Developing upper limb functional electrical stimulation clinical practice guidelines for stroke rehabilitation.

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A thesis submitted in partial fulfilment of the requirements of Sheffield Hallam University for the degree of Doctor of Philosophy

February 2025

Candidate Declaration

I hereby declare that:

1. I have not been enrolled for another award of the University, or other academic or professional organisation, whilst undertaking my research degree.
2. None of the material contained in the thesis has been used in any other submission for an academic award.
3. I certify that this thesis is my own work. The use of all published or other sources of material consulted have been properly and fully acknowledged.
4. The work undertaken towards the thesis has been conducted in accordance with the SHU Principles of Integrity in Research and the SHU Research Ethics Policy, and ethics approval has been granted for all research studies in the thesis.
5. The word count of the thesis is 57,885

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Abstract

This thesis explores the use of upper limb (UL) functional electrical stimulation (FES) in clinical settings in people with stroke and information that supports the development of clinical practice guidelines. **Chapter 1** introduces the thesis and provides an overview of this multimethod programme of research. **Chapter 2** presents the background literature, outlining the context of the rehabilitation of the UL post-stroke and the use of functional electrical stimulation in the management of post-stroke UL impairments to drive functional recovery. **Chapter 3** outlines the research paradigm, focusing particularly on the epistemological and ontological positions taken and the rationale for adopting a pragmatic approach with multimethods. **Chapter 4** is the first study in the thesis and is a systematic review of the treatment parameters for UL FES post-stroke. The systematic review highlighted that there was too much variance between functional electrical stimulation applications to indicate recommended UL treatment parameters. The resulting gaps relating to UL FES treatment parameters in the literature indicated the need for a better understanding of UL clinical presentations that informed prescription/use of UL FES, and this helped shape the methodology used in chapter 5. **Chapter 5** is a review of the medical records within an NHS Foundation Trust stroke pathway. This medical records review indicated the lack of detail within the medical documentation relating to the management of the post-stroke UL and the limited use of UL FES across the stroke pathway, which supported the justification for chapter 6 methodology. **Chapter 6** is a qualitative study exploring the views of physiotherapists, occupational therapists and rehabilitation assistants working within two large NHS Foundation Trust stroke pathways about the management of the UL post-stroke and the use of UL FES. **Chapter 7** concludes the data collection in the thesis using a Delphi method to gain consensus on best practice in the use of UL FES in the management of people with stroke. The findings of this chapter establish a set of consensus statements that will support the development of clinical practice guidelines. **Chapter 8** concludes the thesis by presenting a critical review of the research findings and highlights future research possibilities.

Dedication

Dedicated to Shaun, Grace and Ewan. For being the best ever support team.

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On a personal note, when I first had it confirmed I was accepted on this PhD, my mum was still alive, and my dad was fit and well. My dad now has severe Alzheimer's, and while he will not understand this programme of research, as a previous headteacher he revelled in my family's academic achievements. I know that both my parents would be very proud.

Finally, I want to express my heartfelt thanks to my wonderful husband Shaun and to my children Grace and Ewan. You have celebrated every milestone, encouraged me every step of the way and positively driven me forwards throughout this process. With the three of you in my corner anything is possible; I dedicate this thesis to Team EGGS.

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Abbreviation	Definition
ADL	activities of daily living
ACPIN	Association of Chartered Physiotherapists interested in Neurology
CNS	central nervous system
CIMT	constraint induced movement therapy
CPD	continued professional development
FMA-UE	Fugl-Meyer assessment for upper extremity
FES	functional electrical stimulation
GRASP	graded repetitive arm supplementary program
ISWP	Intercollegiate Stroke Working Party
ICF	International Classification of Functioning, Disability and Health
IFESS	International Functional Electrical Stimulation Society
ILC	iterative learning control
KTA	knowledge-to-action

LL	lower limb
NICE	National Institute for Health and Care Excellence
NIHR CRD	National Institute for Health Research Centre for Reviews and Dissemination
OT	Occupational therapist
PROM	passive range of motion
PT	Physiotherapist
QoL	quality of life
QSUL	Queen Square Upper Limb Neurorehabilitation Programme
SSNAP	Sentinel Stroke National Audit
SOP	standard operating procedure
TENS	transcutaneous electrical nerve stimulation
TIA	transient ischaemic attack
UL	upper limb

Chapter 1 Introduction and thesis structure

This chapter outlines the overall structure of the thesis chapter by chapter with the accompanying rationale for each.

1.1. Chapter One

This thesis explores the use of upper limb functional electrical stimulation (UL FES) in people with stroke. **Chapter 1** introduces the thesis and provides an overview of this multimethod programme of research.

1.2. Chapter Two

This chapter sets the scene for the thesis by presenting the background literature, outlining the context of the rehabilitation of the UL post-stroke and the use of FES in the management of post-stroke UL impairments.

FES is introduced; with a review of current systems used in UL rehabilitation; as application of UL FES is central to the thesis. The aims and objectives and research questions that inform the thesis are then stated.

1.3. Chapter Three

This chapter outlines the research methodology; it will outline the research paradigm, focusing particularly on the epistemological and ontological positions taken, and the rationale for adopting a pragmatic multimethod approach.

1.4. Chapter Four

This chapter is the first study in the thesis and is a systematic review of the treatment parameters for UL FES post-stroke. The resulting gaps relating to UL FES treatment parameters in the literature indicated the need for a better understanding of the clinical environment, which shaped the methodology used in chapter 5.

1.5. Chapter Five

This chapter is a service evaluation based study of an NHS Foundation Trust stroke pathway. This medical records review indicated the lack of detail documented relating to the management of the post-stroke UL and the limited use of UL FES across the stroke pathway, which supported the justification for chapter 6 methodology.

1.6. Chapter Six

This chapter is a qualitative study exploring the views of individuals working within two large NHS Foundation Trust stroke pathways about the management of the UL post-stroke and the use of UL FES.

1.7. Chapter Seven

This chapter concludes the data collection in the thesis using a Delphi method to gain consensus on best practice in the use of UL FES in the management of individuals post-stroke. The findings of this chapter establish a set of consensus statements that will support the development of clinical practice guidelines.

1.8. Chapter Eight

This chapter concludes the thesis by presenting a critical review of the thesis findings and highlights future research possibilities. Limitations to the thesis are reviewed and discussed. The thesis concludes by re-examining the aims of the thesis and outlining the future development of the consensus statements into clinical guidelines to support the application of UL FES in people with stroke.

Phase 1: Development and demonstration of an original research programme.

- **Chapter 1:** Introduction and thesis structure.
- **Chapter 2:** Review of literature and identification of problem. Development of the thesis aims and objectives.
- **Chapter 3:** Outline of the PhD methodology.

Phase 2: Treatment parameters for upper limb functional electrical stimulation.

- **Chapter 4: Study One.** Treatment parameters for upper limb functional electrical stimulation post-stroke: A systematic review.

Phase 3: Understanding the clinical environment.

- **Chapter 5: Study Two.** Clinical management of post-stroke upper limb: a medical record-based service evaluation of an NHS Foundation Trust stroke pathway.
- **Chapter 6: Study Three.** Focus group activity across two NHS Foundation Trust stroke pathways exploring the views of therapists about the management of the hemiplegic upper limb post-stroke.

Phase 4: Addressing how upper limb functional electrical stimulation could be utilised in people with upper limb impairments post-stroke.

- **Chapter 7: Study Four. Post-stroke** upper limb functional electrical stimulation clinical practice guideline development: an international Delphi study.

Phase 5: Review.

- **Chapter 8:**Thesis discussion and conclusions.

Figure 1.1: Research phases that underpin the development of clinical practice guidelines for the use of UL FES in people with stroke.

Chapter 2 Background

This chapter reviews the background and literature relating to the management of the upper limb (UL) post-stroke including the use of functional electrical stimulation (FES). It concludes by reviewing the current gaps in the literature outlined throughout the chapter and highlights the aims and objectives of the thesis.

2.1. Incidence and prevalence of upper limb impairments and functional limitations after stroke

Over 12.2 million strokes occur globally every year and it is the largest cause of complex disability (Feigin et al., 2021). In the UK, approximately 100,000 people have a stroke every year, with a large proportion surviving the stroke (there are approximately 1.2 million stroke survivors living in the UK) and requiring support or rehabilitation (SSNAP, 2023; Steel et al., 2018). The total aggregated cost (including costs to the NHS, formal social care, unpaid care and loss of productivity) of stroke to the UK economy is currently estimated to be £26 billion/annum, including £8.6 billion for NHS and social care (King et al., 2020; Patel et al., 2018, 2020). Furthermore, it has been recently highlighted by the stroke association that the burden of stroke is set to increase to £75.2 billion by 2035 as a result of increasing survival rates due to improvements in acute care, and an ageing population; with the number of stroke survivors set to increase by 60% (King et al., 2020; Patel et al., 2018a).

A stroke occurs when the blood supply to the brain is disrupted, leading to death of nervous tissue due to lack of oxygen and nutrients. There are two main types of strokes: haemorrhagic and ischemic. Haemorrhagic stroke is classified as a brain bleed into surrounding brain tissue and is categorised by the location of the bleed in the brain. An ischemic stroke occurs when a blockage in a blood vessel interrupts the blood supply to the brain, leading to ischemia (lack of oxygen) to the tissues. Ischemic strokes are also classified depending on location and the area affected within the brain (Parmar, 2018). Chronic physical impairment of the UL occurs in approximately 50–80% of people with stroke (Gebruers et al., 2014; Lawrence et al., 2001; Opheim et al., 2015; Persson et al., 2016; Soo et al., 2019); with a variety of UL impairments including reduced range of movement, tonal issues, reduced dexterity and somatosensory impairments (Borisova & Bohannon, 2009; Kessner et al., 2019; Marciniak, 2011; Nakayama et al., 1994; Tomita et al., 2017). Another common complication is post-stroke shoulder pain which can impact active engagement with rehabilitation and consequently impact quality of life for people with stroke (Dyer et al., 2020; Lindgren et al., 2018; Suethanapornkul et al., 2008). Reduced independence and more severe disability is associated with persistent UL motor impairment post-stroke, as this impacts ability to carry out activities of daily living (ADL) and even return to employment post-stroke (van der Kemp et al., 2019). Furthermore, when there is an UL impairment, post-stroke quality of life can be negatively impacted with increased dependency on carers or family for support (Egbert et al., 2006; Martinsen et al., 2012; Pallesen, 2014; van Lieshout et al., 2020).

UL impairments have been traditionally divided into ‘positive’ and ‘negative’ features of an upper motor lesion (Adey-Wakeling & Crotty, 2013; Gillen, 2015); positive features typically being spasticity (which is characterised by increased muscle tone and resistance to movement) (Li & Francisco, 2015; Ward, 2012) and negative features being weakness or loss of motor control (Raghavan, 2015; Teasell et al., 2014). Whilst emphasis is often placed on the impact of spasticity, numerous studies have concluded that the main contributing factor to loss of function in people with stroke is the negative features of weakness and loss of motor control (Burridge et al., 2009; Gray et al., 2012). In addition to these primary motor deficits, secondary impairments often arise post-stroke; these include changes in mechanical properties of the muscles and connective tissue which can lead to adaptive muscle length changes including shortening and even muscle contractures, both of which can impact functional recovery (Teasell et al., 2014). Adapted use of the impaired UL can also impact recovery with learnt non-use during unimanual and bimanual activities, contributing to lack of motor recovery in the hemiplegic UL (Ballester et al., 2022). However, further studies are required to fully understand the complex relationship between motor recovery and the amount of UL use in people with UL impairments post-stroke.

2.2. The Central Nervous System and factors that drive recovery

2.2.1 Neuroplasticity

The central nervous system (CNS) has the ability to adapt and reorganise in response to injury, pathology, environmental or behavioural demands. This process is known as neuroplasticity, which refers to the brain's ability to form new neural connections and reorganise existing ones (Stein & Hoffman, 2003). Post-stroke, the CNS attempts to compensate for lost or impaired functions by reorganising neural pathways, and, if influenced early, this can have a positive effect on the recovery of the UL. However, if this reorganisation is left unstructured, or without suitable guidance, it can lead to maladaptive plasticity which can be detrimental to recovery(Nagappan et al., 2020). Neuroplasticity can be broadly defined as:

> *...the ability of the nervous system to respond to intrinsic and extrinsic stimuli by reorganizing its structure, function and connections; can be described at many levels, from molecular to cellular to systems to behaviour; and can occur during development, in response to the environment, in support of learning, in response to disease, or in relation to therapy. Such plasticity can be viewed as adaptive when associated with a gain in function.*
>
> *(Cohen et al., 1997).*

Neuroplasticity has the potential to significantly enhance recovery post-stroke, but its benefits depend on the timing and quality of rehabilitation interventions (Dimyan & Cohen, 2011; Harvey, 2009). Promoting the right conditions for neuroplasticity in the early stages of recovery post-stroke is crucial for improving outcomes in stroke rehabilitation. Recovery post-stroke occurs through a combination of spontaneous changes and the relearning of skills (Arya et al., 2011; Nudo, 2003, 2011; Zotey et al., 2023). Spontaneous recovery typically occurs in the early phase of stroke recovery, often in the first few days and weeks, and is driven by the brain's natural healing process, including reduction in any swelling and restoration of blood flow, allowing for reorganisation of existing neural pathways. Longer-term recovery mechanisms are driven by more complex neuronal mechanisms such as long-term potentiation, axonal regeneration and sprouting (Nudo, 2013; Zotey et al., 2023). The key to promoting positive recovery through neuroplasticity is balancing compensatory processes and re-establishing neural pathways (Zotey et al., 2023). Strategies such as task-specific training, constraint-induced therapy and other forms of intensive motor practice can help guide neuroplastic changes in a way that promotes functional recovery (Braun & Wittenberg, 2021; Takeuchi & Izumi, 2013; Zotey et al., 2023).

2.2.2 Intensity of practice and feedback on performance

Training needs to be sufficiently intensive to drive improvements in performance when re-learning movement skills post-stroke (Kwakkel, 2006) and animal-based studies have identified that there may be a 'rehabilitation threshold' of activity, below which no recovery occurs (MacLellan et al, 2011). Furthermore, animal models imply that both timing and dose are important to recover function and change cortical mapping (Krakauer et al., 2012). However, skilled movement development not only requires intensity of practice to encourage neuroplasticity, but also importance needs to be placed on the social, environmental and motivational components to enhance motor performance (Wulf & Lewthwaite, 2016).

Motivating and supporting people with stroke to engage with self-management techniques to drive recovery is known to be valuable (Warner et al., 2015) and is recommended in recent guidelines (NICE,2023). Whilst defining intensity of practice in rehabilitation of the UL is complex and quantifying this is problematic for clinicians, there is clear evidence that any therapy needs to be sufficiently intensive to drive sensory-motor recovery (Cramer et al., 2017). Supporting sufficient intensity in clinical practice is often poorly executed. A poor outcome of the UL is considered a major threat to perceived quality of life in people with stroke (Barker et al., 2007; Barker & Brauer, 2005) and several studies highlight that if the UL is treated effectively in the early stages post-stroke, it can have a positive impact on UL recovery in the longer term (Biernaskie et al., 2004).

Feedback is an important component of learning and can be classified as ‘intrinsic’ (provided by the body’s own mechanisms, e.g. visual, sensory, proprioceptive) or ‘extrinsic’ (usually an external environmental source delivered either verbally, manually or visually) (Rajda et al., 2023). Intrinsic feedback is essential for motor learning and movement control. Following a stroke, the ability to process and use intrinsic feedback is often impaired. Positive feedback, an individual’s perception of their ability, perceived task difficulty and intrinsic motivation have all been shown to impact motor control, and, if harnessed correctly, this can help positively direct re-learning of motor control post-stroke (Wulf & Lewthwaite, 2016). Depending on the level of impairment post-stroke, and the individual’s presentation, extrinsic feedback mechanisms can be utilised to support post-stroke rehabilitation (van Vliet & Wulf, 2006).

The evidence indicates that therapy should focus on the things most relevant to the individual, particularly functions that are relevant to their participation, which can be problematic if, as discussed in the focus groups, the majority of people with stroke are more focused on lower limb (LL) rehabilitation in the early stages post-stroke. There is increasing evidence that engagement in UL rehabilitation and repetitive practice can improve functional recovery (Daly et al., 2005). Recovery of the hemiplegic arm is a protracted process, often spanning years rather than months, and although the physical content of therapy is important, learned non-use often has a significant impact on the achievement of UL functional recovery. Some authors suggest that a more behavioural approach is required to achieve optimal long-term UL recovery (de Kroon et al., 2002; Demain et al., 2013; Dobkin, 2005).

2.3. Functional Electrical Stimulation

2.3.1 Functional electrical stimulation: what it is and how it works in principle

Muscle activity is controlled by the CNS and communication between the CNS and the muscles occurs via motor neurons. Muscle responds to neural signals to produce force. A motor unit is a single motor neuron and its associated muscle fibres; once a motor neuron is activated all the muscle fibres it supplies are activated (Zayia & Tadi, 2020). When there is no stimulation, the membrane of the neuron has a negative charge in comparison to its surroundings, this is known as ‘resting potential’; and the neuron can be described as ‘polarised’. When a neuron is stimulated, its resting potential is altered or ‘depolarised’; this is when, due to alteration in ionic balance, the charge inside the cell becomes more positive, causing an ‘action potential’ (**Figure 2.1**). The process of depolarisation and re-polarisation allows the transmission of the nerve impulse along the motor neuron (Crow, 1992). In a myelinated motor neuron, the electrical impulses jump from one 'node of Ranvier' to another to speed up the conduction (**Figure 2.2**). This sequence of depolarisation and re-polarisation underpins the basic mechanism underlying the contraction and relaxation of muscles, as the myosin and actin filaments within the muscle fibre start interacting, i.e. sliding across one another (**Figure 2.1**).

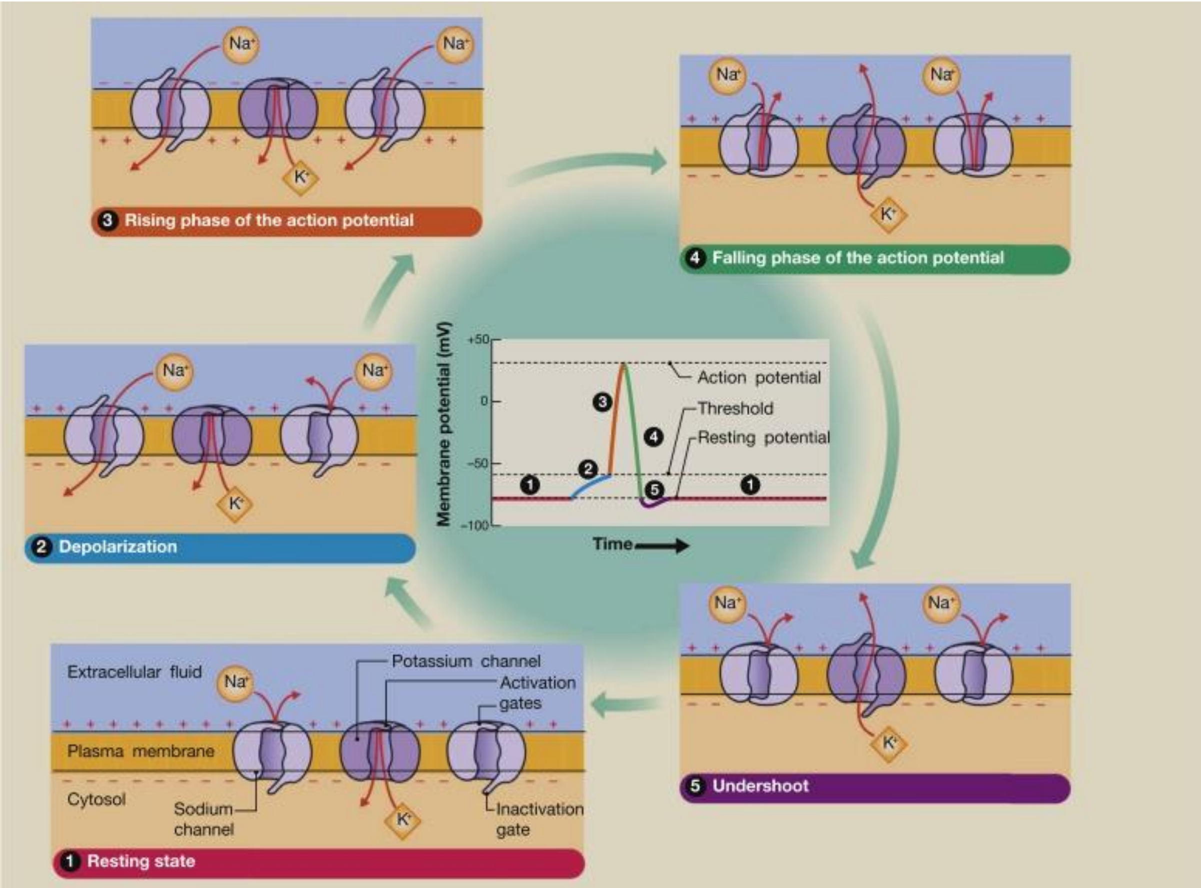

Figure 2.1: Generation of an action potential (Fletcher, 2022).

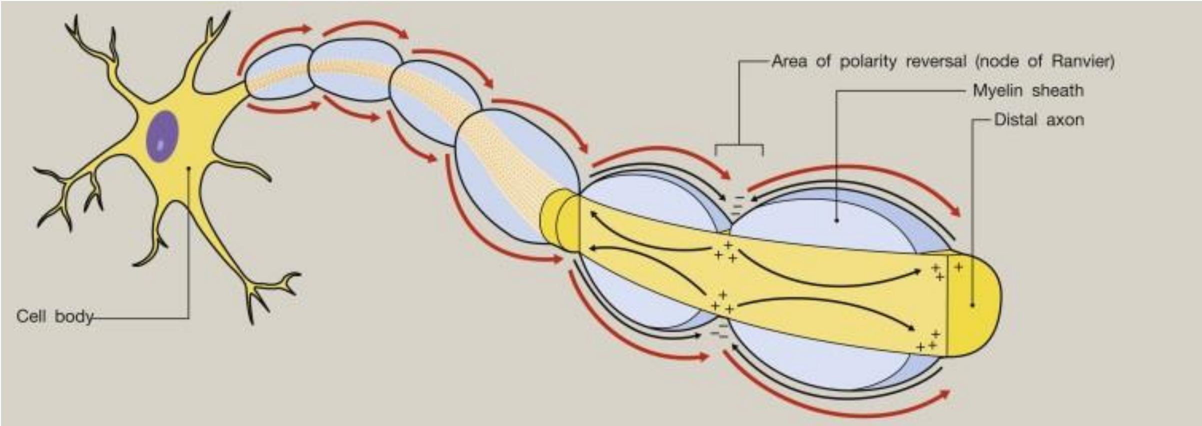

Figure 2.2: Conduction along the axon of a motor neurone (Fletcher, 2022).

Stimulation by the CNS of excitable muscle/nervous tissues provides the basis for the use of FES as a rehabilitation tool in people with stroke. FES delivers controlled low-energy electrical pulses (stimulation) with the aim of generating a muscle contraction and can enable functional tasks to be carried out (Popovic et al., 2022). Action potentials (**Figure 2.1**) are generated by applying electrical stimulation to alter the electrical field surrounding a nerve cell. There are a variety of types of electrodes that can be used in FES systems including subcutaneous systems (which can be percutaneous or implanted); however, the most common systems use surface (transcutaneous) electrodes as shown in **Figure 2.3** (Marquez-Chin & Popovic, 2020). An action potential artificially generated by FES activates motor nerve fibres in both directions (orthodromically (along the axon towards the muscle) and antidromically (along the axon towards the cell body)) from the point of electrical stimulation; this is a unique feature of FES (Rushton, 2003).

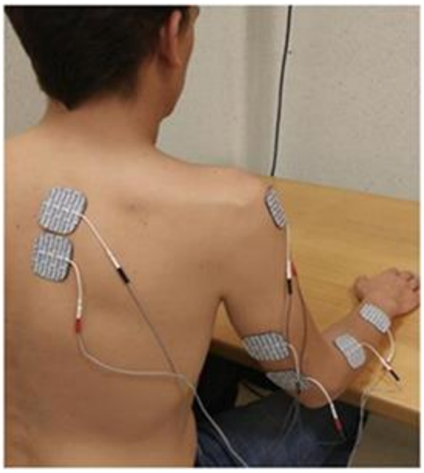

Figure 2.3: Illustration of application of surface electrodes. (Cuesta-Gómez et al., 2017)

Functional electrical stimulation devices have a number of stimulation parameters that impact the effect of the electrical stimulation on the resulting muscle contraction. Depending on the specific device, these parameters can be fixed and/or altered by the clinician/user; they include pulse duration (or pulse width, this is the time the simulation is present), pulse amplitude (the magnitude of the electrical stimulation) and pulse frequency (rate at which electrical stimulation delivered) (**Figure 2.4**) (Marquez-Chin & Popovic, 2020).

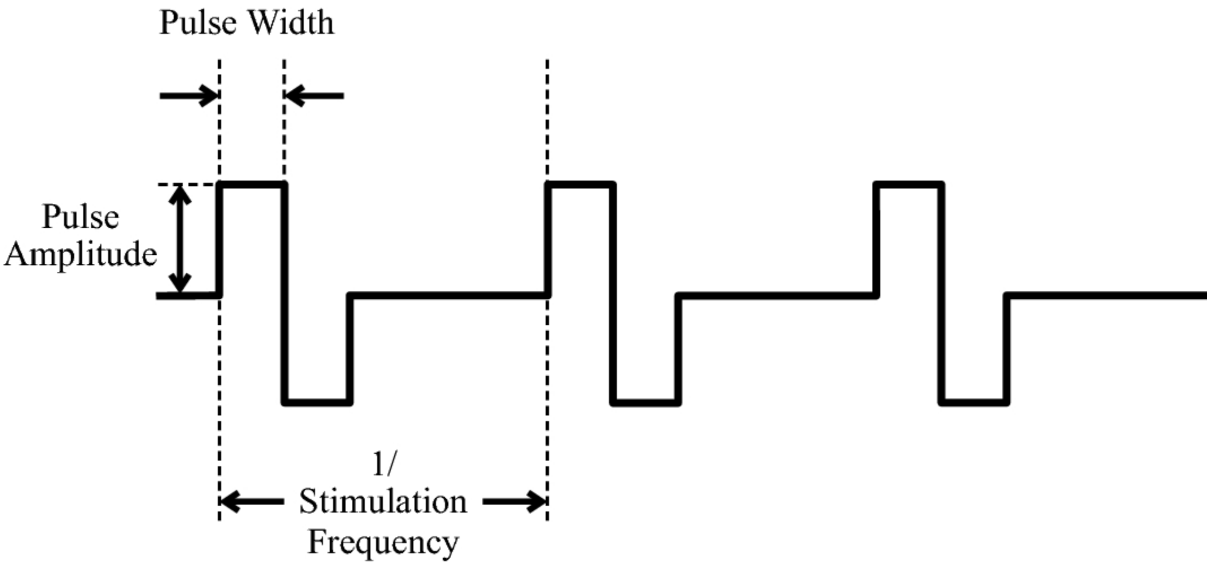

Figure 2.4: Functional electrical stimulation parameters (Marquez-Chin & Popovic, 2020).

2.3.2 Types of functional electrical stimulation

There are a variety of commercially available FES devices. The method of stimulation varies, including the use of open-loop and closed-loop FES control systems. In an open-loop FES device, the stimulation parameters are adjusted during the task by an external 'trigger' from the control system, which could be initiated by the FES user, or the clinician applying the FES. These systems are pre-programmed with a fixed cycle or cyclical electrical stimulation. Whilst some open-loop systems have a trigger button, they are not under voluntary control and require an external trigger to generate muscle activity. Below are two examples of open-loop functional electrical stimulation systems; the SaeboStim Pro (**Figure 2.5**) and the Bioness H200 hand rehabilitation system (**Figure 2.6**).

The SaeboStim Pro is a dual-channel electrical stimulation device (**Figure 2.3**) which uses surface electrodes to trigger the targeted muscles. This particular device has preset programs, or a custom program can be created using a trigger button to initiate the electrical impulse by the therapist or user.

Figure 2.5: SaeboStim Pro.

Some functional electrical stimulation devices, such as the Bioness H200 neuroprothesis (**Figure 2.4**) are combined with a hand/wrist orthosis; this enables stabilisation at the wrist joint whilst the embedded electrodes stimulate the target muscles(IJzerman et al., 1996). With this type of embedded FES system, forearm muscles can be stimulated. The device is pre-programmed and does not permit the therapist or user to trigger muscle contractions externally. Whilst this type of neuroprosthesis will provide stability at the wrist/hand resulting in the desired muscle contraction, an inability to adjust the electrode placement to meet the specific needs of the FES user means the device is limited to the restoration of grasp/release.

Figure 2.6: Bioness H200

FES systems that are controlled via voluntary effort from the user and are supplemented with EMG, EEG or are motion-triggered are classed as closed-loop systems. Closed-loop FES systems can provide precise adaptation to the input in response to the users' actual performance, which is often based on joint position (Chadwick et al., 2011) or force generated (Lawrence et al., 2008). These types of systems only generate the minimum level of stimulation to continually challenge the user, however, they do require a minimum level of voluntary muscle contraction and, therefore, might not be suitable for those with greater UL impairments post-stroke. An example of an EMG triggered FES system is the IVES+ GD-611 (**Figure 2.7**).

Figure 2.7: IVES+ GD-611

There are limitations with all forms of FES systems currently available for use. In current clinical practice, open-loop systems are more frequently used, however, by relying solely on observing the UL's response to the FES, they are less likely to provide accurate feedback and generate more muscle fatigue (Haugland et al., 1999; Hoffer et al., 1996; Marquez-Chin & Popovic, 2020). Similarly, neuroprothesis systems are less suitable for those with more proximal-based UL impairments. Complex UL impairments in people with stroke pose a challenge to clinicians contemplating UL FES as the need for multiple stimulation channels not only impacts set up time, but can also be difficult to coordinate completion of a functional task.

There are a number of more sophisticated FES devices available, however, these systems are either not yet widely available or are similar to more simplistic FES systems, just not frequently used in clinical practice (Abouzakhm et al., 2022; Auchstaetter et al., 2016; Stockley et al., 2019). Motion-controlled FES systems using sensory or kinematic feedback mechanisms to adjust the stimulation cycles have reported positive results (Mann et al., 2011; Meadmore et al., 2014). The FES-UPP flexible finite state machine controller was developed to support delivery of intensive UL practice and consists of a five channel stimulator with a programmable interface including the use of accelerometers (described in detail in (Sun et al., 2018)) (**Figure 2.8**), however, despite promising results (Smith et al., 2019), this equipment is still pending commercial release. Wearable textile based systems with electrodes embedded (**Figure 2.9**) are also now at the point of clinical trials and along with more complex systems like the FES-UPP will likely highlight the future direction of FES systems over the next few years (Marquez-Chin & Popovic, 2020; Moineau et al., 2019; Smith et al., 2019).

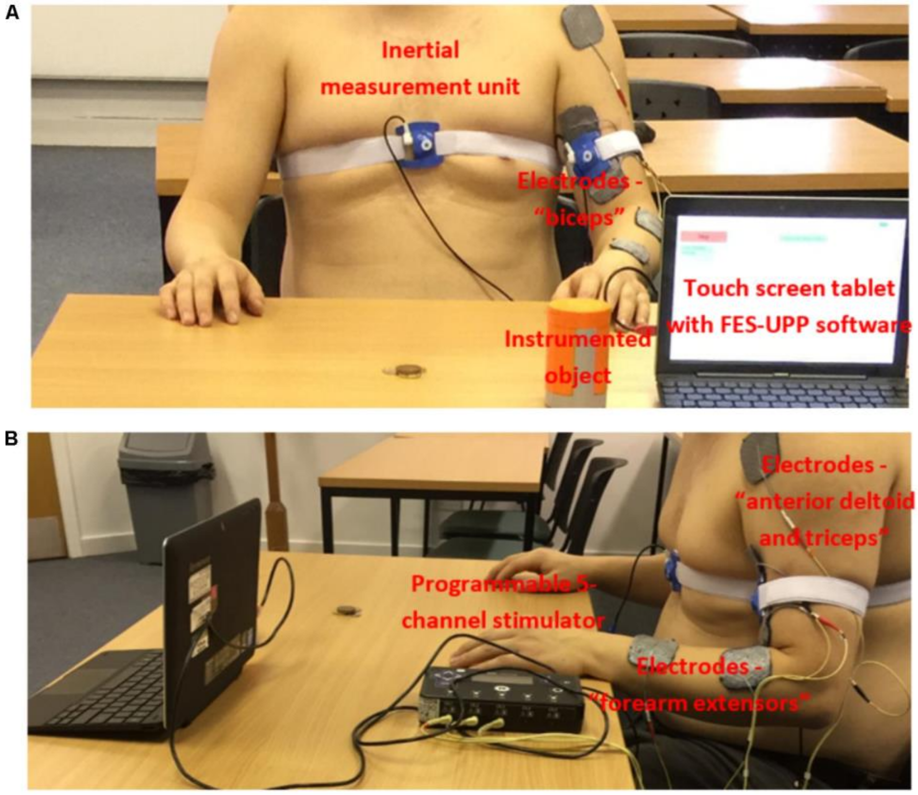

Figure 2.8: Example set-up of the FES-UPP system (Sun et al., 2018)

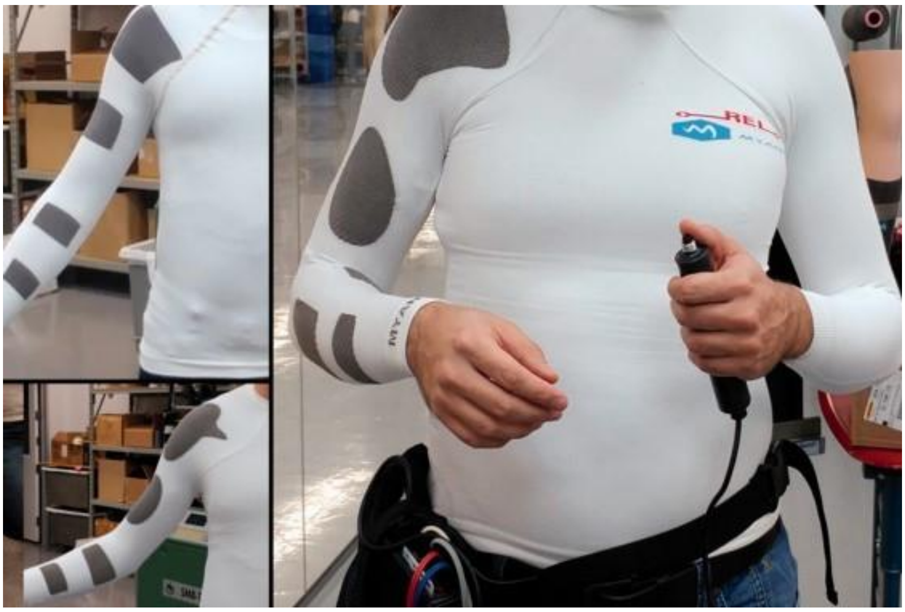

Figure 2.9: Functional electrical stimulation shirt (Moineau et al., 2019).

2.3.3 Use of technology in clinical practice

The use of technology in clinical practice has the potential to impact service delivery from a variety of aspects including time and improving efficiency (Chua & Kuah, 2017; Laut et al., 2016; Mitchell et al., 2023). However, there are a multitude of factors that influence the implementation of technology to enhance rehabilitation, and the views of clinicians, service users, managers and healthcare policy makers are essential to drive use in practice forward (Langan et al., 2018; Murphy et al., 2024; Stockley et al., 2019). Despite the desire to supplement rehabilitation with technology there are a number of complex barriers to adoption, which include the flexibility and availability of the devices themselves (Smith et al., 2018, 2019; Sun et al., 2018), environmental constraints and the need for further robust evidence underpinning technology usage.

Specifically in stroke rehabilitation, how people with stroke present varies significantly as the pathophysiology of stroke is multifactorial. Complexity lies in the fact that any assessing and treating clinician has to clinically reason and justify any approach to the management of an individual post-stroke, and factors such as severity of stroke, any co-morbidities, level of motor and sensory impairment to both the lower limb (LL), UL and trunk will all be influencing factors in this decision making. These factors account for the variation in treatment approaches and potentially the outcomes following intervention. Clinicians cognitively engage in what is known as clinical reasoning to support making decisions about treatment choices (Higgs & Jensen, 2019); there are many factors that influence this cognitive process, including gathering information or interpreting data from the patient's presentation, current literature and clinical guidelines. Furthermore, clinicians' own knowledge, clinical experience and what treatment options clinicians have been exposed to at either an undergraduate or postgraduate level will also influence any clinical decisions made (da Silva Araujo et al., 2022; Kristensen et al., 2012; Longley et al., 2019). Movement analysis, functional ability and taking a holistic view of an individual's presentation are also key elements that influence clinical reasoning for physiotherapists and occupational therapists (Elvén et al., 2015; Huhn et al., 2019; Knis Matthews et al., 2017).

Whilst health technologies aim to promote health, prevent and treat disease and improve rehabilitation the use of health technologies within healthcare remains low. Burridge et al (2010) conducted a review of the most commonly used technologies in clinical practice and they concluded that in spite of some of the technologies having a growing body of evidence uptake remained poor. Low rates of technology uptake in the NHS were again found in the recent Darzi report (Darzi, 2024). Successful adoption or uptake of technology into clinical practice is dependent on a multitude of factors including perceived barriers to adoption and impact of set up time/use. In a survey by Hughes et al (2014) the top five factors that influence adoption were reported as: an evidence-base supporting use, ease of setup, safety, comfort and durability. The Technology Acceptance Model (TAM) (Davis, 1989) or the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh & Davis, 2000); could be used to help understand why clinical uptake is low. The TAM is a widely used framework for understanding why users, including clinicians, may or may not adopt new technologies. It makes the assumption that two primary factors—perceived usefulness (the degree to which a person believes that using a particular technology will enhance their job performance) and perceived ease of use (the degree to which a person believes that using the technology will be free of effort)—directly influence an individual's intention to use a technology(Rahimi et al., 2018). The UTAUT expands on the TAM by incorporating additional determinants including performance expectancy (perceived benefit), effort expectancy (perceived ease), social influence (the degree to which peers influence use), and facilitating conditions (organisational and technical support). Whilst users previous experience of technology has been shown to have an influence on its adoption (Venkatesh & Davis, 2000) barriers to use are often context-specific and possibly may require a more tailored framework that integrates behavioural, psychological, and organisational factors beyond what TAM and UTAUT typically address. The purpose of this thesis was also to explore the wider management of the UL post stroke and for this reason assumptions were not made purely on the basis of use of technology and neither the TAM or UTAUT were adopted at this stage.

2.4. Gaps in the literature

Stroke rehabilitation guidelines in the UK are produced by the National Institute for Health and Care Excellence (NICE, 2023) and the Intercollegiate Stroke Working Party (ISWP], 2023). Clinical guidelines for the management of people with stroke were recently updated in 2023 with a significant focus being on intensity-based rehabilitation strategies, including the management of the UL (ISWP, 2023; NICE, 2023). FES has the potential to support an intensity-based programme of UL rehabilitation and within both the NICE stroke guidelines (NICE, 2023) and the ISWP guidelines (ISWP, 2023) electrical stimulation was recommended. ISWP specifically recommends FES and highlights that bespoke patient-centred stimulation protocols should be implemented; however, the only UL impairment that this was recommended for was reduced function in the wrist and finger extensors (ISWP, 2023). Whilst this is the first recommendation of FES in the management of the UL post-stroke cited within a clinical guideline, it is still limited in terms of detail to support clinical reasoning and application.

It has been previously highlighted that limited time is often given to UL rehabilitation post-stroke, and, coupled with both a shortage of resources in healthcare and an increase in the prevalence of stroke, this is likely to further increase the societal burden (King et al., 2020; Patel et al., 2018, 2020). Furthermore, previous research has identified an underuse of FES in the management of the post-stroke UL and identified a number of barriers to implementation, including staff confidence, equipment availability, lack of resources in terms of environmental and physical equipment (Auchstaetter et al., 2016; Musselman et al., 2024; Stockley et al., 2019). It is apparent people with stroke are not necessarily receiving the recommended level of treatment required to optimise recovery post-stroke, which is believed to be heightened in the acute phase (first few weeks post-stroke)(Dromerick et al., 2021; Krakauer, 2005; Krakauer et al., 2012); and the complexity of the needs of people with stroke and competing priorities, especially in the acute phase, impact prioritisation of the UL and the use of FES. Technology, specifically FES, can help to alleviate this challenge, however, in spite of recent recommendations there is still a low uptake in clinical practice (Musselman, 2024; Stockley et al., 2019). Building on what is already known from previous studies, through this programme of work the thesis author wanted to further understand the reasons for this low uptake and begin to address one of them, namely the lack of clinical practice guidelines.

2.5. Aims and objectives

The increasing prevalence of stroke presents significant implications for future healthcare burden in across the UK and globally. Whilst UL FES and intensity-based rehabilitation have been recommended in recent stroke guidelines (NICE, 2023) there remains a need for additional clinical practice guidelines to support clinicians with adoption and implementation. Clinical practice guidelines are not only used to inform clinical decision making and assist in shaping best practice but have the potential to inform allocation of healthcare resources (Graham et al., 2011). The Institute of Medicine (IOM) defined clinical practice guidelines as *'statements that include recommendations intended to optimise patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options.'* (Graham et al., 2011 Chapter 1). The principal research aim of this thesis was to explore the development of clinical practice guidelines to support the application of post-stroke UL FES.

The objectives of the study were to:

- Undertake a systematic review of the existing evidence relating to UL FES, specifically, to identify commonly used treatment parameters for UL FES (Chapter 4).
- Identify the knowledge, skills, and attitudes of stroke clinicians towards the use of UL FES across two large NHS Foundation Trust stroke pathways (Chapter 6).
- Develop expert consensus on the use of UL FES in people with stroke to support the development of evidence-based clinical practice guidelines for the use of FES to improve UL function in people with stroke (Chapter 7).

The programme of research comprises four studies:

Study One: Treatment parameters for UL FES post-stroke: A systematic review.

Study Two: Clinical management of post-stroke UL: a medical record-based service evaluation of an NHS Foundation Trust stroke pathway.

Study Three: Focus group activity across two NHS Foundation Trust stroke pathways exploring the views of therapists about the management of the hemiplegic UL post-stroke.

Study Four: Post-stroke UL FES clinical practice guideline development: an international Delphi study.

Chapter 3 PhD Methodology

This chapter outlines the research paradigm adopted through this programme of research, focusing particularly on the epistemological and ontological positions taken, and the rationale for adopting a pragmatic approach with multimethods.

3.1. Philosophical stance and research paradigm

A research paradigm refers to a broad framework that guided the entire research process, including the underlying assumptions about the world, knowledge and how we come to understand the truth (Y. S. Lincoln et al., 2011). It represents a set of beliefs about how research should be conducted and what constitutes valid knowledge (Creswell & Clark, 2018). Paradigms influence the types of questions asked, the methods used to gather and analyse data and the interpretations made from the results. Epistemology and ontology are two key elements of any research paradigm. Epistemology concerns the nature of knowledge, how it is acquired and what is considered valid knowledge. It addresses questions such as how do we know what we know? (Cohen et al., 2017).In the context of research, ontology however deals with the nature of reality. It examines what exists and what can be known about the world (Rehman & Alharthi, 2016). These positions exist along a spectrum from realism to relativism, reflecting different beliefs about whether reality is objective and independent of human experience or whether it is constructed by individuals' perceptions and social context (Deforge & Shaw, 2012). A realist view assumes that the world is structured in a consistent way and research can uncover this 'one truth' through appropriate methods. In realist research the aim is to discover factual knowledge that is true regardless of the observers perspective. Realists therefore believe that phenomena exists and operate according to natural laws, and the researcher's role is to identify and explain these objective truths. At the other end of the spectrum, relativism holds that reality is subjective and constructed through individual or group experiences, beliefs and cultural contexts. According to relativism, there is no single, fixed truth but rather multiple realities, each shaped by different perspectives. This view emphasised that knowledge is always context-dependant and influenced by social, historical and personal factors. In relativist research, the goal is often to explore and understand the diverse interpretations and means that people attribute to their experiences (Guba & Lincoln, 1994). Between these two extremes are several other ontological positions that blend elements of realism and relativism including critical realism and pragmatism (Deforge & Shaw, 2012).

Research is inherently shaped by the researcher's worldview, which influences both the design and the approach taken to investigate a particular problem or phenomenon (Creswell, 2003; Opie & Brown, 2023). The philosophical standpoint of the researcher determines how they approach the nature of knowledge (epistemology) and the nature of reality (ontology), which in turn frames the methods and methodologies used in the study (Creswell & Clark, 2018; Y. S. Lincoln et al., 2011).

This thesis is framed within the philosophical assumption of pragmatism, a practical problem-solving approach that emphasises the utility and applicability of knowledge (DeForge & Shaw, 2012). Pragmatism as a philosophical tradition, has roots in the works of American philosophers like Charles Peirce, William James and John Dewey (Ormerod, 2006). Pragmatism rejects the rigid distinctions between objectivist and subjectivist paradigms and focuses on what works best to address research problems. A pragmatist approach assumes that, based on individual human experiences, reality is both constantly changing and actively created (Frey, 2018). From a pragmatist viewpoint, this is also orientated towards practical problem solving. It is rooted in the idea that theories and ideas should be evaluated based on their practical consequences and their usefulness in addressing real-world problems (Kaushik & Walsh, 2019). Pragmatism is as a philosophical approach that priorities practical outcomes over theoretical purity and is considered ‘pluralistic and orientated towards “what works” and real-world practice.’ (Creswell & Plano Clark, 2017, Chapter 2 p. 67). Pragmatism suggests that truth is not static but evolves as new ideas are tested through action and reflection. In this approach, the researcher is open to using a variety of methods, including both qualitative and quantitative techniques, in order to find solutions that best work for the problem identified (Bryman, 2006).

The pragmatic viewpoint is particularly well suited for multiple methods and mixed methods research, as it allows for the combination and integration of both qualitative and quantitative data collection and analysis techniques (Creswell & Plano Clark, 2017; Willig & Rogers, 2017). By combining these approaches researchers can address complex research questions from multiple angles, drawing on the strengths of each method, to achieve a more comprehensive understanding of the phenomena under investigation. This flexibility aligns with the pragmatic view that different tools and strategies should be employed based on their ability to solve problems, rather than adhering to a rigid methodological framework (Andrew & Halcomb, 2006). The ability to use and combine these approaches was considered to be important for understanding the use (and non-use) of FES for the UL post-stroke, since this might require both quantifying current patterns of use as well as in-depth exploration of perceived barriers, facilitators, preferences and prejudices relevant to its use in routine practice.

