme'). The threshold and time interval for prompts can be set for the individual wearer based upon their previous movement record. The wearer is

guided in between prompts by a simple visual representation of coloured LED lights indicating how close they are to achieving their upper limb activity threshold. This additional "live" attention to the impaired limb could be particularly helpful for avoiding the negative impact of "learned non-use" [11] i.e. when patients with some preserved motor function of their impaired side still rely upon their unimpaired arm, particularly in the presence of perceptual difficulties. The CueS prompt has the potential to draw attention to the impaired limb, through periodic vibration, if activity falls below the predetermined threshold.

Currently the optimal dose of therapy for the upper limb following a stroke for any one individual is unknown [12, 13] and difficult to measure during self-supervised practice. As well as short-term encouragement through personalised prompts and ongoing visual feedback, an objective report created by CueS wristband monitoring may help to guide clinical decisions regarding the selection and encouragement of daily activities in the therapy programme.

Research project work completed to date

1. User based design process

An initial user based design process was undertaken with stroke survivors who have long-term upper limb weakness to explore the acceptability and usability of the CueS wristband. To test the design concept, the CueS wristband was set to provide a prompt every hour during patient's daily routine rather than in response to movement. Stroke survivors reported that it was acceptable to receive a frequent prompt by vibration, and CueS data showed an increase in arm movement following prompts [14] .

2. Prospective evaluation of a four week CueS programme (DP-WAVES)

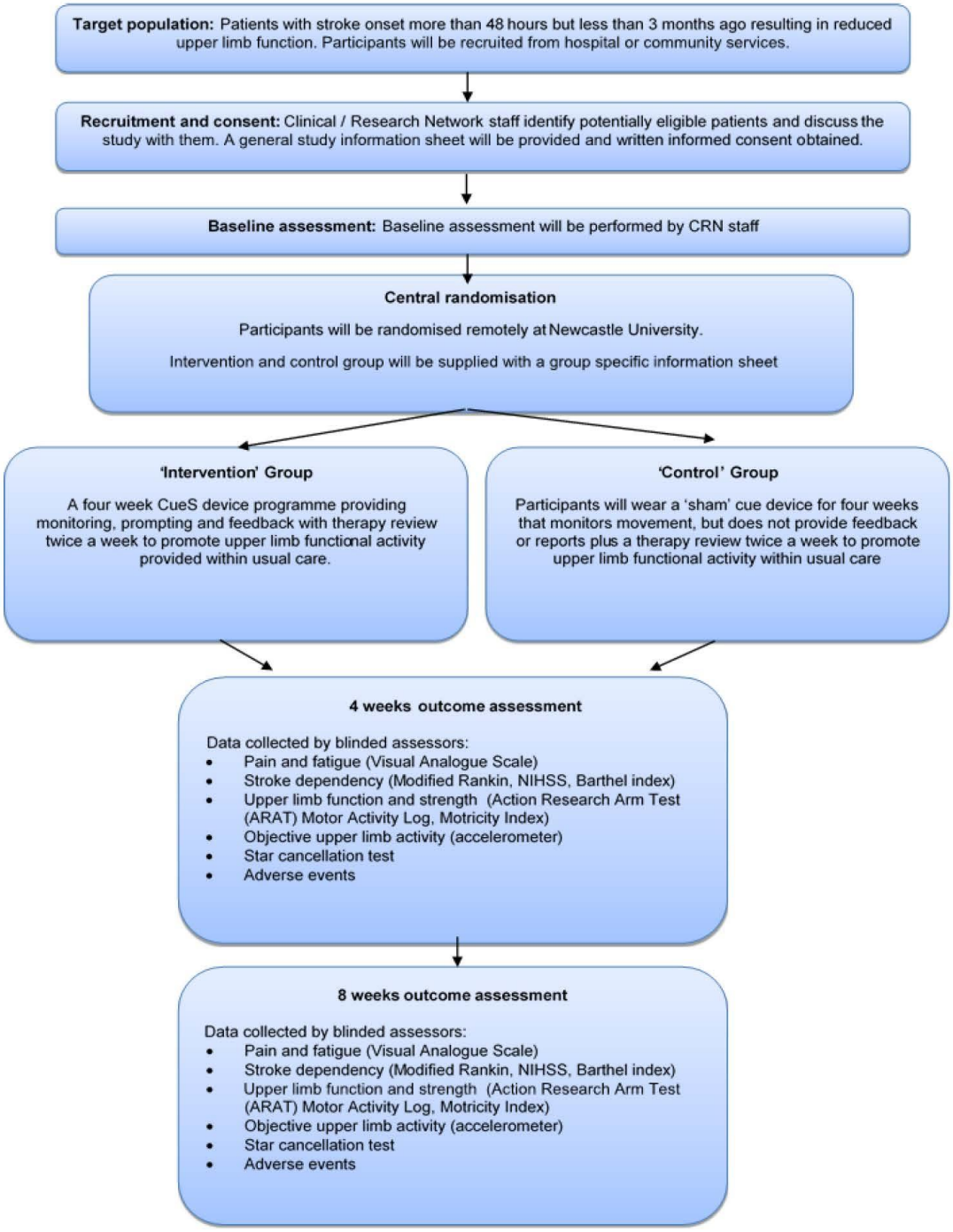
A prospective evaluation of a four week CueS programme with eleven patients after recent stroke (REC number 15/NE/0112) was undertaken. The participants experienced an average of four prompts per day and there was a mean increase in upper limb activity of 21% in the hour following a prompt compared to the previous hour. Feedback collected from study participants and the experience gained by the research occupational therapist allowed further modification and revision of the intervention.

The WAVES study

We have been awarded funding from The Stroke Association to develop and pilot a therapy programme using the CueS wristband ('The WAVES programme') to prompt people with reduced upper limb function and encourage movement following stroke. This work will inform the design of a future large scale multicentre randomised controlled trial to determine the clinical and cost effectiveness of the CueS wristband during stroke rehabilitation.

To test if the CueS wristband is effective participants will be randomised into one of two groups. Both groups will receive a therapy programme (in addition to usual care) but Group 1 (the control group) will wear a 'sham' or placebo CueS wristband and Group 2 (the intervention group) will wear a CueS wristband that provides prompts and visual feedback.

WAVES Study Summary



Study Population

Adults with any stroke subtype who fulfil the following criteria will be eligible:

Inclusion criteria

- Age ≥ 18 years.
- >48 hours but < 3 months post stroke onset
- New reduced upper limb function on one side.
- Able to provide informed consent to participate in the study.
- Living within the community services catchment area of a participating study centre.
- Receiving ≥ twice weekly NHS therapy which is planned to continue for four weeks from the start of the intervention.

Exclusion criteria

- Severely reduced upper limb function which results in inability to lift the affected hand off the lap when sitting.
- Unable to follow the programme due to significant cognitive impairment or communication difficulties.
- Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain that inhibits participation in the programme.
- Diagnosis likely to interfere with rehabilitation e.g. registered blind, severe visual problems as a result of stroke, palliative treatment approach being provided.
- Unable to sense both Cues wristband vibratory prompts and visual display.

Study baseline assessment

A study baseline assessment will be performed by a CRN staff member following patient consent to study participation. Prior to study baseline assessment and participant randomisation, a CRN staff member will check that a member of the local NHS therapy service (OT or physiotherapist) is available to provide an initial therapy session within seven days. Once consent and baseline assessments have been completed the CRN member of staff will contact the treating therapist to inform them that the participant is ready to start the therapy programme and advise them of the participants study number.

Randomisation

The treating therapist must then contact the Stroke Research group office and request that the participant is randomised according to their study number.

To randomised a new patient contact Deborah Jones on Tel: 0191 2083842

Following randomisation the therapist should provide the participant with the appropriate participant handbook and a CueS wristband to wear on their affected wrist.

Outcome assessments

Outcomes will be assessed at four weeks (+/- 3 days) and eight weeks (+/- 5 days) following randomisation for both the 'intervention' and 'control' groups. Assessments will be undertaken by CRN staff members or research staff blinded to participant allocation. Participants will be provided with a CueS wristband to be worn for three days post outcome assessments. They will also be provided with a pre-paid envelope to send the wristband back to the study co-ordinating centre at Newcastle University after three days. CRN staff will contact participants to arrange an appropriate time to conduct the assessment.

The WAVES programme

The WAVES programme lasts for 28 days and consists of a therapy programme and use of the CueS wristband. Both randomisation groups receive the therapy programme. In addition, the intervention group (Group 2) receive the Cues devise and the control group (Group 1) receive a sham CueS wristband. Please be aware that participants are NOT aware that they have been randomised or that there difference between Group 1 and 2. It is important that they are not un-blinded by therapists as this may affect study results.

At the initial therapy session, each participant is provided with a Participant Handbook containing their individualised programme. Control group participants are provided with the Group 1 Participant Handbook and intervention group participants are provided with the Group 2 Participant Handbook.

Therapy Programme (for all WAVES study participants)

The programme has been designed to support and work with normal NHS upper limb therapy programmes. The aim is to increase the use of the affected upper limb and integrate upper limb activities undertaken in therapy into normal daily routines.

Generating the daily activities list

Each participant is provided with a blank Daily Activities List. The process starts with identifying participant specific upper limb activities that can be practised independently by the participant outside of therapy sessions. The range of activities included in the programme is graded, starting with a few simple upper limb activities and increasing the number and complexity of activities gradually over time. The Daily Activities list is reviewed and extra activities added during twice weekly therapy reviews. Participants are also encouraged to add to their Daily Activities List between therapy reviews. This part of the programme aims to facilitate long-term behaviour change and reduce risk of learned non-use.

1. *Identifying Daily Activities for the participant to practise*

The first step is to identify a range of daily activities the participant would be able to complete using their affected upper limb.

The participant is asked to consider which of their everyday activities involve use of the upper limb by thinking about their daily pattern of activities i.e. from waking up in the morning (e.g. getting washed and dressed, making breakfast etc.) to going to bed. If the participant is unable to complete the whole activity they might consider practising just part of the activity, e.g. if unable to pick the cup up, the participant could practice reaching to touch a cup. In order to balance activities throughout the day, a range of activities should be selected.

Movements or activities practiced within 'usual care' therapy sessions should be incorporated to enable the opportunity for the participant to transfer skills into normal daily activities. This aims to provide enhanced therapy practise and encourage the participant to become more active during their daily routines. See appendix 1 for examples of daily activities.

2. *Creating the participant's Daily Activities List*

Participants select and agree to practice 3-5 of the activities discussed (depending on participant ability). Participant's document their chosen activities onto the participant held Daily Activities List located in the Participant Handbook. Each Activity on the list is represented by a letter of the alphabet.

The therapist ensures the participant is confident to practise the selected activities independently and demonstrates how to complete the Daily Log Sheets in the Participant Handbook. The participant logs activities practiced by marking letters on the Alphabet wheel that correspond with activities on the Daily Log Sheet (see Appendix 2). Activities can be logged during practise sessions or at the end of each day. If participants are unable to complete the Daily Log Sheets, the therapist will ask a family member, friend or member of staff to complete the Daily Log Sheets on their behalf. Participants are encouraged to add to the Daily Activities List during the course of the programme.

Identifying suitable activities can be more challenging for participants who have a severely affected upper limb. Some participants could weight bear through their affected upper limb whilst using the non-affected arm. Alternatively, the therapist could suggest frequent practice of therapist prescribed structured exercises from the participant's usual care the table in Appendix 5 offers suggestions of activities that participants might select depending on their level of arm function.

Generating additional activities to practise during therapy reviews

As upper limb function improves, additional activities will be added to the Daily Activities List. Participants will be visited twice per week by the therapist. At twice weekly therapy review sessions the therapist and participant refer to the Daily Activities List and discuss how well they are managing their current list of activities and which additional activities to add. Additional activities can be identified by:

1. Encouraging the participant to think of their daily routines i.e. from waking up in the morning to going to bed at night and how they could incorporate their affected upper limb into activities. Examples are; washing, eating finger foods, holding cutlery, stroking a pet, turning pages of a newspaper, wiping down table tops etc.
2. Walking with the participant around their home to identify activities in each room that could incorporate their affected upper limb e.g. loading clothes one at a time into/out of washing machine; putting shopping away; taking ornaments off the shelf to dust and replacing; plumping cushions; opening and closing curtains or sorting DVDs alphabetically.
3. Asking participants to think about opportunities when they could use their affected upper limb when out of the house for example putting items into a shopping trolley; taking coins from a purse; carrying a shopping bag.

Remember: Whatever the participant must be able to complete the selected activities safely and independently. This part of the WAVES programme will allow development of a personalised therapy programme which encourages activity between therapy sessions in the context of individual patient recovery and preferences. It aims to encourage practise and transference of skills learnt in therapy sessions.

Completion of the Daily Log Sheet

Participants will be asked log activities practised each day using the Alphabet wheel on the Daily Log Sheets. Daily Log Sheets are located in the Participant Handbook. Daily Log Sheets can be completed throughout the day or at the end of the day. The participant logs activities practiced by marking letters on the Alphabet wheel that correspond with activities on a Daily Log Sheet (see Appendix 2). If a participant completes the same activity more than once they should still only mark that letter once as it is the range of activities across the course of the programme which we are interested in.

In addition, participants will be requested to record whether they have received any upper limb therapy during usual care therapy on their Daily Log Sheet. Usual care upper limb therapy is face to face therapy provided by an Occupational Therapist, Physiotherapist or Therapy Assistant.

CueS Wristbands for intervention and control groups

Both groups will receive the therapy programme described above but Group 1 (the control group) will wear a 'sham' or placebo CueS wristband and Group 2 (the intervention group) will wear a CueS wristband that provides prompts and visual feedback.

GROUP 1 - Study control treatment (therapy programme + a "sham" CueS wristband)

Participants allocated to the control group will wear a 'sham' CueS wristband for four weeks which will monitor activity levels of the impaired limb but will **NOT** deliver prompts or reports on upper limb activity. At each therapy review session the therapist will download the data collected from the CueS wristband (further information is available in the WAVES CueS and interface manual). All CueS alerts will be deactivated and activity reports will not be viewable by the therapist after each data download.

The therapist will reviews participants twice weekly to download data from the CueS wristband and review the participant's therapy programme.

GROUP 2 – Intervention Group (therapy programme + a CueS wristband)

The CueS wristband provided to intervention group participants (Group 2) has been developed to support a self-supervised therapy programme by prompting patients to use their affected upper limb to complete activities or practise everyday tasks. Participants will be provided with a CueS wristband on the first day of the therapy programme. Until the first review session (3-4 days later) the CueS wristband will monitor movement, but no prompts will be delivered. At the first review session the therapist will download the data collected from the CueS wristband and agree the prompt threshold with the patient.

At twice weekly therapy review sessions the NHS therapist will review the therapy programme and download the CueS data (further information is available in the WAVES CueS and interface manual). The prompt threshold and frequency of the prompts can be adjusted to suit the participant's progress (see decision tree appendix 4) The aim is to encourage upper limb activity which is in the upper half of the each patient's individual range of ability without triggering inconvenient prompts.

Only NHS therapists who have received training about the CueS therapy programme should be responsible for reviewing the CueS data and setting prompts.

Important Note: Please be aware that participants are NOT aware of the differences between Group 1 and 2. It is important that they are not un-blinded by therapists when downloading data!!

Delivery of the WAVES programme

1. Initial therapy session (ALL participants).

The first therapy session includes identifying activities to practise and providing a CueS wristband. This session will take approximately 15 to 20 minutes.

Prior to session ensure that a fully charged CueS wristband is available

1) Set up New User

Follow New User instructions in the CueS User Manual to assign the wristband to new participant number. This will automatically clear any previous data and default wristband to no prompts.

2) Provision of CueS wristband

- Demonstrate to participant how to don and doff the CueS ensuring wristband is positioned on the participant's affected upper limb around the wrist NOT further up the arm. Ensure that lights are visible on side of wristband nearest the hand/wrist.
- Demonstrate to the participant how to hold hand up against chest to tap wristband so that lights are easily visible.

3) Selection and demonstration of daily activities

- Work with the participant to identify 3 - 5 activities they can either carry out independently or carry out parts of using their affected upper limb. Encourage the participant to practise these activities and to refer back to them either when prompted by the CueS wristband or to increase their upper limb use throughout the course of the day. Future reviews will encourage participant to add more activities to this list as they feel able to (see appendix 3).
- If appropriate advise on how to integrate therapy exercises into daily routines to allow for additional practise of selected activities as and when participant feels able to across the course of the day.

4) Recording of activities

- Demonstrate to the participant how to record activity practise on the daily log sheets (appendix 2) and to add to the Daily Activities Sheet if they identify any further activities that they could practice.

5) Provision and explanation of the participant handbook

- Provide the participant with a study participant handbook according to which group they are randomised into.
- Demonstrate how to use the participant handbook and explain the sections on using the CueS wristband, the WAVES programme and how to complete the daily log sheets.

2. Twice weekly therapy reviews (ALL participants)

CueS data and prompt settings need to be reviewed twice a week. These can be integrated into usual NHS therapy sessions and will only add approximately 10 minutes per session. An example of the documentation to be completed is located in Appendix 1 and can be kept in the Participant's Handbook between sessions.

1) Downloading data from CueS wristband

- Remove CueS device from the silicone wristband and connect to CueS interface on tablet using the USB cable provided. The interface will automatically download the data for the identified study user. No data should be displayed at this point. To display the CueS data for Group 2 participants ONLY click the middle of the screen where it says "Group 2 participants". The data should now be visible and will automatically be shown at subsequent downloads.

Please be careful when downloading data that "Group 2 participants option is NOT inadvertently selected for GROUP 1 participants as this cannot be undone and risks unblinding the participant!!

- Ask participant if they have had any new medical problems since their last review. If the answer is YES then please refer to the Adverse events section in the Site File.

2) Reviewing Daily Activities Sheet

- Review the activity log sheets and check if there have been any difficulties with completion.
- Encourage the participant to consider additional activities that they could use their affected upper limb with throughout the day and to add these activities to the Daily Activities List as they feel able to (see appendix 1)
- Demonstrate how to record completed prompted activities on the daily log sheet.

(GROUP 2 ONLY)

3) Reviewing CueS data and setting thresholds

- Review the data collected by CueS and set the prompt threshold and frequency. Further guidance on this can be found in the CueS User Manual. And the therapy decision tree (appendix 4).
- Try to encourage the participant to use the prompts they receive as a reminder to use their affected upper limb in an activity. They can use the Daily Activities sheet for ideas of appropriate exercises to do. Suggest to the participant that carrying out frequent shorter activities may be more beneficial than doing a lot of activity once or twice a day.

3. Final therapy review (ALL participants)

A final therapy review will take place at the end of week four.

1) Review of functional activities

- Review the activities set during the programme.

2) Download data from CueS

- Download the data from the CueS wristband.
- Complete therapy review form
- Retrieve the CueS wristband from participant
- Inform participant that they will be contacted by a study therapist to complete the 4 week assessment.
- A final enquiry about adverse events should be made and recorded.

Study roles

Role of the Clinical Research Network (CRN) staff

1. To identify potential participants in collaboration with local stroke unit staff.

2. To initially approach potential participants to discuss the research study, provide an information sheet and subsequently obtain written informed consent.

3. To identify and contact the local NHS therapist to ensure the initial therapy assessment can be completed within 7 days of baseline assessment and randomisation.

4. To complete the study baseline assessment.

5. To contact local NHS therapists to let them know baseline assessment has been completed and provide with participant number.

6. To complete week 4 and week 8 assessments. Provide participants with accelerometer wristbands at the assessments / envelopes.

7. To input data onto the CASTOR database

8. To report serious adverse events

Role of the local NHS stroke therapist

1. To assist CRN staff to identify potentially eligible participants for the research project. Be aware that some patients may not be suitable immediately following hospital admission but may become potentially eligible within the study recruitment period (48 hours – 3 months post stroke).

2. To inform the CRN staff about potentially eligible patients. The initial discussion of the research study with a participant should be performed by the CRN staff.

3. To contact Deborah Jones (**0191 2083842)** to randomise the participant.

4. To provide all study participants with a CueS wristband and Patient Handbook according to which group they have been allocated and explain its completion

5. To give advice and information on use of the CueS wristband to study participants.

6. To deliver the WAVES programme.

7. To prompt participants to practise their 'daily activities' where possible.

8. To identify and report potential serious adverse events to the CRN staff member who will complete an SAE form and forward this to the study research therapist/ chief investigator.

9. Perform twice weekly participant reviews with modification of the programme according to progress and or participant wishes.

Role of the participants

Study participants will be asked to:

1. Undergo an initial arm assessment, wear the CueS wristband for the 4 week programme and select appropriate activities to practise.

2. Practise a range of therapy based activities on a daily basis for four weeks.

3. Agree with their therapist an appropriate programme of activities and exercises that they would be able to manage

4. Log activity practice and feedback in their participant handbook.

5. Undergo twice weekly therapy reviews to allow modification of activities according to progress, and provide feedback on the therapy.

6. Undergo a final therapy review at the end of the study to review participant goals (to document progress) and provide further feedback.

7. Undergo outcome assessments.

8. Wear accelerometers for 3 days after outcome assessments and post back to the study coordinating centre.

Role of the study research occupational therapist (based at Newcastle University)

1. To provide training for NHS staff about the study including baseline assessment, CueS wristband and computer interface set-up and randomisation procedure.

2. To provide training to deliver the WAVES programme for the local NHS therapist(s).

3. To provide information about the WAVES programme to other local stroke research staff.

4. To provide support to the local NHS therapist(s) delivering the WAVES programme

Appendix 1: Daily Activities List

The aim of the WAVES study is to increase the amount you use your stroke arm in your normal daily routines because this will help the arm to recover more quickly.

Use this form to make a list of some of the activities you think you would be able to carry out using your stroke hand. Start with around 5 activities and add to the list as you feel able to do more activities.

To make your list it may help to think through your normal daily routine, hour by hour or to go around each room in your house to generate ideas of things you could practise in each room.

The Cues wristband will let you know how much activity your arm has been involved in as the day goes on and will vibrate to remind you to use your arm if activity levels drop.

At the end of each day record on the Daily log sheet which activities you did for that day.

Examples of activities:

- turning the pages of the newspaper over
- drying up the plates
- feeding myself toast
- holding an apple while I eat it
- stroking the dog

When prompted to use my arm I would like to practise:	
A	wiping down benches
B	Making a hot drink, meals
C	Loading washing machine
D	Hanging out washing - pegs
E	Shopping - lifting items off shelf; putting shopping away
F	Emptying and cleaning out cupboards
G	Folding clothes/ towels
H	Moving ornaments to dust shelves

When prompted to use my arm I would like to practise:	
I	Setting table
J	Gardening - dead heading flowers; weeding; planting tubs
K	Personal care - washing body
L	Turning pages in newspaper
M	Playing cards; turning cards
N	Eat Finger foods
O	Using knife/ fork/ spoon
P	Lifting cup to mouth
Q	Cleaning teeth
R	Using remote control for TV
S	Using computer - typing, use of mouse
T	Load/unload dishwasher
U	Light switches; sockets
V	Sort dirty laundry out
W	Ball games - throwing catching, racquet games. Change ball size from large to small. Use balloons.
X	Washing dishes
Y	
Z	

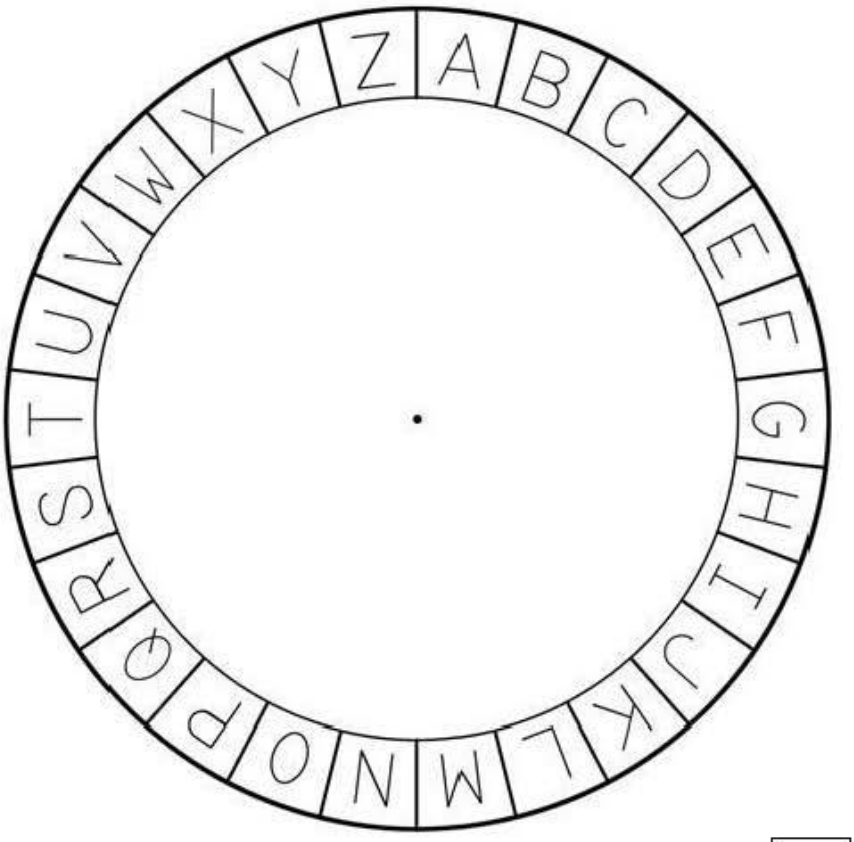
When you complete one of the activities above, circle or cross out the corresponding letter on your daily log sheet. You can add activities to the list whenever you like and discuss them with your therapists.

Appendix 2: Daily Log Sheet

Remember: the aim of the programme is to use your stroke hand as much as possible. Use the activity list for ideas of what you could do using your stroke hand. The Cues wristband will help to ensure that you are doing enough.

At the end of each day, cross out the letters which corresponds with the activities you have practised.