The philosophical stance of this thesis is grounded in the belief that both single and multiple realities should be open to investigation. This view aligns with a pragmatic approach, which recognises that reality is dynamic and ever-changing, shaped by the perspectives and experiences of individuals. In this context, reality is not fixed or static but is influenced by the unique perceptions of each person. Therefore, the thesis author acknowledges that different individuals may experience and interpret the same phenomenon in different ways, which is a key consideration in understanding complex issues.

Clinical practice is inherently complex and multifaceted; making the rigid distinctions between research paradigms problematic for healthcare researchers as it does not fall neatly into a positivist, constructivist or critical paradigm (Parry, 1997). In this body of research, the focus is on providing guidelines for clinicians to support the use of UL FES in people with stroke. By adopting a pragmatic lens, this ensures that a comprehensive, rounded perspective is taken when developing these guidelines. Pragmatism advocates for choosing methods based on the specific research question, rather than adhering strictly to a particular philosophical or methodological tradition (Kaushik & Walsh, 2019; Morgan, 2017). In this way, pragmatism emphasises flexibility and practicality, with the goal of producing findings that are not only meaningful, but also useful and applicable to real-world contexts (Kelly & Cordeiro, 2020). Pragmatism supports the notion that the practical application of knowledge and its potential impact on practice should drive the research process (Morgan, 2014, 2017). The findings of this programme of research aim to be practical, actionable and directly beneficial to clinicians working in stroke rehabilitation, ensuring that the guidelines developed are grounded in real-world needs and considerations.

For this thesis, the researcher followed a multimethod sequential design research approach (see **Figure 3.1**). In the literature that has specifically focused on rehabilitation and clinical practice, multiple methodologies have been identified, yet a number of authors suggest that, in order to comprehensively address patient care, best practice involves the integration of various approaches (Fetters et al., 2013; Shaw et al., 2010; Stricker, 1992). Research used to inform clinical practice should not only rely on high-quality evidence but also consider cultural and contextual factors that have the potential to impact practice (Higgs, 2023). Research that intends to support clinical practice should draw on knowledge from a variety of sources (Higgs & Titchen, 1995). Multimethod or a mixed methods research design, grounded in a pragmatic paradigm, has been suggested to be superior to either qualitative or quantitative methods in isolation (Shaw et al., 2010). The integration of qualitative and quantitative offers a deeper understanding that would be difficult to achieve through either method in isolation (Johnstone, 2004). This is particularly advantageous in the study of health and health service delivery. Given this stance, a multimethod approach was selected for this programme of research, as it allows for the use of both quantitative and qualitative methods. This approach enables the researcher to explore and understand the multiple dimensions of the research question.

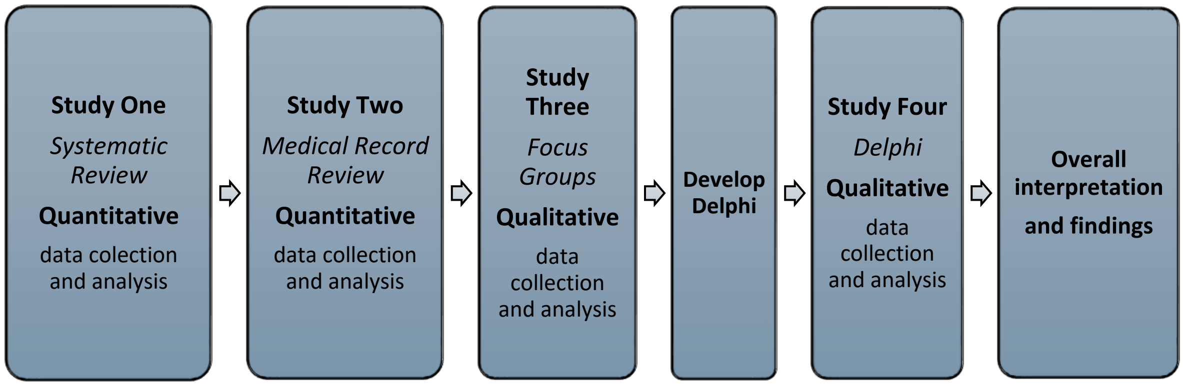

Figure 3.1: Multimethod sequential design adapted from The Oxford Handbook of Multimethod and Mixed Methods Research Inquiry (Hess-Biber & Johnson, 2015)

This study can be considered multimethod design by its use of two different quantitative and qualitative methods, all of which were chosen to support the core qualitative driven sequential multimethod approach.

3.2. Reflexivity and positionality

Reflexivity is an important part of qualitative research (Smith, 2006). Reflexive research fully embraces a researcher's subjectivity and how a researcher's own assumptions or beliefs influence the research process (Jamieson et al., 2023). The thesis author acknowledges that, as a clinical researcher, they cannot fully detach themselves from their previous work and experiences; despite aiming to work inductively during the qualitative research phases any established biases could influence the way in which research is conducted.

As a qualified physiotherapist, the thesis author has had a sustained specialist interest in neurorehabilitation throughout their varied career; both in a clinical setting and in higher education. On being introduced to faradism as a means to enhance muscular movement when training to be a physiotherapist in the early 1990s—despite the limited quality research findings relating to evidence-based practice at that particular time within the profession (Turner, 2001)—this highlighted to the thesis author the potential for electrical stimulation to improve motor recovery in people with stroke to enhance movement and positively impact functional independence.

Self-awareness is central to effective reflective practice and whilst at the beginning of this doctoral journey I was a novice researcher with some experience of data collection but no publication history. I was aware from the offset that I held a positivist perspective towards the use of technology in stroke rehabilitation and I needed to be mindful of this during the research process. In order to ensure the credibility and trustworthiness of the research I employed several strategies to manage and mitigate undue researcher influence including peer debriefing, triangulation and member checking. I engaged in regular discussions with both academic peers and my PhD supervisors to provide critical feedback to help identify any biases relating to the use and application of UL FES in stroke rehabilitation. When transcribing the focus group documentation participants were invited to review and comment on preliminary findings; this permitted them the opportunity to challenge my representations of their perspectives and enhanced the rigor of my findings in Chapter 6. Also, by conducting triangulation of data from multiple sources (Chapter 5 and 6) this enabled cross-validation of findings and reduced the reliance of a singular perspective. Furthermore, informed consent, confidentiality and participant autonomy were prioritised throughout the studies to ensure ethical rigor and respect for the participants voices. These measures collectively enhanced the studies integrity, ensuring that the findings were grounded in participants' realities whilst acknowledging and managing my own influence on the research conclusions.

Over the last decade, the use of technology-enhanced rehabilitation has become more mainstream, and research has established the benefits of using this type of intervention, such as FES, for a variety of people with neurological impairments. However, access to equipment and barriers to implementation present a challenge to adoption and routine use of technology-enhanced rehabilitation in clinical practice. Through their academic role at Sheffield Hallam University, the thesis author was fortunate to work alongside Dr Christine Smith who completed her PhD on the usability of UL FES in people with stroke and, through her work, developed connections with clinicians, academics and researchers linked to the International Functional Electrical Stimulation Society (IFESS) which furthered both the thesis author's knowledge and interest in this area of clinical research.

Whilst working as a full-time senior lecturer at Sheffield Hallam University, the thesis author commenced their doctoral study, and, whilst this was not without its challenges, it created opportunities to share new knowledge and skills gained with learners on both the undergraduate and postgraduate curricula. During the thesis author's doctoral studies, and with the support of their PhD supervisory team, the thesis author has developed not only as a researcher, but also as a clinical academic.

Chapter 4 Treatment parameters for upper limb functional electrical stimulation post-stroke: A systematic review

This chapter reports on a prospectively registered systematic review of the literature, which aimed to critically review and synthesise the evidence for prescription of post-stroke upper limb (UL) functional electrical stimulation (FES) treatment parameters. The title of the review is: *'A Systematic review of the prescription of treatment parameters in the use of Functional Electrical Stimulation of the upper limb post-stroke'.*

This systematic review was accepted and presented as a poster and presented at RehabWeek for the International Functional Electrical Stimulation Society (IFESS) (see Appendix **10.1.1**)

Abstract

Background: FES is a treatment option to help restore UL function following stroke. However, there are multiple potential prescriptions and treatment parameters when applying functional electrical stimulation and no clear guidance on which might be optimal.

Aim: To identify, describe, and critically evaluate the range of post-stroke UL FES treatment parameters reported in published studies.

Methods: For this systematic review and narrative synthesis, we searched CINAHL, MEDLINE, SPORTDiscus, and the Cochrane Central Register of Controlled Trials for studies published between database inception and July 2022. Any study design reporting on any aspect of treatment parameters used in the application of UL FES to people post-stroke was included. The types, doses, durations, locations, and intensities of FES were extracted and described. The quality of the included studies was assessed using an integrated quality criterion for review of multiple study (ICROMS) design and data was not excluded based on the quality of evidence provided.

Findings: Of 1464 records identified, 28 studies (combined n=405 participants) were eligible and included. The selected studies included randomised controlled trials (n=5) feasibility studies (n=5) and systematic reviews (n=5). Most of the selected studies (n=16) were conducted in people >6 months post-stroke onset, living with moderate to severe stroke impairment. Open and closed-loop FES devices were used, with a median (range) of 20 (8 to 168) treatment sessions, and median (range) duration of treatment session of 60 (10 to 150) minutes. Given that the aim of the systematic review was to capture all relevant literature,

data was not excluded based on the quality of evidence provided and, therefore, there is a risk of bias, which impacts the results of this systematic review.

Interpretation: Despite a relatively large number of trials, there was too much variance between FES applications to indicate recommended UL treatment parameters. More robust information on FES treatment parameters would not only assist the treating therapists but would have the added benefit of ensuring future clinical trials offer the optimum conditions to drive post-stroke UL recovery. On the basis of this review, there was limited information to robustly inform electrical stimulation treatment prescriptions for UL recovery post-stroke. Further research is required to inform clinical delivery of UL FES more fully.

Registration: PROSPERO (CRD42018110286)

4.1. Background

In the United Kingdom (UK) there are approximately 1.2 million people living with stroke, and the cost of stroke to the UK economy is estimated to be around £26 billion/annum and this is estimated to significantly increase by 2035 as a result of increasing survival rates due to improvements in acute care, and an ageing population (King et al., 2020; Patel et al., 2018a). A recent systematic review highlighted that the economic burden of stroke is not only a combination of the hospital care required but also the long-term rehabilitation and economic loss to the country (Rochmah et al., 2021). The UL is used for a wide variety of functional tasks that have a direct impact on quality of life (Barker et al., 2007; Barker & Brauer, 2005; van Lieshout et al., 2020) and independence (Akbarfahimi et al., 2011; Nickel et al., 2017). People with stroke place significant importance on restoration of UL functional movement (Barker et al., 2007; Barker & Brauer, 2005). The functional capacity of the UL is not just the ability to reach or manipulate objects, it significantly influences balance reactions and the ability to use the body to maintain stability (Akbarfahimi et al., 2011; Barker et al., 2007; Nickel et al., 2017). People with stroke who have significant UL dysfunction are far more likely to require higher levels of care post-stroke (Anwer et al., 2022; Saka et al., 2009).

Defining intensity of practice in rehabilitation of the UL is complex and quantifying intensity is problematic for clinicians (Goikoetxea-Sotelo & van Hedel, 2023). There is clear evidence that therapy needs to be sufficiently intensive to drive sensory-motor recovery (Krakauer, 2005), however, this is often inadequately reported in studies. Time in therapy sessions or number of repetitions of exercises tend to be the method used to capture ‘intensity’. This alone is not sufficiently robust, as there is often no indication of the speed and quality of the movement or the actual UL movement pattern produced (Connell et al., 2014b; Kwakkel, 2006). MacLellan et al. (2011) examined the critical threshold for rehabilitation in rats and found an important threshold below which recovery will not occur (<300 repetitions). It has been further identified that if this critical threshold in people with stroke is not reached, UL recovery will not occur and the unaffected arm will compensate (Schweighofer et al., 2009; Winstein et al., 2019), strongly supporting the use of intensive rehabilitation therapies for stroke patients (Birkenmeier et al., 2010).

In order to positively impact therapeutic outcomes, there is agreement that any neurorehabilitation intervention should be both goal orientated and repeated multiple times (Kleim & Jones, 2008; Kwakkel, 2006; Kwakkel et al., 2006; Toovey et al., 2017). The clinical presentation of UL impairment is heterogenous amongst people with stroke (Anwer et al., 2022; Burridge et al., 2019). Knowledge of the dose-response relationship of any active intervention aimed at recovering motor function would enable clinicians to be aware of any minimal dose recommendations to maximise recovery. A barrier to this is the use of language that both clinicians and researchers adopt when attempting to quantify or define intensity/dosage of any therapeutic intervention (Goikoetxea-Sotelo & van Hedel, 2023).

In terms of the UL, poor recovery is considered a major threat to perceived quality of life in people with stroke (Dobkin, 2005). Effective treatment of the UL in the early stages post-stroke can have a positive impact on UL recovery in the longer term (Harris et al., 2009). Whilst the CNS has the capacity to reorganise through neuroplasticity (Dimyan & Cohen, 2011), if post-stroke this is not guided through environmental and therapeutic stimulation to promote positive neuroplastic responses, it can be detrimental to recovery (Cramer et al., 2011). A number of factors are essential in influencing functional recovery, such as the timing and dose of therapeutic interventions, and most importantly progressively challenging task specific training to drive recovery (MacLellan et al., 2011). Therapy needs to focus on the things most relevant to the individual, particularly functions that are relevant to participation. Recovery of the hemiplegic arm is a long-term process, often spanning years rather than months (Ingwersen et al., 2021). Although the physical content of therapy is important, learned non-use often has a significant impact on UL functional recovery. This would suggest that a behavioural approach may be required to achieve optimal long-term UL recovery (Connell et al., 2015; Cramer et al., 2017; Lee et al., 2015).

The principle behind the use of FES is to activate weak or paralysed muscles to gain activity through electrode placement on or near innervating nerve fibres (Popović, 2014; M. R. Popovic et al., 2005; Thrasher et al., 2005), restoring movement either temporarily through function but with the aim of long-term carry over and/or prevention of compensatory mechanisms. Deficits in the UL post-stroke are common (de Kroon et al., 2002) and it has been suggested that FES could be used as an adjunct to enhance neural recovery post-stroke and ultimately improve UL function. The use of FES for LL rehabilitation post-stroke is well established with a number of studies highlighting the efficacy of muscle specific electrical stimulation to enable ankle dorsiflexion (for footdrop), and to minimise compensatory strategies in gait (Kesar et al., 2011). A number of studies have shown that FES can have a beneficial effect on UL motor recovery (Farmer et al., 2014; Kutlu et al., 2016; Marquez-Chin et al., 2017; Miyasaka et al., 2016). Marquez-Chin et al. (2017) assessed the efficacy of FES therapy in improving voluntary reaching and grasping after severe hemiplegia and identified that, when combined with standard therapeutic input post-stroke, this resulted in a 'significantly greater recovery'. FES for the UL, when used in a task-oriented manner, with maximum voluntary effort from the patient (Kutlu et al., 2016), can promote clinically significant gains in UL recovery. Despite evidence to support the application of FES for the management of the UL it is not routinely offered within stroke services, primarily due to a lack of understanding and barriers to adoption (Demain et al., 2013). The lack of clinical guidelines is also felt to be a contributing factor to more widespread adoption. More advanced UL FES systems that are capable of enabling clinicians to prescribe treatment parameters more specifically and enable patients to work on a volitional level within function are making their way to market (Smith et al., 2019; Sun et al., 2018). Although therapists have been involved in the co-design of these UL FES systems (Sun et al., 2018), their implementation into mainstream clinical practice is likely to be hampered by set up times (Smith et al., 2018), therapists' lack of knowledge about how to use the systems to augment existing therapy, and an absence of UL FES treatment guidelines (Auchstaetter et al., 2016). To date, clinical functional electrical stimulation studies have only provided a broad indication of treatment parameters, i.e. dosage. More detailed guidelines providing specific algorithms regarding which muscles to stimulate, when to incorporate functional activities for varying levels of UL impairment and when to incorporate other supplementary therapeutic interventions are urgently required. Technology-supported UL rehabilitation could bridge the intensity gap, offer a cost-effective way to support therapeutic input to improve functional ability (Kutlu et al., 2016) and reduce dependence on stroke services for people with stroke (Smith et al., 2019; Sun et al., 2018).

There are currently no clinical decision support tools available that highlight the key parameters and application guidelines that would be useful to clinicians when utilising FES in the management of the UL post-stroke. The aim of this systematic review was to critically review and synthesise the evidence for prescription of post-stroke UL FES treatment from the previous studies. Specifically, the research questions were:

- What informs the prescription of treatment parameters in the use of functional electrical stimulation of the upper limb post-stroke?
- What is reported about the prescription of treatment parameters for upper limb functional electrical stimulation post-stroke?

A search of the National Institute for Health Research Centre for Reviews and Dissemination (NIHR CRD) database (Centre for Reviews and Dissemination. Systematic Reviews: Guidance for Undertaking Reviews in Healthcare. (Sept 2021)) was undertaken to examine whether there were existing or ongoing reviews, which addressed these questions.

4.2. Methods

The systematic review and narrative synthesis was prospectively registered on PROSPERO (CRD42018110286), designed and conducted in accordance with guidance from the Centre for Reviews and Dissemination, and reported with reference to the PRISMA 2020 reporting guidelines (Page et al., 2021).

4.2.1 Eligibility criteria

Full text articles in English language, identified via titles and abstracts, focusing on post-stroke UL deficits were considered for inclusion. A study had to focus on adults (≥18 years) who had sustained a first stroke; or with a history of previous strokes; presenting with post-stroke upper limb deficits. Populations that included those with comorbidities (non-neurological), whether physical or mental, were eligible for inclusion. Studies based on the prescription of UL FES were included. Prescription could be in terms of dose, intensity of functional electrical stimulation and/or any other recommendation in relation to treatment parameters associated with the application of UL FES. As descriptions of UL FES parameters could appear in a wide range of study designs, from single case studies to multicentre trials, the review, therefore, included all study types. (See **Table 4.1** for full eligibility criteria).

Table 4.1: Eligibility criteria

Inclusion Criteria	Exclusion Criteria
English Language	Non-English Language
Stroke, irrespective of cause, chronicity, first or recurrent, and severity	Non-stroke population and studies that included participants with a diagnosis of other neurological conditions
Studies based on the prescription of UL FES. (Upper limb including: arm, scapular, shoulder, forearm, wrist, fingers)	Studies based on the prescription of FES for the management of LL dysfunction and/or studies that do not clearly define the management of the upper limb post-stroke.
Varied study settings and/or location at which the management of the person with stroke occurred	
Adults (18 years+)	
All study types	

4.2.2 Search strategy

The search strategy was developed by the thesis author and reviewed by the PhD supervisory team in conjunction with an information scientist. The following search terms were used for: **Stroke**: stroke, cerebrovascular accident, CVA, hemiplegia, hemiparesis. **Upper Limb:** upper limb, upper extremity, arm, scapula, shoulder, forearm, hand, wrist, finger. **Functional**

Electrical Stimulation: functional electrical stimulation, electrical stimulation, e-stimulation, functional stimulation, microstimulation, muscle stimulation, nerve stimulation.

All search terms were used in the title and abstract fields. The Boolean operators AND OR were used, alongside truncation (*) and phrase searching (“”). When available as a search limiter, the results were filtered to only include English language publications due to lack of language translation services. No date limits were applied. Electronic databases of CINAHL (via EBSCOhost), Cochrane Central Register of Controlled Trials (via Wiley Online), MEDLINE (via EBSCOhost) and SPORTDiscus (via EBSCOhost) were selected as sources because they are the comprehensive databases for therapy and rehabilitation focused literature (see Appendix **10.1.2** for search strategy and study selection process).

4.2.3 Study selection

The study selection process was performed by two reviewers (the thesis author and the director of studies (DoS) from the PhD supervisory team). The two reviewers independently applied the inclusion/exclusion criteria (Table 4.1) to the titles and abstracts for eligibility. Where any disagreement about eligibility occurred, a third reviewer from the PhD supervisory team was consulted and acted as arbiter. Articles not excluded by both reviewers at this stage were recommended for full text reading and obtained for detailed review (Appendix **10.1.3**). Following this, the thesis author assessed the remaining articles, and the PhD supervisory team were contacted to resolve any eligibility issues.

4.2.4 Data extraction and synthesis

The thesis author designed a data extraction form; due to lack of access to Covidence Microsoft Excel was used to support the data extraction and synthesis processes (Appendix **10.1.4**). This was reviewed and approved by the PhD supervisory team prior to commencing data extraction. Data items that were extracted included: study design and baseline characteristics of the population as well as key prescriptive methods including duration of treatment (per session) in time, duration of treatment (total sessions) in weeks, device used and muscles stimulated, intensity of treatment (stimulation frequency), task/functional movement used, and outcome measure utilised.

4.2.5 Quality appraisal

The quality of the full text included studies was assessed using an integrated quality criterion for review of multiple study designs (ICROMS), which is a comprehensive quality assessment tool for the evaluation of a broad range of study designs (Zingg et al., 2016). The ICROMS quality appraisal tool was chosen, as the study design for the systematic review was inclusive in relation to type of data and methodology. On using the ICROMS, each study was awarded a number based on whether each specific criterion was met (Appendix **10.1.5**). Given that the aim of the systematic review was to capture all relevant literature, we did not exclude data based on the quality of evidence provided. Both the thesis author and the PhD DoS quality assessed all individual studies against the ICROMS quality criteria score. Concurrent with guidance provided by Page et al. (2021), where any disagreement about eligibility occurred, a third reviewer from the PhD supervisory team was consulted to arbitrate. On completion of selection, the third review author was informed about the choice of studies included in the final selection (Appendix **10.1.6**).

4.3. Results

4.3.1 Overview

A total of 1464 publications were identified and screened for eligibility by title and abstract (**Figure 4.1**). Twenty-eight studies met the inclusion criteria for this review (see **Table 4.1**) comprising 23 primary studies and 5 reviews. The included primary studies (n=23) reported on a total of 405 participants; and within the five systematic reviews there were a total of 3,737 participants over 115 studies. All the studies included participants who had a confirmed stroke. Seven were case studies (Bustamante et al., 2016; Hedman et al., 2007; Kawashima et al., 2013; Page et al., 2009; da Silva et al., 2018; Silveira et al., 2018; Sullivan & Hedman, 2004), two were pre-test post-test design (Alon et al., 2003; Sullivan & Hedman, 2007), five were randomised controlled trials (RCT's) (Bhalla & Shergill, 2020; Hayward et al., 2013; Mathieson et al., 2018; Obayashi et al., 2020; Park, 2020), five were feasibility studies (Cuesta-Gómez et al., 2017; Hughes et al., 2009; Meadmore et al., 2012, 2014; Smith et al., 2019), five were systematic reviews (de Kroon et al., 2005; Eraifej et al., 2017; Howlett et al., 2015; Vafadar et al., 2015; Yang et al., 2019), three were case series design (Mann et al., 2011; Page et al., 2016; Popovic et al., 2004), and one was a single case experiment (Franck et al., 2019).

Severity of stroke was cited as mild (n=1) (Hedman et al., 2007); moderate (n=2) (Cuesta-Gómez et al., 2017; Page et al., 2016); severe (n=5) (da Silva et al., 2018; Hayward et al., 2013; Kawashima et al., 2013; Obayashi et al., 2020; Smith et al., 2019). Two studies indicated they included moderate to severe strokes (Franck et al., 2019; Page et al., 2009) or a variety of stroke severity (n=6) (de Kroon et al., 2005; Eraifej et al., 2017; Howlett et al., 2015; Meadmore et al., 2012; Vafadar et al., 2015; Yang et al., 2019) without this being specifically broken down into individual categories. Severity of stroke, however, was not noted in 12 studies (Alon et al., 2003; Bhalla & Shergill, 2020; Bustamante et al., 2016; Hughes et al., 2009; Mann et al., 2011; Mathieson et al., 2018; Meadmore et al., 2014; Park, 2020; M. B. Popovic et al., 2004; Silveira et al., 2018; Sullivan & Hedman, 2004, 2007) (see **Table 4.2:**). It was cited in Yang et al. (2019) that regarding stroke severity the included studies did not utilise a direct comparison group for evaluating the effect of stroke severity on motor recovery.

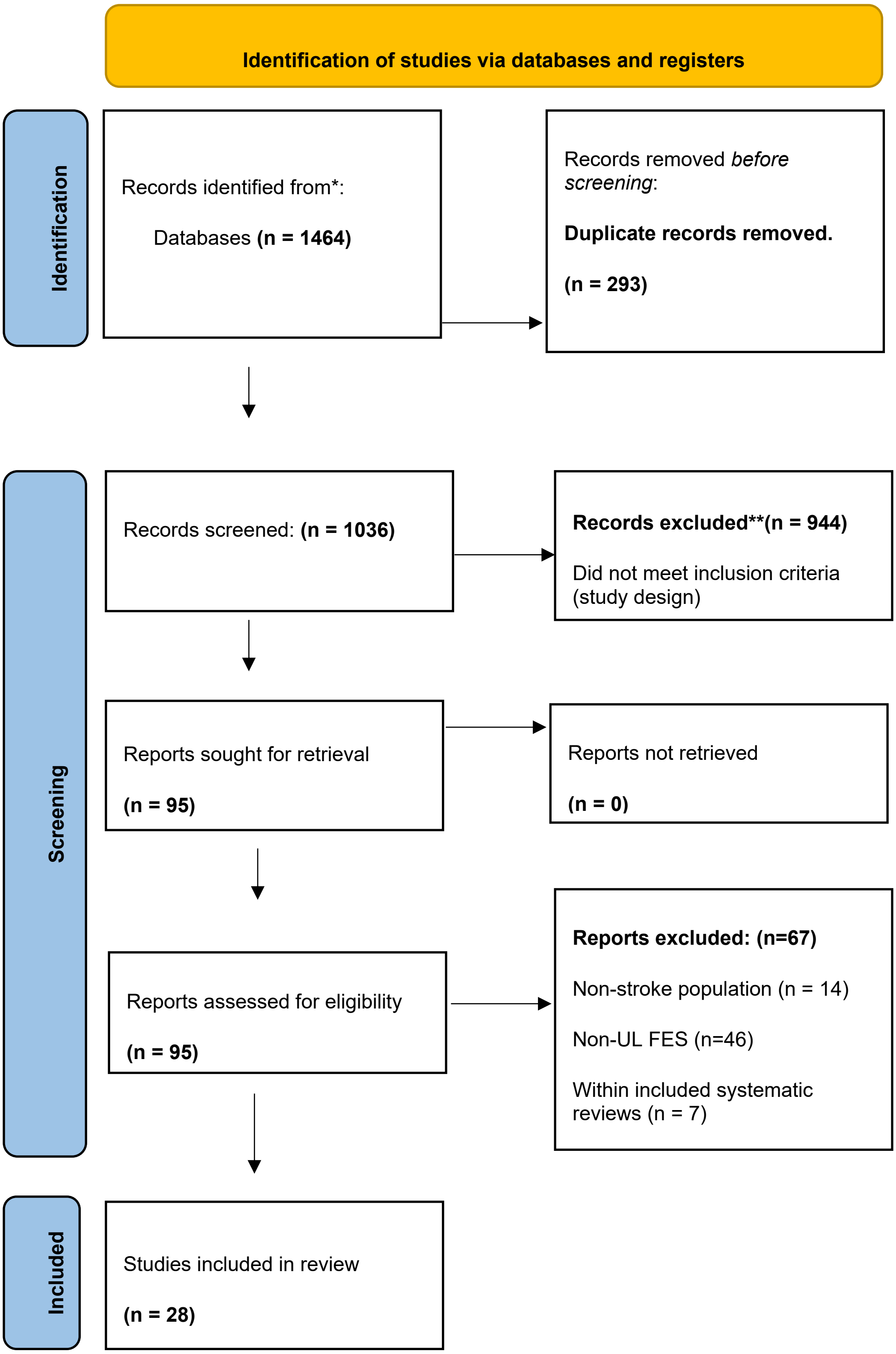

Figure 4.1: PRISMA chart of search methodology and outcome. (Page et al., 2021)

Table 4.2: Characteristics of studies (n=28), including patient characteristics and functional electrical stimulation treatment parameters.

Author, Year, Country.	**Study design**	**Participants (n)**	**Time** Acute (<6m), Chronic (>6m) and Mixed	**Severity of stroke** Mild, Moderate, Moderate-to-Severe, Severe or Mixed.	**Treatment regime** (total number of sessions)	**Treatment duration** (total duration time per session minutes (min))
Alon et al, 2003. **USA.**	Pre-Test Post-Test	77	Chronic	Not stated	99	55
Bhalla & Shergill, 2020. **India.**	RCT	30	Acute	Not stated	30	30
Bustamante et al, 2016. **Chile.**	Case Study	1	Chronic	Not stated	10	60
Cuesta-Gómez et al, 2017. **Spain.**	Feasibility Study	21	Chronic	Moderate	14	30

De Kroon et al, 2005. **Netherlands.**	Systematic review: (clinical trials: 12 RCTs, 2 non-randomised control trials, 2 multiple baseline design and 3 case series.)	578	Mixed	Mixed	Range	Range
Eraifej et al, 2017. **UK.**	Systematic review: (20 RCTs)	431	Mixed	Mixed	Range	Range
Franck et al, 2019. **Netherlands.**	Single case experiment	8	Acute	Moderate-to-Severe	18	90
Hayward et al, 2013. **Australia.**	RCT	28	Acute	Severe	20	60
Hedman et al, 2007. **USA.**	Case Study	1	Chronic	Mild	18	15
Howlett et al, 2015. **Australia.**	Systematic review (15 RCTs, 1 Controlled Clinical Trial, 2	485	Mixed	Mixed	Range	Range

	Crossover Trials)					
Hughes et al, 2009. **UK.**	Feasibility Study	5	Chronic	Not stated	18	60
Kawashima et al, 2013. Japan.	Case Study	1	Chronic	Severe	108	60
Mann et al, 2011. **UK.**	Case Series	15	Chronic	Not stated	168	30
Mathieson et al, 2018. **New Zealand.**	RCT	50	Acute	Not stated	15	60
Meadmore et al, 2014. **UK.**	Feasibility Study	5	Chronic	Not stated	18	60
Meadmore et al, 2012. **UK.**	Feasibility Study	5	Chronic	Mixed	18	60
Obayashi et al, 2020. **Japan.**	RCT	17	Acute	Severe	35	20

Page et al, 2009. USA	Case Study	1	Chronic	Moderate-to-severe	15	150
Page Et al, 2016. **USA.**	Case Series	9	Chronic	Moderate	16	60
Park, 2020. **Korea.**	RCT	68	Chronic	Not stated	30	30
Popovic et al, 2004. **Denmark.**	Case Series	16	Chronic	Not stated	21	30
Da Silva et al, 2018. **Brazil.**	Case Study	4	Chronic	Severe	20	60
Silveira et al, 2018. **Australia.**	Case Study	1	Acute	Not stated	21	60
Smith et al, 2019. **UK.**	Feasibility study	22	Mixed	Severe	8	60
Sullivan & Hedman, 2007.	Pre-Test Post-Test	10	Chronic	Not stated	168	15

USA.						
Sullivan & Hedman, 2004. **USA.**	Case Study	1	Chronic	Not stated	126	15
Vafadar et al, 2015. **Canada.**	Systematic review (9 RCTs and 1 quasi-RCT)	531	Mixed	Mixed	Range	Range
Yang et al, 2019. **Taiwan.**	Systematic review (48 RCTs)	1712	Mixed	Mixed	Range	Range

4.3.2 Timing of application post-stroke

Sixteen studies focused on participants more than six months post-stroke (Alon et al., 2003; Bustamante et al., 2016; Cuesta-Gómez et al., 2017; da Silva et al., 2018; Hedman et al., 2007; Hughes et al., 2009; Kawashima et al., 2013; Mann et al., 2011; Meadmore et al., 2012, 2014; Page et al., 2009, 2016; Park, 2020; Popovic et al., 2004; Sullivan & Hedman, 2004, 2007); seven studies targeted patients in the acute stage post-stroke (Bhalla & Shergill, 2020; Franck et al., 2019; Hayward et al., 2013; Mathieson et al., 2018; Obayashi et al., 2020; Silveira et al., 2018) and six studies included both (de Kroon et al., 2005; Eraifej et al., 2017; Howlett et al., 2015; Smith et al., 2019; Vafadar et al., 2015; Yang et al., 2019). Participants mean time post-stroke was 12.65 months (St Dev, 17.65 months; range, 2 weeks to 5.5 years).

Vafadar et al. (2015) suggest that commencing UL FES in the acute phase post-stroke can significantly reduce the level of shoulder subluxation, whereas Eraifej et al. (2017) identified that early application is more likely to impact improvement in ADLs.

4.3.3 Duration and location of treatment sessions

Interventions varied with a median of 20 treatment sessions (range, from 8 to 168 sessions) and a median of 60 minutes per session (range 10 to 150 minutes). The location of intervention was reported in 19 studies; community-based rehabilitation (n=6) (Alon et al., 2003; Cuesta-Gómez et al., 2017; Hedman et al., 2007; Mann et al., 2011; Sullivan & Hedman, 2004, 2007), in-patient rehabilitation; (n=6) (Franck et al., 2019; Hayward et al., 2013; Kawashima et al., 2013; Mathieson et al., 2018; Obayashi et al., 2020; Silveira et al., 2018), outpatient clinic (n=6) (Bhalla & Shergill, 2020; Bustamante et al., 2016; Meadmore et al., 2012, 2014; Page et al., 2012, 2016) and in one study (Smith et al., 2019) it was documented that the settings were varied as it was a three-centre clinical investigation (in-patient, early supported discharge and community).

4.3.4 Method of stimulation

A variety of FES systems were utilised, and, in some studies, this was also supported by the use of supplementary equipment (e.g. a prosthesis (splint) or an upper limb de-weighting system) and alongside conventional rehabilitation.

4.3.5 Open-loop/closed-loop functional electrical stimulation systems

Open-loop FES systems (manually controlled FES) were used in the majority of studies with (n=9) studies indicating they were clinician triggered (Bhalla & Shergill, 2020; Bustamante et al., 2016; Cuesta-Gómez et al., 2017; Franck et al., 2019; Hayward et al., 2013; Kawashima et al., 2013; Mathieson et al., 2018; Silveira et al., 2018; Smith et al., 2019); and (n=5) user triggered (Hedman et al., 2007; Mann et al., 2011; Popovic et al., 2004; Sullivan & Hedman, 2004, 2007). Positive results were identified to be more common when stimulation was triggered by voluntary movements, rather than non-triggered stimulation (de Kroon et al., 2002). However, in one of the systematic reviews with meta-analysis it was highlighted that, whilst FES effectively improved arm function in people with stroke, when comparing different forms of stimulation no one type was determined to be superior (Yang et al., 2019).

Two studies used a closed-loop electromyography (EMG) triggered neuromuscular electrical stimulation system (Obayashi et al., 2020; Park, 2020), whilst three studies used a robotic workstation and iterative learning control (ILC) mediated by FES (Hughes et al., 2009; Meadmore et al., 2012, 2014).

4.3.6 Prosthesis embedded functional electrical stimulation systems

Six studies utilised a prosthesis as a means of supplementing the effects of FES (Alon et al., 2003; Franck et al., 2019; Hayward et al., 2013; Page et al., 2009, 2012, 2016). Four of the six studies used a neuroprosthesis with the FES electrodes embedded within the splint stimulating wrist extension and flexion (Alon et al., 2003; Page et al., 2009, 2012, 2016). Franck et al. (2019) applied a SaeboGlove hand splint alongside FES application, where Hayward et al. (2013) used a non-robotic sensorimotor active rehabilitation training device (SMART arm) to support reaching with FES application. Both types of application serve to maintain the wrist/hand position to maximise the FES application.

All studies highlighted an improvement in upper limb impairment with Kawashima et al. (2013) and Alon et al. (2003) citing improvement in spasticity as measured by the modified Ashworth scale (MAS). A further four studies (Meadmore et al., 2012, 2014; Page et al., 2009, 2016) noted an improvement in impairment as measured by the Fugl-Meyer Upper Extremity (FM UE) component.

4.3.7 Functional electrical stimulation with a de-weighting system

Four studies utilised an upper limb de-weighting system (Hughes et al., 2009; Meadmore et al., 2012, 2014; Smith et al., 2019); two of which were conducted by the same researcher and followed the same protocol (Meadmore et al., 2012, 2014). Although other studies highlighted that the upper limb was 'de-weighted' or 'guided' by the therapist (Kawashima et al., 2013), with trunk restraint (Hughes et al., 2009) or addition of a harness (Hayward et al., 2013) also being cited.

4.3.8 Functional electrical stimulation and conventional therapy

'Conventional therapy' was poorly defined with no specific definition or justification given as to what constituted 'conventional therapy'. Only two studies (Hughes et al., 2009; Page et al., 2009) highlighted that stretches were conducted on the hemiplegic upper limb prior to application of UL FES. Page et al. (2009) documented that pre-functional electrical stimulation stretches and upper limb weight bearing was carried out pre application of FES; whereas Hughes et al. (2009) indicated three minutes of both pre- and post-functional electrical stimulation active assisted stretches were conducted. Vafadar et al. (2015) found that UL FES intervention does not have a significant effect on upper arm motor function compared to conventional therapy alone. However, Howlett et al. (2015) reported that FES appears to moderately improve activity compared with both no intervention and training alone.

Other modes of therapeutic intervention were also used alongside FES including mirror therapy (Mathieson et al., 2018); modified constraint induced movement therapy (CIMT) and task orientated therapy (Bhalla & Shergill, 2020); mental imagery (Park, 2020) and iPad-based music therapy (Silveira et al., 2018).

4.3.9 Electrode placement and muscles stimulated

Electrode placement and muscles stimulated varied with two studies highlighting that placement was driven depending on patient presentation (Sullivan & Hedman, 2007) or varied based on the task being carried out (Smith et al., 2019). Seven (n=7) studies focused on proximal upper limb muscles (Bustamante et al., 2016; da Silva et al., 2018; Hayward et al., 2013; Hedman et al., 2007; Hughes et al., 2009; Meadmore et al., 2012; Obayashi et al., 2020), twelve (n=12) focused on distal upper limb muscles (Alon et al., 2003; Bhalla & Shergill, 2020;

Franck et al., 2019; Mann et al., 2011; Mathieson et al., 2018; Page et al., 2009, 2012, 2016; Park, 2020; Popovic et al., 2004; Silveira et al., 2018; Sullivan & Hedman, 2004) and five (n=5) focussed on both proximal and distal upper limb muscles (Cuesta-Gómez et al., 2017; Kawashima et al., 2013; Meadmore et al., 2014; Smith et al., 2019; Sullivan & Hedman, 2007). Only one (n=1) study stimulated muscles around the scapula (Cuesta-Gómez et al., 2017).

4.3.10 Intensity of treatment

All of the studies reported on FES parameters with stimulation frequency ranging between 25-50Hz. Justification for FES intensity varied, with three (n=3) citing it was regulated until optimal contraction of muscle activity was observed (Alon et al., 2003; Bustamante et al., 2016; Page et al., 2009); two (n=2) noted comfortable maximum stimulation individually identified (Cuesta-Gómez et al., 2017; Hughes et al., 2009); seven (n=7) stated that intensity was adjusted to achieve the most effective completion of the task (Hayward et al., 2013; Hedman et al., 2007; Mann et al., 2011; Meadmore et al., 2012, 2014; Popovic et al., 2004; Sullivan & Hedman, 2007).

4.3.11 Upper limb tasks and functional movements

All studies highlighted the task that was practised, which predominantly incorporated grasping an object. A variety of functional objects were used such as picking up a bottle (Alon et al., 2003), wooden blocks (Bustamante et al., 2016), or handling a glass or cup (Cuesta-Gómez et al., 2017; Page et al., 2009, 2016). In some cases the objects were not specifically mentioned but grouped together in terms of what movement necessitated different hand grips such as the use of a pen, holding a paper plate (Hedman et al., 2007; Meadmore et al., 2014; Sullivan & Hedman, 2007) using a comb or toothbrush (Popovic et al., 2004) with others less specifically noting the participant was reaching (Hayward et al., 2013) or touching their own nose (Kawashima et al., 2013). One study highlighted that, whilst the task was mainly carried out in sitting, they also encouraged the participant to attempt the task in standing where appropriate (Mann et al., 2011). In three studies a robotic workstation tracked a bespoke participant trajectory using iterative learning control (ILC) mediated by FES (Hughes et al., 2009; Meadmore et al., 2012, 2014). In two of the studies the tracking was pre-set and not functionally goal orientated (Hughes et al., 2009; Meadmore et al., 2012), whilst in the third study (Meadmore et al., 2014) the robotic arm was still used, and the participant was encouraged to reach and grasp for objects maximising voluntary effort. The level of arm support was reduced following successful performance of the task.

4.3.12 Outcome measures used as part of the UL assessment

A variety of outcome measures were used to measure upper limb activity. The most common were the action research arm test (ARAT) (n=13) (Bhalla & Shergill, 2020; Bustamante et al., 2016; Franck et al., 2019; Hedman et al., 2007; Hughes et al., 2009; Mann et al., 2011; Mathieson et al., 2018; Meadmore et al., 2012, 2014; Page et al., 2009; Park, 2020; Sullivan & Hedman, 2004, 2007), Fugl-Meyer (FM) assessment scale (n=11) (da Silva et al., 2018; Hedman et al., 2007; Hughes et al., 2009; Mathieson et al., 2018; Meadmore et al., 2012, 2014; Obayashi et al., 2020; S. J. Page et al., 2009, 2012, 2016; Park, 2020) and the modified Ashworth scale (MAS) (n=7) (Alon et al., 2003; da Silva et al., 2018; Hayward et al., 2013; Kawashima et al., 2013; Mann et al., 2011; Popovic et al., 2004; Sullivan & Hedman, 2007). Others such as the nine-hole peg test (n=2)(Alon et al., 2003; Silveira et al., 2018), stroke impact scale (n=1) (Hayward et al., 2013) and upper extremity functioning test (n=1) (Popovic et al., 2004) were used less frequently. One study used a quality of life (QoL) measure (Bustamante et al., 2016) and one a pain questionnaire (da Silva et al., 2018). One study used kinematic analysis to measure trunk, shoulder, and elbow joint angles; the results of this study identified that patients receiving FES carried out the upper limb activity with less trunk flexion as a compensatory strategy (Cuesta-Gómez et al., 2017). All measures showed improvements in either function or a reduction in upper limb spasticity; however, only two of the studies achieved statistical significance (Hughes et al., 2009; Sullivan & Hedman, 2007).

4.3.13 Justification for choice of treatment parameters

In terms of justification for choice of treatment parameters, very few studies provided any clear rationale for the parameters used. Alon et al. (2003) justified alteration in stimulation parameters based on the ability of the paretic upper limb to grasp, hold and release objects. Both Hayward et al. (2013) and Smith et al. (2019) stated parameters were set to support or achieve the functional task. In the study completed by Hughes et al. (2009), it was stated that the FES level applied was adjusted and decreased over the course of the intervention and that the number of times a task was practised was based on fatigue. Whilst limited in depth of justification, it was apparent from these studies that parameters were individualised based on people with stroke presentation. De Kroon et al. (2002) concluded that muscle response and patient comfort were the only justifications for FES setting applied; fundamentally there were no specific arguments presented for specific setting of upper limb FES parameters.

4.4. Discussion

The aim of this systematic review was to identify, describe, and critically evaluate the range of post-stroke UL FES treatment parameters reported in published studies. It also aimed to understand from the literature what informs the prescription of treatment parameters in the use of UL FES. A range of treatment parameters was identified in the selected literature, however, there was no clear justification for the choice of parameters documented by the authors.

There are a number of rehabilitation interventions that have been developed to support the restoration of upper limb function post-stroke. FES is a controlled electrical stimulation aimed at producing muscle contraction, and the main finding of this review is that, whilst evidence supporting the use of FES in helping restore motor function in people with stroke is well established (Marquez-Chin & Popovic, 2020; Sousa et al., 2022), there is still a lack of clarity about how specifically FES is used as a treatment intervention in the management of upper limb impairments post-stroke. This includes a lack of clarity and clinical guidelines on optimal timing of use post-stroke and the impact it has on ADLs (Eraifej et al., 2017). UL FES treatment parameters to inform FES treatment prescriptions for adults who have upper limb difficulties, post-stroke are needed to support clinical reasoning and influence implementation in clinical practice.

Whilst severity of stroke is thought to influence level of recovery (Howlett et al., 2015), none of the reviewed studies used a recognised tool to categorise severity, limiting the ability to draw conclusions about severity. Severity of stroke impairment is also not often defined in the literature and instead duration post-stroke, i.e. chronicity, is more commonly used.

Despite the fact that there is evidence that UL FES interventions in the early phase post-stroke can have positive long-term outcomes (Farmer et al., 2014; Kutlu et al., 2016; Lawrence et al., 2001) many of the studies (n=16) focused on participants that were >6 months post-stroke (defined in the literature as 'chronic') (Alon et al., 2003; Bustamante et al., 2016; Cuesta-Gómez et al., 2017; da Silva et al., 2018; Hedman et al., 2007; Hughes et al., 2009; Kawashima et al., 2013; Mann et al., 2011; Meadmore et al., 2012, 2014; Page et al., 2009, 2016; Park, 2020; Popovic et al., 2004; Sullivan & Hedman, 2004, 2007). Only six (n=6) studies targeted patients in the acute stage post-stroke (Bhalla & Shergill, 2020; Franck et al., 2019; Hayward et al., 2013; Mathieson et al., 2018; Obayashi et al., 2020; Silveira et al., 2018); with six (n=6) studies including both (de Kroon et al., 2005; Eraifej et al., 2017; Howlett et al., 2015; Smith et al., 2019; Vafadar et al., 2015; Yang et al., 2019). A systematic review identified that the earlier the use of FES post-stroke, the more significant the improvement in ADLs compared to conventional therapy alone, and when FES was initiated over one year post-stroke the benefits were negligible (Eraifej et al., 2017). However, the finding of this current systematic review identified positive results relating to application of UL FES in studies that evaluated acute, subacute and chronic subjects.

Despite the evidence supporting early application (Eraifej et al., 2017) only six (n=6) studies in this systematic review focused on this population; however, there may be a variety of reasons why patients in the acute stage post-stroke were not targeted for UL FES compared to more chronic subjects; this could include barriers such as medical suitability and limited time for UL FES treatment intervention. Furthermore, the question of severity of upper limb impairment post-stroke regardless of chronicity needs to be addressed to be able to potentially identify an optimal therapeutic window for UL FES application (Eraifej et al., 2017).

The findings from this review highlight that a correlation between stroke severity and outcome could not be detected (de Kroon et al., 2005; Eraifej et al., 2017; Howlett et al., 2015; Smith et al., 2019; Vafadar et al., 2015; Yang et al., 2019) primarily in the case of this review due to the lack of severity reporting. It does indicate the need for further representation across stroke presentations and data collection at different times post-stroke in future research.