Today I practised the following activities:



Total number of activities practised today: ☐

Did you receive any therapy on your arm today? Yes ☐ No ☐

Appendix 3: Therapy Review Form

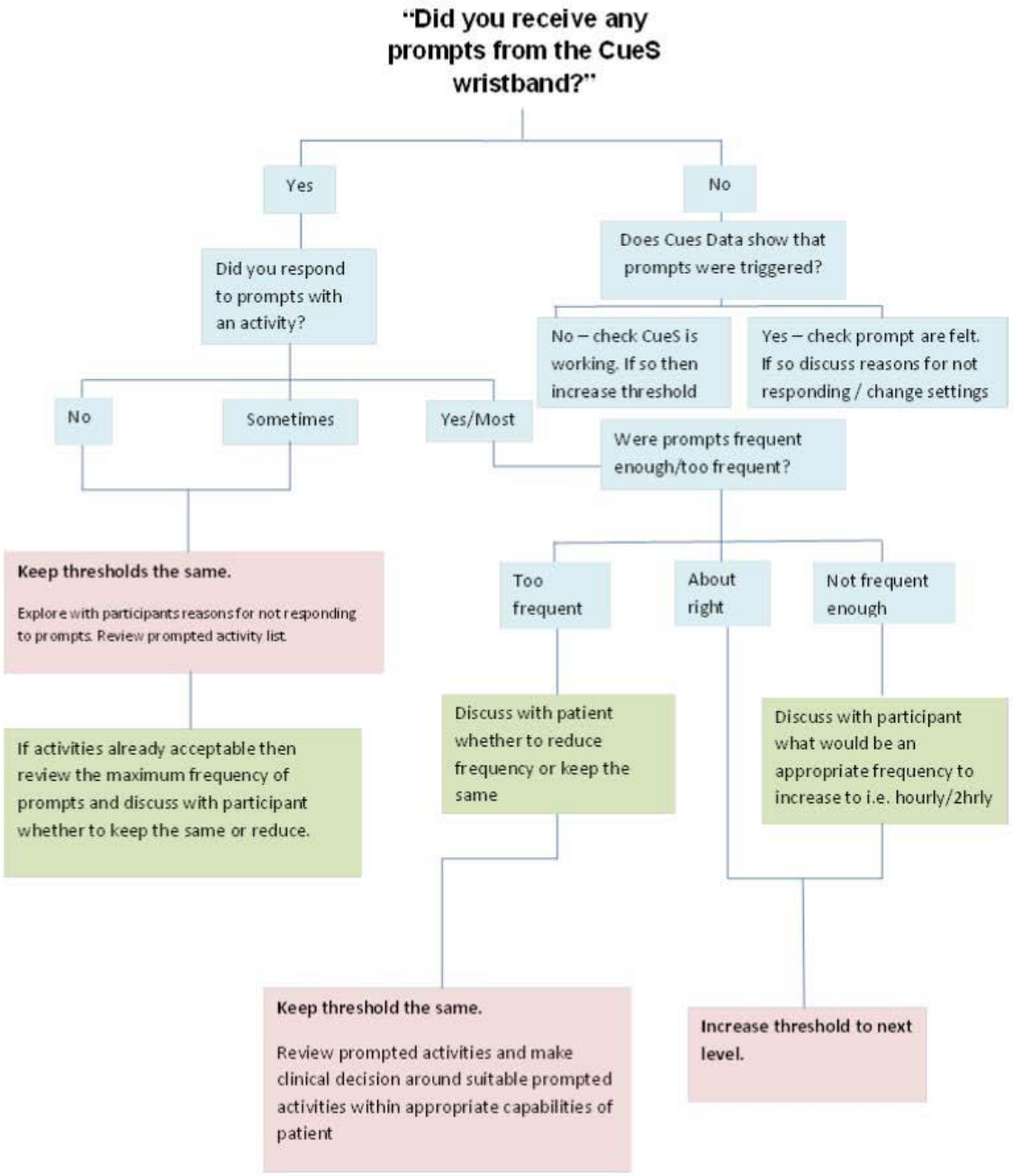
1. Begin session by downloading the CueS data.
2. Following therapy session review how the participant has been finding the activity practice and discuss the CueS data displayed on the computer interface.
3. Complete the following question form to support decisions around setting the prompt settings for the following few days.

	Date:	Date	Date	Date
Are there any new medical problems since the last review? (If so, please refer to decision tree in site file for safety reporting)				
Have there been any times when patient has not worn the CueS devices? Please give reason: (1= forgot to put on; 2=comfort; 3=using water; 4=interfered with routine; 5=other)	n/a	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐
Did participant notice prompts?	n/a	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Approximately how many per day did they feel?	n/a	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐
Was this number: 1. Too much? 2. Not enough? 3. About right? (discuss whether prompts need changing)	 n/a n/a n/a	 1 ☐ 2 ☐ 3 ☐	 1 ☐ 2 ☐ 3 ☐	 1 ☐ 2 ☐ 3 ☐
How did participant respond to the prompts? 1. Practised activity from Daily Activities sheet 2. Practised own self chosen activity 3. Ignored prompt and carried on as normal 4. Other	 n/a n/a n/a n/a	 1 ☐ 2 ☐ 3 ☐ 4 ☐	 1 ☐ 2 ☐ 3 ☐ 4 ☐	 1 ☐ 2 ☐ 3 ☐ 4 ☐
Do the CueS prompts needs to be changed?	n/a	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
1. Prompt threshold setting (n = neutral; l-low; m=medium; h=hard)	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐
2. Frequency of prompts (in mins - 30; 60; 120; 180; 240)	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐

Are there any new medical problems since the last review? (If so, please refer to decision tree in site file for safety reporting.				
Have there been any times when patient has not worn the CueS devices? Please give reason: (1= forgot to put on; 2=comfort; 3=using water; 4=interfered with routine; 5=other)	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐	Yes ☐ No ☐ If no, please state reason: 1 ☐ 2 ☐ 3 ☐ 4 ☐
Did participant notice prompts?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Approximately how many per day did they feel?	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐	0-1 ☐ 2-3 ☐ 4-5 ☐ 5> ☐
Was this number: 1. Too much? 2. Not enough? 3. About right? (discuss whether prompts need changing)	 1 ☐ 2 ☐ 3 ☐	 1 ☐ 2 ☐ 3 ☐	 1 ☐ 2 ☐ 3 ☐	 1 ☐ 2 ☐ 3 ☐
How did participant respond to the prompts? 1. Practised activity from Daily Activities sheet 2. Practised own self chosen activity 3. Ignored prompt and carried on as normal 4. Other	 1 ☐ 2 ☐ 3 ☐ 4 ☐	 1 ☐ 2 ☐ 3 ☐ 4 ☐	 1 ☐ 2 ☐ 3 ☐ 4 ☐	 1 ☐ 2 ☐ 3 ☐ 4 ☐
Do the CueS prompts needs to be changed?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
1. Prompt threshold setting (n = neutral; l-low; m=medium; h=hard)	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐	N ☐ L ☐ M ☐ H ☐
2. Frequency of prompts (in mins - 30; 60; 120; 180; 240)	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐	30 ☐ 60 ☐ 120 ☐ 180 ☐ 240 ☐

Final Therapy Review Session: ask participants for comments about the programme (good and bad points):

Appendix 4: Therapy Decision Tree



Appendix 5: Examples of activities used by different functional level groups

Low levels (unable to grasp)	Medium Level (some flex/ext in hand)	High Level
Reach and touch cup	Pick up phone to ear	Put back onto earring
Rub hand up arm	Pick and place empty cup	Butter bread
Touch wrist	Unscrew lid	Dry cutlery and put in drawer
GRASP exercises (twist etc)	Bring bottle to mouth 2 handed	Fasten buttons
Elastic band on fingers	Pick cup to drink	Put contact lenses on finger tip
Touch elbow	Wipe basin down	Write name and address
Rub leg with stroke hand	Pick n place toothbrush	Put mascara on
Weight bear	Wash hair with both hands	Turn coins over
Stroke cat/dog	Half full cup to drink	Fasten buttons
Wipe bench tops	Pick and place flask	Dry hair with hair dryer
	Alternate hand use within activity	Tie shoelaces
	Cup to mouth	Cut food
	Pick n place hairdryer	shave
	Pick and place flannel	Fasten bra
	Pick up cup to mouth	Spoon sugar into cup
	Pick up knife and fork	Stir cup of tea
	Apply cream to face	Curl hair under brush
	Pick and place cans in cupboard	Cut up food
		Brush hair
		Cut up food and bring to mouth
		Drink from cup
		Pick up marble to mouth
		Finger food to mouth

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Appendix W. WAVES interface user guide

Waves Interface
User Guide

Contents

CueS Device

The *CueS* Device is based on the Open Movement AX9 sensor, with added vibration motor and status LEDs. The device records movement activity level and prompts when activity falls below a programmed threshold. The devices are produced by Open Lab, Newcastle University: http://openlab.ncl.ac.uk/

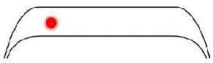
Battery Charge

YOU MUST KEEP THE BATTERY FULLY CHARGED WHEN NOT IN USE.

The easiest way to do this is to:

1. Make sure the device is not recording/prompting by connecting it to the interface and waiting until any data is downloaded and the device is stopped
2. Wait until the battery is fully recharged (all LEDs lit) before unplugging it.
3. Never wait too long between charges: leave connected to a charger to keep topped up.

The device recharges when connected via a micro-USB cable to a powered USB port. When connected, the LEDs indicate charge:

	Device will not operate (less than 5% battery).
	Low battery charge (less than 50%).
	Medium battery charge (less than 80%).
	Good battery charge (more than 80%).
	Fully charged.

Cleaning and Fitting the Device

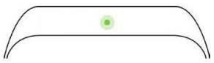
For antimicrobial disinfection, we recommend cleaning using a "Clinimax Difficil-S" solution. For other general cleaning, we recommend using Isopropyl alcohol (IPA) based wipes.

DO NOT SUBMERGE IN WATER.

To insert the device into the silicon band refer to the diagram below. The device must be worn on the wrist, with the LED lights upwards.

Movement Target (Group 2 Participants)

Activating the LED lights will show how close you are to reaching your target. To do this hold your hand up to your chest and firmly tap the top of the watch twice. If all three green lights are, lit then you have reached your target. The target must be maintained to prevent any further prompts.

	No target set for this time of day.
	Working towards 1/3 of the target.
	Achieved at least 1/3 of the target and working towards 2/3.
	Achieved at least 2/3 of the target and working towards the full amount.
	Achieved the target.
	Exceeded the target by 5% or more.

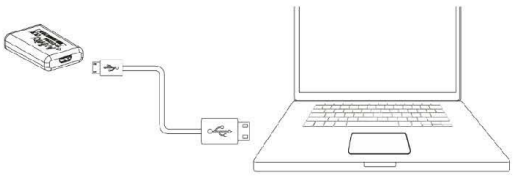
Waves Interface

Starting the Interface

Double click the *Waves* icon to start the program.

Connecting a Device

Connect the device to the computer. Use a standard micro-USB cable to download, re-charge and configure the device.



If the device contains data, the appropriate user should automatically be selected (if you've not already chosen another user), and the data will be downloaded in the background. The status bar at the top of the screen will change when the data download is complete. You can continue using the interface, but must wait until it has finished downloading to configure the device.

IN ALL CASES, WAIT UNTIL THE DEVICE IS FULLY CHARGED (ALL THE LED LIGHTS ARE LIT UP) BEFORE GIVING THE DEVICE TO THE PARTICIPANT.

The top information bar will show the current status of the device:

No device connected – you can connect a device to download or configure it.

Device ID# connected: Downloading data (#%) – The device is busy downloading the raw data in the background. You can continue using the interface, but must wait until it has finished before configuring the device.

Device ID# connected: Cleared – the device has been cleared ready to be put to another use. This will automatically happen when a download has completed. If you are returning the device to the user, you must configure it first.

Device ID# connected: Configured – the device has already been configured, but has not yet collected any data. You can disconnect it to start, or you may re-send an adjusted configuration.

Initial Session/Adding a New User (Groups 1 & 2)

Follow the instructions for *Starting the Interface* and *Connecting a Device*.

Click on the User Menu to expand it.

Click *"Add New User"* button to create a new user.

Enter an study participant number for the new user and press OK to add them.

For both groups, the device will be automatically configured for a recording only (non-prompting) configuration. If the device cannot be configured immediately (e.g. if it is downloading or not yet connected), you will need to press the "Configure Device" button.

Follow-up Sessions: Group 1 Users

Follow the instructions for *Starting the Interface* and *Connecting a Device*.

A mostly blank screen will be displayed – do not click "Show Configuration" for Group 1 users as they should not see their activity.

You must wait until the device data is downloaded and the device has fully recharged.

IF YOU ARE RETURNING THE DEVICE TO THE USER, YOU MUST CONFIGURE THE DEVICE FOR ANOTHER RECORDING.

To configure the device for another recording: click "Configure device" then confirm "Send the recording configuration to the device?" before disconnecting the device.

Follow-up Sessions: Group 2 Users

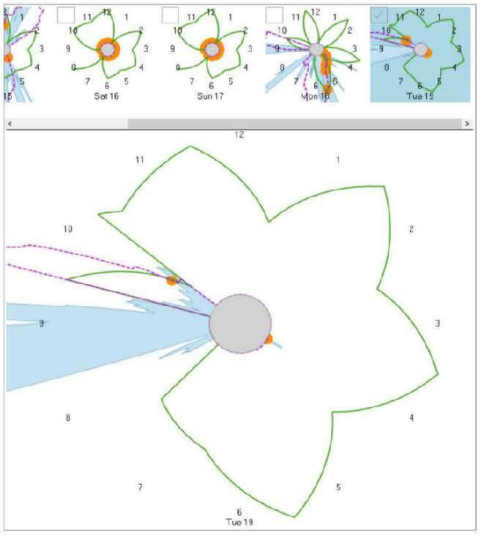
Follow the instructions for *Starting the Interface* and *Connecting a Device*.

The First Review Session

If this is the first review session for a Group 2 user, a mostly blank screen will be displayed. Click on "Show Configuration…" and click on the configuration window (right-hand side of the interface) and a pop up will appear asking if you want to set up a "prompting configuration": click "Yes" to continue.

Day View

The left side of the screen displays a day's view at a time with the highlighted day's data showing.