4.4.1 Method of stimulation: Open-loop/closed-loop functional electrical stimulation systems

The method of stimulation varied between the studies and included both open-loop and closed-loop FES control systems. Within this review, most FES systems were based on an open-loop control in which the stimulation parameters are adjusted during the task by an external 'trigger' from the control system, which could be initiated by the FES user or the clinician applying the FES. An open-loop system does not, therefore, use precise feedback to adapt the FES input, as opposed to closed-loop FES system which can provide precise adaptation to the input in response to the users' actual performance (often based on joint position) (Chadwick et al., 2011) or force generated (Lawrence et al., 2008) and generate minimum levels of stimulation to continually challenge the user. Precise input and minimum levels of stimulation are seen as valuable functions in promotion of motor learning (Hughes et al., 2010). Only two (n=2) studies used a closed-loop EMG-triggered neuromuscular electrical stimulation device (Obayashi et al., 2020; Park, 2020). Obayashi et al. (2020) coupled EMG-triggered and cyclic neuromuscular electrical stimulation (NMES) and identified clinically significant changes in the FM UE measure and the box and blocks test (BBT) indicating a beneficial effect of coupled EMG-triggered and cyclic NMES in both an acute and chronic stroke presentation. Whilst Park (2020) combined EMG-triggered NMES with mental imagery and, again, the results showed significant improvements in outcome measures used in a chronic stroke population. Unfortunately, due to a number of differences in method of application these results cannot be compared but further comparison of EMG-triggered stimulation would be useful as clearly these results indicate a positive impact on independence in ADLs of patients with both acute and chronic stroke presentations. Despite the potential advantages of closed-loop FES systems, most FES applications within this review still used open-loop systems (Bhalla & Shergill, 2020; Bustamante et al., 2016; Cuesta-Gómez et al., 2017; Franck et al., 2019; Hayward et al., 2013; Hedman et al., 2007; Kawashima et al., 2013; Mann et al., 2011; Mathieson et al., 2018; Popovic et al., 2004; Silveira et al., 2018; Smith et al., 2019; Sullivan & Hedman, 2004, 2007). Whilst open-loop systems are frequently used in clinical practice by relying solely on observing the upper limb's response to the FES, they are less likely to provide accurate feedback and generate more muscle fatigue (Haugland et al., 1999; Hoffer et al., 1996; Marquez-Chin & Popovic, 2020).

4.4.2 Prosthesis embedded functional electrical stimulation systems

The use of a neuroprosthesis with FES embedded (Alon et al., 2003; Page et al., 2009, 2016) or supplementary splinting used alongside FES application (Franck et al., 2019; Hayward et al., 2013) in this review has shown a positive impact on upper limb functional recovery. However, whilst the use of a neuroprosthesis or splint will have provided stability at the wrist/hand resulting in the desired muscle contraction, an inability to adjust the electrode placement to meet the specific needs of the FES user means the device would be limited to the restoration of grasp/release (Alon et al., 2003; Page et al., 2009, 2016). Current FES systems for UL rehabilitation using the principle of splinting are inflexible in terms of number and location of muscles to be stimulated. This lack of flexibility in neuroprosthesis-based FES systems complicates comparisons between studies using rigid designs and those with flexible, therapist-determined stimulation sites. It is also difficult to quantify how much support the splint itself gave the user, making the movement possibly easier to execute with FES when compared to application without this external support. Ideally, an FES system should be able to provide sufficient stimulation channels and flexibility over the set of muscles to be stimulated to cover the range of upper limb impairments commonly seen after stroke and a range of functional ADLs.

4.4.3 Functional electrical stimulation with a de-weighting system

There is a diverse range of therapeutic interventions aimed at improving upper limb function after stroke; the use of which is normally dependant on the clinical presentation of the people with stroke, the evidence base relating to the intervention and the clinical reasoning or clinical skill of the therapist treating them (McGlinchey et al., 2024; Pollock et al., 2014). Reduced stability of the scapulothoracic and glenohumeral joint often impacts the functional ability of the upper limb post-stroke and a de-weighting system, such as SaeboMAS, can improve upper limb control by supporting the arm against gravity (Brewer et al., 2007; Mehrholz et al., 2012; Runnalls et al., 2015). Weight support of the upper limb can improve execution of individual movements and facilitate movement repetition, either independently or in conjunction with FES (Brewer et al., 2007; Mehrholz et al., 2012), and it has been hypothesised following studies of healthy adults that weight support may be a valuable tool for driving neuroplasticity in people with stroke (Runnalls et al., 2015).

Out of the 28 (n=28) studies reviewed, only four (n=4) utilised an upper limb de-weighting system (Hughes et al., 2009; Meadmore et al., 2012, 2014; Smith et al., 2019). Two of those studies were conducted by the same researcher and followed the same protocol (Meadmore et al., 2012, 2014), and whilst they both highlighted that with increased practice the amount of electrical stimulation reduced and both FM and ARAT outcome measure scores significantly improved, the sample size was small and, therefore, this impacts the value of the findings. In-depth justification for the use of a de-weighting system was absent from the literature and the amount of weight support offered by the equipment was not documented, making it difficult to replicate.

Whilst similar in principle to using weight support equipment, robotic assisted therapy is the use of a mechanical device to provide support allowing for more control over the impaired arm during upper limb treatment (Kwakkel et al., 2008; Prange et al., 2006). Three studies used a robotic workstation and iterative learning control (ILC) mediated by FES (Hughes et al., 2009; Meadmore et al., 2012, 2014). Interestingly, the recent stroke guidelines have recommended that upper limb robotics could be considered for use post-stroke as an adjunct to usual therapy but preferably in the context of a clinical trial (NICE, 2023). The evidence suggests that, whilst robotics has a place in UL rehabilitation, the improvements on ADLs when used in isolation are minimal (Mehrholz et al., 2012) and, due to the variety of robotics available, this makes it difficult to translate this into practice and justify the cost-effectiveness and use of robotics in a clinical setting (Fernandez-Garcia et al., 2021). It has been identified that upper limb robotics coupled with FES (Straudi et al., 2020) and/or combined with conventional therapy (Takebayashi et al., 2022) has greater impact, and, for this reason, robotics has been signposted in the recent clinical guidelines. This aligns with the findings from Hughes et al. (2009) and Meadmore et al. (2012, 2014) where, on application of robotics and FES in a chronic stroke population, clinically and statistically significant improvements in upper limb impairment were identified. Hughes et al. (2009) cited the greatest improvements were seen in those with the highest level of initial impairment which is supported by a recent systematic review (Wu et al., 2021), which concluded that the target stroke population that might benefit more from robotic therapy is those with severe upper limb impairment and limited potential for spontaneous recovery.

4.4.4 Functional electrical stimulation and conventional therapy

Optimising function whilst reducing the impact of any post-stroke impairments (Teasell et al., 2020) is often the key focus of upper limb rehabilitation and the selection of rehabilitation interventions may have a direct impact on outcomes for the people with stroke (McGlinchey et al., 2024). However, there are many factors that influence clinical decision making; a recent ethnographic study identified that interventions are often used that do not always fully address the physical needs of the people with stroke (McGlinchey et al., 2024) and that whilst the importance of evidence-based practice is recognised it is not always translated into practice (Scurlock-Evans et al., 2014; Upton et al., 2014). There are a number of known barriers that impact translation of research knowledge into clinical practice and it has been identified that a focus on transparency within the literature is important (Abu-Odah et al., 2022). Conventional therapy, whilst mentioned within the included studies, was poorly defined, with only one (n=1) study (Hughes et al., 2009) specifically highlighting that pre-functional electrical stimulation stretches were conducted on the hemiplegic upper limb. None of the remaining studies provided any detail for the composition of conventional therapy.

Other modes of therapeutic intervention were also used alongside FES, including mirror therapy (Mathieson et al., 2018); modified constraint induced movement therapy (CIMT) and task orientated therapy (Bhalla & Shergill, 2020); mental imagery (Park, 2020) and iPad-based music therapy (Silveira et al., 2018). A number of these interventions have a robust evidence base, including CIMT (Kwakkel et al., 2015; Pollock et al., 2014; Yang et al., 2023), mental imagery (Barclay et al., 2020; Stockley et al., 2021) and mirror therapy (Thieme et al., 2018); all three of these therapeutic interventions have been cited in recent stroke guidelines and recommended for people with stroke (NICE, 2023). However, being that FES was coupled with these interventions it is difficult to isolate what was causative of any improvements, and, due to the lack of justification for use of any additional equipment or intervention strategy, this impacts the transferability and reproducibility for clinicians attempting to embed evidence-based practice clinically. Repetitive task practice was also used across all the studies and whilst the evidence base is clear that repetitive task practice is beneficial and is recommended in the recent stroke guidelines (NICE, 2023) what is not clear is the ideal 'dose' (Hayward et al., 2021; Lang et al., 2009). There was a significant variance between the interventions provided to the hemiplegic upper limb in terms of duration (in weeks) number and time length of sessions; the results from this review align with the findings from Hayward et al. (2021) and an optimal time to commence upper limb intervention post-stroke or the dose of any intervention cannot be concluded.

4.4.5 Intensity of treatment

In terms of FES frequency there were similarities across the studies in this review with the majority using between 35-50Hz (Bustamante et al., 2016; Franck et al., 2019; Hayward et al., 2013; Hedman et al., 2007; Hughes et al., 2009; Kawashima et al., 2013; Mann et al., 2011;

Mathieson et al., 2018; Meadmore et al., 2012, 2014; Park, 2020; Silveira et al., 2018; Smith et al., 2019; Sullivan & Hedman, 2004, 2007). It was, however, suggested by de Kroon et al. (2005) that stimulation parameters may not be crucial in determining motor outcomes; despite this future research needs to address the question of treatment parameters in order to allow effective prescription of UL FES.

4.4.6 Outcome measures used in the assessment of the upper limb

A variety of outcome measures were used to measure upper limb activity with the most common ones being the ARAT (n=13) (Bhalla & Shergill, 2020; Bustamante et al., 2016; Franck et al., 2019; Hedman et al., 2007; Hughes et al., 2009; Mann et al., 2011; Mathieson et al., 2018; Meadmore et al., 2012, 2014; Page et al., 2009; Park, 2020; Sullivan & Hedman, 2004, 2007); the FM assessment scale (n=10) (da Silva et al., 2018; Hedman et al., 2007; Hughes et al., 2009; Mathieson et al., 2018; Meadmore et al., 2012, 2014; Obayashi et al., 2020; Page et al., 2009, 2016; Park, 2020) and the MAS (n=7) (Alon et al., 2003; da Silva et al., 2018; Hayward et al., 2013; Kawashima et al., 2013; Mann et al., 2011; Popovic et al., 2004; Sullivan & Hedman, 2007). Significant changes in these measures were identified across several studies with improvement in function and reduction in upper limb spasticity. One study used kinematic analysis to measure trunk, shoulder, and elbow joint angles. It was identified that patients receiving FES carried out the upper limb activity with less trunk flexion as a compensatory strategy (Cuesta-Gómez et al., 2017). There is a growing consensus that objective measurements, such as kinematic analysis, are required to accurately monitor 'true' rather than compensatory recovery. This highlights the limitations in some of the more clinical measures. A further study (Page et al., 2016) attempted to measure compliance with the FES intervention and utilised a home diary and behaviour contract. Compliance is important to ascertain; however, patient-based diaries are notoriously subjective and have been superseded by the use of activity monitoring.

4.4.7 Justification for choice of treatment parameters

There was a clear lack of detail in the justification for chosen treatment parameters within the included studies. Only a few studies cited any detail about alteration in treatment parameters (Alon et al., 2003; Hayward et al., 2013; Hughes et al., 2009; Smith et al., 2019). Whilst numerous studies have investigated the use of FES in the post-stroke population, there are a variety of stimulation parameters reported including duration of stimulation, intensity of stimulation, method of stimulation and subject presentation/characteristics (de Kroon et al., 2005; Eraifej et al., 2017; O. A. Howlett et al., 2015). One systematic review concluded that, due to lack of justification, a relationship between specific FES parameters and clinical outcomes could not be identified, but importantly stated an inability to detect a relationship does not mean that a clinically relevant relationship does not exist, and that further research is indicated to determine optimal prescriptive parameters (de Kroon et al., 2005). In agreement with previous systematic reviews (de Kroon et al., 2002; Eraifej et al., 2017), recommendations for stimulation parameters from this literature review cannot be accurately identified due to lack of reporting and the variability in methodology and design of the included studies.

Despite a relatively large number of trials, there were too many variations between the FES application used in these studies to allow identification of potential prescriptions for UL FES parameters, whilst there are significant gaps in the justification for use of any additional equipment, dose of FES and specific detail about the patient presentation. A recent review on the usability of UL FES post-stroke for the improvement of ADLs similarly highlighted that, due to methodological variability any analysis on both severity of stroke and specific treatment, detail for use of FES was not possible and that, whilst FES could play a part in the future of stroke rehabilitation, there needs to be further high-quality research (Sousa et al., 2022).

4.4.8 Limitations of the review

There were a number of studies in this review that were not RCTs and instead were feasibility studies or case reports. The nature of these studies means they had no control group and only performed the planned rehabilitation protocol on the experimental group; it is, therefore, difficult to know if changes might have happened without the intervention. This makes it challenging to generalise the study findings to a larger population or other settings.

Furthermore, there was a lack of follow up data across all studies. This would have helped determine whether the improvements gained from UL FES were retained over time. It is crucial for research and clinical practice that follow up assessments are carried out to ensure that the benefits of any rehabilitation are sustained or optimised over time and future longitudinal studies would enable more insight into the lasting impact of UL FES in people with stroke.

Using the ICROMS quality criteria (Zingg et al., 2016), the majority of studies achieved a global quality score of between 60–70%, which carry a medium risk of bias and six (n=6) were high risk. The main reasons for these scores were a lack of blinding of patients or therapists to the intervention, lack of justification for the sample choice and lack of robust outcome measures. The nature of FES as an intervention makes it difficult to blind patients or therapists to the intervention and, therefore, one must interpret these findings in light of the risk of bias of included studies. Further to this, the heterogeneity of study design and population size precluded meta-analysis. The study inclusion criteria were not limited to just RCTs because it was considered possible that, despite the quality of smaller case reports or feasibility studies, they might provide more detailed description of UL FES prescription. On consultation with the PhD supervisory team, the thesis author decided to include all studies that were eligible despite the ICROMS quality score.

Finally, it is possible that there was incomplete retrieval of studies—especially non-English language studies that were excluded due to lack of translation facilities. Also, there is the possibility that reporting bias occurred during this review process. In some cases, relevant data is incomplete or unavailable; for example, some studies have not reported on muscles stimulated or specifics relating to duration of intervention delivered. Incomplete reporting of outcomes can lead to reporting bias, affecting the completeness and accuracy of the data available for analysis.

4.5. Conclusion

The results of this systematic review clearly identify a lack of detail within the literature in terms of justification for parameters used in the application of UL FES in people with stroke, despite all of the studies highlighting specific FES parameters.

It was identified that stimulation frequency ranged between 25–50Hz, which aligns with the findings in a systematic review by Howlett et al. (2015); however, justification varied and (de Kroon et al., 2002) reviewing the literature in relation to stimulation characteristics identified that there was no relationship between FES frequency or even duration of stimulation on clinical outcome.

In two (n=2) of the reviewed studies, the amount of electrical stimulation reduced with increased practice and both FM and ARAT outcome measure scores improved (Meadmore et al., 2012, 2014). However, an in-depth justification for the use of a de-weighting system and the rationale for which parameters were changed was absent, making it difficult to draw conclusions from this.

As identified through the review, most studies fail to sufficiently characterise patient severity, and, even where they do, they appear not to adjust treatment parameters accordingly. Treatment prescription for more severe patients could highlight the justification of a de-weighting system and/or orthosis. It would be helpful if this level of detail were more accurately captured in the literature to support clinical application. Similarly, the number of muscles stimulated (this corresponds to number of channels and electrodes used), should be rationalised in accordance with severity of upper limb impairment. Patients with no upper limb movement are likely to require multiple channels with some form of de-weighting system. An alternative would be to target either proximal or distal muscle activity in alternate sessions, although, this level of detail is not documented in the studies reviewed. It is widely accepted that FES could have a significant role in the management of the upper limb post-stroke; however, this systematic review has identified that there is currently still a wide variation in FES treatment parameters utilised in clinical practice. More robust information on FES treatment parameters would not only assist the treating therapists but would have the added benefit of ensuring future clinical trials offer the optimum conditions to drive upper limb recovery.

As identified in a previous systematic review, the evidence is of low quality and does not support clear clinical decisions for application of FES in an adult population post-stroke (Eraifej et al., 2017). The focus of this systematic review was to identify if there was any evidence of prescription of post-stroke UL FES treatment parameters, however, despite a relatively large number of trials, there are too many differences between the FES application used. Further to this, both the small sample size and choice of methodology impact on the overall quality. There are still significant gaps in the research for the justification for treatment parameters and therapy adjuncts likely to complement FES. It would be helpful if there was more robust justification, and a greater level of detail more accurately captured in the literature to support the development of treatment prescription for UL FES post-stroke.

Whilst the findings of this systematic review are limited, potential benefits could be hidden among interstudy variability and lack of documented guidance on FES parameters. It highlights that a need for a better understanding of treatment parameters to optimise the application of UL FES for a broad range of post-stroke impairments. In summary, there is limited justification in the current evidence base to support clinicians when developing treatment prescription for UL FES post-stroke. A clear understanding about what is documented about the management of the UL post-stroke and if UL FES is utilised within this management across a large stroke pathway would enable a greater understanding of what occurs in routine practice and have the potential to help identify what needs to be considered when developing clinical practice guidelines for the use of UL FES in people with stroke. It is for this reason that on the basis of knowledge developed from the systematic review a large-scale medical record-based service evaluation was planned for the next study within this body of research.

Chapter 5 Clinical management of post-stroke upper limb: a medical record-based service evaluation of an NHS Foundation Trust stroke pathway

This chapter is the second study in the thesis and explores the medical records across an NHS Foundation stroke pathway to explore current practice in relation to rehabilitation of the hemiplegic upper limb across an NHS Foundation Trust stroke pathway. While previous studies have highlighted the impact that upper limb functional recovery has on people with stroke it is still unclear how, in routine practice, upper limb problems are managed across stroke pathways in the NHS. Understanding the clinical environment will help identify what needs to be considered when developing clinical practice guidelines for the use of functional electrical stimulation (FES) in upper limb (UL) post-stroke rehabilitation.

Abstract

Background: While previous studies have highlighted the impact that upper limb functional recovery has on people with stroke it is still unclear how, in routine practice, upper limb problems are managed across stroke pathways in the NHS.

Aim: To examine clinical practice via patient medical records and provide a detailed description of how upper limb rehabilitation is documented, and the timing, setting, nature, frequency, and dose of clinical interventions (including FES) delivered.

Design: A record-based service evaluation tracking a cohort of people with stroke across an NHS Foundation Trust stroke pathway from admission to discharge.

Setting: A stroke pathway spanning acute inpatient, inpatient rehabilitation and community services within a single NHS Foundation Trust.

Participants: All people with stroke admitted between 1 January and 30 June 2019 for whom there were medical records available.

Data sources, extraction, and analysis: Medical records, including paper-based records, SystmOne and Lorenzo. A data extraction form was designed using Microsoft Excel. For the purpose of the pilot only, reliability was checked across two data extractors (the thesis author and a clinical member of the stroke pathway approved to data collect by the Service Evaluation Unit); the remainder of the data was extracted by the thesis author.

Findings: The service evaluation clearly identified how the upper limb has previously been managed within the NHS Foundation Trust stroke pathway during the data collection

timeframe and also highlighted that UL FES as a treatment modality is utilised infrequently and with limited evidence of justification in the clinical notes.

Conclusions: Key recommendations from this service evaluation included developing a community of clinical practice for the management of the post-stroke upper limb, including knowledge and use of UL FES; implementing the use of the Fugl-Meyer Assessment for upper extremity (FMA-UE) as a way of measuring upper limb impairment; and to encourage reflective practice among clinicians to further develop knowledge and skills relating to the management of the upper limb post-stroke.

5.1. Background

It is estimated that, in the UK, there are approximately 1.3 million people living with stroke (SSNAP, 2023). It has been well documented that current delivery of rehabilitation post-stroke is inconsistent and that people with stroke often receive below the recommended amount of therapeutic input (SSNAP, 2022) with frequency and duration of physiotherapy being especially low (Gittins et al., 2020). The drive to deliver more patient-centred intensive rehabilitation post-stroke has been supported in recent guideline development (NICE, 2023) and in the NHS Long Term Plan (NHS England, 2019). Whilst the 2017 NICE guidelines for stroke rehabilitation recommend that, following a stroke, the initial treatment duration for those who can actively participate should be at least 45 minutes per day for a minimum of 5 days per week (Frank, 2017; Royal College of Physicians, 2016); the most recent guidelines (NICE, 2023) have reviewed the evidence and now state that a more intensive rehabilitation has clinically important benefits. This recommendation was driven from data highlighting that the percentage of days a patient required physiotherapy on which therapy was received in hospital was only 61.8% in 2022/23 compared to 74.2% in 2019/20. In the community the percentage of days in which therapy was received was 16.5% in 2022/23 compared to 22.3% in 2019/20 (SSNAP, 2023). This increase in therapeutic intensity was also based on recent national recommendations from the Sentinel Stroke National Audit programme (SSNAP) data which further recommend an increase in the proportion of days in which people recovering from stroke receive rehabilitation therapy, both as inpatients and in the community (SSNAP, 2023).

5.1.1 'Real world' clinical management of post-stroke upper limb

A national survey of stroke patients (Stroke Association, 2015) and the stroke clinical audit (Sentinel Stroke National Audit Sixth Annual Report., 2019) identified that current therapy for the upper limb post-stroke is falling significantly short of what is required. The upper limb is used for a wide variety of functional tasks, which has a direct impact on both quality of life and independence. People with stroke place significant importance on restoration of upper limb functional movement (Barker & Brauer, 2005), and those who have significant upper limb dysfunctions are far more likely to require higher levels of care, often depending on families for support, impacting on relationships and quality of life (Dowswell et al., 2000; Pallesen, 2014). A poor outcome of the upper limb recovery is considered a major threat to perceived quality of life in people with stroke (Dobkin, 2005; van Lieshout et al., 2020); however, if the upper limb is treated effectively in the early stages post-stroke, it can have a positive impact on upper limb recovery in the longer term (Harris et al., 2009). Therapy should focus on the things most relevant to the individual, particularly functions that are relevant to their participation. Engagement in upper limb rehabilitation and repetitive practice can improve functional recovery (Harris et al., 2010). Recovery of the upper limb post-stroke varies in time due to the nature of the stroke and the amount of stimulation the upper limb receives as a result of therapy and everyday functional activity (Buma et al., 2013; Pollock et al., 2014). The CNS has the capacity for spontaneous recovery post-stroke; in part, this is due to compensatory pathway activity whilst relearning lost activity and use of residual function (Jones, 2017). Function relevant to the participant is fundamental to any treatment strategy, however, the window for optimal recovery and how that recovery may be achieved is also important (Nudo, 2013); the acute and sub-acute period post-stroke is optimal in terms of axonal sprouting being triggered, enabling neural growth (Carmichael, 2006; Krakauer et al., 2012; Thomas Carmichael et al., 2001). There is evidence to support intensive repetitive task-orientated therapy (Veerbeek et al., 2014) and the use of assisted technology such as FES (Marquez-Chin et al., 2017) to aid in upper limb recovery post-stroke and it has been well documented that two of the key elements in driving neuroplasticity post-stroke is the number of repetitions needed to achieve functional gains and the dose of activity required to sustain this (Nudo, 2013). Despite this knowledge, the upper limb is not always clinically prioritised in stroke rehabilitation (Barker & Brauer, 2005). Whilst two-thirds of people with stroke go on to be independently mobile, less than half have regained basic upper limb functions a year post-stroke. This impacts independence, quality of life and, therefore, makes upper limb rehab a key priority (Stockley et al., 2019).

In order to understand where and how FES was used as a treatment modality in the management of the post-stroke upper limb, it was important to first understand the current clinical environment. Whilst the knowledge from Chapter 4 (systematic review) supported the rationale that the upper limb should be a priority and the impact that recovery of functional use of the upper limb has on people with stroke, it was still unclear how the upper limb was managed across the identified NHS Foundation Trust stroke pathway. On discussion with key stakeholders at the NHS Foundation Trust identified it was highlighted that a key focus for the stroke service was to develop the management of the upper limb post-stroke across the stroke pathway as part of a wider service improvement. Whilst the evidence supports the need for the post-stroke upper limb to be treated intensively, it is clear that this might not necessarily be the case in current clinical practice (SSNAP, 2019). Driving neuroplasticity is a critical component in functional recovery post-stroke, however, this is time dependant with the first six weeks being the optimal window to maximise shaping neural reorganisation (Kwakkel et al., 2003; Thomas Carmichael et al., 2001). This is why the acute (first seven days) and subacute (first three months) phase post-stroke (Bernhardt et al., 2017) often sees the most significant improvements and why early rehabilitation is so important (Grefkes et al., 2020). However, the reasons upper limb interventions are not always clinically prioritised will be due to a number of complex factors such as physical capability of the individual therapist, time limitations within a service and knowledge of the interventions. Behaviour change interventions have been created with the aim of increasing upper limb repetitive task-oriented training in stroke rehabilitation (Connell et al., 2015). It has been highlighted that, in order to improve services for individuals with upper limb impairment post-stroke, it is important to address this at an organisation as well as an individual level.

Following on from Chapter 4, it was necessary to understand the current clinical environment in more detail. There is a lack of upper limb specific indicators in the SSNAP data and so to fully comprehend the management of the upper limb in a large stroke pathway, further examination of the current clinical environment was necessary. Due to the restrictions imposed by the COVID pandemic, a pragmatic way forward was to utilise the medical records to gain this insight. Not only did the medical records provide further insight into the general management of the post-stroke upper limb, it also allowed a better understanding of the proportion of people with stroke entering the stroke pathway who could potentially benefit from UL FES.

5.1.2 Methodology

It was important to differentiate between research, service evaluation and clinical audit to inform how to shape the methodology for this study. A clear distinction was necessary in order to ensure that the study adhered to relevant ethical, legal and governance standards (see **Table 5.1**).

Table 5.1: Definitions of research, service evaluation and clinical audit

	Purpose
Research	A key feature of research is that it is intentionally planned and designed using documented methodology that will allow results to be extrapolated or applied from the study sample to a larger population. This extrapolation/application is what the terms 'generalisable' and 'transferable' refer to. In the case of quantitative research, statistical methods are used to achieve results that are 'generalisable' from a sample to the sampled population. In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.
Service Evaluation	Designed and conducted solely to define or judge current care or service, or to deliver and measure improvements in quality of the current service.
Clinical/Non-Clinical Audit	Designed and conducted to produce information to inform delivery of best care.

The purpose of understanding specifically the local NHS Foundation Trust stroke pathway was to support and develop a community of practice in the management of the upper limb post-stroke whilst establishing the current clinical environment. Furthermore, the pandemic was a major limiting factor, as collecting data across a stroke pathway, identifying people with stroke and applying UL FES was not possible during this time period; therefore, to align with the thesis author's PhD timeframe, a service evaluation approach was favoured.

5.1.3 Service evaluation

A service evaluation helps to define or measure current practice. The knowledge gained from a service evaluation can be used to produce recommendations for a service improvement, inform clinical change and drive best practice. The results of a service evaluation are not intended to be generalisable to other areas or populations; it is specific to the area of data collection. Utilising the Health Research Authority (HRA) tool and the defining research table (see Appendix **10.2.1** and **Table 5.1**), a service evaluation is *'designed and conducted solely to define or judge current care or service, or to deliver and measure improvements in quality of the current service'* and its aim is purely to measure the current service without reference to a standard. A further point in this service evaluation was to generate momentum around the management of the upper limb post-stroke and to use the service evaluation to drive change through future service improvements which can be generated/initiated following the service evaluation recommendations (NHS England, 2005). The HRA tool was utilised to assist in decision-making. In addition, the NHS Foundation Trust Research and Innovation (R&I) and Clinical Effectiveness departments were also in agreement that this was not a clinical audit but a service evaluation as part of a wider service improvement plan, with a view to future service development opportunities.

5.2. Aims and objectives

The **overall aims** of the service evaluation were to:

1. Identify, via the medical records, how the post-stroke upper limb is assessed and managed, including the intensity of clinical interventions within the NHS Foundation Trust stroke pathway.
2. Identify whether FES is utilised as part of upper limb treatment interventions.
3. Make recommendations for future service improvements in the management of the post-stroke upper limb.

The **key objectives** were:

1. To identify the key characteristics of the therapist(s) involved in the management of the upper limb post-stroke.
2. To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.
3. To ascertain the number of patients with upper limb pain post-stroke.
4. To identify the types of outcome measures used in the management of the upper limb post-stroke.
5. To determine the proportion of patients who have upper limb functional goals, including the types of functional goals utilised.

6. To identify the types of adjuncts applied/utilised as part of the management of the upper limb post-stroke.

7. To ascertain the proportion of patients where UL FES had been used as a treatment intervention; including details relating to the frequency of use/therapeutic dose.

8. Identification of the frequency, and nature of self-management regimes.

9. To determine the types of exercise used and if specific upper limb muscle movement is documented in the medical notes.

10. To determine the number of treatment sessions in each clinical setting.

5.3. Methods

5.3.1 Overview of the study design

This was designed as a records-based service evaluation using a retrospective cohort. Data was extracted from the medical records of a cohort of consecutive patients admitted to the NHS Foundation Trust stroke pathway (between January 2019 and June 2019) with a confirmed stroke over a six-month period. This cohort of patients was tracked across acute, intermediate, and community services up until discharge from the service.

5.3.2 Setting and movement of patients across the stroke pathway

The setting was a large NHS Foundation Trust stroke pathway which spanned acute in-patient rehabilitation, through to community services. This NHS Foundation Trust stroke pathway comprises of a regional hyper-acute stroke unit, acute stroke unit, stroke pathway assessment and rehabilitation centre, and community stroke services (see **Figure 5.1**). Individuals with a suspected stroke were taken directly to the regional hyper-acute stroke unit. Following a medical assessment, and on confirmation of a diagnosis of stroke, other medical/therapeutic assessments take place. The severity of stroke determined whether the individual was discharged home (with or without extra support) or if they were moved to the next stage in the stroke unit pathway (see **Figure 5.1**). After 72 hours of assessment and treatment, patients from outside of the local area (postcode dependant) are returned to their nearest stroke service if further care is needed. From SSNAP data (Nov 2023–Oct 2024), 1458 stroke patients were admitted to the regional hyper-acute stroke unit; this is a typical annual average for this stroke pathway. Following the discharge of those not living within the local area, 992 people with stroke went on to access further services across the NHS Foundation Trust stroke pathway. In total 56% (n=558) of this population were transferred to the acute stroke unit for further rehabilitation. A further 32% (n=322) were transferred from acute services to the inpatient stroke pathway rehabilitation centre. Finally in total 92% (n=912) of all individuals living within the local area covered by the NHS Foundation Trust that were admitted with a confirmed stroke (combined from discharges from the hyperacute stroke unit, the acute inpatient stroke unit and the stroke pathway inpatient rehabilitation centre) were referred to community stroke services for ongoing treatment. These figures and the configuration of staffing are comparable to other regional and national stroke services.

All patients admitted to the NHS Foundation Trust stroke pathway are automatically referred to the therapy team unless the person with stroke is medically unstable or transferred out of the service. During an initial assessment it is documented if they have a confirmed stroke and any ongoing therapeutic needs; a therapeutic intervention will then be commenced if indicated.

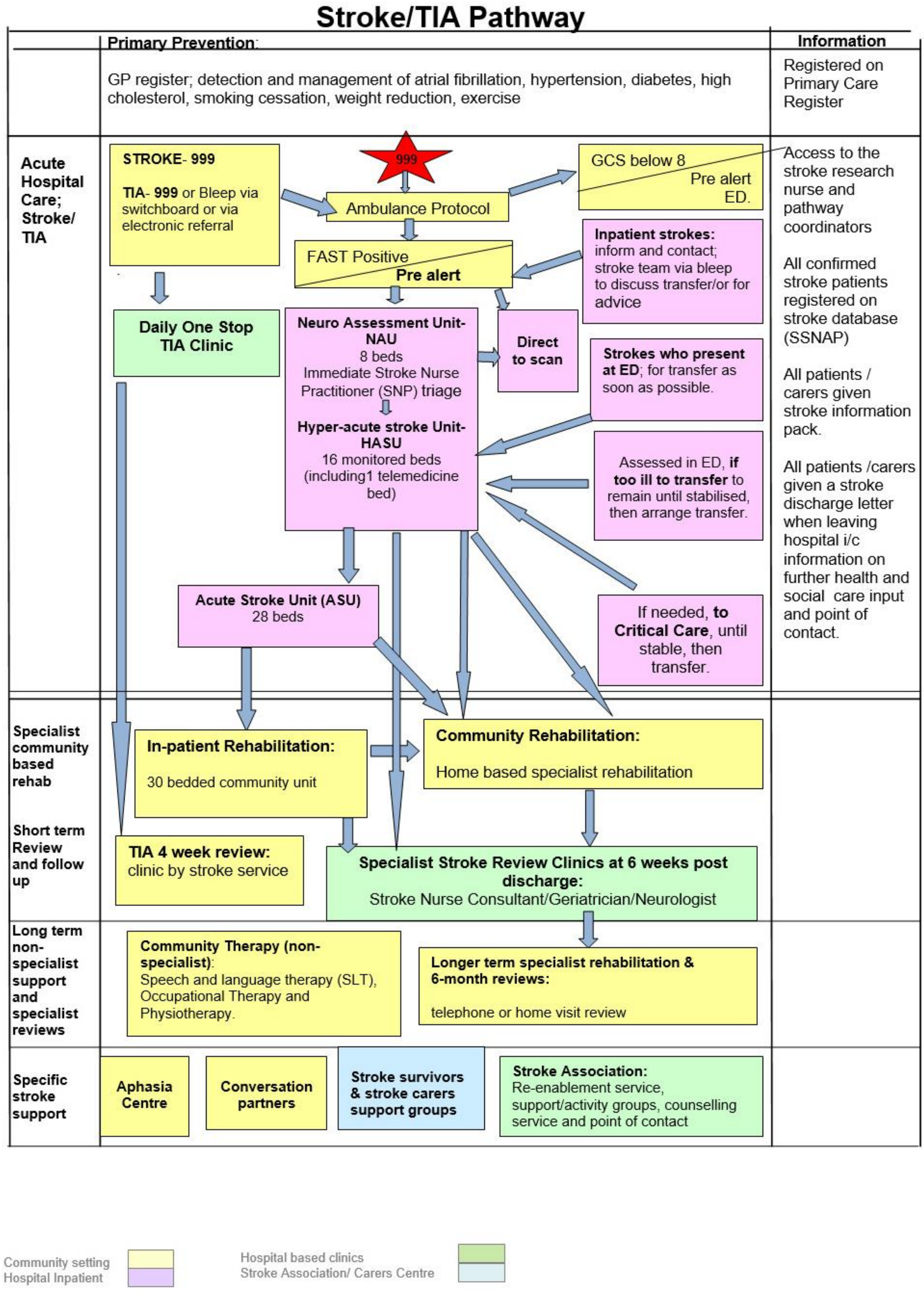

Figure 5.1: The NHS Foundation Trust Stroke Pathway

5.3.3 Participants

Participants were consecutive patients admitted to the NHS Foundation Trust stroke pathway with a confirmed stroke between 1 January 2019 and 30 June 2019. The duration that data was collected for was determined by the average duration of stay with stroke services (SSNAP, 2019); admissions into acute stroke services over a six-month period was deemed long enough to allow for fluctuations in admission rates and provide an adequate representative sample of the clinical service needed for the evaluation to make reasonable judgements about the service provision (see Appendix **10.2.2**). During 2020, the Covid-19 pandemic had significantly impacted national and local NHS services, and, in order to gather a 'normal' representative sample, the thesis author decided to capture pre-pandemic data from 2019. The inclusion and exclusion criteria are provided in **Table 5.2**.

Table 5.2: Inclusion and exclusion criteria

Inclusion	Exclusion
Confirmed stroke (first and subsequent strokes)	Transient Ischaemic Attack (TIA) or ANY other neurological cause of admission, e.g. multiple sclerosis, MND, etc.
Adult aged 18 and over	
Admitted to the NHS Foundation Trust stroke pathway between 1 Jan 2019 and 30 June 2019, via neurological assessment unit/hyper-acute stroke unit	
Lives within the postcode/location of the NHS Foundation Trust stroke pathway (pre stroke was a resident in the local area).	

5.3.4 Data sources

All participants were anonymised using participant numbers, however, in order for the notes to be accessed across the NHS Foundation Trust stroke pathway, the original hospital numbers were required. These were stored safely on a password-protected database and could only be accessed by the medical records team and the thesis author. It was agreed that hospital numbers were required and this was fully approved by the clinical effectiveness unit on the proviso that all documentation was fully secured and a risk assessment form was completed following NHS Foundation Trust guidelines; this risk assessment form was completed in conjunction with the hospital risk assessment lead and approved by the stroke service lead and the clinical effectiveness unit. The thesis author had a research contract with the NHS Foundation Trust for the period of the study to allow access to the medical notes, and also completed all relevant Trust policy training relating to data protection and ethics (see Appendix **10.2.3,10.2.4, 10.2.5**).

Medical records were no longer reviewed if discharged without any further rehabilitation follow up (inpatient rehabilitation or community services). Medical records of individuals that went on to inpatient rehabilitation and/or community rehabilitation services continued to be reviewed and patient hospital numbers were used to identify the individual, as once discharged from acute services all documentation became electronic data sources on either SystmOne or Lorenzo.

5.3.5 Data extraction form and pilot study

Data extraction was performed by the thesis author, however, for the purpose of the pilot only, reliability was checked across two data extractors (the thesis author and a clinical member of the stroke pathway approved to data collect by the service evaluation unit). A data extraction form was designed using Microsoft Excel. An initial draft of the data collection form was generated by the thesis author and reviewed by all stakeholders (stroke service lead, clinical effectiveness unit and PhD supervisory team). Following a review by all stakeholders and a subsequent discussion about the data extraction process, amendments were made to make the table easier to read by adding a key (see Appendix **10.2.6**). Domains and items covered by the data extraction form are displayed in **Table 5.3**–**Table** 5.8.

Table 5.3: Domains linked to objectives

Domain/item	Linked objective*
Background information on the stroke presentation and diagnostic screening: date of stroke classification of stroke	To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.
Therapy assessment date	To identify the key characteristics of the therapist(s) involved in the management of the upper limb post-stroke.
Profession of therapist carrying out assessment	To identify the key characteristics of the therapist(s) involved in the management of the upper limb post-stroke.
Upper limb impairment identified	To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.
Upper limb pain identified	To ascertain the number of patients with upper limb pain post-stroke.
Hand dominance documented	To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.
Specific muscle movement documented	To determine the types of exercise used and if specific upper limb muscle movement is documented in the medical notes.
Outcome measures used	To identify the types of outcome measures used in the management of the upper limb post-stroke.

Upper limb identified on problem list	To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.
Upper limb treatment delivered	To ascertain the proportion of patients where UL FES had been used as a treatment intervention; including details relating to the frequency of use of FES/therapeutic dose.
Upper limb tasks used, technology/adjuncts used and frequency of use	To identify the types of adjuncts applied/utilised as part of the management of the upper limb post-stroke. To ascertain the proportion of patients where UL FES had been used as a treatment intervention; including details relating to the frequency of use of FES/therapeutic dose.
Upper limb exercises given post treatment and type of exercise	Identification of the frequency, and nature of self-management regimes. To determine the types of exercise used and if specific upper limb muscle movement is documented in the medical notes.
Number of therapy sessions	To determine the number of treatment sessions in each clinical setting.
* specific objectives are listed on pages 106-107	

The pilot phase assessed the functionality of the data extraction form, the recording method, checked that data sources were available and provided a more reliable time estimate for the main data collection. The sample size for the pilot was five sets of clinical records. The pilot ran for four weeks in December 2020. The pilot highlighted several practical considerations:

- In light of Covid-19 there were social distancing limitations in place and the thesis author was only permitted to collect data in the evenings and weekends to avoid contact with other staff members due to room capacity regulations in place.
- The thesis author had to personally collect the medical records from the medical record department and take them to an approved secure room within the rehabilitation department at the NHS Foundation Trust.
- The medical notes had to stay in a secured locked location until they had been used and were ready to be taken back to the medical record department.
- If the medical records were recalled by anyone during this period then this also impacted data collection, as medical records needed to be returned.

Further to this, on collection, the medical records were not always in the correct order depending on volume of the individual notes and number of entries. There was also variation in how the data was captured and there was not always consistent use of the Trust specific stroke initial assessment tool. All of the above impacted on time delays in data collection; however, despite this, the data points were appropriate and, following discussion with the PhD supervisory team, it was agreed that the format of the excel sheet would remain as initially approved with no further amendments needed.

Furthermore, for the purpose of the pilot only, reliability was checked across two data extractors (the main thesis author and a clinical member of the stroke pathway approved to data collect by the service evaluation unit) to ensure that there was parity across the data extraction using the same five medical records. This was carried out to ensure that the process of data extraction was robust and enabled any practical considerations that were highlighted during this process to be resolved. On review of the pilot across the two data extractors no issues were identified relating to data collected or the Excel spreadsheet.

5.3.6 Data collection

Once the pilot was completed the remaining data was collected between January–August 2021. Medical records were located and reviewed at the point of inpatient acute admission; these were initially all paper-based medical records and were manually reviewed by the thesis author. This was, however, during the second national Covid-19 lockdown and restrictions were in place that impacted data collection including social distancing regulation and staffing within medical records department, which impacted the retrieval of paper-based medical records for the purpose of research.

Individual hospital medical records were screened, and data was collected from the paper and electronic-based medical records from admission up to the point of discharge/transfer out of the NHS Foundation Trust stroke pathway between January–June 2019. On discharge from acute/inpatient services, the individual medical records were tracked into the community or intermediate care settings within the NHS Foundation Trust stroke pathway; once out of acute services, medical records became electronic notes accessed by the individual’s hospital number. Individual data collection using the proposed data extraction form (Appendix **10.2.7**) was completed in each separate location until discharge from therapy services. Microsoft Excel (version 365) was used to analyse the data.

5.3.7 Data governance and approvals

Key stakeholders were identified to help shape and approve the service evaluation. These included the thesis author, the PhD director of studies, stroke clinical lead, therapy services clinical lead and a link staff member from the clinical effectiveness unit at the NHS Foundation Trust. Study procedures were developed by the thesis author, reviewed by the PhD supervisory team, and then approved by all key stakeholders. Prior to initiating this study, the study was registered and approved by the clinical effectiveness unit at the NHS Foundation Trust (Appendix **10.2.3**).

5.4. Results

5.4.1 Flow of participants and data availability

Over 1037 people were admitted to A&E with a possible stroke presentation during the data collection period. According to the SSNAP data from the NHS Foundation Trust during the period from January 2019–June 2019 (see **Table 5.4**), 478 patients were directly admitted to stroke services with a diagnosis of stroke. The medical records team, in liaison with the clinical effectiveness unit, created a list of potentially eligible stroke admissions using the stroke tracker (a document used for recording stroke patient hospital admission). This identified all admissions to the stroke service with a neurological/stroke acute classification from January 2019 to the end of June 2019. The total number of admissions during this time period was 1037 and an Excel spreadsheet was generated with relevant admissions data, including patient details (name, hospital number and date of birth), diagnosis related to admission and hospital admission date. The inclusion/exclusion criteria (**Table 5.2**) was then applied to the Excel spreadsheet, which was initially used to identify all patients with a confirmed diagnosis of stroke; any patients with a classification of TIA or other neurological presentation were excluded. This resulted in the overall number of patients admitted with a confirmed stroke to 471. As the original process was to identify patients with a confirmed stroke on the stroke pathway, the Excel spreadsheet was further filtered to remove any patients who were not on the stroke pathway who were admitted via other services. This screening left 423 patients who were admitted to the NHS Foundation Trust stroke pathway between January 2019 and June 2019 for inclusion in the study (see **Figure 5.2**). This list was reviewed by the medical records department, as all the original medical notes needed to be located. The medical records team identified the location of the medical notes via the patient's name, date of birth and hospital number. These were collected in batches of 20 sets of notes by the thesis author and reviewed in a private room within the medical records department at the NHS Foundation Trust. Out of the 423 patients, 237 medical notes were located and manually collected by the thesis author for review (see **Figure 5.2**).

Table 5.4: Sentinel Stroke National Audit Programme (SSNAP) standards data from NHS Foundation Trust where data collected from January June 2019

Sentinel Stroke National Audit Programme (SSNAP) standards data from NHS Foundation Trust.			
	Jan–March 2019	**April–June 2019**	**Total**
Number of directly admitted stroke patients	**235**	**243**	**478**
% Requiring physio during inpatient stay	**74.2%**	**84.3%**	
Transfer location post discharge	**No. of patients**	**No. of patients**	**Total no. of patients**
Early supported discharge team	**84**	**76**	**160**
In-patient rehabilitation	**52**	**50**	**102**
Discharged home	**27**	**37**	**64**
Community stroke rehabilitation service	**18**	**24**	**42**
Discharged to care home	**8**	**8**	**16**
Transferred out of stroke pathway	**21**	**12**	**33**
Figures represent numbers (percentage) of patients			

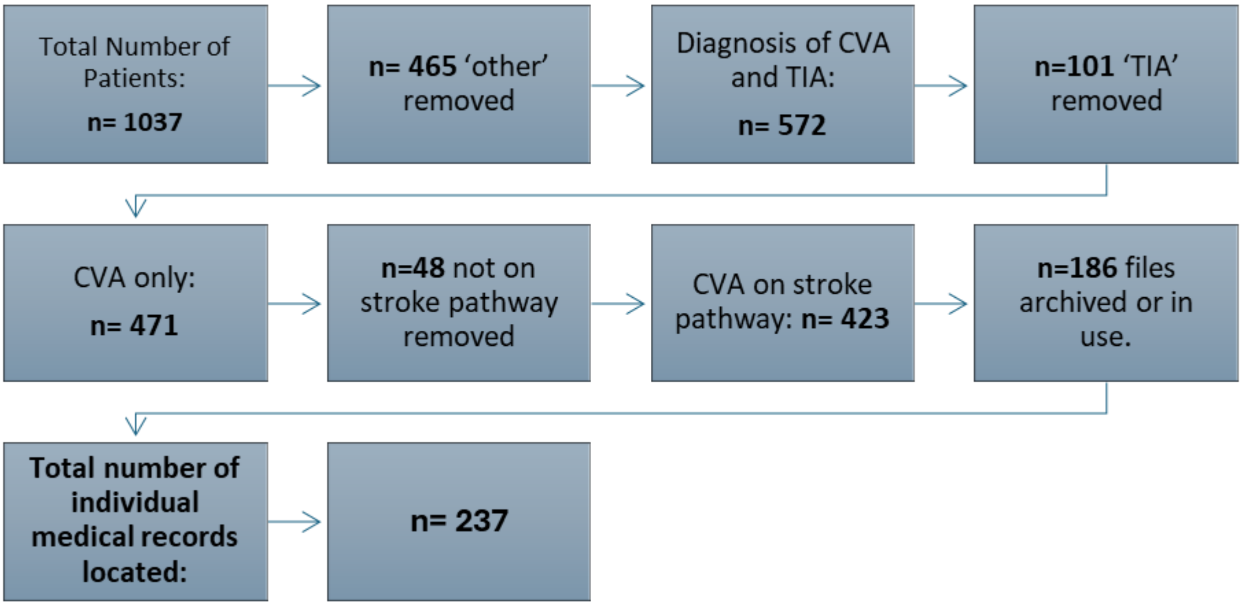

Figure 5.2: Flow chart of data extraction and filtering process

On requesting batches of medical records, there were 186 files archived or in use, resulting in the final sample of 237 medical records (see

Figure 5.3). Whilst 237 individual medical records were identified at the point of admission into acute stroke services, 5 individuals had further admissions within the data collection period; resulting in 245 data collection entries to the Excel spreadsheet in the acute setting.

Patient characteristics

Out of the 237 overall number of patients in the study, the largest proportion sustained an ischaemic stroke (n=161); n=38 sustained a haemorrhagic stroke and n=38 were classified as 'other' (this included no abnormality detected (NAD) and nil new (previous stroke history but not documented in medical records the categorisation of stroke)). The majority of the patients (n=189) received a diagnostic CT scan in accordance with national stroke guidelines (NICE, 2023), n=45 received an MRI scan and, whilst all patients had a scan documented in the medical notes, n=3 did not have the type of scan recorded clearly. From the sample reviewed n=100 had documented they had experienced a right hemiplegia, n=86 a left hemiplegia, n=2 had a bilateral presentation and n=49 were documented to have no motor deficit (**Table 5.5**).

Table 5.5: Descriptive characteristics of the selected patients in the study

	N (%)
Classification of stroke	
Ischaemic	161 (68)
Haemorrhagic	38 (16)
Other	38 (16)
Diagnostic scans:	
CT	189 (80)
MRI	45 (19)
None recorded	3 (1)
Side of hemiplegia	
right hemiplegia	100 (42)
left hemiplegia	86 (36)
both left and right	2 (1)
no motor deficit	49 (21)

CT Computed tomography; **MRI** Magnetic resonance imaging

Following the initial data collection from the acute inpatient setting, a total of 64% (n=152) were discharged home with no further rehabilitation follow up but will have been given an appointment for specialist stroke review clinics at six-weeks post discharge; 25% (n=59) went from acute inpatient services to inpatient rehabilitation unit for further support and management and 11% (n=26) were discharged home with community rehabilitation services (see **Table 5.6** and

Figure 5.3).

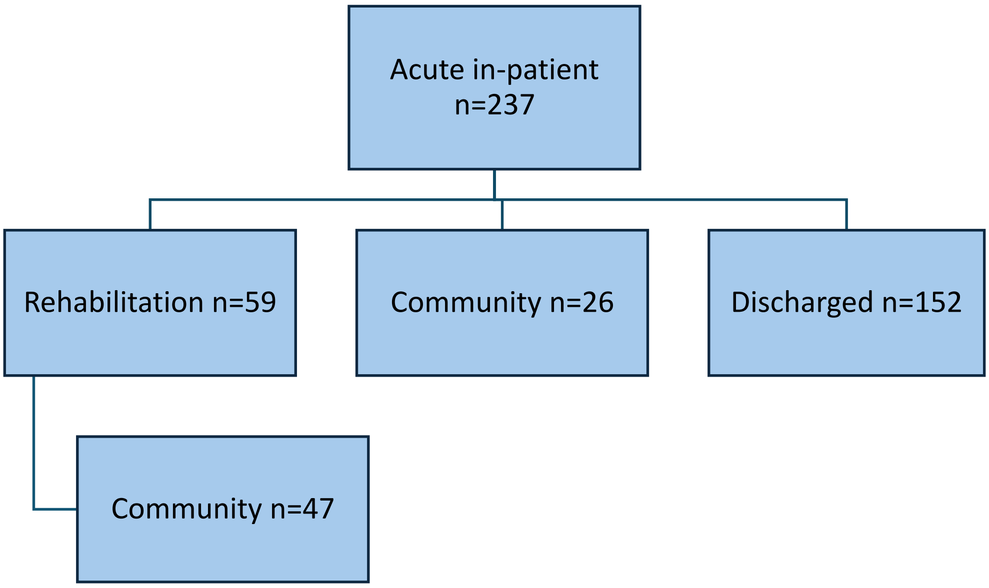

Figure 5.3: Number of medical records screened in each area of the stroke pathway

Table 5.6: Stroke pathway destination

Acute hospital admissions	
Patient sample n=	**237**
Discharged home with no follow up from therapy services	152 (64%)
Referred to inpatient rehabilitation	59 (24%)
Referred to Community Stroke Services	26 (11%)
In-patient rehabilitation	
Patient sample n=	**59**
Discharged home with no follow up from therapy services	1 (2%)
Referred back into acute inpatient setting	9 (15%)
Referred to Community Stroke Services on discharge from in-patient rehabilitation	47 (80%)
Transferred out of region	0 (0%)
Transferred back to a care home on discharge from in-patient rehabilitation	2 (3%)
Died	0 (0%)

Community rehabilitation: (n=73) sample from direct referral from acute services (n=26) and referral post in-patient rehabilitation (n=47)	
Patient sample n=	**73**
Discharged home with no follow up from therapy services	67 (91%)
Referred back into inpatient rehabilitation	2 (3%)
Referred to Community Stroke Services	0 (0%)
Transferred out of region	0 (0%)
Transferred back to a care home	2 (3%)
Died	2 (3%)

When considering the study objectives, physiotherapists carried out more initial assessments and were involved in the management of the upper limb post-stroke within the sample (69% in the acute setting, 86% in the in-patient rehabilitation setting and 57% in the community); with a greater proportion of occupational therapists being involved in the assessment/management of the upper limb in the community setting (43%) in comparison to other areas within the stroke pathway. It was identified that 32% (n=73) of the sample in the acute setting had an upper limb impairment, with 21% (n=15) of those having this cited on a problem list. In-patient rehabilitation noted 42% (n=25) had an upper limb impairment, with 16% (n=4) of those having this cited on a problem list. Whilst in the community, 13% (n=9) were documented to have an upper limb impairment, with 11% (n=1) having this cited on a problem list (see **Table 5.7**).

A variety of outcome measures were used, including the Barthel (acute and in-patient rehabilitation), the modified Ashworth scale (acute), the Berg balance (in-patient rehabilitation and community) and the Montreal Cognitive Assessment (MoCA) (community). In terms of adjuncts, the splints were applied in both the acute and in-patient rehabilitation settings with UL FES being used in both the in-patient and community rehabilitation.

UL FES was not applied in the acute in-patient setting; however, it was applied to 8% (n=2) of those with upper limb impairments in the in-patient rehabilitation setting and 33% (n=3) in the community. In the individual medical records there was evidence of dose/duration/intensity/location of UL FES application; however, there was no justification for the specific dose/duration/intensity/location of FES used. There was also no clinical reasoning documented when these parameters were altered.

Table 5.7: Results aligned to the study objectives

	Data Collection 1 **Acute in-patient**	**Data Collection 2** **In-patient rehabilitation**	**Data Collection 3** **Community rehabilitation**
1. To identify the key characteristics of the therapist(s) involved in the management of the upper limb post-stroke.	Physio: 69% (n=159) OT: 31% (n=72)	Physio: 86% (n=51) OT: 14% (n=8)	Physio: 57% (n=40) OT: 43% (n=30)

2. To determine the number of patients that have upper limb impairment identified in their medical notes and cited on a problem list.	32% (n=73) (16% identified on assessment by an occupational therapist and 84% by a physiotherapist) **% cited on a problem list:** 21% (n=15)	42% (n=25) (12% identified on assessment by an occupational therapist and 88% by a physiotherapist) **% cited on a problem list:** 16% (n=4)	13% (n=9) (67% identified on assessment by an occupational therapist and 33% by a physiotherapist) **% cited on a problem list:** 11% (n=1)
3. To ascertain the number of patients with upper limb pain post-stroke.	8% (n= 6) 100% of those that had identified shoulder pain also had an upper limb impairment	12% (n=3)	11% (n=1)
4.To identify the types of outcome measures used in the management of the upper limb post-stroke.	Barthel and the modified Ashworth scale (MAS)	Barthel and Berg Balance	Berg Balance, MoCA and Tinetti
5.To determine the proportion of patients who have upper limb functional goals, including the types of functional goals utilised.	3% (n=2) Washing and dressing independently Brushing hair Reaching for cup	0% N/A	0% N/A
6.To identify the types of adjuncts applied/utilised as part of the management of the upper limb post-stroke.	Splint/upper limb sling (n=1)	FES (n=2) Callipers (n=1) Splint/upper limb sling (n=1)	FES (n=3)

7.To ascertain the proportion of patients where UL FES had been used as a treatment intervention; including details relating to the frequency of use/ therapeutic dose.	0% **Dose:** N/A	8% (n= 2) **Dose:** FES used on upper limb as trial, but nil documented re dose/frequency/duration.	33% (n=3) **Dose:** In clinical notes there was evidence of dose/duration/location of application and intensity of FES used; however, there was no justification for the specific dose/duration/location of FES used and intensity.
8.Identification of the frequency, and nature of self-management regimes.	5% (n=4)	28% (n=7)	45% (n=4)
9.To determine the types of exercise used and if specific upper limb muscle movement is documented in the medical notes. (From the medical notes of those that had upper limb self-management regimes/ exercises prescribed)	25%: exercise type not documented* 50%: hand/putty exercises * 25%: Lower limb exercises mentioned* *(*no documentation of frequency/intensity.)* **Muscle movement:** 7% (n=5) Muscles identified most frequently: biceps, triceps, traps, scalenes and pectoral muscles.	57%: exercise type not documented* 29%: GRASP exercises* 14%: Self stretches* *(*no documentation of frequency/intensity.)* **Muscle movement:** 24% (n=6) Muscles identified most frequently: biceps, triceps, pecs, wrist flex, and deltoid.	50%: Putty exercises* 25%: Reaching exercises with cup* 25%: strengthening exercises with 1 kg dumbbell* *(*no documentation of frequency/intensity.)* **Muscle movement:** 0%
10.To determine the total number of	Range: 0–58	Range: 0–62	Range: 0–54

treatment sessions in each clinical setting.			

From the 73 (n=73) medical records identified by a therapist as having an upper limb impairment (see **Table 5.8**), in the acute setting sample only 15% (n=11) had an upper limb intervention documented in the medical records. 5% (n=4) were documented as having left hand dominance (three of which had a right hemiplegic presentation and one left) but no upper-limb-specific interventions were documented. 42% (n=31) were documented to have right hand dominance (12 of which had a left hemiplegic presentation, 18 right and 1 bilateral) and only 4 of these notes had upper limb specific interventions documented, which included upper limb exercise and stretches. In total, 52% (n=38) did not have hand dominance documented in the medical records (17 of which had a left hemiplegic presentation and 21 right) with 7 from this sample having upper-limb-specific interventions documented.

From the twenty five (n=25) medical records identified by a therapist as having an upper limb impairment in the in-patient rehabilitation setting sample, 92% (n=23) had upper limb intervention documented in the medical records. 20% (n=5) were documented as having right hand dominance (n=4 of which had a left hemiplegic presentation and n=1 was right) but only three (n=3) medical records reviewed were documented to have upper limb specific intervention, with only one (n=1) citing the detail as hand exercises and fine motor practice. In 80% (n=20) of this sample, hand dominance was not documented (9 of which were left hemiplegic presentations and 11 had right hemiplegic presentations); however, all from this sample had upper limb specific intervention documented in the medical notes. Upper limb specific intervention including stretches, upper limb exercises, massage and passive range of movements; however, the details were non-specific.

From the nine (n=9) medical records identified by a therapist as having an upper limb impairment in the community setting sample, only 56% (n=5) had upper limb intervention documented in the medical records. Among the sample, one participant (n=1 (11%)) was documented as having left-hand dominance. They presented with right hemiplegia and reduced upper limb strength, though no details were provided about any upper limb intervention delivered. Additionally, two participants (n=2 (22%)) were documented as having right-hand dominance, with one presenting with left hemiplegia and the other with right hemiplegia. Both had upper limb intervention with putty exercises and hand dexterity documented but no specific dose or duration. In 66% (n=6) of the sample hand dominance was not documented (n=4 had a left hemiplegic presentation, n=2 right) and only three (n=3) medical records had UL intervention documented however the detail was limited (see **Table 5.8**).

Low toned 'dense' UL paralysis was documented in the medical records across all three settings. In the acute setting, 14% (n=10 (out of a sample of 73)) were documented to have a 'dense' UL impairment. Whilst n=10 were identified as having a UL impairment, only 30% (n=3) had any UL intervention documented. From this small sample (n=3) the average number of treatment sessions was eight (n=8 (with a range of 3–37)). The UL interventions documented included stretches and passive range of movement but no joints were cited or dose of stretches/passive range of movement documented. A resting splint applied to one (n=1) and documented but there were no specific details of the type of splint or prescription of how/when it was to be worn. Discharge destination of those documented to have a ‘dense’ UL (total n=10) included in-patient rehabilitation (80% (n=8)) and community (20% (n=2)).

On transfer to in-patient rehabilitation all eight people with stroke that were identified as having a ‘dense’ UL impairment in the acute setting were further documented as having a UL impairment. However, only 87% (n=7) had any documented UL intervention. The average number of treatment sessions was 15 (n=15 (with a range of 11–45)). The UL interventions documented included stretches, exercises (including GRASP exercise plan) oedema massage and sensory stimulation of the UL (no specifics cited regarding location, frequency, or dose of intervention). Discharge destination post in-patient rehabilitation for those with a ‘dense’ UL (total n=8) included community (63% (n=5)), transferred back to the acute hospital (25% (n=2)) and transferred out of region (12% (n=1)).

Finally, in total, five (n=5) people with stroke documented to have a ‘dense’ UL impairment from in-patient rehabilitation were discharged home with a community referral and two (n=2) were referred from the acute setting; making the total patients referred to community (who on acute admission post-stroke had a dense UL) seven (n=7). In the community, only 14% (n=1) were identified as still having a UL impairment and continued to have UL intervention. This included self-managed exercise and passive range of movement, however, no detail in the notes of exercise plan or dose of intervention. UL FES was documented as a possible treatment intervention but not applied. The total number of treatment sessions during this community episode of care was n=36; however, these treatment sessions were not only focussed on UL rehabilitation.

Table 5.8: Results linked to upper limb impairment, including average number of treatment sessions in each setting and discharge destination.

	Data Collection 1 **Acute In-patient**	**Data Collection 2** **In-patient Rehabilitation**	**Data Collection 3** **Community Rehabilitation**
Average number of treatment sessions in each setting	**7** treatment sessions	**14** treatment sessions	**12** treatment sessions
In cases where UL impairment identified in therapist initial assessment, % of those where UL treatment documented in the therapy notes.	**15%** (n=11)	**92%** (n=23)	**56%** (n=5)
Average number of treatment sessions in subjects receiving UL intervention.	**7** (range: 5–38)	**14** (range: 5–62)	**15** (range: 9–36)
Discharge destination of those where UL impairment identified on initial assessment.	(Out of sample of 73) Home no follow up: **25%** (n=18) In-patient rehabilitation: **48%** (n=35)	(Out of sample of 25) Community: **64%** (n=16) Transferred out of region: **8%** (n=2)	(Out of sample of 9) Home no follow up: **89%** (n=8) RIP: **11%** (n=1)

	Community: **15%** (n=11) Transferred out of region: **4%** (n=3) Transferred to care home: **5%** (n=4) RIP: **3%** (n=2)	Transferred to care home: **8%** (n=2) Transferred back to acute hospital: **20%** (n=5)	
Discharge destination of those that received UL therapy intervention.	(Out of sample of 11) Home no follow up: **9%** (n=1) In-patient rehabilitation: **46%** (n=5) Community: **36%** (n=4) Transferred to care home: **9%** (n=1)	(Out of sample of 23) Community: **70%** (n=16) Transferred out of region: **13%** (n=3) Transferred to care home: **4%** (n=1) Transferred back to acute hospital: **13%** (n=3)	(Out of sample of 5) Home no follow up: **100%** (n=5)
Low toned/ 'dense' UL paralysis documented in medical records.	**14%** (n=10 (out of sample of 73))	On transfer to in-patient rehabilitation, all eight (n=8) were identified as having a UL impairment and **87%** (n=7) of those had UL intervention.	Five (n=5) patients from in-patient rehabilitation were discharged home with a community referral and two (n=2) patients were referred from the acute setting; making the total patients referred to community (who on acute admission post-stroke had a dense UL) **(n=7)**.

5.5. Discussion

The service evaluation clearly identified how the UL has been managed in patients admitted to the NHS Foundation Trust stroke pathway between January 2019 and June 2019 through to discharge. Whilst n=237 individual medical notes were identified at the point of admission into acute stroke services 64% (n=152) of the sample were discharged home with no follow up from therapy services; however, those discharged with a confirmed stroke will have been given an appointment for specialist stroke review clinics at six-weeks post discharge, as per stroke pathway guidelines (see **Figure 5.1**). Trajectory of how a person with stroke moves through this NHS Foundation Trust stroke pathway is guided by the care plan, stroke recommendations and the assessment of clinicians working within the stroke pathway. When reflecting on the aims of the service evaluation and the study objectives identified as part of this medical records review, key discussion points include prevalence and presentation of UL impairment, intensity of UL rehabilitation, UL treatment and management, data sources and reliability of information

5.5.1 Prevalence and presentation of upper limb impairment

According to the International Classification of Functioning, Disability and Health model (ICF), impairments in people with stroke can be classified as those impacting body function (e.g. loss of muscle power or tone) or body structures (e.g. deviation in structure of nervous system) (Geyh et al., 2004; Raghavan, 2015). Both types of impairment may occur in people with stroke. A clear understanding of individual impairments is required to provide optimal treatment, however, as multiple impairments can present simultaneously, it is often complex to define the primary or more pressing impairment that requires treatment. Weakness or paresis is a key impairment that is identified in the post-stroke UL that often leads to learnt non-use (Raghavan, 2015). The most frequently cited statistics for prevalence of UL weakness in acute stroke is 70%, provided by data from the Copenhagen Stroke Study (Nakayama et al., 1994); however, there are challenges of estimating prevalence of UL impairment post-stroke including data collected and variance within measures used to capture this (Simpson et al., 2021). The percentage of documented UL impairment post-stroke from this study (32%) is in line with a recently published cross-sectional observational study looking at the prevalence of UL weakness in early post-stroke data; however, in this specific study there was clear evidence of what measures were used to quantify UL weakness (Dalton et al., 2024). A common UL weakness measure used in the literature is the shoulder abduction and finger extension (SAFE) score (Dalton et al., 2024; Nakayama et al., 1994), however, as this only reviews weakness at the shoulder and hand, a more multicomponent motor impairment measure such as the Fugl-Meyer Assessment Upper Extremity section or the Motor Assessment Scale could be more accurate in demonstrating UL motor impairment (Simpson et al., 2021). Weakness was cited in 32% (n=73) of the individuals with UL impairment in the acute setting, 42% (n=25) in the rehabilitation setting and 13% (n=9) in the community. This was, however, often documented on a body chart and was not often quantified in terms of muscle power, or by the use of an appropriate measurement tool. On review of the medical records, the Fugl-Meyer was noted not to be used across the stroke pathway and the modified Ashworth scale was only used with one person with stroke in the acute setting. The modified Ashworth scale is a muscle tone assessment scale that is known for having poor inter-rater reliability (Vidmar et al., 2023; Zurawski et al., 2019) but is often used clinically as it is quick to perform (Craven & Morris, 2010). The Fugl-Meyer Assessment Upper Extremity section is a stroke specific, performance-based impairment index which has good intra/inter-rater reliability and validity (Gladstone et al., 2002). It is frequently used by researchers in stroke rehabilitation research; however, this is not necessarily reflected in clinical settings (Deakin et al., 2003). Some of the most frequently used UL specific measures include the action reach arm test (ARAT), the box and block test and the Wolf motor function test (Teasell et al., 2024). The Barthel (acute and in-patient rehabilitation setting) and Berg balance (in-patient and community setting) were the only two outcome measures that were used across more than one site within the stroke pathway. Neither are upper-limb-specific measures but are measures of functional independence (Barthel) and balance (Berg). Specific UL outcome measures were infrequently and inconsistently used across all three sites and, furthermore, there were limited upper-limb-specific patient goals documented (in the acute setting 3% (n=2) of those with an identified UL impairment had UL specific goal documented in the medical records). Both the lack of UL-specific outcome measures and specific UL goals within the medical records warrants further discussion. These findings were validated on dissemination across the stroke pathway and incorporated in the methodology chosen for chapter 6.

There is still limited knowledge of the UL use early post-stroke; however, it has been suggested that active use or engagement in UL movement differs with varied UL impairment levels. A study by Chin et al. (2020) concluded that people with stroke who had moderate to severely impaired ULs (categorised by Fugl-Meyer score) used their paretic UL more during therapy. It can be inferred, therefore, that despite motor impairment it is possible to increase paretic limb use. Unfortunately, in the medical records across the stroke pathway there was limited specific UL intervention recorded. Where it was documented it was difficult to identify what was carried out, as the overarching term of ‘UL treatment’ was often used and there was no evidence of any categorisation in terms of severity of UL impairment. Whilst the use of the Fugl-Meyer outcome measure is utilised frequently within research to measure UL impairment (Fugl-Meyer et al., 1975), this was not evident within this evaluation of the stroke pathway medical records.

Initial motor impairment is known to be a strong predictor of UL recovery post-stroke, with mild or moderate UL impairment being more likely to gain functional recovery than those with severe UL motor impairment (Snickars et al., 2017; Wu et al., 2020). Across the NHS Foundation Trust stroke pathway, there was variance in the identification of UL impairment. It has been documented that most motor improvements occur in the first 6-10 weeks post-stroke (Kwakkel et al., 2006). In those with mild to moderate stroke presentations it has been further documented that in approximately 70% of patients spontaneous motor recovery will occur (Prabhakaran et al., 2008; Winters et al., 2015). However, this proportional recovery rule has been challenged for overestimating spontaneous motor recovery, especially in the post-stroke UL (R. van der Vliet et al., 2020).

Physiotherapists predominantly documented UL impairment in the medical records across the stroke pathway (84% (n=61) in the acute setting and 88% (n=22) in the in-patient rehabilitation setting); however, in the community, a greater proportion of occupational therapists (67% (n=6)) documented a UL impairment. This could be linked to local staffing issues and team dynamics within the NHS Foundation Trust at that particular time period (NHS Foundation Trust SSNAP data from the acute setting indicated that physiotherapy staffing was at national average and occupational therapy was slightly below) or this could possibly indicate a role split between which profession is more likely to address UL impairments. A retrospective analysis of conventional UL therapy in a subacute setting post-stroke indicated that, whilst there was considerable overlap in terms of session content, occupational therapists provided a greater focus on the UL in comparison to physiotherapists in the severely impaired population (de Jong et al., 2018).

Post-stroke shoulder pain is a common impairment in people with stroke (S. Kumar et al., 2010; Zhang et al., 2021) and has a significant impact on quality of life and functional independence (Nickel et al., 2017). There are a number of risk factors that are associated with post-stroke shoulder pain including previous shoulder pain, diabetes and impaired UL movement, and evidence has suggested that early identification of these risk factors can guide clinical reasoning and possible preventative strategies (Holmes et al., 2020). Within the acute setting, only 8% (n= 6) were documented to have had UL pain; however, 100% of those that had identified shoulder pain also had a UL impairment documented in the medical records. Only 12% (n=3) were documented to have UL pain in the in-patient rehabilitation setting and 11% (n=1) in the community. A systematic review identified that incidence and prevalence of UL pain post-stroke is high and may be influenced by geographical locations (Zhang et al., 2021). This reported incidence fluctuates, however, based on variation in both methods used and patient cohort (Holmes et al., 2020). An incident rate between 18–22% in the subacute post-stroke time period (3–4 months) has previously been reported (Adey-Wakeling et al., 2015; Lundström et al., 2009), which could indicate that it is more likely for post-stroke UL pain to be identified in both the in-patient and community settings. Whilst the percentage of documented UL pain across the NHS Foundation Trust stroke pathway was lower than in the current evidence base, there was evidence of greater reporting in the subacute period which correlates with this evidence and supports the argument that post-stroke UL pain develops over time (Hansen et al., 2012; Lundström et al., 2009).

5.5.2 Intensity of upper limb rehabilitation

There is clear evidence to support a dose-response relationship between intensity and increases in motor recovery post-stroke (Kwakkel et al., 2004). The SSNAP annual report 2019-2020 (SSNAP, 2019) states the importance of a higher intensity of rehabilitation for people recovering from stroke and the corresponding 2016 national clinical guidelines for stroke highlighted that people with stroke should have access to at least 45 minutes of each appropriate therapy every day that enables them to meet their rehabilitation goals (Frank, 2017). The SSNAP data during this time period, however, highlights that access to therapy varies considerably with only 34% of patients receiving the equivalent of 45 minutes, 5 days a week of physiotherapy and 37% occupational therapy. It states that there needs to be a greater degree of flexibility on how therapy is delivered as part of a specialist stroke service (SSNAP, 2019). It is important to note that this is therapy overall and not just the management of the UL post-stroke. Further to this, it has also been well documented in observational studies that therapists often overestimate therapy time, and in particular the time the people with stroke are engaged in active task practice during the session (Bagley et al., 2009; Kaur et al., 2013; Wittwer et al., 2000). Bearing this in mind, it was extremely difficult to extrapolate from the medical records the exact duration of ‘intensity’/therapy provided purely for the UL. Data presented is, therefore, an estimation of the treatment duration.

The SSNAP data for the NHS Foundation Trust during this time period states that the average duration of physiotherapy contact time was 36.7 minutes, with only 26% of applicable patients receiving the recommended 45 minutes, 5 days a week. In terms of occupational therapy, this was slightly better with an average of 43.3 minutes' contact time. However, this remains with only 39.3% of applicable patients receiving the equivalent 45 minutes, 5 days a week. Again, it must be taken into consideration that the reasons for this variation in data are multifactorial. Time overall was documented (and collected for the purpose of the SSNAP reports), however, it was impossible to attribute the time spent on the UL specifically.

A more significant UL impairment post-stroke causes a reduction in engagement and contribution to active UL movement compared to those with a less significant UL motor impairment (Bailey et al., 2015; Essers et al., 2021; Rand & Eng, 2015); but improvements post six months does not necessarily translate into improvements in UL activity (Waddell et al., 2017). Furthermore, it has been identified that in the chronic stroke population, people with stroke tend to use their affected UL less, with less variation of movement despite good observed UL motor function (Essers et al., 2021). Intensity of UL rehabilitation is complex, however, with the assumed goal that upper limb rehabilitation aims to improve activity of daily life, in order to maximise this, treating clinicians need to quantify UL activity.

5.5.3 Upper limb treatment/management

There has been growing interest in the management of the post-stroke UL, however, this does not necessarily inform what is actually happening in clinical practice, and whilst the SSNAP audit provides data relating to overall therapy time delivered to people with stroke, there is no indication of what this treatment comprises of (SSNAP, 2023). The primary role of the UL is to be able to perform functional tasks, and, often, therapeutic activity for the post-stroke UL is framed around an individual's ability to complete, refine and optimally retain independent UL functional movement. A number of interventions such as constraint induced movement therapy (CIMT) (de Azevedo et al., 2022; Kwakkel et al., 2015)and the graded repetitive arm supplementary program (GRASP) (Harris et al., 2009; Yang et al., 2021) are well-evidenced to support UL recovery. A cross-sectional survey of UK therapists highlighted that some treatments tend to be more embedded in daily clinical practice than others and that intensity of UL rehabilitation is required, which aligns to recent clinical guidelines (NICE, 2023; Stockley et al., 2019).

When considering the data from this service evaluation, management of those with UL impairments in the acute setting include limited recommendation of any self-management techniques (5% (n=4)). This percentage increased both in the in-patient setting (28% (n=7)) and the community (45% (n=4)). Further to this, there were no details about recommendations given in the medical records relating to the self-management techniques advised. Frequency, type and number of repetitions for example would enable a greater understanding of the impact of self-management techniques and their utility. This would enable the treating clinician (and any other clinicians providing follow up intervention/care) to progress the recommendations or even know when to discontinue them.

Self-management techniques (self-directed therapy or self-practice) are recommended in the most recent stroke guidelines in order to promote increased practice in addition to standard rehabilitation sessions and also as a means of motivating people with stroke to maintain engagement and participation (NICE, 2023). Whilst there is limited high quality evidence to indicate particular groups of people with stroke that would benefit from self-management techniques, there is a wealth of evidence to support increasing the number of repetitions post-stroke and how self-management can improve motivation and engagement in people with stroke (Greenway et al., 2022; Nott et al., 2021; Schnabel et al., 2021). Whilst it is currently not fully understood what the recommended dose of self-management should be for different post-stroke presentations, due to the lack of documentation about how and what was advised in the small proportion of individuals that did have self-management recommendations made by their treating clinicians within this study it would be difficult to ascertain if this was a suitable amount or type of self-direction given. In addition, minimal use of UL treatment adjuncts were utilised as part of the overall acute management of the UL, with only one (n=1) having a resting splint applied. In the rehabilitation setting and community stroke services, both exercise and exercise-based self-management techniques were documented; there was, however, limited specific documentations about what form of UL exercise was used and any rationale for any 'prescriptive' dose. Unfortunately, overall guidance on exercise in people with stroke is limited despite there being overwhelming evidence to support the role of exercise in health (Church et al., 2022). The average number of treatment sessions in the acute setting during the data collection time period was only seven (n=7) (see **Table 5.8**).

As previously discussed, the level of UL impairment was not evident within the medical records across the stroke pathway, but the terminology 'low toned' or 'dense' UL was documented in a number of medical records (see **Table 5.8**). In 14% (n=10) of those with UL impairment in the acute setting this terminology was used but despite this only three (n=3) of the medical records had any UL intervention documented to manage this 'dense' UL impairment. Severe UL paresis (or 'dense' UL) is a known risk factor for developing post-stroke spasticity with early intervention being optimal (Glaess-Leistner et al., 2021; Lundström et al., 2010; Opheim et al., 2015). Post-stroke spasticity is more common in post-stroke ULs and, if left untreated, can reduce quality of life (QoL), cause the development of joint contractures, potentially resulting in UL pain. From the acute medical records, the UL of those people with stroke considered to have a dense UL, interventions documented included stretches and passive range of motion (PROM) (however, no joints were cited or dose of stretches/PROM) with one (n=1) having an application of a resting splint to maintain joint positioning (no details were documented of how/when to be worn). Due to the lack of specific detail about the interventions delivered in the acute setting, it was difficult to ascertain the clinical justification for choice of intervention or understand the impact/outcomes for those documented as having a dense UL impairment. All individuals identified as having a 'dense' UL (n=10) were transferred to either inpatient rehabilitation 80% (n=8) or home with community rehabilitation 20% (n=2) for further treatment.

On transfer to inpatient rehabilitation all eight (n=8) people with stroke were identified as having a UL impairment, and seven (n=7) of those had further UL interventions, with an average number of treatment sessions of 15 (range: 11–45). The UL interventions documented included stretches, exercises (including GRASP exercise plan) oedema massage and sensory stimulation of the UL; however, again, there were no specifics cited regarding frequency or dose of intervention.

On reassessment in the community, of the two (n=2) people with stroke transferred from the acute setting with a known UL impairment only one (n=1) continued to have any further UL intervention. This was documented to include self-managed exercises and passive range of movements (no detail in the medical records of exercise plan or dose etc.); FES was mentioned but not utilised. The total number of treatment sessions this individual with a 'dense' post-stroke UL received in the community was 36, but this was a combination of interventions for UL and LL, which made it difficult to quantify how much time was specifically focused on UL management.

The documented use of UL FES as a treatment post-stroke was limited across the NHS Foundation Trust stroke pathway; whilst location of application when utilised was documented, there was no documentation about the clinical decisions made relating to the applied dose. FES was not documented in the acute setting, however, in the in-patient rehabilitation setting it was used in 8% (n=2) of those with UL impairments identified. In both cases it was applied as a 'trial' application and was not followed up with more regular use. In the community it was documented to have been applied in 33% (n=3) of those with identified UL impairments. The location of application was documented but nothing further in terms of justification for the specific dose, duration, location or intensity of FES used. There was no clinical reasoning documented either when parameters were altered or the UL FES was discontinued. There are known benefits to the use of UL FES, especially if applied in the early stages post-stroke (Eraifej et al., 2017), but unfortunately the lack of application in both the acute and in-patient rehabilitation setting within this NHS Foundation Trust does not align to these research recommendations. The limited use of FES, however, does align with conclusions made in a cross-sectional study reporting on post-stroke UL therapeutic input as therapists reported the same lack of use in the post-stroke population (Stockley et al., 2019). The evidence base relating to the use of UL FES is still considered to be emerging and there is the possibility that the lack of studies detailing application parameters and evaluating both usability and optimal therapeutic window impact clinicians considering it as a valid treatment option in the management of the UL post-stroke (Sousa et al., 2022).

5.5.4 Data sources and reliability of information

There are a number of factors inherent in medical records that decrease the accuracy of any abstracted data; this includes missing information or incompleteness of medical records, illegible documentation and variability in the documentation practices among clinicians (Zozus et al., 2015). Whilst accurate documentation is both a professional responsibility and a legal requirement of any treating clinician (Brookes, 2015), this is subject to variation in terms of quality and quantity. Whilst it is mandatory to document all interventions, the specifics of any treatment delivery have a discretionary component in terms of the depth of the detail given. Clinical reasoning, for example, is not often documented despite this having an impact on the treatment delivery, and reasons for this are multifactorial but will include time and staffing limitations, all of which impact on quality/adequacy of documentation and ultimately its use as a data source. Whilst there can be relative confidence in assessment and treatment having been carried out if it is documented in the medical records, the question remains: had anything been done that has not been accurately documented? One of the key findings from this study was the limited detail in the clinical documentation relating to the management of the post-stroke UL. The question, therefore, is was a more holistic body systems treatment approach taken and the engagement of the UL simply not accurately documented?

It has been highlighted by people with stroke that they feel health professionals poorly understand the UL and that recovery of the UL post-stroke is often neglected (Barker &

Brauer, 2005). Post-stroke lower limb (LL) recovery, with a particular focus on walking and independent transfers, is often prioritised to facilitate hospital discharge (Connell et al., 2014a; Doyle et al., 2014). A recent longitudinal study by (Purton et al., 2023) concluded that the importance of UL recovery to people with stroke changes over time and that whilst the ability to walk is often a key initial priority post-stroke, the attention often turns to the UL once they had achieved improved walking ability. The focus being on impairment and functional recovery rather than individualising treatment intervention can impact community transition in people with stroke (Cott et al., 2007). It is important that, when UL dysfunction is present, how this influences social participant is taken into context (Cott et al., 2007; Poltawski et al., 2016) and that realistic expectations of recovery post-stroke are encouraged (Wiles et al., 2002).

In order to explore the findings of this service evaluation, the outcomes presented back to the clinicians working within this stroke pathway in order to validate the findings and following this explore further the thoughts, feelings and experiences of managing UL impairments in people with stroke with a further qualitative study (see Chapter 6). Whilst this service evaluation was conducted in one location, it is likely that there will be similar findings across other stroke pathways and the results are not just reflective of a moment in time at this particular NHS Foundation Trust.

5.5.5 Limitations

The Covid-19 pandemic had a significant impact on the timeframe for the notes review data collection. An advantage of the dates used was they were from a 'normal' non-pandemic time period and, therefore, representative of the stroke service during this timeframe (Jan–June

2019); services post pandemic might look different, and the data reviewed could well represent previous clinical practice. This needs to be taken into context when considering transferability to other stroke populations.

Medical record abstraction (MRA) (the process of a human manually searching through paper and electronic medical records) can produce inconsistent results, especially when it is from narrative data (Zozus et al., 2015). A systems theory-based framework has been developed to improve accuracy with key components being abstractor qualification and training (Zozus et al., 2015, 2019); and whilst this framework was not specifically applied to this service evaluation, a number of the components were incorporated, including the thesis author and second data extractor (for the purpose of the pilot study) being familiar with how data was recorded in the medical records. They also had experience in the clinical area where data was being abstracted, providing feedback about abstraction to the PhD supervisory team. The author situated themselves in a positive abstracting environment with minimal distractions.

Finally, on requesting batches of medical records, there were 186 files archived or in use; resulting in the final sample of 237 medical records. Whilst this was a large enough sample size to represent the time period, the missing 186 medical records might have added value to the outcome of this study.

5.5.6 Feedback to stakeholders and recommendations made.

Overall, it was clear from the documentation during the data collection period that the UL was not a focus in the acute and even subacute settings. Furthermore, this comprehensive review of the medical records highlighted that UL FES as a treatment modality for the management of the UL post-stroke was used infrequently and with limited evidence of justification in the clinical notes. This was disseminated to all key stakeholders with a full report submitted to the clinical effectiveness unit at the NHS Foundation Trust where the study was conducted (see Appendix **10.2.8**). The thesis author delivered a presentation of the findings from the service evaluation to the stroke leadership team and pathway managers at their quarterly meeting (see Appendix **10.2.9**). Following the presentation, there was a discussion led by the thesis author with the leadership team about how to further develop the management of the post-stroke UL within the stroke pathway. Future recommendations included:

- Develop workshops with clinicians across the stroke pathway to discuss the management of the post-stroke UL and develop a community of clinical practice.
- Identifying key UL champions from the clinical team to promote and highlight the importance of quality improvement in the management of the UL post-stroke.
- Consider the use of an appropriate outcome measure specific to the UL post-stroke. The suggested initial focus would be to implement the use the Fugl-Meyer Assessment for upper extremity (FMA-UE), as it is stroke-specific and a way of measuring impairment (Fugl-Meyer et al., 1975; Gladstone et al., 2002).
- Encouraging reflective practice among clinicians and fostering an inclusive learning environment to develop knowledge and skills relating to the management of the UL.
- Developing evidence-based resources/tools relating to the management of the UL post-stroke (to include technology to enhance rehabilitation and current clinical guidelines).

- A repeat of the service evaluation using the same data extraction tool as a measure to identify if there has been any development in the assessment and treatment of the post-stroke UL across the same NHS Foundation Trust stroke pathway.

On agreement with the stroke leadership team, the thesis author presented the findings of the service evaluation in the three key sites across the stroke pathway (acute, rehabilitation and community) (see Appendix **10.2.10**). This opened up the opportunity for clinicians to start discussing the management of the UL and their experience of this. Understanding the clinician's perspective about the management of the UL post-stroke is another aspect that helps to put into context the findings of this service evaluation.

5.6. Conclusion

The service evaluation clearly identified how the UL has previously been managed within the NHS Foundation Trust stroke pathway during the data collection timeframe; and it was apparent that the UL was not a priority in any of the stroke pathway settings but particularly the acute setting. It also highlighted that UL FES as a treatment modality has been utilised infrequently and with limited evidence of justification in the clinical notes. The focus of this study was to identify how and where clinical information about the management of the UL is documented within the medical records. This was important to set a baseline so that any change in clinical practice as a result of training and increased awareness of the importance of UL management by the clinicians is reflected in changes in the case notes across the stroke pathway at the next review (a further review was planned but it is not part of this study).

Although the primary data for this service evaluation was from 2019, the ongoing engagement with clinicians across the stroke pathway provides compelling evidence for the continued relevance and applicability of the findings. Since the completion of the initial data collection, the thesis author has facilitated and led the development of a community of clinical practice (CoCP) involving multidisciplinary stroke clinicians. This sustained collaboration has enabled a dynamic exchange of knowledge, experiences, and emerging challenges in stroke rehabilitation, particularly concerning post-stroke UL management.

Through workshops, and informal discussions within the CoCP, clinicians have consistently reported that the points highlighted by the medical-records review (based on data from 2019) remains pertinent to current practice. While these insights are primarily anecdotal, they are grounded in the lived experiences of experienced clinicians and reflect the ongoing realities of the complexities within stroke rehabilitation services. This iterative engagement process has not only anecdotally validated the original findings but has also highlighted the need for more robust guidance for the use of UL FES post-stroke. In summary, the integration of retrospective data with ongoing professional engagement ensures that this thesis is grounded in both empirical evidence and current clinical reality. This approach strengthens the validity and impact of the study, while also providing a robust foundation for future research aimed at improving outcomes for people with UL impairment post stroke.

Chapter 5 has provided evidence on how the UL post-stoke management has been documented however it is important to explore the perceptions of clinicians within the stroke pathway both to validate the findings and to understand how UL FES could be integrated into clinical practice; this has not been previously investigated and remains unclear. Therefore on the basis of the findings from this medical records review, the next study within this thesis aimed to understand the context from the clinicians involved in the management and treatment of the UL and identify the barriers and enablers to the use of UL FES within the stroke pathway in the future management of suitable people with stroke.

Chapter 6 Focus group activity across two NHS Foundation Trust stroke pathways exploring the views of therapists about the management of the hemiplegic upper limb post-stroke

This chapter presents a qualitative study that explored the views of therapists working within two large NHS Foundation Trust stroke pathways about the management of the hemiplegic upper limb (UL) post-stroke and the use of UL functional electrical stimulation (FES).

This work was accepted for poster and oral presentation at the International Functional Electrical Stimulation Society (IFESS) Conference, 1–3 September 2024, Bath, UK (see Appendix **10.3.1** and **10.3.2**)

Abstract

Background: A service evaluation highlighted that there was very little information documented in the medical records about how the post-stroke UL was managed in any part of the stroke pathway in a local NHS Foundation Trust. Rather than deduce that this accurately reflected the real-life situation, it was important to validate and further explore these findings using six focus groups in two NHS Foundation Trusts; three with clinicians working within the stroke pathway within the same NHS Foundation Trust, and a further three in another local NHS Foundation Trust stroke pathway. It was important to understand the views of clinicians within these areas of stroke services to be able to identify how the UL is currently managed and how UL FES could be integrated into clinical practice.

Aim: The aims of this study were to: 1) validate the findings from the previous medical records study; and 2) to explore physiotherapists', occupational therapists' and rehabilitation assistants' experience of how the post-stroke hemiplegic UL is managed in their own organisation, and their views on how UL FES might be integrated into the management of people with stroke.

Design: Semi-structured focus groups using a topic guide comprising open-ended questions to investigate the views and experiences of physiotherapists, occupational therapists and rehabilitation assistants working within stroke rehabilitation.

Setting: Two NHS Foundation Trusts within South Yorkshire were identified to conduct the focus groups. Institutional ethical approval was granted by the thesis author's university ethics committee (ref: ER44660174), with all participants providing informed written consent prior to the commencement of the study.

Participants: Six face-to-face focus groups (total participants n=37) were carried out with physiotherapists, occupational therapists and therapy assistants working within acute stroke units (n=13), rehabilitation units (n=11), and the community (n=13).

Data sources, extraction, and analysis: Discussions from the focus group were video recorded to aid the transcription process to identify speakers; non-verbal communication was not analysed as part of this process (purely verbatim transcription). Focus group recordings were transcribed by the thesis author, and themes were identified in NVivo (version 12) from the transcripts using thematic analysis (V. Braun & Clarke, 2006, 2021)

Findings: Three key themes were identified: barriers to UL management post-stroke, clinical challenges and use of UL FES in practice. Participant feedback revealed that: (1) Management of the UL post-stroke is not a key rehabilitation focus due to an emphasis on promoting mobility; (2) the key barriers to implementation of UL FES include a perceived lack of therapeutic contact time, a lack of confidence in its use across the stroke pathway and a clear perception that it is both complex and specialist; and (3) there is a desire to use UL FES education, however, further training to support clinical reasoning and application in practice is required.

Conclusions: Participants felt they need more education about UL FES, training to support their understanding of its application and more robust clinical guidelines to support application/translation into clinical practice.

6.1. Background

Effective treatment in the early stages post-stroke can have a positive impact on UL recovery (Harris et al., 2009). A number of studies have shown that FES can have a beneficial effect on UL motor recovery (Eraifej et al., 2017; Farmer et al., 2014; Howlett et al., 2015; Kristensen et al., 2022). Specifically, task-orientated UL FES may promote clinically significant gains post-stroke (Mann et al., 2011), and when combined with conventional therapy improves voluntary reaching and grasping (Marquez-Chin et al., 2017). Recent UK national clinical guidelines for stroke recommend consideration of UL FES in people with wrist and finger weakness post-stroke (ISWP, 2023). Despite the growing evidence base to support use of UL FES post-stroke, there is still minimal use within stroke rehabilitation services. The reasons for this lack of use remain unclear. The service evaluation of an NHS Foundation Trust stroke pathway outlined in Chapter 5 highlighted that there was limited documentation about the management of the post-stroke UL. It was clear from the documentation that the UL was not a focus in the acute and even subacute settings. Even when it was used, there was an absence of a clinical rationale for how, when or why to use UL FES .

6.1.1 Intensity in practice

The concept of increased intensity of UL movements has been highlighted, with a number of studies suggesting that an increased dose of targeted therapeutic input for the hemiplegic UL can lead to more meaningful gains (Lohse et al., 2014; Schneider et al., 2016). Despite recent clinical guidelines also indicating the need for increased intensity in rehabilitation post-stroke (ISWP, 2023), there are often numerous questions about how this can be achieved. A qualitative study exploring the perspective of nurses, therapists and people with stroke regarding the impact of self-directed UL rehabilitation clearly highlighted that there needed to be a shift in culture to encourage people with stroke to be more autonomous in the management of their hemiplegic UL post stroke (Chin et al., 2020). Queen Square Upper Limb Neurorehabilitation Programme (QSUL) (an NHS clinical service that provides 90-hours of therapy over three weeks to people with stroke with UL impairments) conducted a qualitive study to understand the perspective of clinicians and people with stroke that had experienced this 'intensive' UL management programme (Kelly et al., 2020). It identified that whilst the therapy programme was comprehensive, the improvements in recovery were due not only to the 'intensity' of the interventions, but also that the interventions covered both behavioural and psychosocial domains. It was worthy of further exploration within this focus group study, how this type of 'bespoke' programme of UL interventions, and others suggested within the current evidence base, could be applied within a stroke pathway. It was, therefore, important to understand the views of clinicians within these areas of stroke services to be able to identify how the UL is currently managed and how UL FES could be integrated into clinical practice.