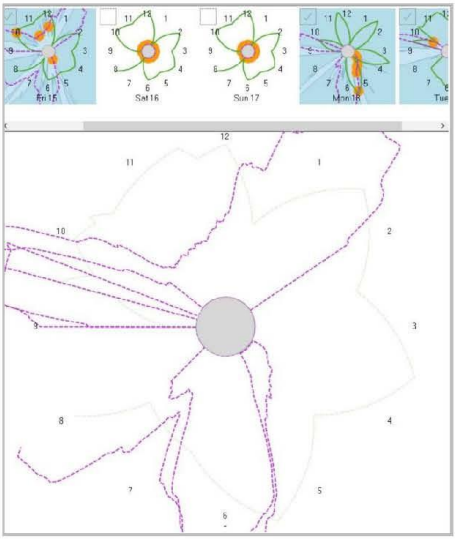
Blue line and area represent the movement data (in a 5 minute window).

Purple dashed line represents the movement average taken in a set window size (default is 60 mins).

Green line represents the threshold set at the time.

Orange dots represent occasions when a user was prompted.

You can select multiples days by clicking in the small dashed box in the top left corner on the thumbnail. This enables you to quickly compare a few days data.

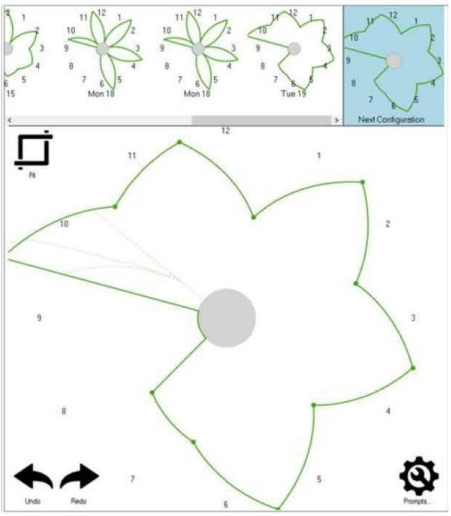


Dashed purple line represents the movement average taken in a set window size (default is 60 mins).

Faint dashed green line represents the maximum prompt threshold for the selected days.

Configuration View: Target Threshold for Prompting

This is displayed on the right hand side of the screen and is where you configure the next prompt settings.



Solid Green Line represents the threshold

The green dots on the solid green line represent handles to adjust the prompting threshold.

Faint dashed Green Line represents the selected days' maximum prompt threshold

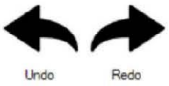
The grey line represents the movement average for selected days (the purple dashed line in the day view)

You should collect data from the user for at least three days before setting a prompting configuration. Select the days you would like to use to determine the prompting threshold from the days bar at the top left (click the small dashed box to select multiple days), then press the “Fit” button in the top left corner of the configuration interface.

Select one of the options available from the given list:

Neutral is 100% of the fit and so will match the threshold to the selected days’ activity, easy is 5% above this level, medium is 10% above this level, and hard is 20% above this level.

To make any fine-grained chenges for specific times, you can click and drag the small green circular “handles” in the configuration interface. To undo or redo any changes use the “Undo” and “Redo” buttons in the lower left corner of the configuration screen:



To change the minimum time between prompts, click the “Prompts” button in the lower right and change the “Minimum Prompt Interval” (one of 30, 60, 120, 180 or 240 mins).

If you want to collect movement data without any prompting, pressing the “No Prompts” button removes all prompting for the user and resets it to the initial, recording-only configuration.

Configuring the device

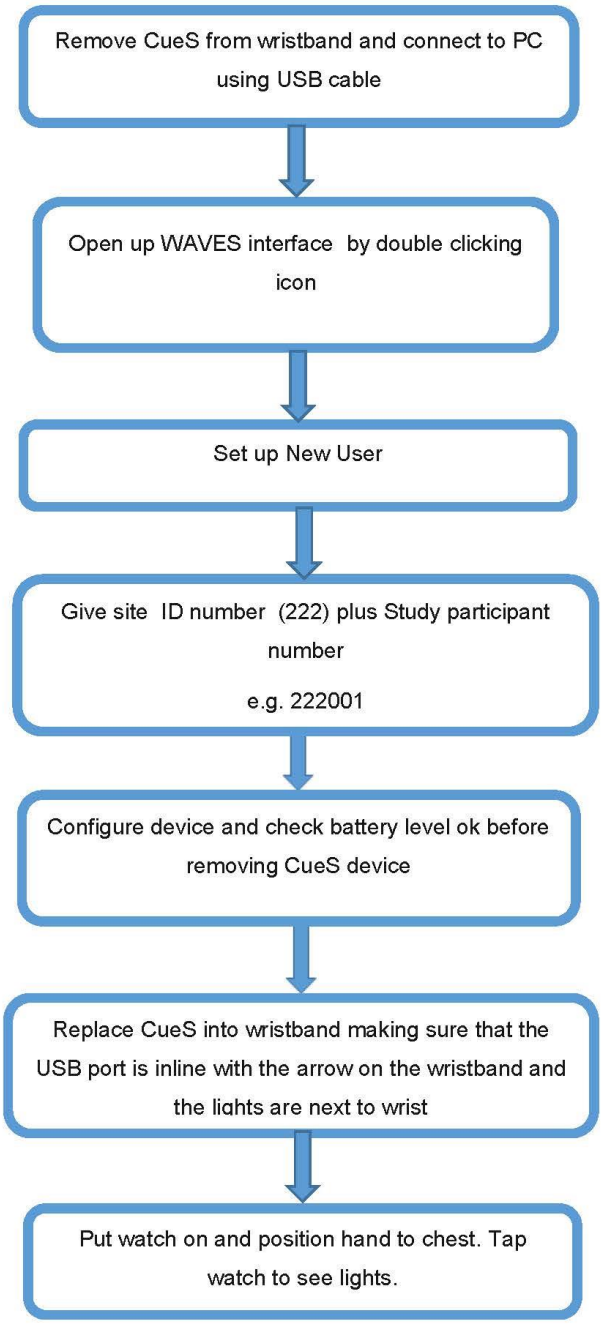
You must wait until the existing device data is downloaded and the device has fully recharged.

IF YOU ARE RETURNING THE DEVICE TO THE USER, YOU MUST CONFIGURE THE DEVICE FOR ANOTHER PROMPTING SESSION.

To configure the device for another prompting session: click “Configure device” then confirm “Send the prompting configuration to the device?” before disconnecting the device.

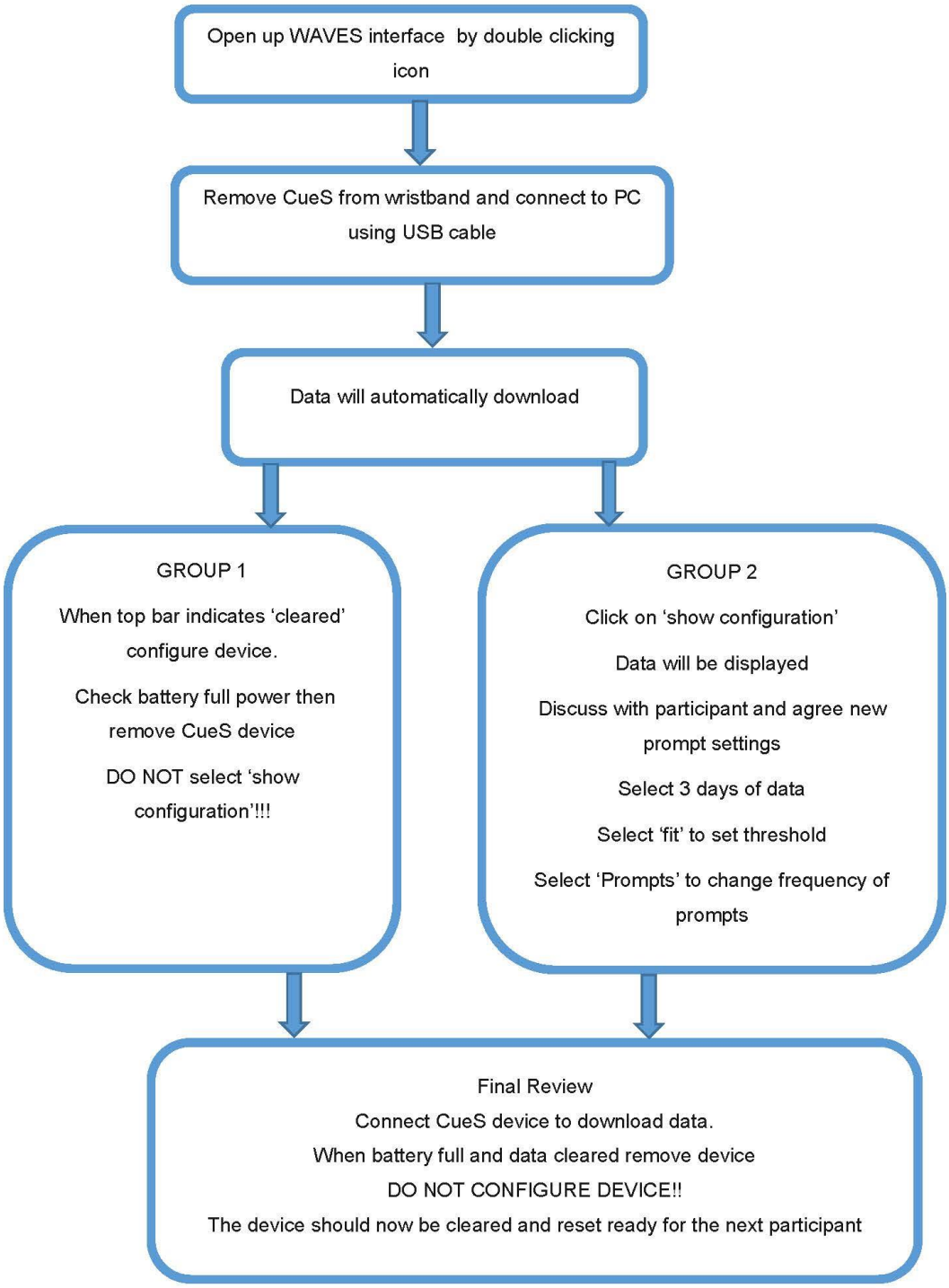
CueS summary flow chart

Initial Set up



CueS summary flow chart

Review sessions



Appendix X Patient information sheet

INSERT NHS SITE LOGO

Wristband Accelerometers to motiVate arm Exercise after Stroke (WAVES Study)

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide whether you would like to take part we would like you to understand why the research is being done and what it would involve for you.

It is important to take time to read this information sheet. One of our research team will go through the study with you and answer any questions that you have. This will take about 30 minutes.

Please feel free to talk to others about the study if you wish. Please ask us about anything that is unclear to you or if you would like any further information.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask us if you are unsure about anything.

Part 1

What is the purpose of the study?

Loss of arm function affects up to 85% of people who have recently had a stroke and is reported to be one of the most distressing long-term effects. Often people feel that rehabilitation does not focus enough on arm recovery.

Recent research has suggested that recovery may be improved by practising activities many times. Patients are being encouraged to carry out additional activities by themselves to increase the amount of practice. However remembering to carry out these activities and using the affected arm throughout the day can still be difficult.

Computer researchers at Newcastle University have developed a wristwatch device called the "CueS wristband". It has been specifically designed to monitor arm movement during the day and may help patients carry out therapy activities to the best possible level.

This small research study will enable us to design a large clinical trial determining if the CueS wristband can be used alongside NHS therapy to improve upper limb recovery after stroke.

This study is being led by a medical consultant and researcher (Dr Christopher Price) and senior occupational therapist (Ruth Da Silva) who work in the NHS and are part of the Stroke Research Group at Newcastle University. It is funded by The Stroke Association, a national charity aiming to improve the care and safety of stroke patients.

Why have I been invited to take part?

You have been invited to take part as you recently had a stroke causing problems with your arm. One of the healthcare professionals involved in your care has suggested that you might be suitable to take part.

Do I have to take part?

No, the decision is entirely up to you. This information sheet is to help you decide. If you agree to take part, we will ask you to sign a consent form. You do not need to give a reason if you don't want to take part. It will not affect the care that you receive if you decide not to be involved.

What will happen to me if I take part?

This research study is a pilot trial. In a pilot trial, we are testing whether the design and practicalities of the trial are appropriate and acceptable. We put people into two groups at random (by chance, like tossing a coin): a 'monitoring' group (group 1) and a 'feedback' group (group 2) who will receive slightly different experiences of wearing the CueS wristband. People taking part in the study and the research team conducting the study cannot choose which group people are allocated to.

Some things that will happen in this research study are the same for all patients who agree to take part, whereas some depend on which group you are allocated into. In order to make the study results more useful, we will not inform you if you are in group 1 or group 2.

All participants who agree to take part in the study will be asked to sign a consent form. Signing a consent form gives your permission to take part in the study. Only sign the form if you want to take part in this study. If you are unable to sign the form, for example because the hand you use for writing is affected by the stroke, you can give your consent verbally, in the presence of someone who will witness your consent and sign the form on your behalf.

All participants who agree to take part in the study will be asked to complete three research assessments:

Research assessment 1: This will take place immediately after you give permission to take part in the study. A member of the research team will collect your contact details and some medical details about your stroke. They will also assess the effects of your stroke by asking you to perform some movements with your arms. In addition, you will be given a small wrist band (called CueS wrist band) which looks like a watch. We will ask you to wear it on your stroke arm during the day for four weeks. The band monitors and records how much you are moving your arm.

Research assessment 2: This will take place four weeks after you enter the study and can be performed in your own home or at the hospital according to your preference. A member of the research team will ask you some questions about how your stroke is affecting your everyday life and ask you to perform some movements with your arms. In addition, they will collect the CueS wrist band you have been wearing.