6.2. Aim

The aims of this study were to: 1) validate the findings from the previous medical records study; and 2) to explore physiotherapists', occupational therapists' and rehabilitation assistants' experiences of how the post-stroke hemiplegic UL is managed in their own organisation, and their views on how UL FES might be integrated into the management of people with stroke.

6.3. Methods

6.3.1 Overview of study design and procedures

This study used a qualitative approach to gain comprehensive descriptions about the experiences and perceptions of staff working within stroke rehabilitation in a variety of locations across the stroke pathway. The focus groups allowed in-depth discussion and sharing of experiences and were used as the primary methods of data collection; they enabled the thesis author to capture views from staff with both shared and varied experiences in terms of location of trust and location of working within the stroke pathway (Duggleby, 2005; Flynn et al., 2018; Peters, 1993). Due to the large sample of staff across two large stroke pathways, it was also important to maximise staff time in the most efficient way whilst minimising disruption to the clinical working day; hence the decision not to conduct 1:1 interviews (Flynn et al., 2018; Hysong et al., 2013; Kitzinger, 1995; Parker & Tritter, 2006). The chosen methodology permitted the opportunity for staff to share their experiences with each other in a more discursive manner, which is a significant benefit of a focus group data collection method in comparison to a 1:1 interview. A semi-structured focus group topic guide was developed by the thesis author which was reviewed and approved for use by the PhD supervisory team (see Appendix **10.3.4**). The interview guide comprised open-ended questions to generate discussion around the following topics:

- Participants' experiences of managing the post-stroke UL in their particular work setting.
- Participants' views on treatment choices and whether this was underpinned by any clinical reasoning when managing the post-stroke UL.

- The use of adjuncts including FES in the management of post-stroke UL impairments.
- What might inform or support the use of UL FES in clinical practice.

6.3.2 Setting

Data was collected in the participants' workplaces (acute in-patient stroke unit, rehabilitation in-patient stroke unit and community rehabilitation services); and was arranged at their convenience.

6.3.3 Participants

A purposive sampling strategy was used across two NHS Foundation Trusts in South Yorkshire; key clinicians working across the stroke pathway were given the opportunity to participate in the focus group activity. Three focus groups were held within each NHS Foundation Trust, one for each location within the stroke pathway; i.e. 1) acute in-patient stroke unit; 2) in-patient rehabilitation stroke unit; and 3) community rehabilitation services. In order to gather meaningful data, and to be representative of the clinicians in the stroke pathway, the aim was to have an optimal overall sample size of n=15 (n=5 participants per location) per NHS Foundation Trust comprising a representative sample of clinicians from those services and from a variety of therapeutic backgrounds (physiotherapists (PT), occupational therapists (OT), and rehabilitation assistants (RA)). Participants were eligible if they worked within the stroke pathway and had experience of managing people with stroke. All individuals who expressed an interest in participating and met the inclusion criteria were included. Participants were provided with a study information sheet and given a minimum of 24 hours to consider their involvement prior to giving consent (see Appendix **10.3.5** and **10.3.6**).

In total, 37 (n=37) participants were involved in the focus groups; the sample comprised physiotherapists (62% (n=23)), occupational therapists (35% (n=13)) and a rehabilitation assistant (3% (n=1)). There were significantly more females (86% (n=32)) than males (14% (n=5)) within the total sample and there was no male representation in either the rehabilitation in-patient or community rehabilitation setting in Trust 1. There was a relatively equal spread of participants across the three stroke pathway locations (acute in-patient (35% (n=13)), in-patient rehabilitation (30% (n=11)), community rehabilitation (35% (n=13))); with overall more participants attending the focus groups from Trust 2 (57% (n=21)) compared to Trust 1 (43% (n=16)) with a greater representation in Trust 2 from both the acute in-patient and in-patient rehabilitation setting. (Full demographic details of the 37 participants and their location of work within the stroke pathway are listed in **Table 6.1**) Institutional ethical approval was granted by the University ethics committee of the thesis author (ref: ER44660174), and the research department associated with each of the NHS Foundation Trusts (Appendix **10.3.3**)

Table 6.1: Characteristics of focus group participants

Sample characteristics: n (%)				
	NHS Trust	**Work setting**	**Role**	**Gender**
	1: 16 (43) 2: 21 (57)	Acute: 13 (35) Rehabilitation: 11 (30) Community: 13 (35)	OT: 13 (35) PT: 23 (62) RA: 1 (3)	Female: 32 (86) Male: 5 (14)
Individual characteristics:				
ID	**NHS Trust** 1: Trust 1 2: Trust 2	**Work setting** Acute: Acute In-patient Rehabilitation: In-patient Rehabilitation Community: Community Rehabilitation	**Role** OT: Occupational Therapist PT: Physiotherapist RA: Rehabilitation Assistant	**Gender**
P1	1	Acute	OT	Female
P2	1	Acute	OT	Female
P3	1	Acute	RA	Female
P4	1	Acute	PT	Female
P5	1	Acute	PT	Male
P6	1	Rehabilitation	PT	Female

P7	1	Rehabilitation	PT	Female
P8	1	Rehabilitation	OT	Female
P9	1	Rehabilitation	OT	Female
P10	1	Community	PT	Female
P11	1	Community	PT	Female
P12	1	Community	OT	Female
P13	1	Community	OT	Female
P14	1	Community	PT	Female
P15	1	Community	PT	Female
P16	1	Community	PT	Female
P17	2	Acute	PT	Female
P18	2	Acute	PT	Female
P19	2	Acute	PT	Female
P20	2	Acute	OT	Female
P21	2	Acute	PT	Female

P22	2	Acute	OT	Female
P23	2	Acute	PT	Male
P24	2	Acute	PT	Female
P25	2	Rehabilitation	OT	Female
P26	2	Rehabilitation	PT	Female
P27	2	Rehabilitation	PT	Male
P28	2	Rehabilitation	PT	Male
P29	2	Rehabilitation	OT	Female
P30	2	Rehabilitation	PT	Female
P31	2	Rehabilitation	OT	Female
P32	2	Community	PT	Female
P33	2	Community	PT	Female
P34	2	Community	PT	Female
P35	2	Community	OT	Female
P36	2	Community	OT	Female

P37	2	Community	PT	Male
OT Occupational therapist; **PT** Physiotherapist; **RA** Rehabilitation assistant				

6.3.4 Data extraction

Participants provided written informed consent before the interviews commenced and reminded of their right to withdraw at any time without providing a reason for doing so. Discussions from the focus group were video recorded to aid the transcription process to identify speakers; non-verbal communication was not analysed as part of this process (purely verbatim transcription).

A focus group topic guide (see Appendix **10.3.4**) was developed by the thesis author and reviewed by the PhD supervisory team. This guide was used across all six focus groups; the topic guide was used to generate discussion about the management of the post-stroke UL and how UL FES could be used to augment practice to drive sensory-motor recovery.

6.3.5. Data Analysis

Thematic analysis (V. Braun & Clarke, 2006, 2021) was used to analyse the data from all six focus groups. The thesis author transcribed the data from the recordings, following which they were cross-checked and coded using NVivo (see Appendix 9.3.7). Initial themes were generated and categorised using the six-phase analytical process as outlined by Braun and Clarke (Byrne, 2022). To ensure rigour, and as part of the iterative process, the generated themes were reviewed by a member of the thesis author's PhD supervisory team. Once the focus groups' data was analysed, the themes were shared with the participants in order to verify the findings (V. Braun & Clarke, 2021). There were no follow up responses or comments generated by the participants on sharing the focus group findings.

6.3.5 Research quality and rigour

The thesis author is a female physiotherapist and has prior experience of conducting qualitative focus groups and managing the post-stroke UL. The thesis author's supervisory team also had experience of managing a post-stroke population and the use of assisted technology in stroke rehabilitation. The member of the supervisory team who was not a physiotherapist was chosen to review the transcriptions and generated themes. This decision was made as they had extensive experience in qualitative research methodology.

6.4. Results

The thesis author conducted all six focus groups using the approved semi-structured topic guide and the focus groups lasted between 58–65 minutes. One focus group session (Trust 2 Community) was conducted on Microsoft Teams at the request of the participants because of their diverse locations and lack of community base. Only one focus group had any rehabilitation assistant representation (Trust 1 Acute).

Thematic analysis highlighted three key themes and 11 sub-themes (see **Figure 6.1**). The three key themes were: (1) barriers to UL management post-stroke, (2) clinical challenges, (3) use of UL FES in practice. Participants' quotes were selected that accurately represented the themes identified in the data, whilst also ensuring representative feedback from all participants.

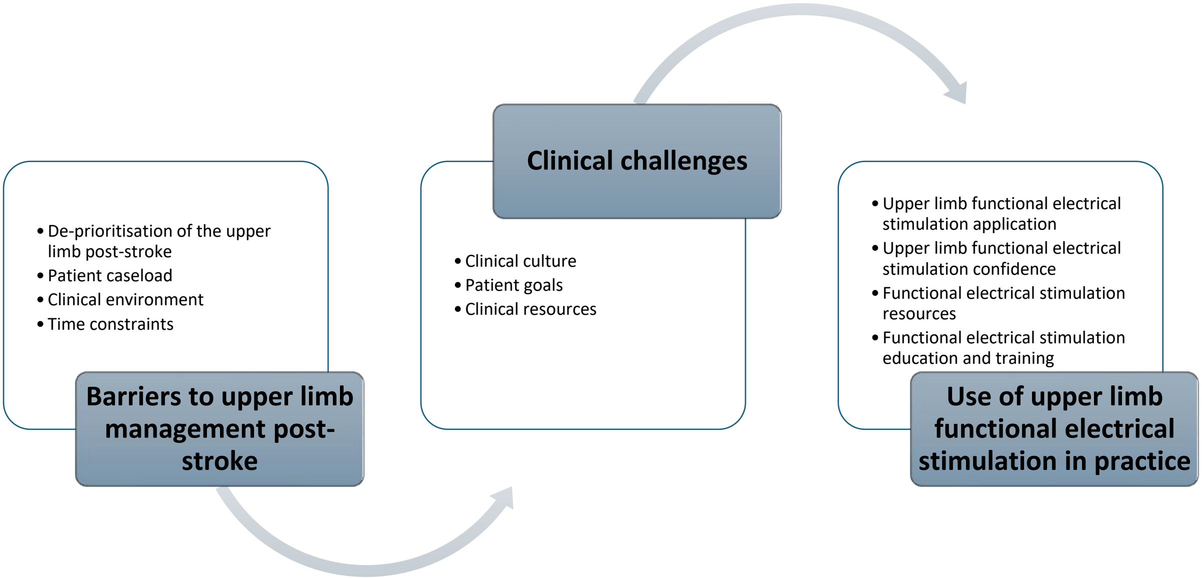

Figure 6.1: Developed thematic map, showing three main themes

6.4.1 Theme 1: Barriers to upper limb management post-stroke

All six focus groups highlighted barriers to UL management post-stroke. From this main theme, there were four sub themes (Figure 6.2); De-prioritisation of the UL post-stroke, patient caseload, clinical environment and time constraints.

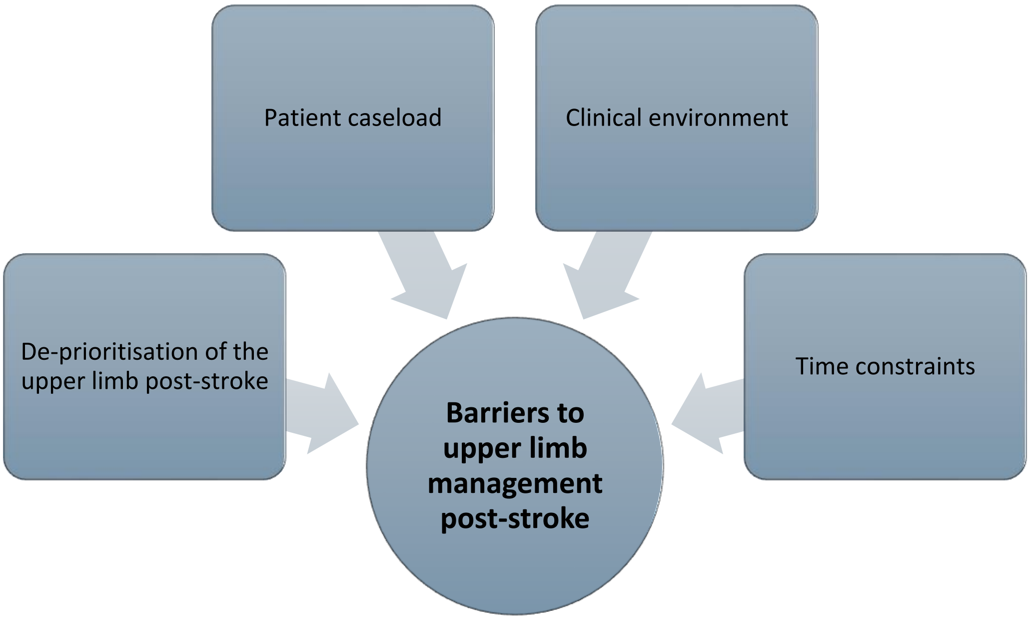

Figure 6.2: Theme 1 Barriers to upper limb management post-stroke and sub themes

- **De-prioritisation of the upper limb post-stroke**

Therapists working in acute stroke services identified that UL management in the acute setting is de-prioritised, especially in people with stroke that present with significant impairments. For instance, once therapist stated:

> *If I've got a more impaired patient it comes at the bottom of a list of a lot of things to do like, I might need to give them personal care and then get them to the gym and I know there's a drive to get them out into a chair or to be standing or to be able to mobilise in some way, so my focus would go there. And then I guess there would tend to be a nod towards something for the upper limb at the end…but a cursory nod…. But you know, it's an afterthought of the main driver of the session I suppose. (P5 T1 Acute).*

This impression of de-prioritisation of the UL post-stroke was further reinforced in Trust 2 rehabilitation setting.

> *The upper limb is not as high on the agenda as it should be. (P27 T2 Rehab)*

Despite this, it was evident in the acute setting that the clinicians were aware of the need for intensity of practice, however, they perceived that there were limitations to achieving this:

> *We are wanting to give more dosage and intensity to our patients, but it is impossible to deliver the amount of repetitions needed within your therapy session. (P17 T2 Acute)*

The discussion about dose of UL intervention was salient across all six focus groups and was not isolated to just the acute setting; in both NHS Foundation Trusts in the rehabilitation settings, it was identified that the UL has less time dedicated to it:

> *I think probably still less time is focused on the upper limb; within a standard physio session there is less time spent on the upper limb overall. (P6 T1 Rehab)*

However, in one rehabilitation setting, there was the perception that it was in the community where the UL had more focus:

> *I think there's a much bigger focus on upper limb in the community. (P6 T1 Rehab)*

Whilst in the community it was discussed that the key driver was a 'functional' approach and a blending together of both upper and lower rehabilitation, rather than a specific focus on the UL; with one participant stating that:

> *It's really hard to determine the minutes for the upper limb and the minutes for the lower because you're always dynamic and using both, trying to treat both as well at the same time. (P35 T2 Community)*

Anxiety about the management of the UL post-stroke was highlighted, especially in the acute and rehabilitation setting within Trust 2:

> *I know in our team meetings; I think there's often been quite a lot of anxiety around the upper limb. (P20 T2 Acute)*

- **Patient caseload**

It was identified that in the acute setting, time for rehabilitation is impacted by patient demographic, general workload and staffing within acute services:

> *I think it's just really subjective like, the demographic of the patients that are in at the time because if they're very much like single, kind of, you don't need the extra set of hands, but I'm freed up to do all the upper limb stuff. And I've gone through periods when I've just done upper limb, and I've thought… I've seen a lot of progress with people and all sorts of like sensory stuff but then we get a whole cohort of people who are totally different, need max assistance of two for everything. So that upper limb takes a back seat because you need the extra help just to get them into a chair or to get them in a better position in bed. (P3 T1 Acute)*

Severity of impairment was also highlighted by participants working in a rehabilitation setting across both NHS Foundation Trusts as a reason people with stroke might not be given UL self-management techniques.

> *I mean I would say probably the more severe people would probably not have as much of a self-management programme because they can't actually do it. (P7 T1 Rehab)*

In one of the trusts, it was highlighted that, in the acute setting, caseload varies with clinicians picking up different patients on a daily basis. It was identified that this was a perceived barrier to implementation of UL FES as there would not be continuity of patient care:

We don't always see the same patients each day. The timetable and we, I mean, there's positives and, you know, pros and cons to that, but we might not see that patient throughout their whole journey again. (P17 T2 Acute)

Furthermore, application of knowledge of UL FES was highlighted as impacted by patient caseload, especially when a clinician was not able to apply newly acquired knowledge following attending a relevant UL FES course:

*I came back from the functional electrical stimulation course in Birmingham, all enthusiastic, and then couldn't use it for months because of my caseload. (P26 T2 Rehab)***.**

- **Clinical environment**

The impact of the clinical environment was highlighted a number of times across both NHS Foundation Trusts. The impact that room availability, space and available equipment have on the ability to manage the UL was seen as a factor in clinical decision making:

I think sometimes the constraint of the environment makes us do the rehab to the best of our ability. (P17 T2 Acute)

It's the environment as a whole, even patients', sort of, almost, personal bed space isn't always conducive to rehab. (P18 T1 Acute)

This was mirrored by participants in the community, with one participant who strongly felt that the environment had such a significant impact that it could alter treatment progression or post-stroke outcomes:

You can have quite a different treatment progression or outcome even depending on the environment sometimes. (P15 T1 Community)

- **Time constraints**

Finally, time constraints were identified across all six focus groups as the main barrier to both UL rehabilitation post-stroke and the use of UL FES, despite clinicians being aware of the need for intensity in UL rehabilitation:

> *I've got people that I would love to use it with every day, but I literally just don't have time, because their goal is walking and stuff. (P7 T1 Rehab)*

> *Time is huge… I mean I think when you come onto FES. Time is the biggest barrier. (P10 T1 Community)*

> *It takes time to set up and requires a certain type of patient and a good environment, so all of that kind of makes me think I don't feasibly have time to do that. (P18 T2 Acute)*

> *So, I think I would really like to use some new techniques but in terms of time and cost it's quicker and easier to do what I've been doing already. (P32 T2 Community)*

6.4.2 Theme 2: Clinical challenges

Within the theme of clinical challenges all six focus groups discussed the impact of clinical culture, limited resources and patient preferences in terms of direction of their rehabilitation on the management of the UL post-stroke. From this main theme there were three sub themes (see **Figure 6.3**); clinical culture, patient goals and clinical resources.

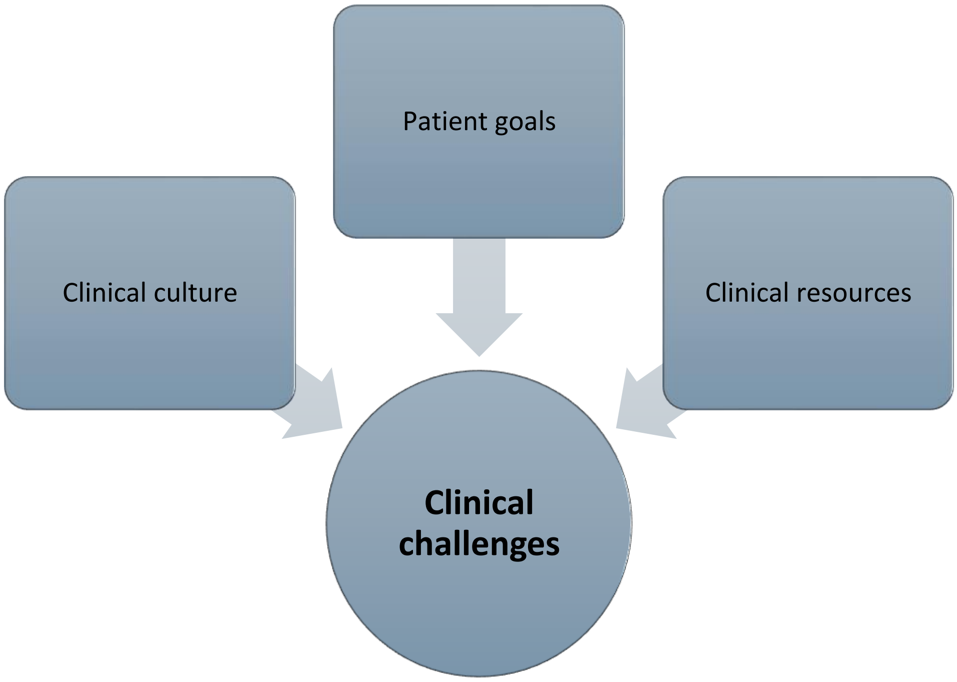

Figure 6.3: Theme 3 Clinical challenges and sub-themes

- **Clinical culture**

Staff described the impact of rotational staff within the stroke pathway and how this made implementing the use of UL FES challenging. The culture was described as one where it was easier, especially in the acute settings, to approach the UL management with a traditional 'hands-on' approach:

> *What I find really difficult is I get pulled into a hands-on where I want to enable them to do more functional task practice. (P5 T1 Acute)*

> *It's the follow through quite often with high numbers of rotational staff, the member of staff who was trying to instigate it then rotates into another area so it, kind of, falls by the wayside a little bit. It's, it's needing someone to take ownership of that and be able to keep it…and that's what I think we lack. There's not many people in our team actually that don't rotate. Upper limb functional electrical stimulation time to set up, so as soon as we're pushed then I feel like that is the bit that suffers and then it falls to just the sessions that I facilitate and not the bit where it could be self-managed. (P2 T1 Acute)*

It was also highlighted that patients transferring across or out of the stroke pathway influenced clinical reasoning and often clinicians could not see the value in commencing UL FES as they were unsure if it would be continued post patient transfer.

> *And I think the pathway thing does come in, if you've just decided "oh yeah, I could…I could do it" and then you get literally told that day, "oh, I've listed them for inpatient rehabilitation" then I do get a little…they're literally going to go to inpatient rehabilitation in a couple of day is there any point in me starting this? (P2 T1 Acute)*

Within this same discussion regarding transfers across the stroke pathway, one clinician in Trust 1 acute in-patient setting highlighted the relative ease by which UL FES would be discontinued if they felt that it was not being either effective or the person with stroke was not fully engaged with it as a treatment adjunct.

> *If I have one session that doesn't go very well…that the patient doesn't like it or they really don't like the sensation or they're not engaging with it well then, I'm quick to say "oh, you don't like it so we're not going to do it." And because I then find it very difficult to really talk them round because I've not seen it work. (P5 T1 Acute)*

There were concerns raised regarding technology enhanced rehabilitation by one participant in an acute setting and the fear that it could replace therapists:

> *The question is always "Is this going to replace therapists?" I think personally I like the idea of it facilitating but I think it should never come front and centre of a treatment. (P23 T2 Acute)*

However, in one focus group (T2 Rehab) the concept of technology enhanced rehabilitation, in particular the use of UL FES, was seen positively, with the view that it enabled patients to be more independent of therapists and more centrally engaged in their UL rehabilitation:

> *I guess it's the way of they are going to have therapy that's not dependent on massive engagement with another person sometimes. (P29 T2 Rehab)*

- **Patient-centred goals**

All six focus groups mentioned the importance of patient-centred goals, and that sometimes the patient's goals could limit UL rehabilitation and provide a challenge to clinicians attempting to shift focus to the UL. Across all settings, it was identified that the primary concern of the majority of people with stroke was often related to lower limb (LL) impairment with most patients wanting to focus on goals relating to independent walking. This was perceived by clinicians to be the primary reason why the UL post-stroke was given less attention during rehabilitation:

> *I find that a lot of patients (obviously it depends on the patient), but their like goal is to walk, if there, so then it does end up being that that is, they want to practise stands, practise walking, over and above the upper limb. Like you say, even if you explain the importance of it, it's just not their main priority. (P9 T1 Rehab)*

> *It depends on what the patient wants as well. A lot of our patients will prioritise mobility and lower limb stuff so if you spend a long time doing upper limb in a session then they will often say "why am I not doing something else?". (P14 T1 Community)*

- **Clinical resources**

Whilst all focus groups identified the need for increased prioritisation of UL rehabilitation, post-stroke clinical resources were identified to be a further barrier to UL management post-stroke. One participant mentioned that clinical resources were being directed at UL rehabilitation, but the Covid pandemic impacted the implementation of these plans:

> *We identified a lot of upper limb teaching and educational priorities just prior to COVID…got a full teaching plan for that and…it didn't happen because of COVID. (P2 T1 Acute)*

In the community setting, resources were highlighted as being stretched and clinicians felt the involvement of the family was necessary to enable UL rehabilitation success:

> *It comes back to resources as well, how much involvement…how much the patient can do themselves, how much family can be involved. (P12 T1 Community)*

Finally, staffing was raised as needing significant investment alongside developing educational and clinical resources to enhance post-stroke delivery:

> *And I think the other thing, talking about along the lines of investment is…guidelines are developed for the management of various conditions…of course there's stroke guidelines out there, with new guidelines of intensity, they've had guideline out for a few years about what the staffing capacity should be within a stroke team, despite going back to commissioners and saying, "we're short by this much on every area", to then be told "just work smarter", it…yeah. So, it's a challenge, when you ask about intensity, we could be doing more, and we could be seeing our patients a lot sooner, but you need the investment in the workforce to support that. (P33 T2 Community)*

6.4.3 Theme 3: Using upper limb functional electrical stimulation in practice

Within the theme of using UL FES in practice all six focus groups highlighted concerns regarding its application. From this main theme, there were four sub themes (**Figure 6.4**); UL FES application, lack of confidence in using UL FES, functional electrical stimulation resources and UL FES education and training.

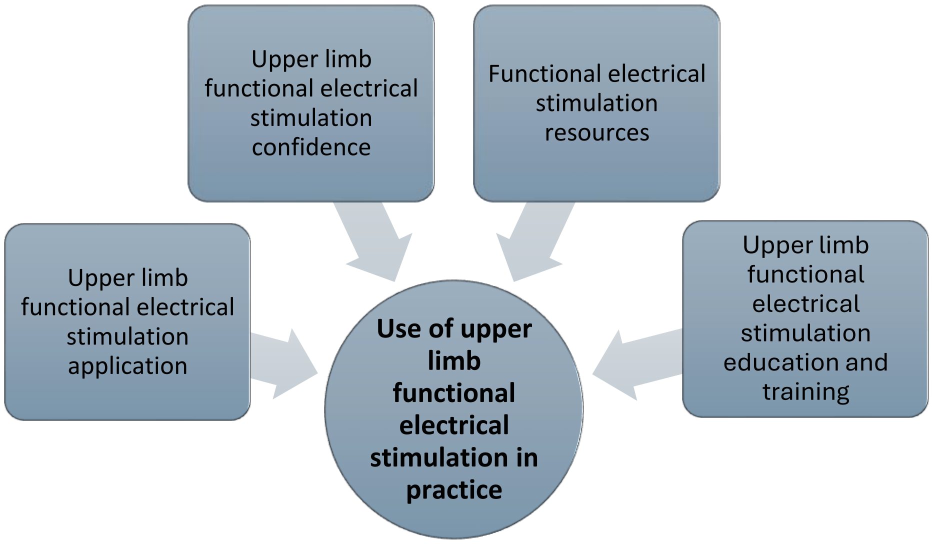

Figure 6.4: Theme 2 Using UL FES in practice and the sub- themes

- **Upper limb functional stimulation application**

Therapists indicated that UL FES set up time was a factor in not choosing it as a treatment intervention in the management of the post-stroke UL despite awareness that it could positively impact recovery.

> *My experience of using it is it needs to be quite personalised, and it takes time to set up and requires a certain type of patient and a good environment so all of that kind of makes me think I don't feasibly have time to do that so I'm going to focus on other bits. (P5 T1 Acute)*

> *It doesn't look very good in front of a patient if you spend 30/40 minutes trying to set up an FES unit. They lose confidence in you. (P14 T1 Community)*

Apprehension with being able to clinically reason UL FES was identified across all areas of the stroke pathway. This included identifying suitable people with stroke that might benefit from it, with participants stating:

I wouldn't even know where to start. I wouldn't. I don't think I'd know how to identify if a patient would be appropriate for it. (P21 T2 Acute)

I think if we felt more confident and competent and able to identify patients, I think we would be using it more…we would feel more confident with it. (P15 T1 Community)

Therapists also described feeling under confident with application because of limited experience in applying UL FES and the fear of just trying it.

I feel like apprehensive just because I haven't done it enough. (P18 T2 Acute)

Specifically reasoning where to stimulate in a complex weak UL presentation was discussed with therapist highlighting feeling overwhelmed because of the complexity of the UL and their concerns with a lack of understanding about how to accurately generate functional UL movement using FES:

I find that really difficult in the early stages when I'm using functional electrical stimulation with someone with a really weak upper limb, like how to incorporate that function because there's so much needs stimulation. (P4 T1 Acute)

In one NHS Foundation Trust specifically, there were discussions in both the acute and rehabilitation setting of the desire to just 'give it a go', especially if other strategies for UL management had not been successful as a means to supplement UL activity, especially in the more impaired people with stroke:

I do default to a little bit of, I've tried everything else and nothing else is working so might as well "give it a crack"…rightly or wrongly. (P2 T1 Acute)

I tended to use it with patients where they had a bit of activity…like to supplement the activity that they've got, whereas now I'm using it for patients with not a lot of activity at all. As well and just giving it a go. (P6 T1 Rehab)

Whilst this was not highlighted in the second NHS Foundation Trust, there was a more positive culture exposed in terms of UL FES application and technology enhanced rehab overall.

It feels the right thing to do for the patients. (P25 T2 Rehab)

I think our patient groups changing, unfortunately, there's lots of younger people that are having strokes. I think they're quite keen to use technology and I know I often have patients that say, so what can I do before you come again? What can I do while you're not here. (P28 T2 Rehab)

- **Lack of confidence in using upper limb functional electrical stimulation**

When discussing application of UL FES, therapists indicated their lack of confidence in its use. Confidence issues were linked to a number of factors. Firstly, lack of 'formal' functional electrical stimulation training was discussed by one clinician and within that focus group the other participants agreed with this statement:

I don't feel confident in doing it. I've never properly been *trained to do it. It's always like observing somebody else doing it. (P1 T1 Acute)*

There was a clear perception that observation in practice was not enough and a 'formal' UL FES training session external to the clinical area was required. This was reinforced in one of the focus groups where it was stated that a standard operating procedure (SOP) for FES application was in place, which stipulated that FES could only be applied by a clinician who had attended an approved FES training programme. Interestingly, it was further discussed in one of the focus groups that, despite other forms of post-stroke rehabilitation being attempted by clinicians who had only observed their use, e.g. mirror therapy or taping, they did not feel this was appropriate for an 'electrical' technology such as functional electrical stimulation, and that 'formal' training to ensure safety was required.

> *I feel slightly edgy just generally about functional electrical stimulation because it's electrical. (P5 T1 Acute)*

> *I think the reason is really because there just feels like a risk of harm with applying functional electrical stimulation. I know they are only fairly low frequency and stuff but applying a modality to somebody like that when you don't really feel like you know what you're doing – if you're not 100% clear on what the precautions are and things you just feel like there's a real increased risk and I think that's probably why we all need to feel quite sure and be clear that we're competent before we use it with patients. I think that's why we kind of feel under confident and protective in not wanting to do any harm. (P11 T1 Community)*

Another area of confidence was related to how the clinicians were perceived by their patients when applying UL FES. Therapists who were working, or had worked in the community, discussed concerns regarding feeling 'foolish' in front of patients when applying FES. They specifically stated they struggled with the application of UL FES and they worried about the lack of confidence the patient would have in them if they did not successfully apply it in a timely manner during the session:

> *It's harder in community I think, because when I've tried to use it in community…if you're just failing to get the right set up, you feel like such an idiot. You've gone all that way, wasting the patient's time. (P6 T1 Rehab)*

> *I wouldn't feel confident implementing functional electrical stimulation (alone) as a single professional during the patient care. (P11 T1 Community)*

Frequency of UL FES application was also identified as a concern that impacted clinician confidence and perceived competence across all six focus groups. This was highlighted by clinicians to be an issue, especially when working in a community location where there is no immediate support or other colleagues to discuss the FES application with:

> *I think you need to able to use it regularly as well to keep confidence. I think confidence of people is the biggest thing. Because I'm sure in the community, that is the main reason why people don't use it. (P6 T1 Rehab)*

> *I'm a physio and I don't feel confident and competent to set it up. I've used it in the past but because we've used it so infrequently, I've always had someone come and set it up and once its set up I can kind of run with it but then I don't use it for so long that I've forgotten how to set it up (and all the machines are slightly different), so yeah, it's not something I use on my own. (P14 T1 Community)*

Finally, therapists discussed at length that, whilst training and frequency of application impacted confidence in the use of UL FES, the primary influencing factor was lack of understanding about how to apply it in the first place, and that this would be a barrier to even attempting UL FES in practice. This included underpinning knowledge of UL anatomy, application of FES electrodes and use of specific FES machines:

> *I think when you're picking, not picking an intervention, deciding whether its suitable to use for a patient, then maybe, its maybe not considered because people aren't sure whether it would work with certain patients. And then just actually, where to put the pads…actual use of the machine. (P7 T1 Rehab)*

Two occupational therapists within the same acute focus group reported that, in their experience, their OT colleagues would not even consider UL FES if they were under confident and that this was often influenced by their level of UL anatomy knowledge and/or exposure to UL anatomy within their undergraduate OT course:

> *A comment from one of our band 5s she did not feel like her anatomy was good enough…to be able to justify it on her own and really feel confident in the placement of the pads. (P2 T1 Acute)*

People don't even get the chance to start an FES programme because they've got an OT who isn't confident using it, so they'll try everything else instead. Or don't even consider it. (P8 T1 Rehab)

They also added that FES was often seen as a physiotherapy treatment and this opinion was echoed in the second NHS Foundation trust and again linked to level of UL anatomy. Lack of opportunity was also cited as a barrier because of the perception that UL FES was more the domain of a physiotherapist:

Physios have probably got more knowledge of anatomy and physiology, and that kind of thing; but I think we've probably not always had the opportunity. (P29 T2 Rehab)

- **Functional electrical stimulation resources**

Availability and cost of FES equipment were issues for most clinicians within both NHS Foundation Trusts:

If we had that access to them, I think we'd be inclined to use them more frequently, we just don't have the resources available. (P13 T1 Community)

Clinicians indicated they felt responsible if the resources were not available and did not feel there was any point in upskilling staff to use UL FES if there wasn't an investment in both staffing and FES equipment in order to regularly carry it out:

I think, as well, again it's like down to resources. So, what you don't want to do is…try functional electrical stimulation with someone once and then not have the resources or staffing availability to then carry it out. (P9 T1 Rehab)

I do think we need to look at resources as though because in some ways there's no point training or increasing knowledge of it if we haven't still got the resources to use. (P10 T1 Community)

The desire to have 'parity' of intervention experience across the stroke pathway was clearly highlighted. It was evidenced that this parity in terms of UL intervention could be managed with 'traditional' approaches to UL rehabilitation but not necessarily when a 'technology'-based intervention (functional electrical stimulation or otherwise) was involved. FES in one of the two NHS Foundation Trusts required an additional piece of written work to be submitted to rationalise UL FES intervention over other forms of intervention that had no associated extra costs.

> *It's the funding stream, so you have to do an additional piece of work to give a rationale why they would be appropriate for upper limb functional electrical stimulation because it's not considered as a standard treatment. (P27 T2 Rehab)*

And whilst not the primary reason for not applying UL FES in the acute setting, it was clearly stated that the cost of the electrodes impacted decision making about attempting to use it if there was any possibility about the viability of it working or having an impact.

> *I'm still a bit twitchy about using it "willy nilly" because of the cost of the electrodes. (P4 T1 Acute)*

- **Upper limb functional electrical stimulation education and training**

All six focus groups were keen for wider UL FES education and training. Discussions about how this learning could be facilitated were aligned to how therapists learn in clinical settings and supported earlier conversations from the focus groups about confidence in UL FES application, and clinical knowledge of the post-stroke UL. There was a desire to have more promoted guidance to support the use of FES and to include specific information about UL FES application, optimal frequency, and dosage:

Something to facilitate somebody's own learning but prompted. (P19 T2 Acute)

Something that guides a little bit… that facilitates somebody's own learning, so there is a little bit of directed learning in there as well… and that's kind of "prompted". A guide to upper limb functional electrical stimulation application…. Definitely about something within there in terms of dosage and frequency. (P2 T1 Acute)

An understanding when functional electrical stimulation is to be utilised, you know what muscle groups should be used or simulated; even just basic upper limb anatomy. (P29 T2 Rehab)

Two participants identified that they thought UL FES clinical guidelines would be helpful with suggestions about how these could be formatted or presented to support clinical application in the post-stroke population:

I think we need clinical guidelines really. (P11 T1 Community)

More practical-based guidelines would be helpful. With diagrams and ideas for progression. (P6 T1 Rehab)

Finally, a bigger picture was addressed in terms of bringing together training and resources in a timely manner. A wider community of practice was touched on by one participant, with some practical considerations about how application of UL FES could be approached to support clinicians and build confidence in the wider management of the post-stroke UL:

I think it's looking at the internal and the external kind of support network as and I think as external is definitely looking at external training and thinking about us being involved in that. But I think as a team it's thinking about maybe how we approach that in terms of the delivery and kind of the in-service training that maybe we offer and keeping up to date with that from an upper limb management. (P25 T2 Rehab)

6.5. Discussion

The aims of this study were to validate the findings from the previous medical records study, and to explore physiotherapists', occupational therapists' and rehabilitation assistants' experiences of how the post-stroke hemiplegic UL is managed in their own organisation, and their views on how UL FES might be integrated into the management of people with stroke. Clinicians reported that there were numerous barriers when it came to prioritising treatment of the UL (especially in the acute setting), and the application of UL FES. Although the appetite to use technology and address the use of UL FES was clear; especially in the in-patient rehabilitation and community settings of the stroke pathway; as a means to increase dose in people with stroke.

From the key themes identified (barriers to UL management post-stroke, clinical challenges and use of UL FES in practice) on analysis of the focus group discussions across both NHS Foundation Trusts participant feedback revealed that:

1) Management of the UL post-stroke is not a key rehabilitation focus due to an emphasis on promoting mobility.
2) The key barriers to implementation of UL FES include a perceived lack of therapeutic contact time, a lack of confidence in its use across the stroke pathway and a clear perception that UL FES is both complex and specialist.
3) There is a desire to use UL FES education, however, further training to support clinical reasoning and application in practice is required.

These points are discussed individually below.

6.5.1 Management of the upper limb post-stroke is not a key rehabilitation focus due to an emphasis on promoting mobility

It was evident from the focus group discussions that, despite the awareness and understanding, the UL post-stroke requires input that this is de-prioritised because a greater emphasis is placed on promoting mobility in people with stroke. This was justified in Trust 1 rehabilitation setting by suggesting that there was a greater focus in community settings on UL rehabilitation. However, this comment was not quantified, and on reviewing data from the community setting in both Chapter 5 and the data generated from both T1 and T2 community settings focus groups this did not appear to be the case. What was apparent in the community setting was clinicians discussing taking a more 'functional' or 'whole body' approach rather than a specific UL focus.

A potential key clinical challenge to the management of the UL post-stroke is clinicians actually having a robust understanding of services across the stroke pathway they are working in; including where the UL has the potential to be actively prioritised and managed. Whilst recent clinical stroke guidelines have highlighted that UL FES could be a treatment option in suitable people with stroke and that intensity is a key factor in post-stroke rehabilitation (NICE, 2023), it must be noted that it is unlikely that these recommendations alone will elicit a change in clinical practice, and awareness of the pressures on clinicians to simply *'do more'* must be considered. When reflecting on the findings from this study, the clinical culture within both NHS Foundation Trust stroke pathways needs to be addressed and a whole pathway approach is required to promote the management of the UL post-stroke in order to minimise active de-prioritisation of UL activity in favour of mobility.

6.5.2 Key barriers to implementation of upper limb functional electrical stimulation include a perceived lack of therapeutic contact time, a lack of confidence in its use across the stroke pathway and a clear perception that upper limb functional electrical stimulation is both complex and specialist.

The findings from this study have clearly identified that the key barriers to UL FES implementation include time limitations, limited resources and clinicians' concerns over lack of UL FES application knowledge. This aligns with findings from a qualitative study exploring Canadian therapists' use of FES post-stroke which identified that FES is not widely used due to lack of both knowledge base and resources (Auchstaetter et al., 2016). Participants across the stroke pathway discussed a desire to have access to more UL FES education and training to support clinical reasoning and use of UL FES with appropriate people with stroke. Barriers to implementation were further highlighted by Musselman et al. (2024) who developed a training package to support therapists' learning needs relating to FES application to attempt to mitigate barriers and increase adoption in clinical practice.

Limited clinical contact time across the stroke pathway was highlighted as another significant barrier to implementation of UL FES (especially in the acute rehabilitation settings). Time for UL rehabilitation is a frequently identified challenge post-stroke (McLaren et al., 2020; Meadmore et al., 2019) and this initiated conversations about conventional 'hands-on' approach to rehabilitation in comparison to use of technology. There was a perception that, despite wanting to engage people with stroke to be independent in their management of the UL in order to drive recovery, it was almost easier to stick to conventional hands-on treatment. This could be because there was a bias towards traditional therapeutic input due to it being embedded in clinical culture, or that clinical reasoning was easier to justify coupled with participants' perception that UL FES application was time consuming. As previously identified, FES set up time is considered to be a barrier to implementation (Auchstaetter et al., 2016). Although increased use can enable a clinician to become more efficient at setting it up, it is acknowledged that further research to reduce set up time, especially with more complex systems, is needed (Sun et al., 2018).

Lack of knowledge and skill in FES application is widely accepted as a significant barrier to therapists use of UL FES. It is known that increased confidence and knowledge translates to increased use of FES in clinical practice (Musselman et al., 2024). Whilst knowledge was a key point highlighted throughout the focus groups, there was also a discussion about FES being a form of electrical equipment and the perception that it could possibly cause harm and was, therefore, deemed more complex and specialist than other forms of UL intervention. It was apparent that this anxiety relating to FES application negatively influenced clinical confidence and it being considered a viable treatment option in the management of the UL. Clinicians' learning is often enhanced by professional skills development and application in practice (Knecht-Sabres, 2013; Snowdon et al., 2020) and there is a possible correlation that needs further exploring relating to lack of support and supervision with UL FES application in clinical practice perseverating the lack of UL FES confidence and use.

In one NHS Foundation Trust specifically (Trust 1), there were discussions in both the acute and rehabilitation setting of the desire to just 'give it a go' if other strategies to UL management had not been successful as a means to supplement UL activity, especially in the more impaired people with stroke. Interestingly, this did not correspond with the findings from the medical records review (Chapter 5) as UL FES was rarely utilised and there was documented evidence of complex UL impairment in people with stroke. However, in terms of the application of UL FES in a more impaired UL post-stroke presentation there is documented evidence that, with the severely impaired UL post-stroke population, FES can make a difference to functional recovery (O. A. Howlett et al., 2015; Sousa et al., 2022). This highlights that the clinicians are considering application of UL FES with suitable people with stroke; however, the question remains, why is this only being considered when other treatment methods have been ineffective? Why is UL FES not a more widely-adopted treatment method of UL impairment post-stroke? The focus group discussions illuminate similarities across both NHS Foundation Trusts with the primary reason for lack of clinical application being confidence in the use of UL FES and the perception that it is both complex and specialist.

6.5.3 There is a desire to use upper limb functional electrical stimulation education, however, further training to support clinical reasoning and application in practice is required.

Increased understanding of neuroplasticity has positively impacted development in terms of FES (Marquez-Chin & Popovic, 2020). However, UL FES is still underused in clinical environments, often due to lack of understanding about application and optimal window for therapeutic use (Sousa et al., 2022). In agreement with previous research findings, there was a confirmed lack of use of UL FES within the previous medical records review (Chapter 5) and in both NHS Foundation Trusts this was reinforced in discussions within the individual focus groups. The availability of educational resources and opportunities for clinical application would, therefore, likely benefit the translation of this technology into clinical practice (Brown et al., 2024; Tedesco Triccas et al., 2023). It has already been identified that postgraduate experience with FES influences application (Auchstaetter et al., 2016) and that continued professional development (CPD) is integral to how clinicians develop and maintain their clinical knowledge and skills (Gunn & Goding, 2009; Musselman et al., 2024). Participants across the six focus groups were clearly stating they did not have enough knowledge or understanding of UL FES to utilise it in the management of the post-stroke UL. This reported lack of knowledge, combined with existing environmental barriers, such as limited treatment space and lack of suitable equipment, creates a 'perfect storm' that hinders the implementation of UL FES post-stroke.

This study contributes to the understanding that there is a need for an approach to implementation of UL FES across the stroke pathway. There needs to be an increase in resources (educational and physical) and ultimately an element of clinical behaviour change to influence adoption and implementation. It is clear from the findings of this study that clinicians will find it challenging to consider UL FES without this; and whilst a co-design of suitable materials would be a valuable approach in the long term to make sure that any developed resources are supportive of learning needs and preferences, there is a more pressing need for an expert-informed clinical guidelines for the application and use of UL FES. Once this has been established then a framework for implementation of UL FES can be developed and this will support clinicians to invest in upskilling and implementing UL FES in clinical practice.

6.5.4 Limitations

A limitation of this study was the lack of rehabilitation assistant representation and the high proportion of physiotherapists in comparison to occupational therapists (OTs) and rehabilitation assistants (RAs); OTs and RAs could have failed to register an interest in this study because of a pre-conceived opinion that UL FES was more of a physiotherapeutic treatment strategy (as highlighted by P29 T2 Rehab) and, therefore, in a focus group setting this might have raised concerns about their ability to actively participate in any discussions. Furthermore, whilst the most suitable time was sought by the thesis author prior to committing to a schedule for the focus group, the impact of this must be taken into consideration as wider representation might have been gained under different circumstances.

The Lincoln & Guba evaluative criteria (Lincoln et al. 1985) could have been used to reflect on the limitations (and strengths) of this study. Whilst techniques to establish credibility of the data collected were used including prolonged engagement and verification of findings there were missed opportunities to produce thicker descriptions to achieve both external validity and transferability of the resulting conclusions. Furthermore the use of an independent researcher to audit the processes would have enhanced dependability.

6.6. Conclusion

These findings substantiate those in other studies that the post-stroke UL is not the main priority for therapy in the acute or even sub-acute setting and the intensity of UL intervention is markedly less than what is likely to be effective (Stockley et al., 2019). This is often due to the emphasis on promoting recovery of mobility and the pace of discharge. Despite the robust national clinical practice guidelines (ISWP, 2023; NICE, 2023), stroke clinicians identified they were still unsure how to clinically reason and effectively apply UL FES in the post-stroke population. Confidence in application of UL FES was cited as a significant reason it was not regularly used by clinicians, in spite of a clear appetite to do so. Clinicians could identify the benefits of UL FES to support sensory-motor recovery post-stroke and highlighted the need for more clinical practice-based guidelines and further training in its use.

This Chapter has provided some of the first documented insights into clinicians' perspectives about the practical use of UL FES across the stroke pathway and clearly identified the perceived barriers to implementation in a real world clinical setting. However, with limited detailed guidance in the current evidence base as identified in the systematic review (Chapter 4) further research is required to inform clinical reasoning and support post-stroke UL FES implementation. Due to the lack of knowledge and clinical expertise in the use of UL FES as identified from both the service evaluation (Chapter 5) and the focus group activities (Chapter 6) the following chapter will employ a Delphi method to gain expert consensus on the application of UL FES post-stroke. The findings from the Delphi study will support the development of post-stroke UL FES clinical practice guidelines.

Chapter 7 Post-stroke upper limb functional electrical stimulation clinical practice guideline development: an international Delphi study

This chapter outlines the Delphi study used to gain consensus, underpinned by findings in Chapters 4–6, on the application of post-stroke upper limb (UL) functional electrical stimulation (FES). The findings of this chapter have supported the development of post-stroke UL FES clinical practice guidelines.

Abstract

Background: Whilst the application of UL FES has been highlighted and recommended in the recent stroke guidelines (NICE, 2023), clinical implementation remains problematic, and it is evident that, in the UK, UL FES is not widely used in stroke rehabilitation.

Aim: To inform best practice in the use of UL FES in the management of people with stroke and to inform clinical guidelines by seeking expert consensus on (i) the factors that influence application of UL FES in people with stroke; (ii) how a broad range of post-stroke UL presentations influence clinicians' decisions on the application of UL FES; (iii) treatment adjuncts and/or exercises used alongside FES in the management of the post-stroke UL.

Methods: A three-round online Delphi method was employed and people working with FES both clinically and/or in a research capacity and experts in UL rehabilitation were invited to participate. In round one, participants answered ten open-ended questions based on the current evidence base and best practice. Responses from round one were analysed using reflexive thematic analysis. In rounds two and three, participants rated statements using a four-point Likert scale and measures of collective agreement or disagreement were calculated.

Results: Twenty-one (n=21) expert participants completed round one, nineteen (n=19) round two, and seventeen (n=17) round three. Responses from round one resulted in ninety-four (n=94) statements about best UL FES practice across four dimensions: (1) clinical presentations of people with stroke; (2) UL FES application; (3) treatment progression; (4) treatment evaluation.

Following round three, in total eighty-seven (n=87) statements (out of ninety-four (n=94) in round one) across four domains had agreed consensus (clinical presentation of people with stroke: n=23; UL FES application: n=39 ; treatment progression: n=15 ; treatment evaluation: n=10).

Conclusion: This study established consensus on the practical clinical application of post-stroke UL FES and the findings of this consensus will support the development of UL FES clinical practice guidelines.

7.1. Introduction

The previous chapters in this thesis have gathered information on both the current clinical environment across two NHS Foundation Trust stroke pathways and the views of stroke clinicians working in those services, in particular factors that influence the management of the hemiplegic UL post-stroke. The findings from Chapters 4–6 highlighted the need to gain consensus from a broad sample of experts who worked in the clinical field of post-stroke UL management and who used FES; specifically on which people with stroke could potentially benefit the most from the use of UL FES, how it should be applied to a broad range of UL impairments, how and when treatment should be progressed and evaluated.

An evidence review was undertaken (see Chapter 4) to explore the current evidence base in terms of application of UL FES and it concluded that there was a lack of detail relating to the specific application detail although rigour on the included studies varied. The studies included did not provide extensive detail about the type of UL impairment and the clinical reasoning or justification for the FES application used (i.e. duration, progression of treatment intervention and recommendations).

Experiential knowledge and the clinical expertise of therapists working in two large NHS Foundation Trust stroke pathways in Chapter 6 emphasised that the management of the UL was not always a priority and that clinicians lack confidence in the application of UL FES primarily because they perceived the need for specific training and further application guidance. These recommendations provided rich insight into both the current clinical environment and the thoughts and feelings of clinicians' working in stroke pathways. From this body of research it was apparent that further work was needed to inform development of a clinical guideline that could have impact in supporting clinical reasoning of the application of UL FES in individuals with UL impairments post-stroke.

Delphi methods have been used previously to gain consensus where there has been a limited evidence base. (Hasson et al., 2000; Jorm, 2015). The Delphi method has a variety of iterations, but typically consists of a sample of subject experts responding anonymously to a series of iterative questionnaires, with feedback used between rounds to reach consensus among the group (Hasson et al., 2000). Two LL FES clinical practice guidelines to support walking in individuals with neurological impairments have recently been developed (Bulley et al., 2024; Johnston et al., 2021), one of which was developed using a Delphi methodology to provide expert consensus on best practice (Bulley et al., 2024; Queen Margaret University & Association of Chartered Physiotherapists Interested in Neurology [ACPIN], 2022). The Delphi methodology is widely regarded as a robust consensus-building technique in health research and unlike other in-person consensus techniques such as the Nominal Group Technique (NGT) the Delphi method ensures particiants' responses are anonymous and therefore allows for more independent and honest opinions from participants reducing the risk of bias. A contributing factor that influenced the decision to utilise a Delphi methodology included the fact that being that Delphi methods can be conducted remotely this would enable the inclusion of experts from diverse geographical locations broadening the expertise base and enhancing the generalisability and credibility of the consensus reached.

7.2. Aims and Objectives

This chapter's aim was to gain expert opinion on the application of UL FES post-stroke. In particular, consensus was required on:

(i) clinical presentations of people with stroke.

(ii) upper limb functional electrical stimulation application.

(iii) treatment progression.

(iv) treatment evaluation.

The findings from this consensus study will inform the development of clinical practice guidelines for the use of UL FES post-stroke.

7.3. Methods

7.3.1 Research design

The Delphi is a structured process based on a series of 'rounds' where experts respond/rate non-leading, unambiguous statements using a Likert scale (Vogel et al., 2019). The primary reason for choosing a Delphi approach over other guideline development approaches was to incorporate the 'voices' of a variety of post-stroke UL FES experts on its use and application.

The study adopted an online Delphi approach consisting of three iterative rounds (Holloway, 2012). The current Guidance for Reporting Involvement of Patients and the Public (GRIPP2) guidelines evidence base was used to develop the short answer questions used in the Delphi round one (Staniszewska et al., 2017) (Appendix **10.4.1**: diagrams of mind maps). The short answer questions from round one were qualitatively analysed, and the data was used to develop short statements for the following rounds. The overall Delphi study process was underpinned by a pragmatic approach (Jason & Glenwick, 2016), with the author placing the research aim centrally. Following guidelines for the development of a pragmatic Delphi inclusion/exclusion criteria for selecting experts, number of rounds, threshold for consensus and analysis method were all agreed prior to commencing the data collection phase (Iqbal & Pipon-Young, 2009).

7.3.2 Panel selection

Three types of experts were recruited for participation in this Delphi study. These were defined as (i) people working with FES clinically, (ii) people working with FES in a research capacity, and (iii) experts in UL rehabilitation. These groups were specifically targeted for inclusion in the study given their expert knowledge of UL FES and their ability to apply research findings from their work. Renowned FES and UL experts were specifically targeted for inclusion in the study from across the globe. Participants who fitted more than one of the categories were required to indicate their 'primary' affiliation at the start of the questionnaire process (Delphi round one). A purposive sampling strategy was used selecting from clinical networks, Research Gate, and two specialist interest groups (Association of Chartered Physiotherapists interested in Neurology (ACPIN) and the International Functional Electrical Stimulation Society (IFESS)) with the aim of recruiting a group of 'experts'. To be eligible to participate in the study at the time of recruitment, eligible participants had to have a minimum of three years' experience working with functional electrical stimulation in a clinical or research capacity and/or have a minimum of three years' experience working in UL rehabilitation specifically (**Table 7.1**). Anyone interested was asked to contact the lead researcher by email and was then sent participant information.

Table 7.1: Inclusion and exclusion criteria for the Delphi study

Inclusion criteria	**Exclusion criteria**
• 3 years working with FES in a clinical and/or research capacity. • 3 years working specifically in UL rehabilitation	• Less than 3 years' experience
• Relevant degree/diploma in a related subject area/profession	• Not working with FES in a clinical or research capacity

Sample sizes in Delphi studies are dependent on group dynamics in reaching consensus, with 10–18 expert respondents considered sufficient for consensus to be achieved in the present study (Okoli & Pawlowski, 2004; Atkins et al., 2005; Vogel et al., 2019). All interested participants were sent via email a participant information sheet, a consent form, confidentiality of information and GDPR guidelines (Appendix **10.4.1, 10.4.2, 10.4.3, 10.4.4**). Thirty-five (n=35) experts that met the inclusion criteria were invited to participate in the online Delphi study, with twenty-one (n=21) experts responding and agreeing to participate. This resulted in twenty-one (n=21) participants completing round one (60% response rate), nineteen (n=19) of whom completed round two (90.4% response rate) and seventeen (n=17) of those completed round three (89.4% response rate). The panel comprised clinical specialist physiotherapists, senior occupational therapists, assistant professors, a professor, a clinical director, senior lecturers, a clinical scientist, a post-doctoral fellow, a consultant FES specialist, and consultant UL specialists. Included in the final panel were renowned and well published experts from the field of UL rehabilitation and FES; a number of whom were very well published and had previously participated in the LL FES Delphi (that informed the LL FES clinical practice guidelines) (Bulley et al., 2024). The thesis author's university ethics committee granted institutional ethical approval, with all participants providing written informed consent prior to the commencement of the study (Converis ID: ER61126668 see appendix **10.4.1**).

7.3.3 Procedure

It has been highlighted that, optimally, a Delphi method should have three rounds to be able to reach consensus (Iqbal & Pipon-Young, 2009). This online Delphi procedure consisted of three structured rounds of discussion (see **Figure 7.1**). For this study, consensus was defined as agreement among 70% of the panel (Diamond et al., 2014). Each round was conducted electronically, using a secure commercial survey provider (Qualtrics, Provo, USA).

Figure 7.1: Steps within the Delphi procedure

7.3.4 Round one

The current evidence base (Chapters 3 and 4) and experiential knowledge of the supervisory team relating to the use of UL FES in people with stroke supported the development of thirteen (n=13) open-ended short answer questions. Open-ended questions were separated into four dimensions: (1) clinical presentation of people with stroke (2) UL FES application (3) treatment progression (4) treatment evaluation. Once the thesis author developed the initial questions, the draft e-survey was sent to the research supervisory team to provide feedback on its suitability, including details about the length and clarity of the questions to be used. The supervisory team then met with the thesis author to discuss the relevance of each question, relative to answering the research aims and to ensure clarity, sensitivity, and accuracy. The questions were discussed at length and accepted without revision, modified to remove bias in the use of language, or removed (**Figure 7.1**) (Fischer et al., 2013). In total, ten (n=10) open-ended questions were agreed upon and the online questionnaire for round one was distributed to all participants via a secure email link, which remained open for four weeks (see Appendix **10.4.6** for the full list of questions used in round one).

Responses from round one were analysed in Microsoft Excel using reflexive thematic analysis (V. Braun & Clarke, 2021). Reflexive thematic analysis blends elements of both an inductive (i.e. data driven) and a deductive (i.e. researcher or theory driven) coding and theme development approach. A deductive analysis represented the first part of the coding stage, which was conducted by the thesis author. Dataset familiarisation was conducted by reading the free-text responses numerous times and, through this immersion in the raw data, language relating to the free-text responses from the open-ended questions were organised into four dimensions; these were: (1) clinical presentation of people with stroke; (2) UL FES application; (3) treatment progression; (4) treatment evaluation. Codes classified in more than one of the themes were assigned into the one perceived to best ‘fit’. To maintain analytical rigour this first-stage analysis was then circulated to the supervisory team for independent review and a discussion about the findings was conducted. This gave the thesis author and members of the supervisory team the opportunity to voice their own interpretations of the higher and lower order themes, and, during this process, peer discussion supported evaluation and any alteration of codes as appropriate. It is also important to acknowledge the thesis author and the supervisory team’s previous clinical experience and research work, as this may have informed the development of the study’s methodology (see Chapter 3). Following this, both deductive and inductive analysis was undertaken in the second coding stage (Braun & Clarke, 2021).

7.3.5 Round two

Using the higher and lower order themes from the thematic analysis and the language from the free-text responses from the questions presented in round one, the thesis author developed short statements which were organised into four deductive dimensions: (1) clinical presentation of people with stroke; (2) UL FES application; (3) treatment progression; (4) treatment evaluation. The dimensions and higher order themes informed the grouping of the questions, and the lower order themes informed the question focus, with each question relating to a lower order theme from the reflexive thematic analysis. When developing each short statement, there needed to be no ambiguity, with only one idea per statement and each had to be reviewed to ensure there was minimum overlap between statements (Jorm, 2015). The first draft of the statements was circulated to the supervisory team and individually reviewed. Following this, the thesis author and the supervisory team met to discuss the importance and relevance of each statement relative to the research aims. It was important that all the statements retained as much of the original wording of the participants from the free text responses as possible (Fischer et al., 2013). Statements were accepted without revision, modified to remove bias in language, or deleted (**Figure 7.1**). The full list of final statements used in round two and round three are available in Appendix **10.4.7**.

The second online questionnaire was distributed to participants that responded to round one via a secure email link and remained open for four weeks. Participants were asked to rate each scale using a four-point Likert scale as: strongly agree, agree, disagree, strongly disagree (Vogel et al., 2019). A further option of 'don't know' was also given alongside the traditional Likert scale (**Figure 7.2**). This was a pragmatic decision to enable any participant who did not have an opinion on a particular statement to be able to report that instead of falsely having to use the other options (Lavrakas, 2012). Raw data responses were analysed descriptively using relative and absolute frequencies to give a calculated measure of collective agreement or disagreement for each statement.

Please select one answer for each statement. The questionnaire will auto-advance onto the next statement once you have selected answer.

UL FES should be used in the early stages (first 6 weeks) of stroke rehabilitation. (1/27)

Strongly Agree

Agree

Disagree

Strongly Disagree

Don't Know

Figure 7.2: Example Delphi statement from round two of the Qualtrics questionnaire

7.3.6 Round three

The final round was sent to all participants that responded to round two. They were sent an individualised online questionnaire, which, again, used the original ninety-four (n=94) statements from round two. Their initial response was also provided, along with a summary of the groups’ responses expressed as a relative frequency. Participants were, therefore, able to confirm or amend their original rating from round two based on the information provided (**Figure 7.3**). Through this step, the initial findings were evaluated independently by the participants. Raw response data were analysed descriptively using relative and absolute frequencies to give a calculated measure of collective agreement or disagreement for each statement.

Please select one answer for each statement. The questionnaire will auto-advance onto the next statement once you have selected an answer. If your choice of answer has not changed between rounds, please select the same response as last time. If you want to change your answer from the last round, please select a different response.

UL FES should be used in the early stages (first 6 weeks) of stroke rehabilitation. (1/27)

Your answer from round 2 was: **Strongly Agree**

Group Responses: Strongly Agree: 42.1%; Agree: 31.6%; Disagree: 5.3%; Strongly Disagree: 10.5%; Don't know: 10.5%

Strongly Agree

Agree

Disagree

Strongly Disagree

Don't Know

Figure 7.3: Example Delphi statement from round three of the Qualtrics questionnaire

7.3.7 Criteria for consensus

Previously documented Delphi studies have used a wide range of consensus levels (Hasson et al., 2000). Consensus for the purpose of this Delphi was defined after discussions between the thesis author and the supervisory team as >70% of the panel agreeing/strongly agreeing or disagreeing/strongly disagreeing with a statement in rounds two and three (Runswick et al., 2021; Vogel et al., 2019). Responses marked as 'I don’t know' were excluded from the analysis to ensure that the percentage of agreement or disagreement reflected the views of those participants who had a definite opinion on the statement. Stability of consensus was considered to be reached if the between round group responses (between round two and round three in this instance) varied by <10% (Duffield, 1993). This approach helps to ensure that the conclusions drawn from the Delphi study are based on a stable and strong level of agreement among the experts involved.

7.4. Results

7.4.1 Participant characteristics

Of thirty-five (n=35) experts who were invited to participate in the expert panel, twenty-one (n=21) people completed round one (60% response rate), nineteen (n=19) of whom completed round two (90.4% response rate) and seventeen (n=17) of those completed round three (89.4% response rate). **Table 7.2** summarises the characteristics of the expert panel members. Most respondents were living in the UK (71.4%) at the time of completing the survey, however, there was also international representation (21.6%). The majority of participants were involved in the use of FES clinically including the assessment and follow up of people using UL FES (n=13; 62%). People who used UL FES in a research capacity were also represented (n=6; 29%) and there was a small representation of participants who defined themselves as experts in UL rehabilitation (n=2; 9%). Panel demographics are outlined in **Table 7.2**.

Table 7.2: Sample Demographics

	Round one	Round two	Round three
	(*n*= 21)	(*n*=19)	(*n*=17)
Age (years): mean	(49.2)	(49.5)	(50.4)
Female	8	7	7
Male	13	12	10
Expert Category:			
Expert working with FES clinically	3	3	3
Expert working with FES in a research capacity	6	5	3
Expert working with FES in both a clinical and research capacity	6	6	6
Expert in UL rehabilitation	2	2	2
Expert in UL rehabilitation that uses FES clinically	4	3	3
Current Role:			
Clinical specialist physiotherapist	8	6	6
Senior occupational therapist	2	2	2
Clinical director	1	1	1
Assistant professor	2	2	1
Professor	1	1	0
Senior lecturer	2	2	2
Clinical scientist	1	1	1
Postdoctoral fellow	1	1	1
Consultant FES specialist	1	1	1
Consultant UL specialist	2	2	2
Academic Qualifications:			
Undergraduate degree	1	1	1
Master's degree	11	10	10
Doctoral degree	9	8	6
Country of Employment:			
Canada	3	3	3
China	1	1	0
France	1	0	0
UK	15	14	13
USA	1	1	1

Figures are numbers of participants unless otherwise stated. **FES:** Functional electrical stimulation

Delphi Study Round One

- 35 experts invited
- **21 experts completed**
- 60% response rate

Draft version of the e-survey to be used in Delphi Round Two

- **Changes suggested by supervisory team. Statements:**
- Modified (n=28) Not modified (n=66) Added (n=0) Deleted (n=37)

Delphi Round Two

- Consisted of 94 short statements across 4 domains
- 21 experts invited:
- **19 experts completed**
- 90.4% response rate

Delphi Round Three

- 19 experts invited
- **17 experts completed**
- 89.4% response rate

Figure 7.4: Delphi results overview

Following round one ninety-four (n=94) statements were developed and in round two, nine (n=9) of those statements did not reach consensus. The remaining statements reached consensus with a mean of 92% (range 71 to 100% agreement) of the respondents selecting ‘strongly agree’ or ‘agree’. In round three a further two statements reached consensus and stability of consensus was achieved in eighty-four (n=84) statements across all four dimensions (90.9% mean, ranging from 70.6 to 100% agreement) (see Appendix **10.4.8**). Findings from round three will be used to develop the clinical practice guidelines based on the consensus achieved (Ross et al., 2022).

Table 7.3 provides a summary of the Delphi statements and the number of statements which reached consensus in round two and round three

Table 7.3: Summary of grouped statements by dimension

Statement dimensions	Number of statements in each domain		Proportion of statements where consensus was achieved (*n*)	
	Round 2	**Round 3**	**Round 2**	**Round 3**
Clinical presentation of people with stroke	27	27	85% (23)	85% (23)
UL FES application	40	40	95% (38)	98% (39)
Treatment progression	17	17	82% (14)	94% (15)
Treatment evaluation	10	10	100% (10)	100% (10)

Note: Consensus was achieved when ≥70% of participants strongly agreed/agreed or strongly disagreed/disagreed with a statement.

Stability of consensus (≤10% variation) was achieved between round two and round three in 84 statements (89%) out of the original 94 statements. Stability of consensus was not achieved in 3 statements within the clinical presentation of people with stroke domain (3%) but due to threshold being reached and the evidence base supporting the consensus-based statement, these 3 statements were included.

7.4.2 Clinical presentation of people with stroke

In this dimension, the panel reach consensus (**Table 7.3**) on twenty-three (n=23) important elements of clinical presentation on the individual presenting with a UL impairment post-stroke when considering UL FES. Eight (n=8) statements achieved 100% agreement; five (n=5) of which achieved 100% agreement in round one. Panellists agreed that UL FES can improve motor control and decrease spasticity in both subacute and chronic stroke presentations. Specifically, the panel agreed that UL FES can be used in individuals with a variety of post-stroke UL impairments including reduced co-ordination, sensory inattention, reduced shoulder stability and post-stroke shoulder pain. In addition to the physical presentation, panellists also agreed that suitable individuals needed to have sufficient cognitive ability to understand the aims of UL FES treatment and that individual user motivation to engage with UL FES needs to be established prior to application.

Lowest agreement was 81% in a statement that related to the impact of the practice environment on UL FES application (*the practice environment for application of UL FES should be considered as this could impact the treatment application*). Whilst consensus was agreed on this statement, the percentage of agreement had reduced from 83% in round one.

Table 7.4: Responses to statements relating to the clinical presentation of an individual with an upper limb impairment

Clinical presentation of people with stroke	**Round Two (n=19)**		**Round Three (n=17)**	
	Agreement (%)	Disagreement (%)	Agreement (%)	Disagreement (%)
UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation.	82%	18%	***94%**	6%
UL FES can improve motor control and decrease spasticity in subacute and chronic stroke.	95%	5%	**100%**	0%
Application of FES on the shoulder complex has a positive impact on the management of post-stroke hemiplegic shoulder pain.	89%	11%	**94%**	6%
FES can be used to stimulate muscles stabilisers of the shoulder.	100%	0%	**100%**	0%
UL co-ordination can be improved if UL FES is used to stimulate the correct sequence and timing of muscles.	83%	17%	**88%**	12%
UL FES can be used as a tool to motivate patients in the early stages of recovery post-stroke.	100%	0%	**100%**	0%
Application of UL FES can prevent muscle atrophy.	94%	6%	**94%**	6%
UL FES can be applied to increase joint range of motion in patients with UL hypertonicity.	84%	16%	**94%**	6%
UL FES can be effective in the management of learnt non-use.	100%	0%	**100%**	0%

UL FES can reduce sensory inattention of the hemiplegic UL.	94%	6%	**94%**	6%
A painful shoulder would be the main reason for applying UL FES to hemiplegic subluxed shoulder.	53%	47%	33%	67%
UL FES can be used where there is no residual movement or function.	89%	11%	***100%**	0%
Sufficient cognitive ability is required to understand the aims of UL FES treatment.	78%	22%	**82%**	18%
Severe cognitive impairment would inhibit the use of UL FES.	47%	53%	47%	53%
The patient must be able to give informed consent to apply UL FES.	83%	17%	***94%**	6%
Patient motivation to engage with UL FES needs to be established prior to application.	88%	12%	**88%**	12%
Patient commitment to a UL FES treatment plan is required. The patient should be able to apply regularly (either independently or with aid of carers, family, therapists).	100%	0%	**100%**	0%
Patient compliance with a UL FES treatment plan is required.	95%	5%	**100%**	0%
To gain maximum benefit from UL FES the patient needs to be able to see progress.	89%	11%	**88%**	12%
Affordability of FES equipment might impact the decision to commence with UL FES as a treatment option.	95%	5%	**94%**	6%

The practice environment for application of UL FES should be considered as this could impact the treatment application.	83%	17%	**81%**	19%
A cognitive impairment that inhibits the patient from engaging with UL FES would inhibit application.	88%	12%	**82%**	18%
A patient presenting with severe anxiety, agitation and/or confusion should not be considered for UL FES.	56%	44%	53%	47%
If a patient is unable to engage in functional tasks, even when postural support is provided, UL FES should not be applied.	16%	84%	0%	100%
Patient engagement with UL FES is essential when considering application.	94%	6%	**94%**	6%
Poor adherence to application would influence the decision to apply UL FES.	79%	21%	**82%**	18%
UL FES can be suitable for UL oedema management and prevention of UL muscle atrophy.	100%	0%	**100%**	0%

Note: Bold **%** in shaded areas denotes that ≥70% consensus was achieved; Agreement = agree + strongly agree; Disagreement = disagree + strongly disagree.

*****denotes that whilst consensus was agreed, there was a ≤10% shift in responses between rounds indicating a lack of stability.

7.4.3 Upper limb functional electrical stimulation application

In this dimension, the panel reached consensus (**Table 7.5**) on thirty-nine (n=39) recommendations that would influence UL FES application. Twenty-four (n=24) statements achieved 100% agreement; twenty-two (n=22) of which achieved 100% agreement in round one. Panellists agreed that treatment goals and appropriate pre- and post-application UL measurement is important to assess individual progress. Specifically, the panel agreed that UL FES should have a clear rationale, that the 'dose' should be dependent on patient tolerance, achievement of functional goal, and that a frequency of between 20–35Hz should be used so as to not fatigue the stimulated muscle(s).

Lowest agreement was 72% in a statement which related to the FES frequency applied to a target muscle presenting with high levels of spasticity (*lower FES frequencies should be used when the target muscle is presenting with high levels of spasticity);* however, this percentage of agreement had increased from 67% in round one. In this dimension, 39 out of 40 statements achieved the threshold for consensus in round three and all 39 statements achieved stability between rounds two and three.

Table 7.5: Responses to statements relating to FES application

Upper limb functional electrical stimulation application	Round Two (n=19)		Round Three (n=17)	
	Agreement (%)	Disagreement (%)	Agreement (%)	Disagreement (%)
Appropriate measures need to be taken pre- and post-UL FES application to measure progress.	95%	5%	**100%**	0%
Tolerance for UL FES should be assessed prior to application.	94%	6%	**94%**	6%
UL FES should not cause any discomfort.	61%	39%	59%	41%
Individual patient-centred goals need to be established prior to use of UL FES and monitored to identify the impact of UL FES application.	95%	5%	**94%**	6%
Patients should be educated in the use of UL FES.	100%	0%	**100%**	0%
Posture of the trunk and neck are important to consider and assess pre-UL FES application.	89%	11%	**88%**	12%
Active UL movement should be assessed prior to application of UL FES.	100%	0%	**100%**	0%
Passive and active joint ROM should be assessed prior to UL FES application.	100%	0%	**100%**	0%
UL alignment including the glenohumeral joint and scapula should be assessed pre application of UL FES.	95%	5%	**100%**	0%

Skin integrity must be assessed prior to decision to apply UL FES.	100%	0%	**100%**	0%
UL sensation should be assessed prior to UL FES application.	94%	6%	**94%**	6%
Priming activities such as UL stretching, and joint mobilisations should be considered prior to application of UL FES.	78%	22%	**77%**	23%
Treatment goals should be agreed prior to commencing UL FES.	100%	0%	**100%**	0%
Goals of UL FES treatment should be regularly reviewed and clearly documented.	100%	0%	**100%**	0%
UL FES should be used in conjunction with conventional UL treatment.	95%	5%	**94%**	6%
UL FES where possible should be used in conjunction with task specific training/exercise.	100%	0%	**100%**	0%
A clear UL FES practice schedule should be documented and communicated to the patient.	100%	0%	**100%**	0%
The patient should be in a well-supported appropriate position during UL FES application.	95%	5%	**94%**	6%
A rationale for UL FES use should be agreed and documented.	100%	0%	**100%**	0%
Adverse effects to UL FES must be regularly monitored and documented.	100%	0%	**100%**	0%

Cyclical UL FES can be used prior to task-orientated activity with or without FES.	100%	0%	**100%**	0%
Patient-triggered UL FES can help with motivation and engagement in UL recovery.	100%	0%	**100%**	0%
When applying UL FES, the patient should always be taught self-passive movements.	80%	20%	**79%**	21%
UL FES should always be applied at a comfortable level for the patient and then built up whilst remaining within tolerance levels.	100%	0%	**100%**	0%
UL FES programme intensity should be increased gradually to a level where a functional outcome is achieved.	100%	0%	**100%**	0%
UL FES frequency of between 20–35Hz should be used so as to not fatigue the stimulated muscle(s).	73%	27%	**73%**	27%
Dosage of stimulation of UL FES should be incrementally increased over time to ensure no adverse responses and to minimise the chance of muscle fatigue.	100%	0%	**100%**	0%
Intensity of stimulation of UL FES should be dependent on what is required to achieve the necessary muscle contraction.	100%	0%	**100%**	0%
Lower FES frequencies should be used when the target muscle is presenting with high levels of spasticity.	67%	33%	**72%**	27%
Dose of training of UL FES should be quantified by the number of repetitions of a task or tasks.	87%	13%	**88%**	12%
UL FES training needs to take account of the amount of training time the patient can commit to.	94%	6%	**94%**	6%

UL FES dose of training should be dependent on individual patient existing ability and muscle fatigue.	100%	0%	**100%**	0%
UL FES dose of training should consider individual patient motivation to engage with the training schedule.	89%	11%	**94%**	6%
Patients with good cognition should be given a home program for UL FES use.	95%	5%	**94%**	6%
All UL FES patients should have a good understanding of usage and application if using independently.	100%	0%	**100%**	0%
Safety of UL FES should always be assessed prior to decision about independent use.	100%	0%	**100%**	0%
If support is needed to use UL FES, then family/carer support should be taken into consideration when making a decision about independent use.	100%	0%	**100%**	0%
User expectation of UL FES should be taken into consideration and discussed pre-treatment.	100%	0%	**100%**	0%
Triggered UL FES should be used in combination with task-based UL practice.	100%	0%	**100%**	0%
Cyclical UL FES can be useful when functional movement is limited.	94%	6%	**94%**	6%

7.4.4 Treatment progression

In this dimension, the panel reached consensus (**Table 7.6**) on fifteen (n=15) recommendations for UL FES treatment progression. Eleven statements achieved 100% agreement across both rounds one and two. Panellists agreed that progression of UL FES treatment is indicated when there is an improvement in the consistency and quality of UL movements or when strength and functional ability of the hemiplegic UL improves following FES use. Whilst it was clear that physical benefits are significant when considering progression of treatment, it was also agreed that meaningful benefits to the user of UL FES should be taken into consideration when deciding on treatment progression. What constitutes progression was highlighted by agreement that this could include increasing number of movement repetitions, duration of movement practice or complexity of movement during use of UL FES. It was also agreed upon by all participants that variability of UL FES usage could be important to maintaining user interest and motivation.

Importantly the panel also agreed that UL FES should be discontinued when co-morbid medical diagnosis requires it, if the individual is experiencing notable adverse effects, when the individual does not want to continue or are facing FES application challenges/issues or if they are able to fully perform the specific functional task without FES use.

Lowest agreement was 71% in a statement that related to UL FES being discontinued if the patient is not achieving their goals (*UL FES could be discontinued if the patient is not achieving their goals.)*; however, this percentage of agreement had increased from 67% in round one.

Table 7.6: Responses to statements relating to treatment progression

Treatment Progression	Round Two (n=19)		Round Three (n=17)	
	Agreement (%)	Disagreement (%)	Agreement (%)	Disagreement (%)
Improvement in UL muscle strength could justify a progression of FES usage.	100%	0%	**100%**	0%
Improvement in consistency and quality of UL movements could justify a progression of UL FES usage.	100%	0%	**100%**	0%
Increased functional use of the hemiplegic UL could justify a progression of UL FES usage.	100%	0%	**100%**	0%
Meaningful benefits to the user of UL FES should be taken into consideration when deciding on treatment progression.	100%	0%	**100%**	0%
Variability of UL FES usage could be important to maintaining user interest and motivation.	100%	0%	**100%**	0%
UL FES progression could include increasing number of movement repetitions, duration of movement practice or complexity of movement.	100%	0%	**100%**	0%
A lack of measurable improvement could justify discontinuing the use UL FES.	73%	27%	**80%**	20%
UL FES should be discontinued when the patient is able to perform the task/movement independently.	80%	20%	**81%**	19%

UL FES should be discontinued when comorbid medical diagnosis requires UL FES discontinuation.	100%	0%	**100%**	0%
UL FES should be discontinued when the patient shows signs of notable adverse effects/reaction.	100%	0%	**100%**	0%
UL FES could be discontinued if the patient is not achieving their goals.	67%	33%	**71%**	29%
UL FES should be discontinued if the patient does not want to continue with FES application/use.	100%	0%	**100%**	0%
UL FES should be discontinued when a patient is demotivated and perceives no benefit in UL FES application.	60%	40%	63%	37%
UL FES could be discontinued when a patient has accepted their level of UL functional movement.	35%	65%	31%	69%
UL FES could be discontinued if the patient is facing application issues due to lack of family/carer support in the community/home environment.	100%	0%	**100%**	0%
UL FES could be discontinued when the patient has improved QoL and no longer sees the benefit of continued UL FES application.	71%	29%	**77%**	23%
UL FES could be discontinued when the patient is able to fully perform the specific task without it.	100%	0%	**100%**	0%

7.4.5 Treatment evaluation

In this dimension, the panel reached consensus (**Table 7.7**) on all ten recommendations for UL FES treatment evaluation. Six (n=6) statements achieved 100% agreement across both rounds one and two. Panellists agreed that relevant standardised outcome measures, individual patient goals and functional measures should be used when evaluating the use of UL FES. The importance of patient-reported measures and feedback from family/carers was also agreed. Specifically, the panel agreed that assessment tools that contribute to the ICF assessment should be used to evaluate the use of UL FES.

Lowest agreement was 73% in two statements, both of which related to the use of monitoring equipment (activity monitors and motion capture/video) to evaluate/measure the use of UL FES (*Activity monitors should be used to evaluate/measure the use of UL FES* and *Use of motion capture and video should be used to evaluate/measure the use of UL FES);* however, this percentage of agreement had increased in both statements from 71% in round one.

Table 7.7: Responses to statements relating to treatment evaluation

Treatment Evaluation	Round Two (n=19)		Round Three (n=17)	
	Agreement (%)	Disagreement (%)	Agreement (%)	Disagreement (%)
UL FES use should be evaluated using appropriate standardised, evidence-based outcome measures.	88%	12%	**88%**	12%
Goal attainment scales/measures should be used when evaluating the use of UL FES.	100%	0%	**100%**	0%
A combination of functional and patient-reported measures should be used when evaluating the use of UL FES.	100%	0%	**100%**	0%
Assessment tools that contribute to the ICF assessment should be used to evaluate the use of UL FES.	93%	7%	**93%**	7%
Patient feedback about UL FES should be taken into consideration when evaluating treatment.	100%	0%	**100%**	0%
Patient reported outcome measures should be used when evaluating the use of UL FES.	100%	0%	**100%**	0%
Carer feedback should be considered when evaluating/measuring the use of UL FES.	100%	0%	**100%**	0%
Activity monitors should be used to evaluate/measure the use of UL FES.	71%	29%	**73%**	27%
Use of motion capture and video should be used to evaluate/measure the use of UL FES.	71%	29%	**73%**	27%

Understanding individual patient goals should be established to direct the application of UL FES.	100%	0%	**100%**	0%

In total, eighty-seven (n=87) statements (out of ninety-four (n=94) in round one) across four domains had agreed consensus (clinical presentation of people with stroke: n=23; UL FES application: n=39; treatment progression: n=15; treatment evaluation: n=10). All accepted statements that were developed using a Delphi consensus methodology will be included within the final clinical practice guidelines document and this will be structured to support clinical application of UL FES. A provisional format for the guideline was developed by the thesis author and has been reviewed and approved by the thesis author's research supervisory team.

Table 7.8: Evidence-based clinical practice guidelines for the use of functional electrical stimulation on the upper limb post-stroke: quick reference guide

1	**Post-stroke presentations that would potentially benefit from using upper limb functional electrical stimulation.**
1.1	UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation.
1.2	UL FES can improve motor control and decrease spasticity in subacute and chronic stroke.
1.3	Application of FES on the shoulder complex has a positive impact on the management of post-stroke hemiplegic shoulder pain.
1.4	FES can be used to stimulate muscles stabilisers of the shoulder.
1.5	UL co-ordination can be improved if UL FES is used to stimulate the correct sequence and timing of muscles.
1.6	UL FES can be suitable for UL oedema management and prevention of UL muscle atrophy.
1.7	Application of UL FES can prevent muscle atrophy.
1.8	UL FES can be applied to increase joint range of motion in patients with UL hypertonicity.
1.9	UL FES can be effective in the management of learnt non-use.
1.10	UL FES can reduce sensory inattention of the hemiplegic UL.
1.11	UL FES can be used where there is no residual movement or function.

2	**Considerations and precautions when using upper limb functional electrical stimulation.**
2.1	Skin integrity must be assessed prior to decision to apply UL FES.
2.2	Adverse effects to UL FES must be regularly monitored and documented.
2.3	Affordability of FES equipment might impact the decision to commence with UL FES as a treatment option.
2.4	The practice environment for application of UL FES should be considered, as this could impact the treatment application.
2.5	Dosage of UL FES should be incrementally increased over time to ensure no adverse responses and to minimise the chance of muscle fatigue.
2.6	UL FES training needs to take account of the amount of training time the patient can commit to.
2.7	UL FES dose of training should be dependent on individual patient existing ability and muscle fatigue.
2.8	All UL FES patients should have a good understanding of usage and application if using independently.
2.9	Safety of UL FES application should always be assessed prior to decision about independent use.
2.10	The patient should be in a well-supported appropriate position during UL FES application.

3	**Cognition, motivation and engagement.**
3.1	The patient must be able to give informed consent to apply UL FES.
3.2	A cognitive impairment that inhibits the patient from engaging with UL FES would inhibit application.
3.3	Sufficient cognitive ability is required to understand the aims of UL FES treatment.
3.4	UL FES can be used as a tool to motivate patients in the early stages of recovery post-stroke.
3.5	Patient motivation to engage with UL FES needs to be established prior to application.
3.6	Patient engagement with UL FES is essential when considering application.
3.7	Poor adherence to application would influence the decision to apply UL FES.
3.8	Patient compliance with a UL FES treatment plan is required.
3.9	Patient commitment to a UL FES treatment plan is required. The patient should be able to apply regularly (either independently or with aid of carers, family, therapists).
3.11	To gain maximum benefit from UL FES, the patient needs to be able to see progress.
3.12	Variability of UL FES usage could be important to maintaining user interest and motivation.
3.13	Patients with good cognition should be given a home program UL FES use.
3.14	UL FES dose of training should consider individual patient motivation to engage with the training schedule.

4	**Initial assessment and treatment for use of upper limb functional electrical stimulation.**
4.1	**Initial Assessment**
4.1.1	Tolerance for UL FES should be assessed prior to application.
4.1.2	Posture of the trunk and neck are important to consider and assess pre-UL FES.
4.1.3	Active UL movement should be assessed prior to application of UL FES.
4.1.4	Passive and active joint range of motion (ROM) should be assessed prior to UL FES application.
4.1.5	UL alignment including the glenohumeral joint and scapula should be assessed pre-application of UL FES.
4.1.6	UL sensation should be assessed prior to UL FES application.
4.1.7	User expectation of UL FES should be taken into consideration and discussed pre-treatment.
4.1.8	If support is needed to use UL FES, then family/carer support should be taken into consideration when making a decision about independent use.
4.2	**Treatment**
4.2.1	UL FES should always be applied at a comfortable level for the patient and then built up whilst remaining within tolerance levels.
4.2.2	UL FES programme intensity should be increased gradually to a level where a functional outcome is achieved.
4.2.3	UL FES frequency of between 20–35Hz should be used so as to not fatigue the stimulated muscle(s).

4.2.4	Intensity of UL FES should be dependent on what is required to achieve the necessary muscle contraction.
4.2.5	Lower FES frequencies should be used when the target muscle is presenting with high levels of spasticity.
4.2.6	Dose of training of UL FES should be quantified by the number of repetitions of a task or tasks.
4.3	**Treatment adjuncts/exercises**
4.3.1	Priming activities such as UL stretching, and joint mobilisations should be considered prior to application of UL FES.
4.3.2	UL FES should be used in conjunction with conventional UL treatment.
4.3.3	UL FES, where possible, should be used in conjunction with task specific training/exercise.
4.3.4	When applying UL FES, the patient should always be taught self-passive movements.

5	**Upper limb functional electrical stimulation measurement and monitoring.**
5.1	Individual patient-centred goals need to be established prior to use of UL FES and monitored to identify the impact of UL FES application.
5.2	Appropriate measures need to be taken pre- and post-UL FES application to measure progress.
5.3	Patients should be educated in the use of UL FES.
5.4	Treatment goals should be agreed prior to commencing UL FES.

5.5	Goals of UL FES treatment should be regularly reviewed and clearly documented.
5.6	A clear UL FES practice schedule should be documented and communicated to the patient.
5.7	A rationale for UL FES use should be agreed and documented.
5.8	UL FES use should be evaluated using appropriate standardised, evidence-based outcome measures.
5.9	Goal attainment scales/measures should be used when evaluating the use of UL FES.
5.10	A combination of functional and patient reported measures should be used when evaluating the use of UL FES.
5.11	Assessment tools that contribute to the ICF assessment should be used to evaluate the use of UL FES.
5.12	Patient feedback about UL FES should be taken into consideration when evaluating treatment.
5.13	Patient reported outcome measures should be used when evaluating the use of UL FES.
5.14	Carer feedback should be considered when evaluating/measuring the use of UL FES.
5.15	Activity monitors should be used to evaluate/measure the use of UL FES.
5.16	Use of motion capture and video should be used to evaluate/measure the use of UL FES.
5.17	Understanding individual patient goals should be established to direct the application of UL FES.

6	**Upper limb functional electrical stimulation treatment progression.**
6.1	Improvement in UL muscle strength could justify a progression of FES usage.
6.2	Improvement in consistency and quality of UL movements could justify a progression of UL FES usage.
6.3	Increased functional use of the hemiplegic UL could justify a progression of UL FES usage.
6.4	Meaningful benefits to the user of UL FES should be taken into consideration when deciding on treatment progression.
6.5	UL FES progression could include increasing number of movement repetitions, duration of movement practice or complexity of movement.

7	**Discontinuing upper limb functional electrical stimulation treatment.**
7.1	A lack of measurable improvement could justify discontinuing the use of UL FES.
7.2	UL FES should be discontinued when the patient is able to perform the task/movement independently.
7.3	UL FES should be discontinued when comorbid medical diagnosis requires UL FES discontinuation.
7.4	UL FES should be discontinued when the patient shows signs of notable adverse effects/reaction.
7.5	UL FES could be discontinued if the patient is not achieving their goals.
7.6	UL FES should be discontinued if the patient does not want to continue with FES application/use.

7.7	UL FES could be discontinued if the patient is facing application issues due to lack of family/carer support in the community/home environment.
7.8	UL FES could be discontinued when the patient has improved QoL and no longer sees the benefit of continued UL FES application.
7.9	UL FES could be discontinued when the patient is able to fully perform the specific task without UL FES.

8	**Types of upper limb functional electrical stimulation.**
8.1	Cyclical UL FES can be used prior to task-orientated activity with or without FES.
8.2	Patient-triggered UL FES can help with motivation and engagement in UL recovery.
8.3	Triggered UL FES should be used in combination with task-based UL practice.
8.4	Cyclical UL FES can be useful when functional movement is limited.

7.5. Discussion

This chapter's aim was to gain expert opinion on the application of UL FES post-stroke. The focus was on reaching expert consensus on:

(i) the factors that influence application and treatment evaluation of UL FES in people with stroke.

(ii) how a broad range of post-stroke UL presentations influence clinicians' decisions on the application of UL FES.

(iii) treatment adjuncts and/or exercises used alongside FES in the management of the post-stroke UL.

This study sampled expert opinion from clinicians, researchers and UL specialists on factors relating to the application of UL FES in the stroke population. From this consensus study, clinical practice guidelines for the use of UL FES post-stroke will be developed.

A key point of agreement between the expert group was the broad range of post-stroke presentations that would potentially benefit from using UL FES. It has been evidenced that FES can improve motor control (Wang et al., 2002), have a positive impact on post-stroke hemiplegic shoulder pain (Koyuncu et al., 2010; NICE, 2023), prevent muscle atrophy (Meadmore et al., 2014) and improve UL co-ordination (Cuesta-Gómez et al., 2017). However, it has also been previously identified that translation of knowledge from research into clinical practice has challenges for health care professionals (Jette et al., 2003; Zidarov et al., 2013). In Chapter 3, clinicians highlighted their concerns that they did not fully know which patients would be most suitable for UL FES application despite having some understanding of the current evidence base. A cross-sectional survey of Canadian clinicians identified the key barriers to clinicians' application of FES in the post-stroke population included difficulty translating research into practice and the perception of FES being inappropriate for certain patients with stroke (including those with spasticity or acute impairment) (Auchstaetter et al., 2016). The consensus reached on the statements in this study will facilitate enhanced clinical understanding of which post-stroke presentations are likely to benefit most from UL FES and hopefully develop clinical confidence in the justification for choosing it as a treatment modality.

Consensus was also achieved on the statement relating to use of FES in the management of UL spasticity post-stroke. The evidence relating to the use of FES in the management of spasticity varies, with a number of studies demonstrating positive results on UL spasticity with the use of electrical stimulation with conventional treatment (cited as splinting, passive range of movement exercises, stretches and splinting) (Hardy et al., 2010; Nakipoğlu Yuzer et al., 2017; Sahin et al., 2012). However, recent NICE guidelines state that people with spasticity in the upper (or lower) limbs post-stroke should not be treated with electrical stimulation to reduce spasticity unless they have had botulinum toxin for wrist/finger spasticity and the electrical stimulation is to maintain the range of movement post injection (NICE, 2023).

Consensus relating to factors that influence application of UL FES in people with stroke was highlighted by the nineteen (n=19) agreed statements covering initial assessment and treatment; there were a number of similarities between the consensus statement in this study and the consensus statements in the LL FES clinical guidelines (Queen Margaret University & ACPIN, 2022). These included that during the initial assessment, tolerance for

FES should be assessed prior to application. This should be part of a wider holistic assessment of the user and their situation. User expectations should also be taken into consideration and discussed pre-treatment.

As findings from this study suggest, application of UL FES needs to take a patient-centred approach, depending on the presentation of the people with stroke and that it should be used in conjunction with ‘conventional’ post-stroke UL management. Respondents agreed that priming activities should be considered prior to the application of UL FES in order to optimise the benefits of FES. Broad statements were agreed relating to the use of task-specific training, exercise and conventional therapy, all of which are supported in the current evidence base (Alon et al., 2008; Nakipoğlu Yuzer et al., 2017; Popovic et al., 2011; Sun et al., 2018). The specific details would depend not only on the level of individual UL impairment, but also the motivation, goals and aims of the patient. This agreement that UL FES should be applied alongside, or as an adjunct to other treatment strategies enables the clinician a degree of autonomy to make the management of the UL bespoke to patient requirements, within the framework suggested by the results of this Delphi study.