Research assessment 3: This will take place eight weeks after you enter the study. The assessment consists of similar questions and arm movements to research assessment two. At research assessment three we will provide you with a CueS wrist band for you to wear for three days. You will be given a freepost envelope to send the monitor back to the research team after the three days.

The therapy programme

You will take part in a four week therapy programme for your arm. You will be given a CueS wristband to wear on your stroke side from 8am to 8pm during this four week period and will be reviewed by your NHS therapist twice a week. Your therapist will suggest appropriate arm activities you can practise to support your therapy sessions and work with you to discuss how you can use your stroke arm in normal daily activities.

If the programme started in hospital and you go home before the end of this four weeks, we will ask you to continue your activities at home. The therapist will review you at home, or you can return to the hospital as an outpatient if you prefer. Your usual rehabilitation will continue as normal during your involvement in the study.

In addition, all patients who agree to take part in the study will be given a study handbook which explains the study and contains information about stroke, rehabilitation and positioning of the arm and hand after stroke.

Expenses and payments.

There are no payments for participation in this study. If you need to travel to any additional appointments just for the study, your local hospital will be able to help with transport arrangements.

What will I have to do?

If you agree to take part in the study you will be asked to wear a CueS wristband device on your affected wrist during the day and to practise selected activities each day over the four weeks. When and how long you practice is up to you. You will also be asked to complete a daily log sheet to record your practice.

What are the possible advantages of taking part?

In this study, the arm therapy programme is extra on top of the rehabilitation you would receive. Research has suggested that people who have had a stroke are helped most by practising everyday activities regularly. These are the types of activities we are using in this study. Having this programme early on after stroke will hopefully make the most of the potential to recover.

It is hoped that the results from this study may help us develop a much larger study that could improve treatments for people who have had a stroke in the future

What are the possible risks of taking part?

It is common for people to feel tired after a stroke. Taking part in the study and doing the extra therapy could be tiring. There is a chance that you may feel too tired from practising the study programme to work on your usual therapy. If this happens then you need to tell your therapist and the study programme will be altered or stopped.

You may notice some discomfort in your arm when practising the programme but this should be no greater than the discomfort you may feel during your 'usual' therapy and you can rest at any time.

If the information in Part 1 has interested you and you are considering participation, please read Part 2 before making any decision.

Part 2

What happens if I change my mind about taking part in the study?

You are free to withdraw from the study at any point without giving a reason. If you agree to participate, but later decide that you no longer wish to take part in this study, please contact a member of the study team using the details at the end of this leaflet. It will not affect the care that you receive whether or not you decide to be involved at any point. Information collected about you will be used by the research team unless you specifically withdraw your permission for this.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team at the address below. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanisms are available to you through your local hospital. You can contact the Patient Advisory Liaison Service:

[local contact details for PALS to be added to local version PIS]

What information will you collect about me?

We will need to take some medical information from your hospital records and simple measurements of your stroke arm. We will also collect data about your arm movement through the CueS wristband. This anonymous data will be combined with data from other volunteers to understand how people recover after stroke.

Will my taking part in this study be kept confidential?

All personal data and information that is collected about you during the course of the research will be regarded as strictly confidential. Your privacy will be protected at all times. A study code number will be used so that your identity will not be known by anyone other than the people directly involved in the study.

Paper records containing information we have collected about you for the study will be kept in locked filing cabinets in secure rooms. Your information will also be placed on secure computers at Newcastle University. In accordance with research regulations, at the end of the study, the records containing your study data will be retained for 5 years in a secure archive. After 5 years, your study data will be destroyed.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from Northumbria Healthcare NHS Foundation Trust (the study sponsor) and your local hospital trust to check that the study is being conducted to the correct standards. All your study records and your rights to them will be protected in accordance with the UK data protection laws. You will not be identified by name or context in any report or publications arising from this research. Any feedback comments you give us will be anonymous.

What happens if I become unable to make decisions about carrying on with the research study?

If you become unwell during the study and are no longer able to make decisions about carrying on with the project, you will be withdrawn from the study. We will keep and use the information you provided when you were able to make decisions.

What will happen to the results of the research study?

The results will be shared at research meetings and published in medical journals. A report will be submitted to the Stroke Association, who fund the research. You will not be identified in any report or publication. We will send a summary of the results to all participants once the study has been completed. A copy of the final report will also be available to participants upon request.

Who is organising and funding the research?

The study is being organised by Newcastle University and Northumbria Healthcare NHS Foundation Trust. It is funded by The Stroke Association. There is no payment to healthcare staff or the hospital for patients who are included in the study.

Who has reviewed the study?

All research in the NHS is reviewed and approved by an independent group of people to protect your interests, called a Research Ethics Committee. The study was reviewed by stroke experts on behalf of the Stroke Association.

If you require further information about the study please contact:

Ruth Da Silva
Research Occupational Therapist
Stroke Research Group
3 – 4 Claremont Terrace
Newcastle University
NE2 4AE
Telephone (0191) 2086261

Thank you for taking the time to read this information sheet.

Appendix Y. Baseline assessment

Wristband Accelerometers
To
MotiVate arm Exercise after Stroke

(WAVES)

Baseline Assessment

Version 2.0: July 2017

Patient Study Number:	
Assessment Date:	☐☐/☐☐/☐☐☐☐
Assessor Name (print name):	
Assessor Contact Number:	
Site Name:	

Chief Investigator: **Dr Christopher Price**

Address: **Stroke Research Group, Institute for Neuro Science, Newcastle University, 3-4 Claremont Terrace, Newcastle NE2 4AE**

Telephone: **0191 208 3842**

Fax: **0191 208 5540**

GENERAL INSTRUCTIONS

The baseline assessment form should only be completed by members of staff who have received training about the study.

Please write clearly using a black ballpoint pen.

Always make sure that the "YES/NO" square box answers are completed with a tick.

Errors

If an error needs to be rectified after the forms have been completed:

1. Draw a single line through the error, do not obscure the original entry
2. Enter the correct data beside
3. Initial and date the change and add a comment if necessary
4. Never use correction fluids.

Missing Data

Please do not leave blank boxes where a response is expected.

If data is missing the following should apply:

1. **ND** (for not done) should be entered into the field for all tests and examinations which should have been carried out but were omitted.
2. **NA** (for not applicable) should be entered into the field for missing data if a question does not apply to a patient status.
3. **NK** (for not known) should be entered when historical information, such as dates of onset of medical conditions is not known/not available.

Time

Please use the 24 hour clock eg: 15:30 (and not 3.30pm).

Dates

Please record a date as follows: DD/MM/YYYY.
If part of a date is unknown, please complete the corresponding boxes with NK.

Patient Identification

Please complete the header of all pages with the patient's study number.

Outcome measurements

Please complete outcome measures for both sides of the body if indicated.

SECTION 1: INFORMED CONSENT

1. Has the patient given written informed consent to take part in the study?

Yes ☐ Date of consent: ☐☐/☐☐/☐☐☐☐

The patient **MUST NOT** be included in the study until consent has been obtained.

SECTION 2: CONFIRMATION OF STUDY ELIGIBILITY

	No	Yes
1. Is the patient aged ≥ 18 years?	☐	☐
2. Is the patient between 48hrs and 3 months of stroke onset?	☐	☐
3. Does the patient have **new** reduced upper limb function due to acute stroke but with retained ability to lift the affected hand off their lap?	☐	☐
4. Is the patient capable of undertaking the therapy programme and adhering to the study protocol?	☐	☐
5. Does the patient live within the community services catchment area of a participating study centre?	☐	☐
6. Is the patient currently receiving at least twice weekly NHS therapy which is likely to continue for the next four weeks?	☐	☐
7. When tested is the patient able to either feel vibratory prompt or see visual display on the CueS device?	☐	☐

The answer must be YES to all of questions 1 – 7. If the answer is NO to any of questions 1 - 7, the patient is NOT eligible to participate in the WAVES study. If the answer is NO to any question, please do NOT continue with this baseline assessment form.

	No	Yes
8. Does the patient have any other significant upper limb impairment (e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain) that will inhibit participation in the programme?	☐	☐
9. Does the participant have a diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care?	☐	☐

The answer must be NO to all of questions 8- 9. If the answer is YES to any of questions 8 - 9, the patient is NOT eligible to participate in the WAVES study. If the answer is YES to any question, please do NOT continue with this baseline assessment form.

SECTION 3: PATIENT DETAILS

1. Sex Male ☐ Female ☐

2. Age _____ years

SECTION 4: STROKE DETAILS

1. Please record date of current stroke: ☐☐/☐☐/☐☐☐☐

2. Side of body affected by current stroke: Right ☐ Left ☐ Both ☐

3. Is dominant hand affected by stroke?: Yes ☐ No ☐

4. Participant's current status:

Inpatient ☐ Discharged but still under community therapy ☐

5. **Current stroke aetiology**

Ischaemic ☐
Intracerebral haemorrhage ☐

6. **Stroke subtype (of current stroke)**

Total Anterior Circulation Stroke (TACS) ☐
Partial Anterior Circulation Stroke (PACS) ☐
Lacunar Stroke (LACS) ☐
Posterior Circulation Stroke (POCS) ☐
Uncertain ☐

7. Was this a first ever stroke? No ☐ Yes ☐

8. If no, did the patient have any residual neurological deficit due to previous stroke(s)? No ☐ Yes ☐

9. Did it affect either arm? No ☐ Yes ☐

PRE-STROKE BARTHEL ACTIVITIES OF DAILY LIVING INDEX

For each question below, please ask the patient which answer best describes them **BEFORE THEIR STROKE** and tick the box.

Function	Description	Score	
Bowels	Incontinent (or needs to be given enema) Occasional accidence (once a week) Continent	0 1 2	☐
Bladder	Incontinent, or catheterised and unable to manage Occasional accident (max. once per 24 hours) Continent (for over 7 days)	0 1 2	☐
Grooming	Needs help with personal care: Independent face/hair/teeth/shaving	0 1	☐
Toilet Use	Dependent Needs some help but can do some things alone Independent (on and off, dressing, wiping)	0 1 2	☐
Feeding	Unable Needs help in cutting, spreading butter etc. Independent (food provided in reach)	0 1 2	☐
Transfer	Unable - no sitting balance Major help (1 or 2 people, physical), can sit Minor help (verbal or physical) Independent	0 1 2 3	☐
Mobility	Immobile Wheelchair independent, including corners etc. Walks with help of one person (verbal or physical) Independent (but may use aid e.g. stick)	0 1 2 3	☐
Dressing	Dependent Needs help but can do about half unaided Independent (including buttons, zips, laces etc.)	0 1 2	☐
Stairs	Unable Needs help (verbal, physical, carrying aid) Independent up and down	0 1 2	☐
Bathing	Dependent Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)	0 1	☐
Total (0-20)			☐

POST-STROKE BARTHEL ACTIVITIES OF DAILY LIVING INDEX

For each question below, please ask the patient which answer best describes them **NOW** and tick the box.

Function	Description	Score	
Bowels	Incontinent (or needs to be given enema) Occasional accidence (once a week) Continent	0 1 2	☐
Bladder	Incontinent, or catheterised and unable to manage Occasional accident (max. once per 24 hours) Continent (for over 7 days)	0 1 2	☐
Grooming	Needs help with personal care: Independent face/hair/teeth/shaving	0 1	☐
Toilet Use	Dependent Needs some help but can do some things alone Independent (on and off, dressing, wiping)	0 1 2	☐
Feeding	Unable Needs help in cutting, spreading butter etc. Independent (food provided in reach)	0 1 2	☐
Transfer	Unable - no sitting balance Major help (1 or 2 people, physical), can sit Minor help (verbal or physical) Independent	0 1 2 3	☐
Mobility	Immobile Wheelchair independent, including corners etc. Walks with help of one person (verbal or physical) Independent (but may use aid e.g. stick)	0 1 2 3	☐
Dressing	Dependent Needs help but can do about half unaided Independent (including buttons, zips, laces etc.)	0 1 2	☐
Stairs	Unable Needs help (verbal, physical, carrying aid) Independent up and down	0 1 2	☐
Bathing	Dependent Independent (Bath: must get in and out unsupervised and wash self. Shower: unsupervised/unaided)	0 1	☐
Total (0-20)			☐

Current National Institutes of Health Stroke Scale (NIHSS)

1a. Level of consciousness	0	Alert		
	1	Not alert, but arousable with minimal stimulation		
	2	Not alert, requires repeated stimulation to attend		
	3	Coma		
1b. LOC questions Ask month now and age	0	Answers both correctly		
	1	Answers one correctly		
	2	Both incorrect		
1c. LOC commands Ask to open/close eyes and form/release fist	0	Obeys both correctly		
	1	Obeys one correctly		
	2	Both incorrect		
2. Best gaze	0	Normal		
	1	Partial gaze palsy		
	2	Forced gaze palsy		
3. Visual field testing	0	No visual field loss		
	1	Partial hemianopia		
	2	Complete hemianopia		
	3	Bilateral hemianopia (blind, incl. cortical blindness)		
4. Facial palsy	0	Normal symmetrical movement		
	1	Minor paralysis (flattened nasolabial fold, asymmetry on smiling)		
	2	Partial paralysis (total or near total paralysis of lower face)		
	3	Complete paralysis of one or both sides (in the upper and lower face)		
5. Motor function arm	0	Normal (extends for 10 sec without drift)		
	1	Drift	Right	
	2	Some effort against gravity		
	3	No effort against gravity		
	4	No movement	Left	
		Untestable (limb amputated)		
6. Motor function leg	0	Normal (holds leg for 5 sec without drift)		
	1	Drift	Right	
	2	Some effort against gravity		
	3	No effort against gravity		
	4	No movement	Left	
		Untestable (limb amputated)		
7. Limb ataxia	0	No ataxia		
	1	Present in one limb		
	2	Present in two limbs		
8. Sensory	0	Normal		
	1	Mild to moderate decrease in sensation		
	2	Sever to total sensory loss		
9. Best language	0	No aphasia		
	1	Mild to moderate aphasia		
	2	Severe aphasia		
	3	Mute		
10. Dysarthria	0	Normal articulation		
	1	Mild to moderate slurring of words		
	2	Near unintelligible or unable to speak		
		Intubated or other physical barrier		
11. Inattention	0	Normal		
	1	Inattention or extinction to bilateral simultaneous stimulation		
	2	Sever hemi-inattention or hemi-inattention to more than one modality		
		Total Score:		

STROKE DEPENDENCY: Modified Rankin Scale

Please ask the patient which **ONE** statement below best describes them **SINCE** the current stroke:

Tick ***one box***.

0 No symptoms at all..... ☐

1 No significant disabling symptoms..... ☐

2 Slight disability but does not require substantial help from other person, can walk ..... ☐

3 Moderately severe disability, requires substantial help from other person, can walk..... ☐

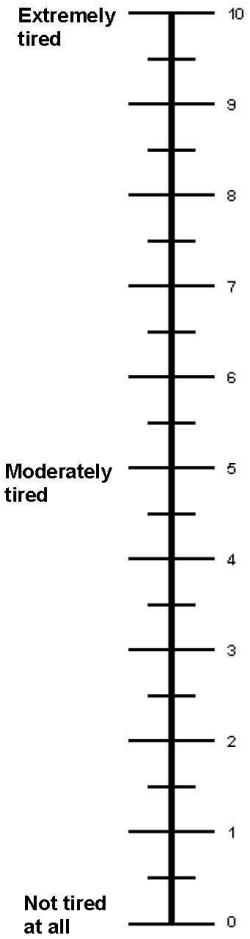
4 Moderately severe disability, requires substantial help from other person, unable to walk ..... ☐

5 Severe disability, bedbound..... ☐

FATIGUE VISUAL ANALOGE SCALE

In general, how **tired** has the participant felt since having their stroke?

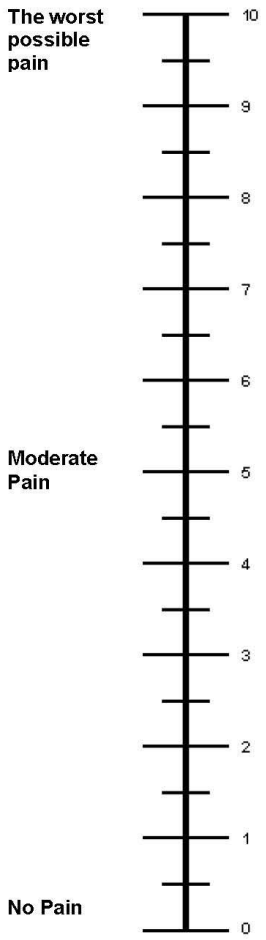
Please explain the Visual Analogue Scale (VAS) to the participant and ask the participant to select a score. Mark their score on the VAS below:



PAIN VISUAL ANALOGE SCALE

Since their stroke has the participant had any **pain** in their arm?

Please show participant VAL scale and explain the Visual Analogue Scale (VAS) to the participant. Ask the participant to select a score. Mark their score on the VAS below:



Motricity Index

Arm (in sitting position)

A. Pinch grip; 2.5cm cube between thumb and forefinger
B. Elbow flexion; from 90 degrees, voluntary contraction/movement
C. Shoulder abduction; from against chest

A. Pinch grip

0	No movement
11	Beginnings of prehension (any movement of finger or thumb)
19	Grips cube, but unable to hold against gravity
22	Grips cube, held against gravity, but not against weak pull
26	Grips cube against pull, but weaker than other side
33	Normal pinch grip

Score R arm ☐ Score L arm ☐

B. Elbow flexion

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

C. Shoulder abduction

0	No movement
9	Palpable contraction in muscle, but no movement
14	Movement seen, but not full range/not against gravity
19	Movement; full range against gravity, not against resistance
25	Movement against resistance, but weaker than other side
33	Normal power

Score R arm ☐ Score L arm ☐

Total Arm score = (A) + (B) + (C) + 1 (to make 100)

TOTAL RIGHT ARM ☐ **TOTAL LEFT ARM** ☐

Action Research Arm Test (ARAT)

Instructions - There are four subtests: grasp, grip, pinch and gross movement. If a subject passes the first task in each subtest then they score top marks and move onto the next subtest. If a subject fails the first and the second task in a subtest, then they score zero overall for that subtest and move onto the next**. The patient must be able to sit unaided in order to attempt the test**. If not, the patient scores 0.

Score 0 = cannot perform any part of the test **1 = performs test partially**
2 = completes test, but takes abnormally long time or has great difficulty **3 = performs test normally**

Ask patient to **demonstrate** using the least impaired arm first:

a) Grasp

1. 10cm cube (if score = 3 then total = 18 & go to *Grip*)
2. 2.5cm cube (if Grasp score = 0 so far then Grasp total = 0 & go to *Grip*)
3. 5cm cube
4. 7.5cm cube
5. cricket ball
6. stone

Grasp total:

b) Grip

1. Pour water glass to glass (if score = 3 then total = 12 & go to *Pinch*)
2. 2.25cm tube (if Grip score = 0 so far then Grip total = 0 & go to *Pinch*)
3. 1cm tube
4. washer over bolt

Grip total:

c) Pinch

1. 6mm bearing 3rd finger & thumb (if score = 3 then total = 18 & go to *Gross*)
2. marble index & thumb (if Pinch score = 0 so far then Pinch total = 0 & go to *Gross*)
3. 6mm bearing 2nd finger & thumb
4. 6mm bearing 1st finger & thumb
5. marble 2nd finger & thumb
6. marble 3rd finger & thumb

Pinch total:

d) Gross

1. Place hand behind head (if score = 3 then total = 9 & finish)
2. Place hand on top of head
3. Hand to mouth

Gross total:

ARAT Total

Star cancellation

Place Star cancellation sheet (next page) in front of patient with the arrow position at participant's midline.

Ask the participant to cross out all of the small stars on the page.

Demonstrate this to the participant by crossing out the two small stars in the middle of the page and ask the participant to cross out the rest.

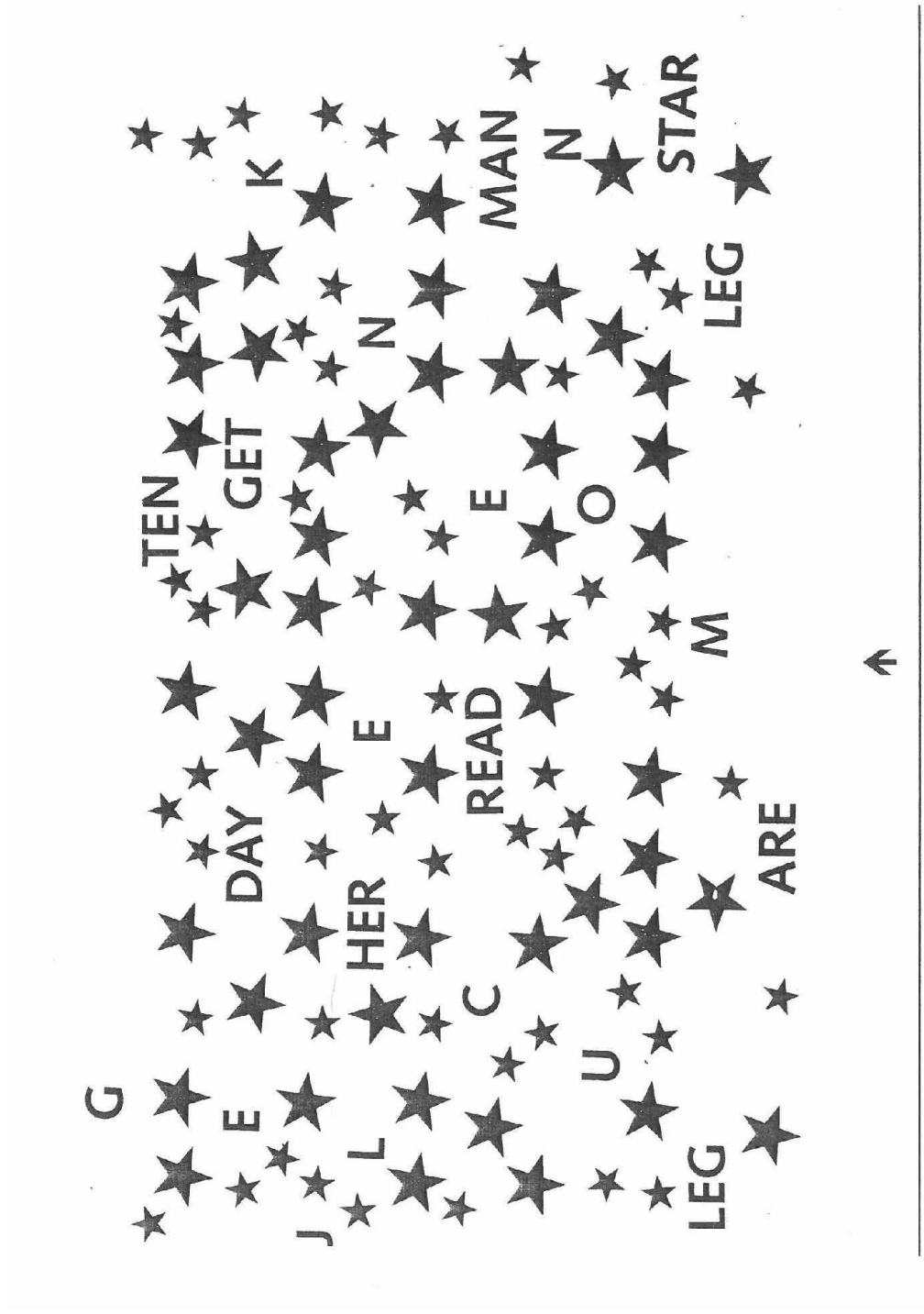
The participant should use their normal writing hand to complete the exercise.

Do not allow participant to turn or move the sheet away from midline.

If participant is unable to hold a pen/pencil to complete exercise they are permitted to point to all the small stars and assessor may cancel them out on the sheet.

Use the transparency template to check and record below the number of stars on the:

Left Side Right Side Total


STAR
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MOTOR ACTIVITY LOG (MAL) SCORE SHEET

Using the rating scale overleaf, ask the participant if they have used their stroke hand to carry out the following activities and to rate the amount they have used their stroke hand in the activity and their ability to carry out each one.

If the participant has not used their stroke hand to carry out an activity use the "Possible reasons for not using the stroke arm" rating scale to enquire why not.

List of motor Activities	Amount Used	How Well	If no, why? (use code and give Comments)
Turn on a light with a light switch	☐	☐	☐
Open Drawer	☐	☐	☐
Remove an item of clothing from a drawer	☐	☐	☐
Pick up phone	☐	☐	☐
Wipe off a kitchen counter or other surface	☐	☐	☐
Get out of a car (just sit to stand movement)	☐	☐	☐
Open refrigerator	☐	☐	☐
Open a door by turning a door knob/handle	☐	☐	☐
Use a TV remote control	☐	☐	☐
Wash your hands	☐	☐	☐
Turning water on/off with tap	☐	☐	☐
Dry your hands	☐	☐	☐
Put on your socks	☐	☐	☐
Take off your socks	☐	☐	☐
Put on your shoes	☐	☐	☐
Take off your shoes	☐	☐	☐
Get up from a chair with armrests	☐	☐	☐

MOTOR ACTIVITY LOG (MAL) SCORE SHEET

List of motor Activities	Amount	How Well	If no, why? (use code and give Comments)
Pull chair away from table before sitting down	☐	☐	☐
Pull chair toward table after sitting down	☐	☐	☐
Pick up a glass, bottle, drinking cup or can	☐	☐	☐
Brush your teeth	☐	☐	☐
Put on makeup / shaving cream on face	☐	☐	☐
Use a key to unlock a door	☐	☐	☐
Write on paper (if non-writing hand N/A)	☐	☐	☐
Carry an object in your hand	☐	☐	☐
Use a fork or spoon for eating	☐	☐	☐
Comb your hair	☐	☐	☐
Pick up a cup by a handle	☐	☐	☐
Button a shirt	☐	☐	☐
Eat half a sandwich or finger foods	☐	☐	☐
Total Score	_____	_____	
Average Score (Total score divided by 30*)	_____	_____	

*If an activity was not carried out because of reason C – "I never do that activity, with or without help from someone else because it is impossible." Score as N/A and work out the average based on the remaining activities. This should be used sparingly and only if the response would also have applied before the stroke

AMOUNT SCALE

0 **Not Used** Did not use my weaker arm

1 **Very Rarely** Occasionally used my weaker arm, but only very rarely

2 **Rarely** Sometimes used my weaker arm but most of the time with my stronger arm

3 **Half Pre-stroke** Used my weaker arm about half as much as before the stroke

4 **¾ Pre-stroke** Used my weaker arm almost as much as before the stroke

5 **Same as pre-stroke** Used my weaker arm as often as before the stroke

HOW WELL SCALE

0 Not used at all for that activity

1 Moved during that activity but was not helpful

2 Movements were very slow and made with difficulty - needed help from the stronger arm

3 Movements slow or made with only some effort

4 Almost normal - not quite as fast or accurate as normal

5 Normal as well as before the stroke

****

POSSIBLE REASONS FOR NOT USING THE WEAKER ARM FOR THE ACTIVITY

If participant has not used their stroke arm in a particular activity please discuss with them the reason for this and select one of the possible reasons below:

Reason A. "I used the unaffected arm entirely."