Another important aspect of the use of UL FES that had agreed consensus on was when to discontinue treatment. Agreement on discontinuing the use of UL FES when either co-morbid medical diagnosis required it, or there were notable adverse effects aligned with the LL FES recommendations (Queen Margaret University & ACPIN, 2022; Bulley et al., 2024). However, interestingly, consensus was also agreed on discontinuing treatment when the patient was facing application issues due to lack of community support. Lack of focus on therapy for the UL and FES application issues in the community have also previously been cited as a barrier to implementation (Auchstaetter et al., 2016; Musselman et al., 2023; Stockley et al., 2019). This warrants further research, as usability is an important factor that clearly impacts implementation.

The Delphi study followed previous good-quality research design and recommendations to improve rigour (Bulley et al., 2024; Hasson & Keeney, 2011; Strafford et al., 2022), and, although there was a drop out between rounds one and two, retention of 81% of participants was encouraging. Unlike the Delphi that informed the LL FES clinical practice guideline (Bulley et al., 2024), this study did not address FES service provision or recommendations relating to referral to FES services. Further research would be needed to address this gap.

The aim of the resulting clinical practice guidelines is to facilitate the use of best practice and to encourage clinicians to implement UL FES in stroke rehabilitation and the expert group for the Delphi study was decided on this basis. However, on reflection, whilst it was important for this Delphi study to have representation from clinicians and FES researchers, it would have further added value to develop another study following on from this Delphi process to engage the 'wider community' of FES users' perspectives including a variety of service users and service managers.

The outcome of this Delphi, and the plans for the subsequent clinical guideline development, is aligned with existing guidelines that recommend FES (ISWP, 2023) but provides more practical detail that will support clinicians when considering UL FES application in people with UL impairments post-stroke.

7.6. Conclusion

This study identified expert opinion on the application of UL FES in individuals post-stroke. It is the first study to gain consensus on: (i) factors that influence application of UL FES in people with stroke, (ii) different post-stroke UL presentations and how this impacts UL rehabilitation, (iii) FES application parameters for the management of a variety of post-stroke UL clinical presentations, (iv) adjuncts and/or exercises used alongside functional electrical stimulation in the management of the post-stroke UL. Consensus was achieved from a range of stakeholders with different types of expertise and clinical experience. Informed by the findings from this study, clinical practice guidelines will be developed to support clinicians in their understanding of how and when to apply UL FES in the post-stroke population. Further ongoing research will be required to ensure that the developed clinical guideline remains current and that it is implemented into clinical practice in the most useful way.

Chapter 8 Thesis discussion and conclusions.

This chapter concludes the thesis with a critical synthesis of findings from the studies reported in Chapters 4 to 7, a discussion of their contribution to existing and other emerging new knowledge in the field, a reflection on limitations in the series of doctoral studies, including lessons arising from this, and consideration of the implications for practice and future research.

8.1. Summary of study findings

This programme of research utilised both quantitative and qualitative methods to further develop knowledge on the application of upper limb (UL) functional electrical stimulation (FES) in people with stroke. The overarching purpose of the doctoral programme of research was to explore the development of clinical practice guidelines to support the application of post-stroke UL FES. The existing literature suggests that FES can positively impact functional recovery of the UL in people with stroke (Eraifej et al., 2017; Khan et al., 2023), however, the systematic review revealed that there was little evidence on the recommended applications and uncertainty around the optimal therapeutic window for different UL impairments post-stroke (Sousa et al., 2022). This is significant given that the annual incidence of stroke in the UK is 100,000; with between 50–80% of stroke survivors having a UL impairment (SSNAP, 2023). It has been recently recommended that intensity and duration of therapy is enhanced (ISWP, 2023); however, it is well documented that there are challenges to delivering intensity of post-stroke rehabilitation (Ballester et al., 2022; Connell et al., 2018), and whilst people with stroke value being actively involved in their UL recovery (Purton et al., 2023), healthcare professionals have a number of competing priorities in the management of people with stroke (Clark et al., 2023).

The thesis author designed and undertook a series of linked studies using multiple research methods, working towards the overall goal of going at least some of the way towards producing clinical practice guidelines for the use of UL FES in people with stroke (physiotherapists, occupational therapists and rehabilitation assistants). This research programme comprised: a systematic review of the treatment parameters for UL FES post-stroke (Chapter 4), a medical record-based service evaluation of an NHS Foundation Trust stroke pathway (Chapter 5), a qualitative focus group study of two large NHS Foundation Trust stroke pathways (Chapter 6), and an international consensus-based Delphi study of experts on best practice in the use of UL FES in the management of people with stroke (Chapter 7). The studies in this programme of research have collectively explored the application of UL FES and provided rich insights into the management of the UL post-stroke in real-world settings. The findings of this thesis have been synthesised and are considered within four overarching sections; (8.1.1) use of FES in people with stroke, (8.1.2) therapeutic attitudes towards the use of UL FES in people with stroke, (8.1.3) post-stroke clinical presentations that inform use of UL FES, (8.1.4) challenges to implementation of UL FES and implications for clinical practice.

8.1.1 Use of functional electrical stimulation in people with stroke

The findings from the medical records review across the NHS Foundation Trust stroke pathway identified that despite evidence supporting the use of UL FES in people with stroke (Eraifej et al., 2017) and recent intensity-based recommendations (NICE, 2023), the use of UL FES was very limited, especially in the acute setting. Evidence, however, highlights the need to focus on UL motor control in the acute phase post-stroke and illustrates the potential for novel interventions to maximise recovery during this time period (Cortes et al., 2017; Dromerick et al., 2021).

The lack of documented evidence of interventions for the hemiplegic UL, including the use of UL FES, reinforced the need for a more detailed exploration of the perceptions and practices of clinicians working within stroke pathways. More in-depth exploration was conducted to understand how the UL was managed in people with stroke and if UL FES was part of that management. The findings confirmed the lack of focus and prioritisation of the UL, which was attributed to a number of factors, including lack of therapy time, limited resources and patients' preference to focus on mobility. This aligns with previous research that has identified an underuse of FES in the management of the post-stroke UL and identified a number of similar barriers to implementation, including staff confidence, equipment availability, lack of resources in terms of environmental and physical equipment (Auchstaetter et al., 2016; Musselman et al., 2024; Stockley et al., 2019). The collective findings across the exploration of the clinical environment phase of this programme of study indicate that people with stroke are not necessarily receiving the recommended level of treatment required to optimise recovery post-stroke, which is believed to be heightened in the acute phase (first few weeks post-stroke)(Dromerick et al., 2021; Krakauer, 2005; Krakauer et al., 2012). The complexity of the needs of people with stroke and competing priorities, especially in the acute phase, impact prioritisation of the UL and the use of FES as is clearly illustrated in this programme of studies. Whilst there are a number of variables that potentially contribute to this, what was identified was that lack of specific guidance in the current evidence base and perceived set up times of FES were two influencing factors on its lack of use. Lower limb (LL) clinical practice guidelines for the application of LL FES to support mobility have recently been developed (Queen Margaret University & ACPIN,2022). Following the publication of these guidelines, during the consultation on how best to support implementation, it was also highlighted that clinicians felt that the current evidence is not descriptive enough to inform and support application of FES. Clinical practice guidelines could go some way to addressing this gap (Brown et al., 2023).

The lack of specific treatment parameters documented within the current evidence base was highlighted in the systematic review. Whilst the systematic review provided evidence to support the use of UL FES, notably, there was a lack of clarity about how best to apply it for the diverse hemiplegic UL presentations seen in people with stroke. The findings from this systematic review suggest that, for clinicians seeking practical information on the optimal treatment parameters to use when applying UL FES in people post-stroke, published research studies may not be a particularly useful source of guidance. This affirms the challenges previously identified by clinicians working in the field of neurorehabilitation both in the UK (Stockley et al., 2019) and Canada (Auchstaetter et al., 2016; Musselman et al., 2024). The findings from Auchstaetter et al. (2016) hypothesised that the lack of knowledge about FES application and misconceptions related to the evidence base possibly reflects an inadequate translation of knowledge from research into clinical practice. Equally, in the UK, the cross-sectional survey by Stockley et al. (2019) alluded to the fact that UL FES was not considered to be well evidenced in comparison to UL interventions such as CIMT and GRASP, and it was, therefore, not reported to be used often. During the qualitative phase of this programme of research, the lack of clarity to support application of UL FES in people with stroke within the current evidence base was raised as a point of frustration, with one participant stating: *"More practical based guidelines would be helpful. With diagrams and ideas for progression."* (P6 T1 Rehab). This statement illustrates the need for more detailed clinical practice-based guidelines.

Time associated with set-up of FES was clearly highlighted within the focus groups as a barrier to use; one participant in an acute setting stated: *"It takes time to set-up and requires a certain type of patient and a good environment, so all of that kind of makes me think I don't feasibly have time to do that…"* (P5 T1 Acute). When considering use of technology in rehabilitation, previous research has indicated that set-up time needs to be relatively quick and easy for clinicians, as lengthy set-up times could influence adoption (Hochstenbach-Waelen & Seelen, 2012). Research has been carried out with the aim of attempting to reduce set up time with more complex and flexible FES systems; however, despite positive clinical results, further work to reduce set-up time is still required (Smith et al., 2019; Sun et al., 2018).

It was highlighted in Study Two that UL FES was generally not used across the stroke pathway but did clearly identify how the UL was managed within the variety of locations and at different points post-stroke (this included the use of stretches, exercises (including the GRASP exercise plan) oedema massage and sensory stimulation of the UL). This experiential knowledge of individuals working within two large NHS Foundation Trust stroke pathways in Study Three provided rich insights into the management of the UL post-stroke and the use of FES. The results of this qualitative study identified a number of barriers impacting implementation of UL FES; namely clinical confidence in the management of the UL and use of FES, coupled with a lack of education and training relating to application. Organisational factors, including staffing issues and limited patient contact time, is known to influence clinical decisions in stroke rehabilitation (Longley et al., 2019); it has also previously been documented that there are a number of barriers to use of technology in stroke rehabilitation including cost and availability of equipment (Langan et al., 2018) and training requirements to facilitate acceptance and use of suitable technologies as an adjunct to rehabilitation (Hamilton et al., 2019). Informed by these findings, it was apparent that to be able to attempt to address the detail required to support use of UL FES in clinical practice, the final study required expert knowledge to arrive at a consensus for its application. Delphi methodology is a common method for clinical practice guideline development (van der Linde et al., 2005) and was the approach taken in the development of the clinical practice guidelines in the use of

FES to support upright mobility in people with an upper motor neurone lesion (Bulley et al., 2024). The outcome of these LL FES clinical practice guidelines aligned with the existing evidence base and achieved consensus within two survey rounds, which the authors attribute to the depth of consultation with varied stakeholders (Bulley et al., 2024). This illustrated the benefits of the Delphi methodology and its utility in clinical practice guideline development; supporting the justification for use within this programme of study.

Whilst the systematic review highlighted conventional therapy was poorly defined, there were a number of studies that indicated that treatment was carried out, either prior, or in conjunction with UL FES. Findings from the Delphi study (Study Four: Chapter 7) had agreed consensus on the use of priming activities prior to application of UL FES including UL stretching, and joint mobilisations and this was in agreement with two studies from the systematic review (Hughes et al., 2009; Page et al., 2009). Consensus was also established relating to the use of UL FES in conjunction with conventional UL treatments and, where possible, task specific training. The current evidence base supports the use of task-specific training alongside UL FES with a variety of functional objects, predominantly incorporating grasping an object, such as picking up a bottle (Alon et al., 2003), wooden blocks (Bustamante et al., 2016), or handling a glass or cup (Cuesta-Gómez et al., 2017; Page et al., 2009, 2016). Interestingly, consensus was agreed in the Delphi study that when applying UL FES, the patient should always be taught self-passive movements. Self-management techniques (self-directed therapy or self-practice) are recommended in the most recent stroke guidelines to promote increased practice in addition to standard rehabilitation sessions and also as a means of motivating people with stroke to maintain engagement and participation (NICE, 2023). Despite this recent recommendation within this programme of studies, neither the medical records (Study Two: Chapter 5) nor focus groups (Study Three: Chapter 6) especially highlighted the use of self-management techniques. Severity of impairment was highlighted as a possible reason why people with stroke might not be given self-management as part of their UL rehabilitation: *'I mean, I would say probably the more severe people would probably not have as much of a self-management programme because they can't actually do it.'* (P7 T1 Rehab). The use of UL FES post-stroke was specifically recommended for consideration as a form of self-management in the recent stroke guidelines:

> *People with arm weakness after stroke, who are able and motivated to follow regimes independently or with the support of a carer, should be considered for self-directed upper limb rehabilitation to increase practice in addition to usual therapy, e.g. patients undergoing constraint-induced movement therapy or functional electrical stimulation. (NICE, 2023).*

One interpretation of this recommendation is that UL FES could be used in-between therapy sessions, possibly as a home-based modality that people with stroke could continue to use over a prolonged period of time. The findings from Study Three (Chapter 6) highlighted a perception that the community setting was a possible location where UL management was more likely to occur, and from the medical records review (Study Two: Chapter 5) this was where UL FES occurred most frequently (although it was not used as a self-management activity) (Table 5.7). However, unless the people with stroke that are suitable for self-management utilising UL FES are being identified in the early phase post-stroke, there is still a risk that it will not be implemented early enough to maximise on the potential benefits. Overall, when considering the findings from the Delphi study, including consensus when UL FES is recommended to be used ('*UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation.')* and the suggestions about self-management *('Patient commitment to a UL FES treatment plan is required. The patient should be able to apply* *regularly (either independently or with aid of carers, family, therapists).');* considering the lack of use of early application of UL FES and self-management in people with stroke, these recommendations will require implementation with possible organisational support in clinical practice.

Pulse frequency is described as the number of pulses per second or the rate at which electrical stimulation is delivered (see Figure 2.4) (Marquez-Chin & Popovic, 2020). This frequency impacts the muscle contraction; with too low a frequency resulting in muscle twitches and too high a frequency causing prolonged stimulation and associated muscle fatigue (Ferrarin et al., 2001). The strength of the muscle contraction can be altered by changing the pulse frequency delivered with the aim of optimising muscle contraction whilst minimising problems associated with fatigue (Strojnik & Peckham, 2003). Findings from the systematic review reported FES frequencies ranging between 25–50Hz (Bustamante et al., 2016; Franck et al., 2019; Hayward et al., 2013; Hedman et al., 2007; Hughes et al., 2009; Kawashima et al., 2013; Mann et al., 2011; Mathieson et al., 2018; Meadmore et al., 2012, 2014; Park, 2020; Silveira et al., 2018; Smith et al., 2019; Sullivan & Hedman, 2004, 2007). The frequency, however, was lower within the Delphi, with consensus being achieved (73%: Table 7.5) on the use of UL FES frequencies between 20–35Hz with the reasoning being as to not fatigue the stimulated muscle(s). A further consensus statement with 100% agreement (Table 7.5) reinforces this by stating dosage of UL FES should be incrementally increased over time to ensure no adverse responses and to minimise the chance of muscle fatigue.

Within the current evidence base, both optimal contraction of observed muscle activity (Alon et al., 2003; Bustamante et al., 2016; Page et al., 2009) and intensity being adjusted to achieve the most effective completion of the task (Hayward et al., 2013; Hedman et al., 2007; Mann et al., 2011; Meadmore et al., 2012, 2014; Popovic et al., 2004; Sullivan & Hedman, 2007) have been cited as justification for FES intensity. Both of these points were reinforced in the findings from the Delphi with two statements being agreed: *intensity of stimulation of UL FES should be dependent on what is required to achieve the necessary muscle contraction* and *UL FES programme intensity should be increased gradually to a level where a functional outcome is achieved.* This further reinforces the understanding that stimulation intensity should be kept at the lowest point to be maximally effective and minimise unwanted side effects of prolonged stimulation (Ferrarin et al., 2001) and gives clear guidance to clinicians for application parameters relating to FES optimal frequencies.

Open-loop FES systems (manually controlled FES) were used in the majority of studies within the systematic review (Study One: Chapter 4) with nine (n=9) studies indicating they were clinician triggered (Bhalla & Shergill, 2020; Bustamante et al., 2016; Cuesta-Gómez et al., 2017; Franck et al., 2019; Hayward et al., 2013; Kawashima et al., 2013; Mathieson et al., 2018; Silveira et al., 2018; Smith et al., 2019); and five (n=5) user triggered (Hedman et al., 2007; Mann et al., 2011; Popovic et al., 2004; Sullivan & Hedman, 2004, 2007). In a study by de Kroon et al. (2002), positive results were identified to be more common when stimulation was triggered by voluntary movements rather than non-triggered stimulation. Experts within the Delphi reinforced this view of patient-triggered systems as two consensus statements were agreed in relation to the use of patient-triggered FES and the use of patient-triggered electrical stimulation being used in conjunction with UL task-based practice (**Table 7.5**).

8.1.2 Therapeutic attitudes towards the use of upper limb functional electrical stimulation in people with stroke

The findings of Study Two (Chapter 5) indicated that across the NHS Foundation Trust stroke pathway under review, UL FES was used infrequently and this aligned as previously highlighted to a cross-sectional survey of UK therapists (Stockley et al., 2019). An impression of de-prioritisation was clearly made by therapists within the focus groups. Despite the awareness by therapists of the need to deliver greater intensity of practice to people with stroke, UL FES was not utilised frequently. One hypothesis is that the clinicians within the stroke pathways were working in localised silos and were either unaware of clinical activity delivered in alternative settings across the stroke pathway or perceived this as a barrier to implementation. This was highlighted by statements relating to perceptions that a greater emphasis was made in a community-based setting relating to UL management (*'I think there's a much bigger focus on upper limb in the community.'* (P6 T1 Rehab)), and that often clinicians could not see the value in commencing UL FES, as they were unsure if it would be continued once the patient was transferred home ('*…they're literally going to go to inpatient rehabilitation in a couple of days, is there any point in me starting this?'* (P2 T1 Acute)). Whilst this is not directly related to therapeutic attitudes towards FES specifically, clearly the clinical culture impacts on therapeutic attitudes and beliefs regarding what options are available when managing people with stroke. Barriers including perceptions of working patterns across the stroke pathways and time limitations will influence therapeutic attitudes and have the potential to minimise opportunity to utilise technology-enhanced rehabilitation with interventions such as FES. One suggestion is that an agreed approach to rehabilitation of the UL post-stroke needs to be determined across stroke pathways to avoid this mismatch of practice. This could include where clinicians are either utilising UL FES and other adjuncts to UL rehabilitation, or could feasibly implement it. Recent stroke guidelines state that where resources to support application (including physical and educational) are available, there should be greater utilisation of UL FES in patients with post-stroke impairments, if clinically indicated (ISWP, 2023) and this pragmatic solution to identifying where and how the UL is managed across a stroke pathway could inform practice, cultivate a culture/community of practice (including knowledge transfer and confidence building) and also potentially help raise awareness of the potential uses of UL FES amongst staff working within the stroke pathway. Furthermore, this pragmatic solution could also be included within clinical practice guidelines.

An underpinning knowledge of UL anatomy is required to support FES application in people with stroke and this was reinforced in the Delphi with agreed consensus statements relating to assessment of the UL (including the glenohumeral joint and scapula alignment) and use of FES to stimulate muscle stabilisers of the shoulder. Having a 'good' knowledge of UL anatomy was seen as a facilitator to UL FES application in people with stroke and also interestingly highlighted as a barrier by one of the senior occupational therapists, who indicated that within their team there was a perception that physiotherapists had greater UL anatomical awareness and were, therefore, more likely to consider use of UL FES. Other studies have reported that occupational therapists can feel disadvantaged due to having less underlying anatomical knowledge (Giles et al., 2021; Schofield, 2018), however, this evidence is based on data from the USA and is not necessarily transferable to a UK occupational therapy population, but does warrant further investigation.

The focus group discussions illuminated similarities across both NHS Foundation Trusts with the primary reason for lack of clinical application being confidence in the use of UL FES and the perception that it is both complex and specialist (Study Three: Chapter 6). Several participants highlighted feelings of anxiety associated with use of UL FES, including a fear of incorrect use, not wanting to be the only therapist present during application and the risk of feeling inadequate in front of people with stroke if they appeared unsure of its application. Evidence shows that there are differences in performance of novice and expert, and in a clinical context this can impact clinical reasoning (clinical reasoning is defined as the thinking that is associated with conducting clinical practice) (da Silva Araujo et al., 2022; Higgs, 1992) and confidence (Unsworth, 2001). Improved clinical confidence in FES is important; adoption and implementation of clinical practice guidelines in other settings and professional groups has highlighted the importance of leadership (Gallione et al., 2022) and an element of behaviour change from clinicians (Musselman et al., 2024). Expert guidance, theory and application of new knowledge often underpin clinical learning (Flannery Wainwright et al., 2011; Mylopoulos et al., 2018) and can support a 'novice' to develop in their clinical confidence. Expert opinion and development of clinical practice guidelines has the potential to influence the use of UL FES in people with stroke. This was the primary rationale for why experts were approached in the form of a Delphi methodology.

The Delphi was focused on gaining expert consensus on factors relating to the use of UL FES in people with stroke. However, in terms of attitudes towards application of UL FES in several statements that achieved consensus (i.e. achieved over the 70% threshold), there were still some variations in opinion with 23% of the experts disagreeing with a statement related to the use of priming activities (*Priming activities such as UL stretching, and joint mobilisations should be considered prior to application of UL FES)* and 29% disagreeing with discontinuing when goals are not achieved *(UL FES could be discontinued if the patient is not achieving their* *goal).* Importantly, what this highlights is there is often variation in clinical opinion, both within a 'novice' and 'expert' population, and with the knowledge that depth and breadth of experience informs clinical decisions (Flannery Wainwright et al., 2011) this should be factored into any future clinical practice guidelines.

An interesting point that was highlighted from both the focus groups and the Delphi was cost or funding of FES. Availability and cost of FES equipment were highlighted across both NHS Foundation Trusts and clearly influence clinical attitudes and, therefore, use (*'So, what you don't want to do is…try functional electrical stimulation with someone once and then not have the resources or staffing availability to then carry it out.* (P9 T1 Rehab)). This aligns with an agreed consensus statement based on the impact of cost influencing use of FES (*Affordability of FES equipment might impact the decision to commence with UL FES as a treatment option.*) and previous qualitative research which identified that, despite the potential of assistive technologies (such as UL FES) to support self-management, lack of funding and clinical advice/support were significant barriers to accessing to them (Demain et al., 2013). Whilst lack of funding provision and/or cost of equipment should not necessarily influence therapeutic attitudes, it is evident from these findings that it does. Furthermore, it has already been established that there are wider factors that influence therapeutic attitudes towards the use of any technology including cost, ease of use and organisational support (Bower et al., 2021).

8.1.3 Post-stroke clinical presentations that inform the use of upper limb functional electrical stimulation

Identifying suitable people with stroke that might benefit from UL FES was discussed within the focus groups and caused apprehension, with participants stating they would not know who it would be most suitable for, or even why it might optimally suit. One participant highlighted that they believed competence in identifying suitable people with stroke would lead to greater use (‘*I think if we felt more confident and competent and able to identify patients, I think we would be using it more…we would feel more confident with it*.’ (P15 T1 Community)). Findings from the Delphi clearly highlighted a number of post-stroke presentations that would benefit from UL FES. These included agreed consensus on early use of UL FES in the acute phase post-stroke (*UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation*). There is evidence that UL FES interventions in the early phase post-stroke can have positive long-term outcomes (Farmer et al., 2014; Kutlu et al., 2016; Lawrence et al., 2001). Further to this, a systematic review identified that the earlier the use of FES post-stroke, the more significant the improvement in ADLs compared to conventional therapy alone, and when FES was initiated over one year post-stroke the benefits were negligible (Eraifej et al., 2017).

Post-stroke shoulder pain was another clinical presentation that consensus was agreed upon (*Application of FES on the shoulder complex has a positive impact on the management of post-stroke hemiplegic shoulder pain).* Hemiplegic shoulder pain occurs in approximately 40% of people with stroke (Kumar et al., 2022) with recommendations including full UL assessment and analgesia (NICE, 2023). Studies have shown that electrical stimulation can positively impact shoulder pain associated with shoulder subluxation post-stroke (Vuagnat &

Chantraine, 2003); however, some people with stroke present with shoulder pain when no subluxation is evident, either because the pain is of musculoskeletal origin, or due to altered upper limb usage post-stroke. A RCT of EMG-triggered neuromuscular electrical stimulation coupled with bilateral arm training (compared to transcutaneous electrical nerve stimulation (TENS) combined with bilateral arm training) highlighted positive results including reduction in shoulder pain and a pain-free increase in range of shoulder motion in people with stroke (Chuang et al., 2017). These findings highlight that use of electrical stimulation is beneficial in conjunction with movement, and further reinforces consensus statements from the Delphi study relating to use of FES in conjunction with either passive or task specific training/exercise.

Finally, specifically reasoning where to stimulate in a complex weak UL presentation was discussed, with one participant in the focus groups highlighting feeling overwhelmed because of the complexity of the UL and their concerns with a lack of understanding about how to accurately generate functional UL movement using FES (*'I find that really difficult in the early stages when I'm using functional electrical stimulation with someone with a really weak upper limb, like how to incorporate that function because there's so much needs stimulation.'* (P4 T1 Acute)). Whilst there were no formulated consensus statements specifically relating to weak UL presentations post-stroke, evidence would indicate that UL FES, if applied to dense ULs, has significant benefit (Eraifej et al., 2017; Howlett et al., 2015). Importantly, in the most recently updated stroke guidelines, consideration of FES is recommended for UL impairments post-stroke where exercise against gravity cannot be performed independently ('People with stroke who are unable to exercise against gravity independently should be considered for adjuncts to exercise (such as neuromuscular or functional electrical stimulation), to support participation in exercise training.' (NICE, 2023)).

Due to the findings from Study 6, the lack of clarity on optimal dose and stimulation protocols (NICE, 2023) and because of the variety of possible post-stroke UL presentations, further research is warranted relating to post-stroke presentations and application of FES. Whilst clinical decisions should be made based on patient needs, goals and preferences, it would be beneficial to build a body of case studies to highlight UL FES application. The early clinical practice guidelines developed through this programme of studies could support their development.

8.1.4 Challenges to implementation of upper limb functional electrical stimulation and implications for clinical practice.

The findings from Studies Two and Three (Chapters 5 & 6) of this programme of study highlight the lack of use of UL FES across two large NHS Foundation Trust stroke pathways. The findings were in agreement with previous research which concurred that, despite being recommended in the Canadian stroke guidelines, FES was the least utilised intervention; preference to other treatment options and lack of training in FES were cited as the main barriers to use (Auchstaetter et al., 2016; Musselman et al., 2024). Similarly, a large-scale cross-sectional survey of UK therapists (physiotherapists and occupational therapists) on the management of post-stroke UL impairments highlighted that UL FES was not often used (Stockley et al., 2019). Focus group discussions (Study Three: Chapter 6) revealed many important opinions about the management of the UL and the use of FES in people with stroke. Clinicians did not see the treatment of the hemiplegic UL as a priority and consequently did not often utilise UL FES (especially in the acute setting). Although the appetite to use technology and address the use of UL FES was highlighted by participants in both the in-patient rehabilitation and community settings as a means to increase dose in people with stroke.

Clinical practice guidelines are backed by strong scientific evidence and are based on recommendations to optimise care (Graham et al., 2011). However, guidelines are not always applied and there are numerous barriers to implementation (Gallione et al., 2022). A number of previous reviews relating to clinical practice guideline implementation have identified extrinsic factors that could act as barriers or facilitators to adoption including the clarity and credibility of the guideline, the work environment, time as a resource and strategies used to promote guideline adherence (Correa et al., 2020; Francke et al., 2008; Keiffer, 2015; Lugtenberg et al., 2009). The findings generated from the focus groups relating to barriers to use of UL FES (Study Three: Chapter 6) align with the outcomes of these reviews. A number of intrinsic barriers were identified during the focus groups in relation to concerns about UL FES application and use competency; how clinicians are perceived by their patients if they appear indecisive about the application of UL FES and the impact this might have on patients' confidence in their clinical ability.

A mixed-method systematic review by Gallione et al. (2022) highlighted that one of the key intrinsic factors to nurses' use of clinical practice guidelines includes knowledge and skills; a lack of training and experience prior to implementation of new guidelines can lead to staff feeling inadequate. In turn, this limits adoption. The key extrinsic factors included the environmental impact of lack of resources and organisational limitations. Whilst identification of barriers that might hinder implementation of clinical practice guidelines is important, there is also potentially an argument for pre-guideline implementation strategies to increase adherence. Pre-emptive education and training relating to FES for example prior to adoption of new guidelines could minimise the impact of barriers and maximise the likelihood of success with guideline implementation and adoption.

This programme of research has created new knowledge and it has highlighted the need for greater guidance for clinicians to support application of UL FES in clinical practice. Recently, two clinical practice guidelines were developed on the use of FES for walking (Bulley et al., 2024; Johnston et al., 2021); however, there are currently no UL-specific clinical practice guidelines available. Whilst the current stroke guidelines (ISWP, 2023) have recommended use of UL FES, there is a lack of specific detail relating to application. The Association of Chartered Physiotherapists Interested in Neurology (ACPIN) evidence-based LL clinical practice guidelines (Bulley et al., 2024) provide much more detail relating to application of LL FES and this is equally required to support the management of the UL.

Alongside clinical practice guidelines, the need to facilitate the clinical implementation of UL FES in rehabilitation practice is clear. As documented in both this thesis (Chapter 6) and in the literature, clinicians perceive lack of knowledge as one of the most significant intrinsic barriers to the use of UL FES (Auchstaetter et al., 2016; Brown et al., 2023; Musselman et al., 2024). Recently, Musselman et al. (2024) explored learning needs and preferences for education on FES with the aim of exploring physiotherapists’ and occupational therapists’ perspectives. A knowledge-to-action (KTA) framework was used to support clinical implementation of FES. This KTA framework was utilised to identify the key barriers to implementation and, on identification of those barriers, a clinical decision support tool was created by the authors to support increased use of FES in clinical practice. Whilst this was not unique to UL management, it is an example of how to address the underlying issue of implementation. Further to this, an e-learning educational package was developed and following use by clinicians was evaluated.

8.2. Future development and evaluation

The concurrency of findings outlined in the chapters of this thesis is further evidence of the importance of having clear practical guidance, informed by expert knowledge, combined with the evidence base for post-stroke UL management; particularly for UL FES due to the complexity of treating the UL and the technical nature of some FES devices. The recommendations for use of UL FES in Study Four provide consensus on a series of expert informed recommendations based on clinical presentation, UL FES application, treatment progression and treatment evaluation; in addition to creating new knowledge to advance and support use of UL FES by clinicians in stroke rehabilitation. Informed by the findings from Study Four, an initial outline for clinical practice guidelines for the use of UL FES in people with stroke has been created (see Table 7.8). However, there are a number of key areas that warrant further investigation to support the novel work developed in Study Four; these areas are discussed below and include (8.2.1) contribution to existing and emerging new knowledge, (8.2.2) limitations and lessons learnt and (8.2.3) future research directions.

8.2.1 Contribution to existing and emerging new knowledge

This research comprised of a systematic review, a medical-records review, six focus groups and an international Delphi study. The systematic review summarised the current evidence relating to the application of UL FES and identified that despite a relatively large number of trials there was too much variation between FES applications to indicate recommended UL treatment parameters. The systematic review informed the data collection for the medical-records review and the first round of the Delphi study. The medical-record review provided detailed understanding of the assessment and management of the post-stroke UL across a large NHS Foundation Trust stroke pathway and identified that UL FES as a treatment modality was utilised unfrequently and with limited evidence of justification in the clinical notes. Both the systematic review and the medical records review laid the foundations for both the in-depth focus group activity and the Delphi study. Utilising a multimethod approach to understand the use of UL FES in stoke rehabilitation has allowed for a clearer picture of clinicians' experiences relating to the management of the UL post-stroke across the stroke pathway and highlighted the need for further guidance to support implementation. This body of research includes:

- the first study to follow people with stroke across a large NHS Foundation Trust stroke pathway and report on UL management and application of UL FES.
- the first study to explore the perceptions of individuals working across two large NHS Foundation Trust stroke pathways about the management of the UL post-stroke and the application of UL FES.
- the first study to develop consensus-based statements relating to the application of UL FES in people with stroke. These will be further developed post-doctorly to produce clinical practice guidelines (see draft guidelines Chapter 7 and (8.2.3) future research directions).

8.2.2 Limitations and lessons learned

When reflecting on Study One, one limitation of the systematic review was that systematic reviews were included. This was a decision made early in this body of research, however, with hindsight, a scoping review or mapping review might have been more suitable.

Within Study Two, the medical record-based service evaluation of an NHS Foundation Trust stroke pathway, although a large sample of 237 medical records were examined, there were 186 files archived or in use. These files might have shed further light on the management of the post-stroke UL.

The aim of the resulting outline clinical practice guidelines is to support best practice and to encourage clinicians to implement UL FES in stroke rehabilitation. A strength of the conducted research was that there was international representation from expert clinicians and FES researchers which produced consensus agreements using the Delphi methodology. The LL guideline Delphi research engaged the 'wider community' of FES users' perspectives including service users. Whilst this was not the focus of this particular clinical guideline development, a further study canvassing the opinions of both service users and service managers could enhance and add to the depth to the findings. Unlike the Delphi that informed the LL FES clinical practice guideline (Bulley et al., 2024), this study did not address FES service provision or recommendations relating to referral to FES services; however, the findings from the LL FES guidelines can be drawn upon to guide service provision for UL FES. What is clear from this programme of research relating to the use of UL FES in people with stroke is that a systems approach is required; the need for strategies to support implementation resonates within the LL FES guidelines (Brown et al., 2023; Bulley et al., 2024) and ongoing research is needed to address the gap between research and translation into clinical practice.

Finally, there were a number of alternative methodologies that could have been conducted to further enhance/support the findings related to application of UL FES including alternative consensus method-based methodologies or observational studies. Originally, when mapping out the potential direction of investigation into the topic of UL FES post-stroke, there was an intention to carry out a co-design of a clinical practice guideline with clinicians across an NHS Foundation Trust stroke pathway, however, following the outcome of Studies Two and Three (Chapters 5 & 6), it was clear that UL FES was not frequently utilised, that UL rehabilitation post-stroke was not a priority across the stroke pathway, and clinical knowledge of UL FES application post-stroke was limited. Whilst a co-design would have both engaged and actively included clinicians in the use of UL FES across the stroke pathway, due to these findings an alternative approach was chosen. Furthermore, the data for Study Two was collected during a global pandemic, and whilst this influenced the time taken to obtain and complete the medical record-review, it also enabled the research to continue and facilitated a significant amount of learning regarding real-world data collection.

Reflexivity, particularly within qualitative research, is widely recognised as a fundamental component of rigorous research practice (Watt, 2015). It involves the researcher's ongoing critical self-examination of their own role, assumptions, values, and potential biases throughout the research process. This reflective practice is especially important in capturing the complex and dynamic nature of qualitative inquiry, allowing the researcher to view the process through their individual lens while maintaining transparency and integrity. My journey as a researcher has been shaped by my professional background and personal interests. I have recognised and acknowledged my positivist approach to the use of technology-enhanced rehabilitation, and throughout my career has I have had a sustained interest in UL rehabilitation post-stroke. This lived experience has provided me with valuable insights; however, I am acutely aware that it may also have influenced my approach to this research, particularly in the design and interpretation of qualitative studies exploring the potential use of UL FES in post-stroke rehabilitation.

Recognising my positionality, I have sought to both leverage its strengths and critically address its limitations. My professional expertise enabled me to engage meaningfully with participants and interpret nuanced clinical perspectives. At the same time, I remained aware of the risk of confirmation bias and the potential for my enthusiasm for technology-enhanced interventions to shape data collection, analysis, and interpretation. To ensure the credibility and trustworthiness of this research, I implemented a range of strategies to manage and mitigate undue researcher influence. One key approach was peer debriefing. I engaged in regular, structured discussions with academic peers and my PhD supervisors throughout the research process. These dialogues provided an essential external lens through which my assumptions, interpretations, and methodological decisions could be critically examined. Peer debriefing sessions were particularly valuable in surfacing and challenging potential biases related to the use and application of UL FES in stroke rehabilitation. Feedback from these sessions prompted me to revisit and refine my analytic approach, consider alternative explanations, and ensure that my interpretations remained grounded in the data rather than my preconceptions. Through this process, peer debriefing not only enhanced the rigour and transparency of my research but also fostered ongoing reflexivity, prompting me to continuously reflect on my positionality and its impact. While these strategies cannot entirely eliminate researcher influence, they have been instrumental in strengthening the integrity and trustworthiness of my findings.

8.2.3 Implications for future research

This thesis contributes to new knowledge and advances practice focusing on the application of UL FES in people with stroke. This was achieved by gaining expert consensus on the use of UL FES in people with stroke (Chapter 7, informed by findings from Chapters 4, 5 and 6). Following the studies outlined in this thesis, future research would be to build on these outline clinical practice guidelines to create a user-centred version that combined the expert consensus statements with the views of service users and the existing evidence base that informs how best to optimise functional recovery.

Specifically, future research should include:

1) **Further development of the clinical practice guidelines.**

Development of the findings from the Delphi study (Study Four: Chapter 7) including evaluating the suggested format (Table 7.8) into more formal guidelines. These could be sense checked with the participants of the original Delphi study (Study Four) and a newly developed steering group. The steering group could be comprised of members of ACPIN and participants from Study Three. Recommendations could be made including content and structure of the clinical practice guidelines. The thesis author has already been in consultation with the authors of the LL clinical practice guidelines (Bulley et al., 2024) and ACPIN with an agreement to continue development of the UL clinical practice guidelines post-doctorly with the aim of publication and endorsement from ACPIN.

2) **Implementation of the clinical practice guidelines**

Following publication of the clinical practice guidelines, future research should address implementation of UL FES, including a clear understanding of how clinicians use clinical practice guidelines and how best to practically support use of FES in clinical practice. Multiple barriers to the management of the UL post-stroke and the use of FES have been highlighted within this programme of study and supported by the current evidence base (Auchstaetter et al., 2016; Brown et al., 2024; Howlett et al., 2018; Musselman et al., 2024). The focus should be on making a shift towards understanding the knowledge gap, developing a community of practice and building clinical confidence to facilitate greater implementation. Future research should also aim to develop educational materials relating to the application of UL FES. This should be focused at clinical application to support those applying UL FES across the stroke pathway to increase confidence and build competence. It should also be user focused with materials to support educating people with stroke and their family/carers to understand the use and application of UL FES. This could support independent use and application outside of the clinical setting. With foundations rooted in findings from this thesis, these future studies could provide more in-depth support for clinicians working with people with stroke and have the potential to influence greater implementation across the stroke pathway.

3) Review of clinical practice guidelines implementation

Following the development and publication of the LL clinical practice guidelines (Bulley et al., 2024) the focus has shifted to implementation (Brown et al., 2023). On further development of the consensus statements developed in Study 4 and future publication of the clinical practice guidelines for the use of UL FES in people with stroke, there will be a need to review implementation.

8.3. Conclusion

In conclusion, this thesis has explored application of UL FES in people with stroke; with the overall aim of exploring the development of clinical practice guidelines to support the application of post-stroke UL FES. From the studies included in this thesis, individuals working across the stroke pathway have highlighted the value of the use of UL FES in the management of UL impairments post-stroke. However, it was also apparent that there was not enough guidance within the literature to support clinical application and, therefore, clinical experts were approached to gain valuable insight with UL FES application to develop consensus-based UL FES clinical guidelines.

This work has clarified critical deficits in published studies as a source of practical guidance, important gaps in the actual provision of UL FES in an NHS Foundation Trust stroke care pathway, and key barriers perceived by healthcare practitioners. The expert-based consensus recommendations produced in this work form a basis for developing future clinical practice guidelines with professional endorsement. It is recognised that effective implementation of UL FES in stroke pathways will require a range of other barriers to be addressed; however, this work arguably takes an important step towards this goal, and to the realisation of improved care for the many people each year who experience UL impairments following a stroke.

Chapter 9 References

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Chapter 10 Appendices

10.1. Chapter 4 appendices

10.1.1 Poster presented at RehabWeek for the International Functional Electrical Stimulation Society (IFESS)

Sheffield Hallam University

A systematic review of treatment parameters for post-stroke upper limb functional electrical stimulation.

ifess

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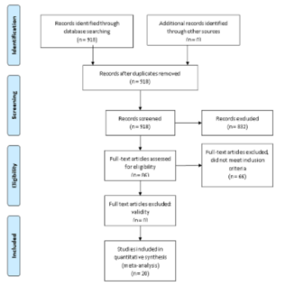
Background

- Task orientated functional electrical stimulation (FES) promotes clinically significant gains in upper limb (UL) recovery post stroke [1]
- FES combined with conventional therapy improves voluntary reaching and grasp [2]
- Barriers to use include set up time and lack of knowledge of UL FES application [3]
- Underpinning clinical reasoning on the management of the UL and treatment strategies is sparse.

Aim

- To identify UL FES treatment parameters from previous research to inform future post-stroke interventions.

Methods	
Inclusion	• English language publications • adult (+18 years) stroke population • UL FES
Exclusion	• Non-stroke or mixed neurological presentations • studies not documenting the use of UL FES
Searches	Electronic databases (CINAHL, COCHRANE, MEDLINE AND SPORTDiscus)
Quality Review	An integrated quality for reviews of multiple study designs (ICROMS) [4]



Results

Study Design	Number
case	n=6
pre-test post-test	n=4
randomised controlled trial	n=4
feasibility	n=3
pilot	n=2
case series	n=1

outcome measures	Most frequent use
1. Action Research Arm Test (ARAT)	n=10
2. Fugl Meyer assessment scale (FM)	n=7
3. Modified Ashworth Scale (MAS)	n=6

Duration post stroke	
>6 months post stroke	n=15
acute stage	n=5

Participant mean time post stroke
12.65 months (±, 17.65 months; range, 2 weeks to 5.5 years).

Mean no. and duration of treatment sessions	
41.7 treatment sessions	(±38.42; range, 10 to 168 sessions)
51 mins per session	(±23.48; range,10 minutes to 1.5 hours)

Location of muscle stimulated:

- proximal UL muscles (n=4)
- distal UL muscles (n=6)
- both (n=7)
- scapula (n=1)

de-weighting system with FES (n=4)

prosthesis as a means of supplementing the effects of FES (n=6)

Conclusion

- FES in conjunction with conventional treatment reduces UL spasticity and improves functional activity.
- Wide variation in FES treatment parameters.
- Lack of justification for use of adjuncts with FES.
- More robust detail of FES treatment parameters are required to assist treating therapists.

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10.1.2 Search strategy and study selection process

((Stroke OR "Cerebrovascular accident" OR CVA OR Hemiplegia OR Hemiparesis) AND ("Upper limb" OR "Upper extremity" OR Arm* OR Scapula* OR Shoulder* OR Forearm* OR Hand* OR Wrist* OR Finger*) AND ("Functional Electrical Stimulation" OR "Electrical stimulation" OR "e-stimulation" OR "Functional stimulation" OR Microsimulation OR "Muscle stimulation" OR "Nerve stimulation")).
All search terms were looked for in the title and abstract fields. The Boolean operators AND OR were used, alongside truncation (*) and phrase searching (""). When available as a search limiter, the results were filtered to only include English language publications. No date limits were applied.