Reason B. "Someone else did it for me"

Reason C. "I never do that activity, with or without help from someone else because it is impossible." For example, combing hair for people who are bald.

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

Reason E. "That is an activity that I normally did only with my dominant hand before the stroke, and continue to do with my dominant hand."

Baseline assessment is now complete. Please:

1. Enter data from baseline assessment onto the CASTOR database
2. Add the allocated patient study number onto each page of the Baseline assessment form
3. Place this form in the patient site file.
4. Complete the 'WAVES' study sheet and place in the patient's medical notes with a copy of the PIS and completed consent form.
5. Add the participant's contact details and study number to the Enrolment List located in the Site file
6. Inform nominated person to carry out randomisation process and establish when the first therapy session will take place.
7. Inform participant that they will be contacted in three weeks time to arrange the 4 week outcome assessment. NB the assessment needs to be completed 4 weeks (+/- 3 days) since the first therapy session (i.e. day 1 of wearing CueS).

Appendix Z Therapist flow charts

Delivering the WAVES programme to participant

1. Initial therapy session (ALL participants).

The first therapy session includes identifying activities to practise and providing a CueS wristband. This session will take approximately 15 to 20 minutes.

Prior to session ensure that a fully charged CueS wristband is available

1) *Set up New User*
   Follow New User instructions overleaf to assign the wristband to new participant number. This will automatically clear any previous data and default wristband to no prompts.

2) *Provision of CueS wristband*
   - Demonstrate to participant how to don and doff the CueS ensuring wristband is positioned on the participant's affected upper limb around the wrist NOT further up the arm. Ensure that lights are visible on side of wristband nearest the hand/wrist.
   - Demonstrate to the participant how to hold hand up against chest to tap wristband so that lights are easily visible.

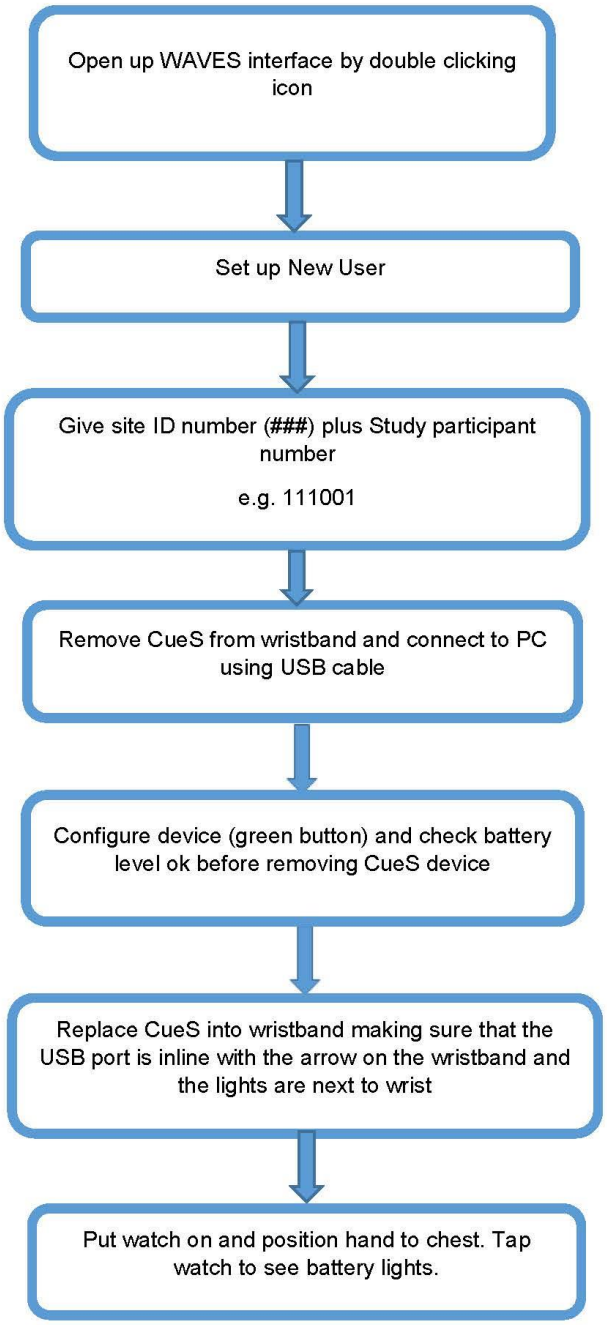
3) *Selection and demonstration of daily activities*
   - Work with the participant to identify 3 - 5 activities they can either carry out independently or carry out parts of using their affected upper limb. Encourage the participant to practise these activities and to refer back to them to increase their upper limb use throughout the course of the day. Future reviews will encourage participant to add more activities to this list as they feel able to (see appendix 3).
   - If possible advise on how to integrate therapy exercises into daily routines to allow for additional practise of selected activities as and when participant feels able to across the course of the day.

4) *Provision and explanation of the participant handbook*
   - Provide the participant with a study participant handbook according to which group they are randomised into.
   - Demonstrate how to use the participant handbook and explain the sections on using the CueS wristband, the WAVES programme and how to complete the daily log sheets.

5) *Recording of activities*
   - Demonstrate to the participant how to record activity practise on the daily log sheets and to add to the Daily Activities Sheet if they identify any further activities that they could practice.

CueS summary flow chart

Initial Set up



Twice weekly therapy reviews (ALL participants)

CueS data and prompt settings need to be reviewed **twice** a week. This is important in order to ensure that the settings are correct for the patient but also These can be integrated into usual NHS therapy sessions and will only add approximately 10 minutes per session. An example of the documentation to be completed is located in Appendix 1 and can be kept in the Participant's Handbook between sessions.

1) Downloading data from CueS wristband

- Remove CueS device from the silicone wristband and connect to CueS interface on tablet using the USB cable provided. The interface will automatically download the data for the identified study user. No data should be displayed at this point. To display the CueS data for Group 2 participants ONLY click the middle of the screen where it says "Group 2 participants". The data should now be visible and will automatically be shown at subsequent downloads.

Please be careful when downloading data that "Group 2 participants option is NOT inadvertently selected for GROUP 1 participants as this cannot be undone and risks unblinding the participant!!

Ask participant if they have had any new medical problems since their last review. If the answer is YES then please refer to the Adverse events section in the Site File.

2) Reviewing Daily Activities Sheet

- Review the activity log sheets and check if there have been any difficulties with completion.
- Encourage the participant to consider additional activities that they could use their affected upper limb with throughout the day and to add these activities to the Daily Activities List as they feel able to (see appendix 1)
- Demonstrate how to record completed prompted activities on the daily log sheet.

(GROUP 2 ONLY)

3) Reviewing CueS data and setting thresholds

- Review the data collected by CueS and set the prompt threshold and frequency. Further guidance on this can be found in the CueS User Manual. And the therapy decision tree (appendix 4).
- Try to encourage the participant to use the prompts they receive as a reminder to use their affected upper limb in an activity. They can use the Daily Activities sheet for ideas of appropriate exercises to do. Suggest to the participant that carrying out frequent shorter activities may be more beneficial than doing a lot of activity once or twice a day.

3. Final therapy review (ALL participants)

The final therapy review will take place on the last day of the four week programme.

1) Review of functional activities

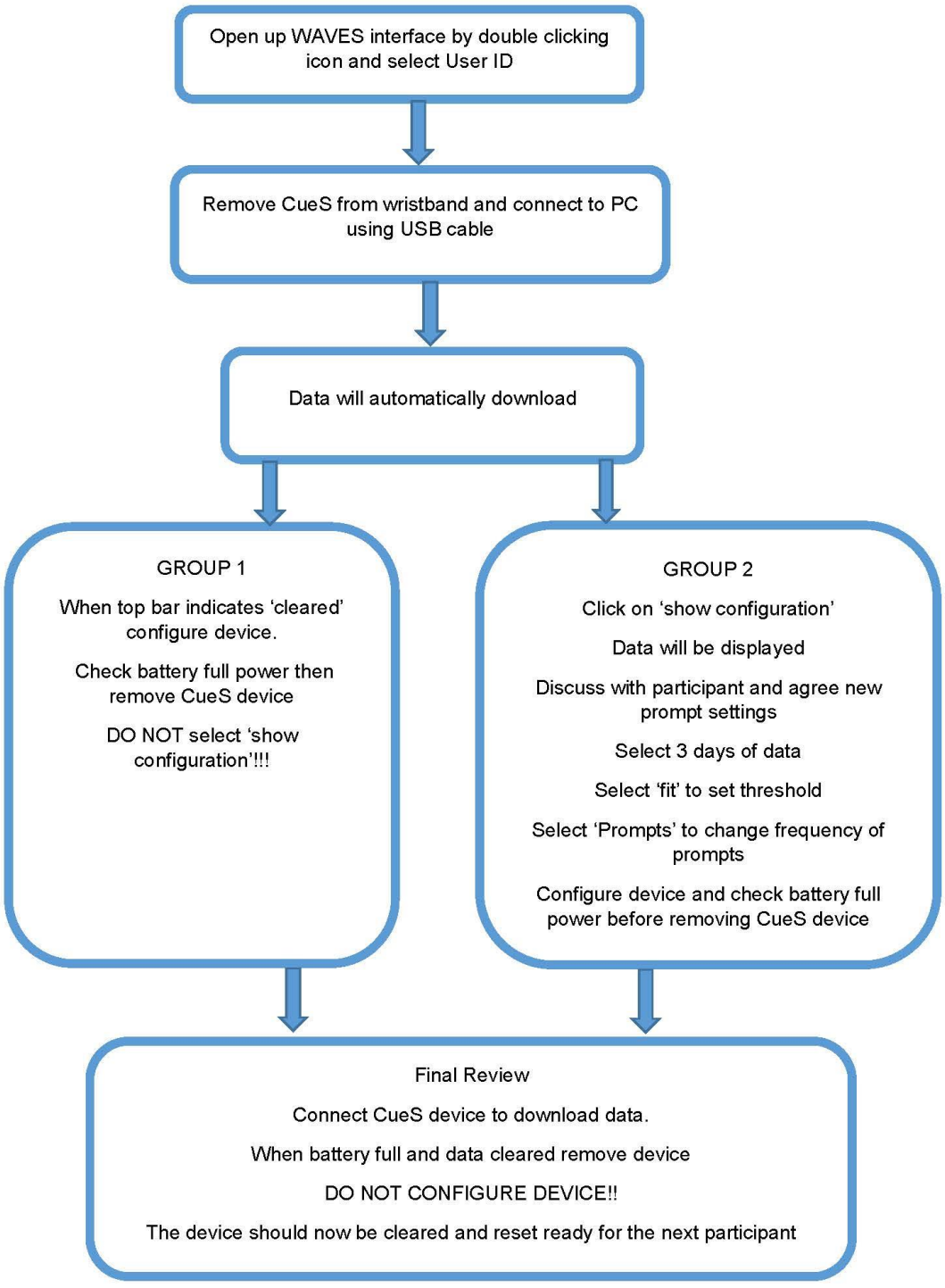
- Review the activities set during the programme.

2) Download data from CueS

- Download the data from the CueS wristband.
- Complete therapy review form
- Retrieve the CueS wristband from participant
- Inform participant that they will be contacted by a study therapist to complete the 4 week assessment.
- A final enquiry about adverse events should be made and recorded.

CueS summary flow chart

Review sessions



Appendix AA. Participant handbook Group 2 (intervention)

Wristband Accelerometers to motiVate arm Exercise after Stroke

(WAVES study)

Participant Handbook

Group 2

Name _____

Please do not hesitate to contact Ruth Da Silva at the Newcastle University Stroke Research Group if you have any queries on:

Tel 0191 2083842

Email: Ruth.Da-Silva@ncl.ac.uk

Participant Handbook

Thank you for agreeing to take part in the WAVES study.

This booklet tells you about the WAVES arm rehabilitation programme and information about the CueS wristband.

At the back of the handbook you will find some useful information about stroke and rehabilitation after stroke.

We have also included some advice on stroke recovery and how to look after your affected arm.

Use of the CueS Wristband

- You will be provided with a CueS wristband to wear on your stroke arm. Your therapist will make sure that you can put the wristband on and take it off yourself.

- The wristband will measure the amount of activity in your arm throughout the day between the hours of 8am and 8pm. It is important, therefore, that you wear it from waking up in the morning until going to sleep at night.

- The therapist will agree with you an arm movement target for each hour.

- The CueS wristband will provide you with advice about your arm activity. It has a small visual display which will let you know how close you are to achieving your hourly activity target. To activate the visual display simply tap the front of the CueS wristband.

- The CueS will also vibrate if your arm activity level drops. This is to remind you to use your arm in any way which increases your movement activity.

- Twice a week the therapist will review your progress and discuss whether you want to change the activities in your arm programme.

- During these visits he/she will download the data from the CueS wristband and re-charge the battery.

- They will look at the information collected by the CueS wristband and talk to you about whether you want to change the arm movement target or frequency of the vibration reminders.

Caring for the CueS wristband

- The CueS wristband is not fully waterproof and should not be worn when you are getting washed/showered, doing the dishes or during any other activity that may involve putting it in water.

- If the CueS wristband gets dirty or sticky it can be wiped down with a damp cloth but try not to keep it under water.

- Try to ensure that CueS wristband is dried thoroughly before wearing it to prevent any possibility of developing skin irritations under the band. If you notice any discomfort, inform a member of staff or your therapist.

The WAVES programme

During rehabilitation we believe that it is important that you practise some activities on your own, rather than just during therapy and that you build up a range of activities which suit you.

- Your NHS therapist will help you to think of a selection of normal everyday activities that you can complete with the help of your stroke arm.
- You can use this list to build up the range of functional activities you are able to use your stroke arm with throughout each day.
- We recommend that these activities are practised on a daily basis. This can be as many times as you like as long as your arm does not feel uncomfortable.
- At the end of each day check your Daily Activities sheet and record on the "alphabet wheel" any activities from the list that you have carried out.
- If you can think of any additional activities where you used your stroke hand, you can also add these to your Daily Activities log sheet.
- Twice a week your therapist will download the data collected by the CueS wristband and you will be able to see a report about the amount of movement and prompts during the previous days. You can use this report to discuss with your therapist how you are progressing.
- Your therapist will set the CueS wristband for how often it should prompt you. If you forget to use your arm or have not used it as much as you have in previous days, the CueS wristband will vibrate gently to remind you to do more.
- The CueS wristband will ONLY prompt you if it senses that you have not moved your arm as much as on previous days. You can then decide how you would like to respond to the prompt.

- You can decide if you want to do one of the activities from the daily activities list or to carry out another activity that may be more appropriate to where you are currently situated e.g. use your affected hand to put shopping into shopping trolley.

- You may also choose not to carry out an activity when prompted in which case you can simply ignore it, but try to remember to use your arm more over the next hour.

- You can tap the CueS wristband at any time to see a light display which indicates how near you are to your target during that hour.

Remember: at the end of each day, mark down on the alphabet wheel of your daily log sheet which activities you have completed and add any not already on the list.

Safety Advice

1. Please inform the study therapist as soon as possible if pain stops you from doing the activities or if you cannot participate in your normal therapy on the ward as the study exercises are making you feel too tired.

2. If you feel that your arm is stiffening up or getting tired during the exercises take a short rest after each repetition of the exercise.

3. If you notice any discomfort from wearing the CueS device please discuss this with your therapist who will feedback to the research study team.

4. If you are concerned that the CueS wristband is prompting an activity too frequently or not often enough you can discuss this at your next review meeting and have the number and frequency of prompts adjusted. Alternatively, you can contact the research therapist Ruth Da Silva for further advice.

Please remember to fill out your 'daily log sheets' so you can keep track of your progress.

What is a stroke?

- The brain needs a constant supply of blood in order for it to function.
- A stroke occurs when the blood supply to the brain is blocked or interrupted. When this happens, the brain cells are damaged or can die.
- Control of movement, speech, bodily functions (such as going to the toilet) and thinking are co-ordinated by the brain. These functions may be lost or disrupted when a stroke takes place.
- Common symptoms of stroke are loss of movement and numbness down one side of the body. This is due to the stroke affecting parts of the brain that control arm and leg movement and/or sensation, rather than a problem in the muscles themselves.
- If the stroke happens in the right side of the brain it affects the left side of the body and vice versa. It is also possible to have problems on both sides at the same time.

Rehabilitation after stroke

- Rehabilitation is about relearning skills and the ability to do things again. The aim is to live the most independent life possible.
- This means taking an active, positive approach focusing on what you *can* do rather than what you *can't* do.
- As stroke affects people differently, it is difficult to work out exactly how much recovery is possible in each person.
- It may take a long time for some people to recover after stroke.
- Research has found that the more you do the better you might get. However, it is important to rest regularly as tiredness can be a problem.
- Therefore, it is important that you find a balance between rest and activity that is right for you.

Suggestions to aid recovery

- Concentrate on what you would like to achieve and take the support that is on offer to reach your potential.

- Staying positive will help with your rehabilitation – focus on what you are able to do rather than what you can no longer do.

- Try and be realistic about what you would like to achieve in the short term and in the long term – your physiotherapist / occupational therapist can help guide you with this.

Arm and hand recovery after stroke

- A lot of people with stroke often use their non-affected arm to do activities as this is easier than using their affected arm.

- The problem with this is that you get used to not using your affected arm. This can impact on arm recovery.

- Arm recovery is different to leg recovery. People who have had a stroke are often forced to use their affected leg, such as when they want to get up from a chair. This means that rehabilitation is more automatic in the leg.

- Considering this, it is important to spend as much time working on your arm as on your leg recovery.

Positioning of the arm and hand after stroke

- After a stroke some people may develop some pain and tightness in your arm and hand. It is important to handle and position your arm and hand carefully as described below

- The following recommendations are to be used as a guide. Please consult the study therapist if you are unsure whether something applies to you.

PLEASE TRY TO

- ✓ Sit upright in a supportive chair, preferably with arm rest support.
- ✓ Be aware of where your arm is.
- ✓ Move your own arm rather than asking somebody to move it for you.
- ✓ Support your arm at the wrist when you move it.

If you have **minimal movement** in your arm:

- ✓ When sitting, place both of your arms onto a pillow, on your lap or on the table in front. Make sure the palm of your hand is facing downwards.

- ✓ In bed arms should be placed on either side of your body, resting on pillows.

- ✓ If someone is helping you ask them to support your arm with one hand under your elbow and one hand under your wrist.

PLEASE DON'T

- ✗ Let your arm hang over the side of the chair as this can cause problems and pain in your shoulder.
- ✗ Cradle your arm across your body as this may cause muscle tightness.
- ✗ Allow anyone to pull on your arm by holding your hand.

Appendix AB. Participant handbook Group 1 (control)

Wristband Accelerometers to motiVate arm Exercise after Stroke

(WAVES Study)

Participant Handbook

Group 1

Name _____

Please do not hesitate to contact Ruth Da Silva at the Newcastle University Stroke Research Group if you have any queries on:

Tel 0191 2083842

Email: Ruth.Da-Silva@ncl.ac.uk

Stroke association

Newcastle University

Participant Handbook

Thank you for agreeing to take part in the WAVES study.

This booklet tells you about the WAVES arm rehabilitation programme and information about the CueS wristband.

At the back of the handbook you will find some useful information about stroke and rehabilitation after stroke.

We have also included some advice on stroke recovery and how to look after your affected arm.

Use of the CueS Wristband

- You will be provided with a CueS wristband to wear on your stroke arm.
- The wristband will measure the amount of activity in your arm throughout the day between the hours of 8am and 8pm. It is important, therefore, that you wear it from waking up in the morning until going to sleep at night.
- This will help us to understand how people's arms recover after stroke
- Twice weekly the therapist will connect the CueS wristband to a computer and download the information collected.

Caring for the CueS wristband

- The CueS wristband is not fully waterproof and should not be worn when you are getting washed/showered, doing the dishes or during any other activity that may involve putting it in water.
- If the CueS wristband gets dirty or sticky it can be wiped down with a damp cloth but try not to keep it under water.
- Try to ensure that the CueS wristband is dried thoroughly before wearing it to prevent any possibility of developing skin irritations under the band. If you notice any discomfort, inform a member of staff or your therapist.

The WAVES programme

During rehabilitation we believe that it is important that you practise some activities on your own, rather than just during therapy and that you build up a range of activities which suit you.

- Your NHS therapist will help you to think of a selection of normal everyday activities that you can complete with the help of your stroke arm.
- You can use this list to build up the range of functional activities you are able to use your stroke arm with throughout each day.
- We recommend that these activities are practised on a daily basis. This can be as many times as you like as long as your arm does not feel uncomfortable.
- At the end of each day check your Daily Activities sheet and record on the "alphabet wheel" any activities from the list that you have carried out.
- If you can think of any additional activities where you used your stroke hand, you can also add these to your Daily Activities log sheet.

Remember: at the end of each day, mark down on the alphabet wheel of your daily log sheet which activities you have completed and add any not already on the list.

Safety Advice

1. Please inform the study therapist as soon as possible if pain stops you from doing the activities or if you cannot participate in your normal therapy on the ward as the study exercises are making you feel too tired.

2. If you feel that your arm is stiffening up or getting tired during the exercises take a short rest after each repetition of the exercise.

3. If you notice any discomfort from wearing the CueS device please discuss this with your therapist who will feedback to the research study team.

Please remember to fill out your 'daily log sheets' so you can keep track of your progress.

What is a stroke?

- The brain needs a constant supply of blood in order for it to function.
- A stroke occurs when the blood supply to the brain is blocked or interrupted. When this happens, the brain cells are damaged or can die.
- Control of movement, speech, bodily functions (such as going to the toilet) and thinking are co-ordinated by the brain. These functions may be lost or disrupted when a stroke takes place.
- Common symptoms of stroke are loss of movement and numbness down one side of the body. This is due to the stroke affecting parts of the brain that control arm and leg movement and/or sensation, rather than a problem in the muscles themselves.
- If the stroke happens in the right side of the brain it affects the left side of the body and vice versa. It is also possible to have problems on both sides at the same time.

Rehabilitation after stroke

- Rehabilitation is about relearning skills and the ability to do things again. The aim is to live the most independent life possible.
- This means taking an active, positive approach focusing on what you *can* do rather than what you *can't* do.
- As stroke affects people differently, it is difficult to work out exactly how much recovery is possible in each person.
- It may take a long time for some people to recover after stroke.
- Research has found that the more you do the better you might get. However, it is important to rest regularly as tiredness can be a problem.
- Therefore, it is important that you find a balance between rest and activity that is right for you.

Suggestions to aid recovery

- Concentrate on what you would like to achieve and take the support that is on offer to reach your potential.

- Staying positive will help with your rehabilitation – focus on what you are able to do rather than what you can no longer do.

- Try and be realistic about what you would like to achieve in the short term and in the long term – your physiotherapist / occupational therapist can help guide you with this.

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Appendix AC. SAE reporting form

Wristband Accelerometers to MotiVate arm Exercise after Stroke

Serious Adverse Event (SAE) Report

Participant study ID e.g. GHT001, NHC003	☐☐☐☐☐☐

Serious Adverse Event

A serious adverse event is any untoward medical occurrence that:

1. Results in death;
2. Is life-threatening;
3. Results in in-patient hospitalisation or prolongation of existing hospitalisation;
4. Results in a persistent or significant disability/incapacity;
5. Results in congenital anomaly or birth defect.
6. Is otherwise considered medically significant by the investigator

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important medical events that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

All serious adverse events regardless of randomisation group or suspected relationship to the study intervention must be reported immediately (within 24 hours) to the WAVES study office. The WAVES office team will forward details to the chief investigator (Dr. Christopher Price) and regulatory bodies as required.

CONTACT FOR REPORTING

Ruth Da Silva

Stroke Research Group
Newcastle University
3-4 Claremont Terrace
Newcastle upon Tyne
NE2 4AE
Tel: 0191 2083842
Fax: 0191 2085540
Email: Ruth.Da-Silva@ncl.ac.uk

Wristband Accelerometers to MotiVate arm Exercise after Stroke

STUDY ID: | | | | | | |

Serious Adverse Event (SAE) Report

1. REPORT TYPE: INITIAL ☐ FOLLOW-UP ☐

SERIOUS ADVERSE EVENT (SAE) DETAILS:

2. SAE IN MEDICAL TERMS (DIAGNOSIS IF POSSIBLE):

3. CASE DESCRIPTION OF ABOVE SAE: (include related signs/ symptoms, suspected cause, any de-challenge and re-challenge information – please continue on separate page if required)

4. ONSET OF FIRST SIGN/SYMPTOM OF SAE:

Day Month Year

5. SERIOUSNESS:

☐ Subject died Day Month Year

AND/OR

☐ See key below and insert all appropriate number(s) for SAE (may be more than one)

6. OUTCOME OF SAE:

☐ Completely Recovered (enter date of recovery):

Day Month Year

OR

☐ See key below and insert appropriate letter.

1 = Life-threatening
2 = Involved or Prolonged inpatient hospitalisation
3 = Involved persistent or significant disability or incapacity
4 = Other significant medical event

A = Recovered with sequelae
B = Condition improving
C = Condition still present & unchanged
D = Condition deteriorated
E = Death (if yes, provide autopsy report if autopsy performed)

7. RELEVANT MEDICAL HISTORY: (including allergy, drug or alcohol abuse, family history)

8. STUDY THERAPY DETAILS (complete if applicable):

Start date for therapy programme:

Day	Month	Year

Most recent therapy review session prior to this SAE:

Day	Month	Year

If the participant has not yet started the therapy programme please tick this box ☐

9. ACTION TAKEN REGARDING STUDY THERAPY. Please mark all as appropriate.

- ☐ No action taken
- ☐ Study therapy dose reduced
- ☐ Study therapy permanently discontinued due to this adverse event
- ☐ Study therapy temporarily Interrupted
- ☐ Other treatment given

10. TREATMENT OF SAE

Please provide full details of any treatment given for the SAE below (e.g. drugs/non-treatment, details of study therapy dose reduction/interruption):

11. ASSESSMENT OF CAUSALITY (principal investigator (PI) decision). In your judgement, is there a reasonable possibility that the event may have been caused by a study treatment?

☐ YES OR ☐ NO

If causality is "YES" for a study treatment, please also indicate whether the nature of SAE is "expected" or "unexpected"

→ ☐ Expected OR ☐ Unexpected

PI signature _____ Day | Month | Year

INFORMATION SOURCE

12. Name, profession, address and telephone number of reporter

Reporter signature

_____

13. Reporting date (by person reporting event) Day | Month | Year

ON COMPLETION THIS FORM MUST BE FAXED OR EMAILED TO THE WAVES OFFICE:

FAX: 0191 208 5540
EMAIL: Ruth.Da-Silva@ncl.ac.uk

FOR WAVES OFFICE USE ONLY:

SAE NO.

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