Exclusion Criteria:
* Non-Stroke Patients
* Non-FES
* Non-Upper Limb
Inclusion criteria
* Adult patients (18+ years)
* Stroke patients
* UK and non-UK studies
* Upper Limb FES

10.1.3 Systematic review screening

Key	Number
Exclude	0
Include	1
Key reason for exclusion, screened in order of: study type, population, intervention, outcomes.	**Number**
Study type	1
Population	2
Intervention	3
Outcomes	4
Other	5

1	Alon,G.; Levitt,A.F.	Acute stroke survivors' residual deficits of upper limb function after 12 weeks of physical rehabilitation training and FES	0
2	Alon,G.; McBride,K.S.; Levitt,A.F.	Neuromuscular electrical stimulation (NMES) training dose vs. response of upper limb in the acute post-stroke rehabilitation	0
3	AGUIAR, L.T., NADEAU, S., MARTINS, J.C., TEIXEIRA-SALMELA, L., BRITTO, R.R. and FARIA,CHRISTINA DANIELLI COELHO DE MORAIS,2020.	Efficacy of interventions aimed at improving physical activity in individuals with stroke: a systematic review. *Disability & Rehabilitation*, *42*(7), pp. 902–917.	0
4	Alon,G.; Sunnerhagen,K.S.; Geurts,A.C.H.; Ohry,A.	A home-based, self-administered stimulation program to improve selected hand functions of chronic stroke	1
5	ALON, G., 2009.	Defining and measuring residual deficits of the upper extremity following stroke: a new perspective. *Topics in Stroke Rehabilitation*, *16*(3), pp. 167–176.	0
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10	Bustamante,Carlos; Brevis,Francisco; Canales,Sebastián; Millón, Sebastián; Pascual,Rodrigo	Effect of functional electrical stimulation on the proprioception, motor function of the paretic upper limb, and patient quality of life: A case report	1
11	CHAE, J., SHEFFLER, L. and KNUTSON, J., 2008.	Neuromuscular electrical stimulation for motor restoration in hemiplegia. *Topics in Stroke Rehabilitation*, *15*(5), pp. 412–426.	0
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16	Cuesta-Gómez, Alicia; Molina-Rueda, Francisco; Carratala-Tejada, Maria; Imatz-Ojanguren, Eukene; Torricelli,Diego; Miangolarra-Page, Juan	The use of functional electrical stimulation on the upper limb and interscapular muscles of patients with stroke for the improvement of reaching movements: A feasibility study	1
17	DALY, J.J., HOGAN, N., PEREPEZKO, E.M., KREBS, H.I., ROGERS, J.M., GOYAL, K.S., DOHRING, M.E., FREDRICKSON, E., NETHERY, J. and RUFF, R.L., 2005.	Response to upper-limb robotics and functional neuromuscular stimulation following stroke. *Journal of Rehabilitation Research & Development*, *42*(6), pp. 723–736.	
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		Extremity Function in Subjects with Acute Cerebro Vascular Accident. *Indian Journal of Physiotherapy & Occupational Therapy*, *12*(3), pp. 71–75.	
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22	Eraifej 2017	Effectiveness of upper limb functional electrical stimulation after stroke for the improvement of ADLs and motor function: a systematic review and meta-analysis	1
23	FARRELL, J.F., HOFFMAN, H.B., SNYDER, J.L., GIULIANI, C.A. and BOHANNON, R.W., 2007.	Orthotic aided training of the paretic upper limb in chronic stroke: results of a phase 1 trial. *NeuroRehabilitation*, *22*(2), pp. 99–103.	0

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52	Marquez-Chin, Cesar; Bagher,Shaghayegh; Zivanovic,Vera; Popovic,Milos R.	Functional electrical stimulation therapy for severe hemiplegia: Randomized control trial revisited	
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54	MAZZOLENI, S., DURET, C., GROSMAIRE, A.G. and BATTINI, E., 2017.	Combining Upper Limb Robotic Rehabilitation with Other Therapeutic Approaches after Stroke: Current Status, Rationale, and Challenges. *BioMed Research International*, *2017*, pp. 1–11.	0
55	Meadmore,Katie L.; Exell,Timothy A.; Hallewell,Emma; Hughes,Ann-Marie; Freeman,Chris T.; Kutlu,Mustafa; Benson,Valerie; Rogers,Eric; Burridge,Jane H. 2014	The application of precisely controlled functional electrical stimulation to the shoulder, elbow and wrist for upper limb stroke rehabilitation: a feasibility study	1

56	Meadmore,Katie L.; Hughes,Ann-Marie; Freeman,Chris T.; Cai,Zhonglun; Tong,Daisy; Burridge,Jane H.; Rogers,Eric. 2012	Functional electrical stimulation mediated by iterative learning control and 3D robotics reduces motor impairment in chronic stroke	1
57	MEADMORE, K.L., EXELL, T.A., BURRIDGE, J.H., HUGHES, A., FREEMAN, C.T. and BENSON, V., 2018.	Upper limb and eye movement coordination during reaching tasks in people with stroke. *Disability & Rehabilitation*, *40*(20), pp. 2424–2432.	0
58	MERRING, C.A. and GOBERT, D.V., 2011.	Recovery 9 Years Post-stroke with Standardized Electrical Stimulation. *Occupational Therapy in Health Care*, *25*(2), pp. 108–118.	0
59	Meijer, J. et al.	Short-term effects and long-term use of a hybrid orthosis for neuromuscular electrical stimulation of the upper extremity in patients after chronic stroke. 2009. *Journal of Rehabilitation Medicine (Stiftelsen Rehabiliteringsinformation)*, *41*(3), pp. 157–161.	0
60	OBAYASHI, S., TAKAHASHI, R. and ONUKI, M., 2020.	Upper limb recovery in early acute phase stroke survivors by coupled EMG-triggered and cyclic neuromuscular electrical stimulation. *NeuroRehabilitation*, *46*(3), pp. 417–422.	1
61	Page,S.J.; Maslyn,S.; Hermann,V.H.; Wu,A.; Dunning,K.; Levine,P.G. 2009	Activity-based electrical stimulation training in a stroke patient with minimal movement in the paretic upper extremity	1
62	Page,Stephen J.; Levine,Peter G.; Basobas,Brittani A. 2016	“Reps” Aren't Enough: Augmenting Functional Electrical Stimulation With Behavioral Supports Significantly Reduces Impairment in Moderately Impaired Stroke	1

63	PAGE, S.J., LEVINE, P. and HILL, V., 2015.	Mental Practice–Triggered Electrical Stimulation in Chronic, Moderate, Upper-Extremity Hemiparesis After Stroke. *American Journal of Occupational Therapy*, *69*(1), pp. 1–8.	0
64	PAGE, S. and HILL, V., 2012	Longer Versus Shorter Daily Durations of Electrical Stimulation During Task-Specific Practice in Moderately Impaired Stroke	
65	PARK, J., 2020.	Effects of mental imagery training combined electromyogram-triggered neuromuscular electrical stimulation on upper limb function and ADLs in patients with chronic stroke: a randomized controlled trial. *Disability & Rehabilitation*, *42*(20), pp. 2876–2881.	1
66	Popovic,Mirjana B.; Popovic,Dejan B.; Schwirtlich,Laszlo; Sinkjaer,Thomas 2004	Functional Electrical Therapy (FET): Clinical Trial in Chronic Hemiplegic Subjects	1
67	POPOVIC, M.B., POPOVIC, D.B., SINKJÆR, T., STEFANOVIC, A. and SCHWIRTLICH, L., 2003.	Clinical evaluation of functional electrical therapy in acute hemiplegic subjects. *Journal of Rehabilitation Research & Development*, *40*(5), pp. 443–453.	
68	QU, H., XIE, Y., LIU, X., HE, X., HAO, M., BAO, Y., XIE, Q. and LAN, N., 2016.	Development of network-based multichannel neuromuscular electrical stimulation system for stroke rehabilitation. *Journal of Rehabilitation Research & Development*, *53*(2), pp. 263–278.	0

69	RING, H. and ROSENTHAL, N., 2005.	Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. *Journal of Rehabilitation Medicine*, *37*(1), pp. 32–36.	0
70	RONG, W., TONG, K.Y., HU, X.L. and HO, S.K., 2015.	Effects of electromyography-driven robot-aided hand training with neuromuscular electrical stimulation on hand control performance after chronic stroke. *Disability & Rehabilitation: Assistive Technology*, *10*(2), pp. 149–159.	0
71	SAHIN, N., UGURLU, H. and ALBAYRAK, I., 2012.	The efficacy of electrical stimulation in reducing the post-stroke spasticity: a randomized controlled study. *Disability & Rehabilitation*, *34*(2), pp. 151–156.	0
72	SEO, N.J., WOODBURY, M.L., BONILHA, L., RAMAKRISHNAN, V., KAUTZ, S.A., DOWNEY, R.J., DELLENBACH, B.H.S., LAUER, A.W., ROARK, C.M., LANDERS, L.E., PHILLIPS, S.K. and VATINNO, A.A., 2019.	TheraBracelet Stimulation During Task-Practice Therapy to Improve Upper Extremity Function After Stroke: A Pilot Randomized Controlled Study. *Physical Therapy*, *99*(3), pp. 319–328.	0
73	SILVEIRA, T.M., DORSCH, S., THOMPSON, G. and TAMPLIN, J., 2021.	Functional electrical stimulation+iPad-based music therapy for upper limb recovery after stroke: Study protocol for a mixed methods randomised controlled trial. *Nordic Journal of Music Therapy*, *30*(4), pp. 314–337.	0
74	SILVEIRA, T.M., TAMPLIN, J., DORSCH, S. and BARLOW, A., 2018.	Let's Improvise! iPad-based music therapy with functional electrical stimulation for upper limb stroke rehabilitation. *Australian Journal of Music Therapy*, *29*, pp. 1–16.	1

75	Smith et al	A Three-Site Clinical Feasibility Study of a Flexible Functional Electrical Stimulation System to Support Functional Task Practice for Upper Limb Recovery in People With Stroke	1
76	SOUZA, I.G.D., SOUZA, R.F.D., BARBOSA, F.D.S., SCIPIONI,KELLY REGINA DIAS DA SILVA, AIDAR, F.J. and ZANONA, A.D.F., 2021.	Protocols Used by Occupational Therapists on Shoulder Pain after Stroke: Systematic Review and Meta-Analysis. *Occupational Therapy International*, *May 2021*, pp. 1–9.	0
77	SULLIVAN, J.E. and HEDMAN, L.D., 2004.	A home program of sensory and neuromuscular electrical stimulation with upper-limb task practice in a patient 5 years after a stroke. *Physical Therapy*, *84*(11), pp. 1045–1054.	1
78	Sullivan,J.E.; Hedman,L.D. 2006	Effects of home-based sensory and motor amplitude electrical stimulation on arm dysfunction in chronic stroke	1
79	SULLIVAN, J., GIRARDI, M., HENSLEY, M., ROHAUS, J., SCHEWE, C., WHITTEY, C., HANSEN, P. and MUIR, K., 2015.	Improving arm function in chronic stroke: a pilot study of sensory amplitude electrical stimulation via glove electrode during task-specific training. *Topics in Stroke Rehabilitation*, *22*(3), pp. 169–175.	0
80	Thrasher,T A.; Zivanovic,Vera; McIlroy,William; Popovic,Milos R.	Rehabilitation of reaching and grasping function in severe hemiplegic patients using functional electrical stimulation therapy	

81	TiLKiCi, Mehmet; ALEMDARO?LU, Ebru; MANDIRO?LU, Sibel; ORDU GÖKKAYA, Nilüfer,Kutay; UÇAN, Halil; AYKAN,Sanem Asl?han	The Effect of Upper Extremity Electrical Stimulation in Addition to Conventional Rehabilitation in Individuals with Chronic Stroke: Randomized Controlled Study	
82	TÜRKKAN, C., ÖZTÜRK, G.T., U?URLU, F.G. and ERSÖZ, M., 2017.	Ultrasonographic assessment of neuromuscular electrical stimulation efficacy on glenohumeral subluxation in patients with hemiplegia: a randomized-controlled study. *Turkish Journal of Physical Medicine & Rehabilitation* (2587-1250), *63*(4), pp. 287–292.	0
83	URTON, M.L., KOHIA, M., DAVIS, J. and NEILL, M.R., 2007.	Systematic literature review of treatment interventions for upper extremity hemiparesis following stroke. *Occupational Therapy International*, *14*(1), pp. 11–27.	0
84	VAFADAR, A.K., CÔTÉ, J.N. and ARCHAMBAULT, P.S., 2015.	Effectiveness of Functional Electrical Stimulation in Improving Clinical Outcomes in the Upper Arm following Stroke: A Systematic Review and Meta-Analysis. *BioMed Research International*, 2015, pp. 1–14.	1
85	VALKENBORGHS, S.R., CALLISTER, R., VISSER, M.M., NILSSON, M. and VAN VLIET, P., 2019.	Interventions combined with task-specific training to improve upper limb motor recovery following stroke: a systematic review with meta-analyses. *Physical Therapy Reviews*, *24*(3), pp. 100–117.	0
86	VASCONCELLOS DA SILVA, W., DE MEDEIROS CIRNE, GABRIELE NATANE, MENESES DA SILVA FILHO, EDSON, WALKER AZEVEDO CACHO, E., LOPES, J.M., DE OLIVEIRA CACHO, R. and PEGORARO BARONI, M., 2018.	Functional electrical stimulation reduces pain and shoulder subluxation in chronic post-stroke patients? Manual Therapy, *Posturology & Rehabilitation Journal*, *16*, pp. 1–5.	1

87	Wang,R Y.	Neuromodulation of effects of upper limb motor function and shoulder range of motion by functional electric stimulation (FES)	0
88	Wang,R.; Chan,R.; Tsai,M.	Functional electrical stimulation on chronic and acute hemiplegic shoulder subluxation	0
89	Wang,R.; Yang,Y.; Tsai,M.; Wang,W.T.J.; Chan,R.	Effects of functional electric stimulation on upper limb motor function and shoulder range of motion in hemiplegic patients	0
90	WHITEHAIR, V.C., CHAE, J., HISEL, T. and WILSON, R.D., 2019.	The effect of electrical stimulation on impairment of the painful post-stroke shoulder. *Topics in Stroke Rehabilitation*, *26*(7), pp. 544–547.	0
91	WILSON, R.D., PAGE, S.J., DELAHANTY, M., KNUTSON, J.S., GUNZLER, D.D., SHEFFLER, L.R. and CHAE, J., 2016.	Upper-Limb Recovery After Stroke. *Neurorehabilitation & Neural Repair*, *30*(10), pp. 978–987.	0
92	Ya-yun Lee; Keh-chung Lin; Hsiao-ju Cheng; Ching-yi Wu; Yu-wei Hsieh; Chih-kuang Chen; Lee,Ya-Yun; Lin,Keh-Chung; Cheng,Hsiao-Ju; Wu,Ching-Yi; Hsieh,Yu-Wei; Chen,Chih-Kuang	Effects of combining robot-assisted therapy with neuromuscular electrical stimulation on motor impairment, motor and daily function, and quality of life in patients with chronic stroke: a double-blinded randomized controlled trial	0
93	YOUNG-RIM PAIK; JEONG-HOON,L.E.E.; DOO-HO,L.E.E.; HEE-SU PARK; DONG-HWAN,O.H.	Effect of mirror therapy and electrical stimulation on upper extremity function in stroke with hemiplegic patient: a pilot study	0

94	Yun,Gi Jeong; Chun,Min Ho; Park,Ji Young; Kim,Bo Ryun	The synergic effects of mirror therapy and neuromuscular electrical stimulation for hand function in stroke patients	0
95	ZHENG, Y., MAO, M.A.O., YINGHUI, C.A.O. and XIAO, L.U., 2019.	Contralaterally Controlled Functional Electrical Stimulation Improves Wrist Dorsiflexion and Upper Limb Function in Patients with Early-Phase Stroke: a Randomized Controlled Trial. *Journal of Rehabilitation Medicine (Stiftelsen Rehabiliteringsinformation)*, *51*(2), pp. 103–108.	0

10.1.4 Data extraction.

Paper No.	Author(s)	Title	Year	Study design	No Participants (n)	Time post-stroke	Severity of stroke	Total number of FES sessions	Total number of weeks	Device type	Device Used	Muscles stimulated	Number of electrodes	Pulse Width	Frequency	Tasks	Outcome Measure	Results
1	Alon,G.; Sunnerhagen.	A home-based. self-	2003	1	77	2	0	99	5	1	1	1,2,3,4,5	5	0	36HZ	1	1,2,3,4	Improvements in all OM
2	BHALLA, N. and	Comparison of Task	2020	2	30	1	0	30	6	2	0	6	2	0	0	1	5,6	Improved hand
3	Bustamante, Carlos: Brevis	Effect of functional	2016	8	1	2	0	10	2	2	2	7	0	300	50	1	5,7	Improvement in both OM
4	Cuesta-Gómez.	The Use of Functional	2017	4	21	2	2	14	1	0	3	6, 8-11	8	200	25	2	8	Improved reach
5	DE KROON, J.R..	Relation between	2005	5	20 studies	3	1,2,3	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Positive results more

6	Eraifej et al	Effectiveness of upper limb	2017	5	20 studies	3	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Early application
7	FRANCK, J.A., SMEETS.	Evaluation of a functional	2019	9	8	1	2,3	18	6	0	5	12	2	200	40	1	5,10	The use of a non-actuated
8	HAYWARD, K.S.. BARKER.	SMART Arm with	2015	2	28	1	3	20	4	2	6	9	2	200	50	2	4,11,12	Increased number of
9	Hedman,L.D.; Sullivan.J.E.:	Neuromuscular electrical	2007	8	1	2	1	18	6	4	0	9,10	2	300	35	3	5,9,13	ARAT and MAL
10	Howlett,Owen A.	Functional Electrical	2015	5	18 studies	3	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	FES improved upper-limb
11	Hughes,A M.: Freeman.	Feasibility of iterative	2009	4	5	2	0	18	not doc	3	0	9	2	300	40	4	5,9	Statistically significant
12	Yang, Jheng-Dao 1. Chun-	Effectiveness of electrical	2019	5	48 studies	3	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Electrical stimulation

13	KAWASHIMA, N.. POPOVIC.	Effect of Intensive	2013	3	1	2	3	108	12	2	3	9-10, 13-17	6	250	40	5, -7	4, 14-15	MAS reduced. No
14	Mann,Geraldi ne:	Acceleromete r-triggered	2011	7	15	2	0	4	2	5,6	7	6, 14, 15	4	350	40	3,8,9	4,5	ARAT IMPROVED
15	MATHIESON, S.. PARSONS.	Combining functional	2018	2	50	1	0	15	3	0	0	1, 2	2	200	45	0	5,9,11	FES alone provides
16	Meadmore,K atie	The application of	2014	4	5	2	0	18	not doc	3	0	1-2,6,9-10	0	0	40	1, 2	5, 9	FM and ARAT both showed
17	Meadmore,K atie	Functional electrical	2012	4	5	2	4	18	not doc	3	0	9, 10	2	0	40	0	5, 9	FM scores improved as
18	OBAYASHI, S., TAKAHASHI.	Upper limb recovery in	2020	2	17	1	3	3, 35	2, 4	5, 7	9	7	4	50	30	0	2, 9, 17	High clinical significant
19	Page,S.J.; Ma slyn.S.: Herm	Activity-based	2009	3	1	2	2, 3	15	3	1	10	1 to 5	5	0	11, -36	1, 3	5, 9	notable changes in

20	Page,Stephen J.: Levine.Pet	“ Reps” Aren't	2016	7	9	2	2	16	8	1	10	1 to 5	5	0	11, -36	1, 3	2, 9, 13	Increased FM score also
21	PARK, J. et al.	Effects of mental	2020	2	68	2	0	30	6	7	11	6	3	200	35	8, 10	5, 9	Improvement in MIT EMG
22	Popovic,Mirja na	Functional Electrical	2004	7	16	2	0	21	3	4	0	0	0	0	0	3	4, 18-19	Improved function with
23	SILVEIRA, T.M..	Let's Improvise!	2018	8	1	1	3	21	8	0	12	6	0	200	50	3	3	
24	Smith et al	A Three-Site Clinical	2019	4	22	3	3	8	6	2	13	VARIED	5	0	50	0	17	The system enabled
25	SULLIVAN, J.E. and	A home program of	2004	8	1	2	0	126	18	4	14	6	2	250	35	1	5, 20	ARAT and STREAM
26	Sullivan,J.E.; Hedman.L.D.	Effects of home-based	2007	1	10	2	0	168	8	4	14	VARIED	2, 4	250	35	1	4, 5	A statisticaly significant

27	VAFADAR, A.K.. CÔTÉ.	Effectiveness of Functional	2015	5	10 studies	3	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	Range	
28	SILVA, W., DE MEDEIROS	Functional electrical	2018	3	4	2	0	20	7	8	16	10, 18	0	300	30	2, 11	4, 9, 22	FES with functional

10.1.5 ICROMS summary

Dimensions	Specific Criteria (a)	RCT	CBA	CITS	NCITS	NCBA	CS	QUAL
1 Clear aims and justification	A. Clear statement of the aims of the research?	✓✓	✓✓	✓✓	✓✓	✓✓	✓✓	✓✓
	B. Rationale for number of pre- and post-intervention points or adequate baseline measurement			✓	✓✓	✓✓		
	C. Explanation for lack of control group				✓	✓		
	D. Appropriateness of qualitative methodology							✓
	E. Appropriate study design							✓✓
2 Managing bias in sampling or between group	A. Sequence Generation	✓✓						
	B. Allocation Concealment	✓✓						
	C. Justification for sample choice				✓✓	✓✓		
	D. Intervention and control group selection designed to protect against systematic difference/selection bias		✓✓					
	E. Comparability of groups						✓✓	
	F. Sampling and recruitment							✓✓
3 Managing bias in outcome measurements and	A. Blinding	✓✓						
	B. Baseline measurement protection against selection bias		✓✓					
	C. Protection against contamination		✓✓					
	D.Protectionagainstsecularchanges			✓✓				
	E. Protection against detection bias: Blinded assessment of primary outcome measures	✓	✓	✓	✓	✓	✓	
	F. Reliable primary outcome measures	✓	✓	✓	✓	✓	✓	✓
	G. Comparability of outcomes						✓✓	
4 Managing bias in follow-up	A. Follow-up of subjects (protection against exclusion bias)	✓						
	B. Follow-up of patients or episodes of care	✓						
	C. Incomplete outcome data addressed	✓	✓	✓	✓	✓	✓✓	✓
5 Managing bias in other study aspect	A. Protection against detection bias: Intervention unlikely to affect data collection	✓	✓	✓	✓	✓		
	B. Protection against information bias						✓	
	C. Data collection appropriate to address research aims							✓
	D. Attempts to mitigate effects of no control				✓✓	✓✓		
6 Analytical rigour	A. Sufficient data points to enable reliable statistical inference			✓✓				
	B. Shaping of intervention effect specified			✓				
	C. Analysis sufficiently rigorous/free from bias	✓	✓	✓	✓	✓	✓	✓
7 Managing bias in reporting/ethical considerat	A. Free of selective outcome reporting	✓	✓	✓	✓	✓	✓	✓
	B. Limitations addressed	✓	✓	✓	✓	✓	✓	✓
	C. Conclusions clear and justified	✓	✓	✓	✓	✓	✓	✓
	D. Free of other bias	✓	✓	✓	✓	✓	✓	✓
	E. Ethical issues addressed	✓	✓	✓	✓	✓	✓	✓

Key		
	✓✓	Mandatory criteria to be met
	✓	Criteria to be included in quality assessment for study design
		Criteria not to be applied in quality assessment for study design
	RCT	Randomised controlled trial
	CBA	Controlled before-after
	CITS	Controlled interrupted time series
	CS	Cohort Study
	NCITS	Non-controlled interrupted time series
	NCBA	Non-controlled before and after
	Qual	Qualitative
	0	Criteria not met
	1	Unclear if met or not met
	2	Criteria met

10.1.6 Full included studies

Paper No.	Author(s)	Title	Year
1	Alon,G.; Sunnerhagen,K.S.; Geurts,A.C.H.; Ohry,A.	A home-based, self-administered stimulation program to improve selected hand functions of chronic stroke	2003
2	BHALLA, N. and SHERGILL, N., 2020.	Comparison of Task Oriented Therapy and Modified Constraint Induced Movement Therapy along with Functional Electrical Stimulation to Improve Hand Function In Sub Acute Stroke survivors: a Randomized Control Trial. *Indian Journal of Physiotherapy & Occupational Therapy*, *14*(4), pp. 84–90.	2020
3	Bustamante,Carlos; Brevis,Francisco; Canales,Sebastián; Millón, Sebastián; Pascual,Rodrigo	Effect of functional electrical stimulation on the proprioception, motor function of the paretic upper limb, and patient quality of life: A case report	2016
4	Cuesta-Gómez, Alicia; Molina-Rueda, Francisco; Carratala-Tejada, Maria; Imatz-Ojanguren, Eukene; Torricelli,Diego; Miangolarra-Page, Juan	The Use of Functional Electrical Stimulation on the Upper Limb and Interscapular Muscles of Patients with Stroke for the Improvement of Reaching Movements: A Feasibility Study	2017

5	DE KROON, J.R., IJZERMAN, M.J., CHAE, J., LANKHORST, G.J. and ZILVOLD, G., 2005.	Relation between stimulation characteristics and clinical outcome in studies using electrical stimulation to improve motor control of the upper extremity in stroke. *Journal of Rehabilitation Medicine*, *37*(2), pp. 65–74.	2005
6	Eraifej et al	Effectiveness of UL FES after stroke for the improvement of ADLs and motor function: a systematic review and meta-analysis	2017
7	FRANCK, J.A., SMEETS, R.J.E.M. and SEELEN, H.A.M., 2019.	Evaluation of a functional hand orthosis combined with electrical stimulation adjunct to arm-hand rehabilitation in subacute stroke patients with a severely to moderately affected hand function. *Disability & Rehabilitation*, *41*(10), pp. 1160–1168.	2019
8	HAYWARD, K.S., BARKER, R.N., BRAUER, S.G., LLOYD, D., HORSLEY, S.A. and CARSON, R.G., 2015.	SMART Arm with Outcome-Triggered Electrical Stimulation: A Pilot Randomized Clinical Trial. *Topics in Stroke Rehabilitation*, *20*(4), pp. 289–298.	2013
9	Hedman,L.D.; Sullivan,J.E.; Hilliard,M.J.; Brown,D.M.	Neuromuscular electrical stimulation during task-oriented exercise improves arm function for an individual with proximal arm dysfunction after stroke	2007
10	Howlett,Owen A. MaOT,a,b Natasha A. Lannin, PhD,a,c,d Louise Ada, PhD,e Carol McKinstry, PhD	Functional Electrical Stimulation Improves Activity After Stroke: A Systematic Review With Meta-Analysis	2015

11	Hughes,A M.; Freeman,C T.; Burridge,J H.; Chappell,P H.; Lewin,P L.; Rogers,E.	Feasibility of iterative learning control mediated by functional electrical stimulation for reaching after stroke	2009
12	Yang, Jheng-Dao 1, Chun-De Liao1,2, Shih-Wei Huang1,3 , Ka-Wai Tam4,5,6, Tsan-Hon Liou1,3, Yu-Hao Lee1, Chia-Yun Lin7 and Hung-Chou Chen1,3,	Effectiveness of electrical stimulation therapy in improving arm function after stroke: a systematic review and a meta-analysis of randomised controlled trials	2019
13	KAWASHIMA, N., POPOVIC, M.R. and ZIVANOVIC, V., 2013.	Effect of Intensive Functional Electrical Stimulation Therapy on Upper-Limb Motor Recovery after Stroke: Case Study of a Patient with Chronic Stroke. *Physiotherapy Canada*, *65*(1), pp. 20–28.	2013
14	Mann,Geraldine; Taylor,Paul; Lane,Rod	Accelerometer-triggered electrical stimulation for reach and grasp in chronic stroke patients: a pilot study	2011
15	MATHIESON, S., PARSONS, J., KAPLAN, M. and PARSONS, M., 2018.	Combining functional electrical stimulation and mirror therapy for upper limb motor recovery following stroke: a randomised trial. *European Journal of Physiotherapy*, *20*(4), pp. 244–249.	2018
16	Meadmore,Katie L.; Exell,Timothy A.; Hallewell,Emma; Hughes,Ann-Marie; Freeman,Chris T.; Kutlu,Mustafa; Benson,Valerie; Rogers,Eric; Burridge,Jane H. 2014	The application of precisely controlled functional electrical stimulation to the shoulder, elbow and wrist for upper limb stroke rehabilitation: a feasibility study	2014

17	Meadmore,Katie L.; Hughes,Ann-Marie; Freeman,Chris T.; Cai,Zhonglun; Tong,Daisy; Burridge,Jane H.; Rogers,Eric. 2012	Functional electrical stimulation mediated by iterative learning control and 3D robotics reduces motor impairment in chronic stroke	2012
18	OBAYASHI, S., TAKAHASHI, R. and ONUKI, M., 2020.	Upper limb recovery in early acute phase stroke survivors by coupled EMG-triggered and cyclic neuromuscular electrical stimulation. *NeuroRehabilitation*, *46*(3), pp. 417–422.	2020
19	Page,S.J.; Maslyn,S.; Hermann,V.H.; Wu,A.; Dunning,K.; Levine,P.G. 2009	Activity-based electrical stimulation training in a stroke patient with minimal movement in the paretic upper extremity	2009
20	Page,Stephen J.; Levine,Peter G.; Basobas,Brittani A. 2016	“Reps” Aren't Enough: Augmenting Functional Electrical Stimulation With Behavioral Supports Significantly Reduces Impairment in Moderately Impaired Stroke	2016
21	PARK, J. et al.	Effects of mental imagery training combined electromyogram-triggered neuromuscular electrical stimulation on upper limb function and ADLs in patients with chronic stroke: a randomized controlled trial. *Disability & Rehabilitation*, *42*(20), pp. 2876–2881.	2020
22	Popovic,Mirjana B.; Popovic,Dejan B.; Schwirtlich,Laszlo; Sinkjaer,Thomas 2004	Functional Electrical Therapy (FET): Clinical Trial in Chronic Hemiplegic Subjects	2004

23	SILVEIRA, T.M., TAMPLIN, J., DORSCH, S. and BARLOW, A., 2018.	Let's Improvise! iPad-based music therapy with functional electrical stimulation for upper limb stroke rehabilitation. *Australian Journal of Music Therapy*, *29*, pp. 1–16.	2018
24	Smith et al	A Three-Site Clinical Feasibility Study of a Flexible Functional Electrical Stimulation System to Support Functional Task Practice for Upper Limb Recovery in People With Stroke	2019
25	SULLIVAN, J.E. and HEDMAN, L.D., 2004.	A home program of sensory and neuromuscular electrical stimulation with upper-limb task practice in a patient 5 years after a stroke. *Physical Therapy*, *84*(11), pp. 1045–1054.	2004
26	Sullivan,J.E.; Hedman,L.D. 2006	Effects of home-based sensory and motor amplitude electrical stimulation on arm dysfunction in chronic stroke	2007
27	VAFADAR, A.K., CÔTÉ, J.N. and ARCHAMBAULT, P.S., 2015.	Effectiveness of Functional Electrical Stimulation in Improving Clinical Outcomes in the Upper Arm following Stroke: A Systematic Review and Meta-Analysis. *BioMed Research International*, *2015*, pp. 1–14.	2015
28	SILVA, W., DE MEDEIROS CIRNE, GABRIELE NATANE, MENESES DA SILVA FILHO, EDSON, WALKER AZEVEDO CACHO, E., LOPES, J.M., DE OLIVEIRA CACHO, R. and PEGORARO BARONI, M., 2018.	Functional electrical stimulation reduces pain and shoulder subluxation in chronic post-stroke patients? *Manual Therapy, Posturology & Rehabilitation Journal*, *16*, pp. 1–5.	2018

10.2. Chapter 5 appendices

10.2.1 Health Research Authority (HRA) tool.

	RESEARCH*	Service Evaluation/ Improvement/ Development	Clinical/ Non-Financial Audit	Health Surveillance
PURPOSE	A key feature of research is that it is intentionally planned and designed using documented methodology that will allow results to be extrapolated or applied from the study sample to a larger population. This extrapolation/application is what the terms 'generalisable' and 'transferable' refer to. In the case of quantitative research, statistical methods are used to achieve results that are 'generalisable' from a sample to the sampled population. In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.	Designed and conducted solely to define or judge current care or service, or to deliver and measure improvements in quality of the current service.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted to assess priorities, evaluate interventions, and detect and manage threats to health and adverse health status (including incidents, risk factors, hazards, outbreaks and epidemics; may also address health inequalities).
QUESTION/ HYPOTHESIS	Aims to generate a new hypothesis or test a hypothesis. The approach to this may be quantitative, qualitative or both.	Service evaluation is designed to answer the question: 'What standard does this service achieve?' This is normally addressed by asking those in receipt of the service.	Designed to answer the question: 'Does this service reach a predetermi ned,	Designed to answer the questions: 'Is there a need to start, continue or stop defined public health interventions?', or 'Is there need for further

		Service development or improvement seeks to find out what improvement can be achieved within that service only	recognised or pre-established standard?'	investigations?', or 'What is the cause of this outbreak (often of a disease) or incident and how do we manage it?'
AIM	Has clearly defined aims and objectives. The project seeks to answer a specific research question or questions.	Measures current service without reference to a standard. (In the case of service improvement/development the current service may be compared to the previous service).	Measures against a standard.	Measures against historical (or geographical) comparators and/or defined levels (triggers) for action. Systematic, quantitative or qualitative methods may be used.
INTERVENTIONS	May involve evaluating or comparing interventions, particularly new ones. Not all research involves interventions.	Service evaluation involves an intervention or service already in use only. Service improvement or development involves a new intervention or service, or one that is new to that context. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention or service already in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Intervention (if relevant) in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus, but may also be used to assess the need for an intervention when none is being taken currently.

PARTICIPANT ALLOCATION	Quantitative research study design may involve allocating patients/service users/healthy volunteers to an intervention. Purely qualitative research does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/service user have chosen intervention independently of the service evaluation/improvement/ development.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	May involve analysis of existing routine data supplied under licence, agreement or administration of interview or questionnaire to those in the population of interest. This includes collection of data on hazards, exposures and other data to enable interpretation of issues relevant to the population rather than the individual. May also require evidence review.
DATA	Quantitative research study design may involve allocating patients/service users/healthy volunteers to an intervention. Purely qualitative research does not usually involve allocating participants to an intervention.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interviews or questionnaires.	May involve analysis of existing routine data supplied under licence, agreement or administration of interview or questionnaire to those in the population of interest. This includes collection of data on hazards, exposures and other data to enable interpretation of issues relevant to the population rather than the individual. May also require evidence review.
RANDOMISATION	May involve randomisation.	May involve randomisation for sampling, but not for	May involve randomisation for sampling, but not for treatment/	May involve randomisation for sampling, but not for

		treatment/care/intervention.	care/ intervention.	treatment/care/intervention.
NHS REC review required?	Normally requires NHS REC review but not always. Refer to http://hradecisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

10.2.2 Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust; January–June 2019.

Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust.	Jan-March 2019	April - June 2019
Number of directly admitted stroke patients	235	243
% Requiring physio during inpatient stay	74.2%	84.3%
Transfer post discharge from the NHS Foundation Trust		
Community early supported discharge team	84	76
In-patient rehabilitation	52	50
Discharge home	27	37
Community stroke rehabilitation	18	24
Discharge to care home	8	8
Transferred out of stroke pathway	21	12

10.2.3 Clinical Effectiveness Project Registration Form

Clinical Effectiveness Project Registration Form.

Project type: Case note review.

Project Title: What is recorded in the case notes about the clinical management of the upper limb post-stroke from acute admission through to discharge across the NHS Foundation Trust stroke pathway.

Project background:

It is estimated that, in the UK, there are approximately 1.2 million people living with stroke [1]. The UL is used for a wide variety of functional tasks that have a direct impact on both quality of life and independence. People with stroke (People with stroke) place significant importance on restoration of UL functional movement [2]. The NICE guidelines for stroke rehabilitation (2013) [3] recommend that, following a stroke, the initial treatment duration for those who can actively participate, should be at least 45 minutes per day for a minimum of 5 days per week. It has been documented that people with stroke (People with stroke) might receive as little as 5 hours of physiotherapy while in hospital [4]. A national survey of stroke patients [1] and the stroke clinical audit [5] identify that current therapy for the UL post-stroke is falling significantly short of what is required.

People with stroke who have significant UL dysfunctions are far more likely to require higher levels of care post-stroke [6] with a poor outcome of the UL considered a major threat to perceived quality of life in People with stroke [7]. If the UL is treated effectively in the early stages post-stroke it can have a positive impact on UL recovery in the longer term [8]. Therapy should focus on the things most relevant to the individual, particularly functions that are relevant to their participation. Engagement in UL rehabilitation and repetitive practice can improve functional recovery [9]. Recovery of the UL post-stroke varies in time due to the nature of the stroke and the amount of interaction the UL receives as a result of therapy and everyday functional activity.

References:

1. Stroke Association. (2016). State of the nation: Stroke statistics. https://www.stroke.org.uk/resources/state-nation-stroke-statistics

2. Barker, R. N. & Brauer, S. G. (2005). Upper limb recovery after stroke: The stroke survivors' perspective. *Disability and Rehabilitation*, *27*(20): pp. 1213–1223.

3. NICE. (2013). Stroke Rehabilitation Long term rehabilitation after stroke Clinical guideline 162 Methods, evidence and recommendations 29 May 2013 Final Draft. Commissioned by the National Institute for Health and Care Excellence.

4. McHugh, G. & Swain, I. D. (2014). A comparison between reported therapy staffing levels and the department of health therapy staffing guidelines for stroke rehabilitation: a national survey. *BMC Health Service Research*. *14*, p. 216.

5. Sentinel Stroke National Audit Programme (2019) The Sixth SSNAP Annual Report Programme Stroke care received for patients admitted to hospital between April 2018 to March 2019. https://www.strokeaudit.org/Documents/National/Clinical/Apr2018Mar2019/Apr2018Mar2019-AnnualReport.aspx

6. Hunter, S. M. & Crome, P. (2002). Hand Function and Stroke. *Reviews in Clinical Gerontology*, *12*(1), pp. 68–81.

7. Dobkin, B. H. (2005). Clinical practice. Rehabilitation after stroke. *N Engl J Med*, *352*(16), pp. 1677–84.

8. Harris, J., Eng, J., Miller, A., & Dawson, A. (2009). A self-administered Graded Repetitive Arm Supplementary Program (GRASP) improves arm function during inpatient stroke rehabilitation: a multi-site randomized controlled trial. *Stroke*, *40*(6), pp. 2123–2138.

9. Harris, J., Eng, J., Miller, A., Dawson, A. (2010) The role of caregiver involvement in upper-limb treatment in individuals with sub-acute stroke, *Physical Therapy*, 90(9), pp. 1302–1310.

Reason for project: Priority 4. Clinical interest.

Project aims:

The aim is to provide a representation of how UL rehabilitation is documented in the clinical notes within the NHS Foundation Trust stroke pathway and to identify how the post-stroke UL has been clinically managed to date including the frequency/dose of the clinical intervention. This will help establish current clinical practice for treatment of the UL across the Sheffield Stroke Pathway and from this identify the baseline knowledge, skills and attitudes towards post-stroke upper limb management including the use of functional electrical stimulation (FES).

Project objectives:

1. To identify the therapist(s) involved in the management of the upper limb post-stroke.

2. To determine the number of patients that have upper limb impairment identified in their medical notes.

3. To ascertain the number of patients with upper limb pain post-stroke.

4. To ascertain if specific upper limb muscle movement is documented in the medical notes.

5. To identify the types of outcome measures used in the management of the upper limb post-stroke.

6. To ascertain the proportion of patients who had the upper limb identified on a problem list.

7. To determine the proportion of patients who have upper limb functional goals.

8. To identify the types of functional goals used.

9. To identify the types of adjuncts applied/utilised as part of the management of the upper limb post-stroke.

10. To ascertain the proportion of patients that have had FES used on their upper limb post-stroke.

11. To ascertain the frequency of use of FES/therapeutic dose.

12. To ascertain if patients receive post-session exercises.

13. To determine the types of exercise used.

14. To determine the number of treatment sessions in each clinical setting.

Project potential for change:

This project will identify how and where clinical information about the management of the upper limb is documented. This sets a baseline so that any change in clinical practice as a result of training and increased awareness of the importance of upper limb management by the clinicians is reflected in changes in the case notes across the stroke pathway at the next review.

Involvement of patients/public representatives.

Planning to involve patients: NO

Methodology.

Target population:

Stroke patients admitted to the NHS Foundation Trust Neurological Assessment Unit/Hyper Acute Stroke Unit over a six-month period from January 2019–June 2019. All patients admitted with a confirmed stroke are automatically assessed by the therapy team and during this initial assessment it will be documented if they have any ongoing therapeutic needs and a treatment plan will be commenced. Medical records will be identified from patient admissions documentation and data will be collected from the medical notes up to the point of discharge/transfer out of the NHS Foundation Trust stroke pathway or confirmation of no upper limb impairment. On discharge from acute/inpatient services, the individual medical records will follow into the community or intermediate care settings within the NHS Foundation Trust care pathway. Individual data collection using the proposed data extraction form will be completed in each separate location until discharge from therapy services. There will be two data collectors; Gerry Scott (primary reviewer) and Dominic Skerratt (second reviewer).

Based on the Sentinel Stroke National Audit Programme (SSNAP) data from the NHS Foundation Trust during the period January 2019–June 2019 (Table 1), there were 478 patients directly admitted to this hospital following a stroke. This number will enable data to be collected to reflect the stroke population within the NHS Foundation Trust stroke pathway. A review of the data after the first three months (January–March 2019) will be carried out. If there are not enough data points to allow clear reporting and answers to the above questions, data collection will continue for time period (April–June 2019).

Table 1: Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust; January–June 2019.

Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust.		
	Jan–March 2019	**April–June 2019**
Number of directly admitted stroke patients	**235**	**243**
% requiring physio during inpatient stay	**74.2%**	**84.3%**
Transfer post discharge from the NHS Foundation Trust.		
Community stroke ESD team	**84**	**76**
In-patient rehabilitation	**52**	**50**
Discharge home	**27**	**37**
Community stroke rehabilitation	**18**	**24**
Discharge to care home	**8**	**8**

Transferred out of NHS Foundation Trust stroke pathway	**21**	**12**

Sample size: 235 (Jan–March) 243 (April–June). Please see Table 1.

How will the data be analysed:

A data extraction form has been designed using Microsoft Excel.

Questions include: background information on the stroke presentation and diagnostic screening; date of stroke, classification of stroke, therapy assessment date, profession of therapist carrying out assessment, upper limb impairment identified, upper limb pain identified, hand dominance documented, specific muscle movement documented, outcome measures used, upper limb identified on problem list, upper limb treatment delivered, upper limb tasks used, technology/adjuncts used and frequency of use, upper limb exercises given post treatment and type of exercise, number of therapy sessions; discharge destination and discharge date. Microsoft Excel and SPSS will be used to analyse the data.

Sample size: 235 (Jan–March) 243 (April–June). Please see above.

How will the data be analysed:

A data extraction form has been designed using Microsoft Excel.

Questions include: background information on the stroke presentation and diagnostic screening; date of stroke, classification of stroke, therapy assessment date, profession of therapist carrying out assessment, upper limb impairment identified, upper limb pain identified, hand dominance documented, specific muscle movement documented, outcome measures used, upper limb identified on problem list, upper limb treatment delivered, upper limb tasks used, technology/adjuncts used and frequency of use, upper limb exercises given post treatment and type of exercise, number of therapy sessions; discharge destination and discharge date. Microsoft Excel and SPSS will be used to analyse the data.

Method of sample selection: Time interval. Patients admitted into the NHS Foundation Trust stroke pathway between January–June 2019.

Data collection method: Case note review.

Data collection time period, collection stated and analysis dates

Pilot of data collection tools:

Reliability will be checked across the two data extractors (GS, DS) to ensure that when they look at the medical records they extract the same information. This will be done with the first 5 sets of patient medical records and following this, a pilot of 30 patient records will ensure that the process of data extraction is robust and enable any practical considerations that are highlighted during this process to be resolved. Once the pilot is completed, the remaining data will be collected.

Ethical principles and considerations: Tickbox – Confidentiality/Access to data/data security.

Internal disclosure/external disclosure.

Timescales:

Dissemination

The findings of the clinical notes review will be discussed with clinicians across the stroke pathway in the form of focus groups. Current practice will be discussed and, from this, baseline knowledge will be identified including skills and attitudes towards post-stroke upper limb management. During this team meeting, reflective practice will be encouraged including any changes/improvements that might need to be made following the findings of the case note review. The service evaluation will also form a chapter in the primary reviewer's PhD thesis.

Resources: Tickbox - case note retrieval/sample identification.

Assistance is required: Case note retrieval and sample identification.

Stakeholders/Project Team Members: Gerry Scott/Chris Smith/Karen Sage.

10.2.4 NHS foundation trust confidentiality form

DECLARATION OF DUTY TO MAINTAIN CONFIDENTIALITY

PERSONS NOT EMPLOYED BY THE TRUST

I understand that I have a duty of confidentiality to patients/clients/employees (including ex-patients/previous clients/ex-employees) and an implied duty of confidentiality and loyalty to the Trust.

I understand that any information which, I am exposed to during the course of my placement/visit/research must not be divulged to other employees, patients, relatives, visitors to the Trust and/or any other person without the explicit and prior consent of an authorised officer. I also understand that in no circumstances should confidential information be divulged to sources outside the Trust or taken off site, including data related to research for example, without permission from the Head of Department.

Where any unauthorised disclosure of confidential information occurs, I understand that justification will be sought and will require defending and, therefore, should be soundly based. I am aware that action may be taken under the Trust's Standards of Performance and Conduct and that any unauthorised disclosure of confidential information will be treated as a serious breach of discipline, normally resulting in the withdrawal of your placement/visit/research.

As part of your induction to the Trust and to your department, you should ensure that you familiarise yourself with the Trust's Standards of Performance and Conduct; the Policy for Security and Confidentiality of Computer and Data and Systems and Guidance on the Transfer of Person Identifiable Data and Other Sensitive or Confidential Information including any specific local confidentiality requirements as defined by your Head of Department/Placement Supervisor.

Signed: G.Scott Date: 1/3/2019
Full Name: Gerry Scott
Work Placement Area: Therapy Services

10.2.5 Service evaluation approval evidence

Service Evaluation Approval Evidence:

CEU. Approval for project reference number 9784

Dear All

Your proposed Service Evaluation project, titled 'Upper limb clinical management documentation across the NHS Foundation Trust stroke pathway.', was approved by the project panel to proceed and I have registered it on the database as Ref 9784. Please use this reference number when corresponding with the unit about this project.

It has been included on the Directorate's Clinical Audit and Effectiveness Programme to ensure that the project's progress can be monitored throughout all the stages of the cycle. It is placed on the programme as a P4 Locally Managed project. Please refer to the attached roles and responsibilities comparison table for details of individual key roles responsibilities throughout all stages of the project.

At this point I must remind you of the importance of the submission of a report for the project on completion. To help with this I will be able to provide you with a draft report template at that stage of the project. The Trust is required by the Department of Health to provide evidence of audit and evaluation in the form of written reports, <u>not presentations</u>, to maintain our Foundation status. We are also required to provide evidence of where and when results were reviewed so we also require you to identify in the report the group or meeting within your directorate where this happened or a timescale for when this would happen.

The Trust has a legal obligation to preserve Service Evaluation reports for five years post-date of submission to the Clinical Effectiveness Unit. However, any project relating to NICE is stored indefinitely within the Trust and any national audit will be kept for ten years. The Clinical Effectiveness Unit will store and record these audit reports for this period of time.

10.2.6 Data extraction form Microsoft Excel

NUMBER	ITEM	Scoring
1	Date of admission recorded in medical notes	DDMMYYYY
2	Date of birth	DDMMYYYY
3	Date of stroke	DDMMYYYY
4	Classification of stroke	Left MCA=1 Right MCA=2 Left ACA=3 Right ACA=4 Left PCA=5 Right PCA=6 Left Multiple ischemic areas =7 Right Multiple ischemic areas = 8 Left ICH=9 Right ICH =10 Left SAH=11 Right SAH= 12 Pontine Stroke=13 TIA=14 Nil New=15 NAD=16 L Corona Radiata (brainstem)=17 R Corona Radiata (brainstem)=18 L VERTEBRAL ARTERY DISSECTION=19 Heparin induced stroke: multi teritory infarts secondary to HIT=20 L IC infarct = 21 R IC infarct =22 L cerebellar infarct=23 R cerebellar infarct=24 SMALL VESSEL DISEASE=25 ACUTE INTRA Axial haemorrage in cerebellum=26 BG infarct=27 L THALAMIC LARGE BLEED=28 R THALAMIC LARGE BLEED=29 MENINGIOMA=30 Epilepsy and Headaches=31 L Lacunar infarct=32 R Lacunar infarct=33 5cm intraparenchymal haematomoa on temporal lobe with mass effect=34 Acute Large Haematomma R parietal Lobe=35 INTRAPARENCHMAL bleed=36
5	Scan	Yes=1, No=2
6	Type of scan	Nil = 0 CT =1 MRI =2
7	Side of hemiplegia	0= nil motor Left=1, Right=2, Bilateral=3
8	Medically doc issue with UL	Yes=1, No=2
9	UL Scoring	0 UL, 1 DRIFT, 2 CAN'T RESIST GRAVITY, 3 NO EFFORT AGAINST GRAVITY, 4 NO MOVEMENT

10	Referral to therapy	Yes=1, No=2
11	If YES, record when patient was referred to therapy	DDMMYYYY
12	Therapist carrying out assessment	Physio=1, OT=2, Nurse=3, Therapy Assistant=4
13	Therapy assessment date	DDMMYYYY
14	UL impairment identified	Yes=1, No=2
15	Hand dominance	Left=1, Right=2, not documented=3, 4= ambidextrous
16	Specific muscle movement documented	Yes=1, No=2
17	If YES, record the specific muscles identified	0 no muscles recorded, 1 Biceps, 2 Triceps, 3 Traps, 4 Scalene, 5 Pecs, 6 Wrist Flex, 7 Deltoid
18	Outcome measure used	Yes=1, No=2
19	If YES, record the outcome measure used	0 no OM recorded, 1 Barthel, 2 MAS, 3 Berg, 4 MoCA, 5 Tinetti

20	UL identified on problem list	Yes=1, No=2
21	Upper limb tasks used	Yes=1, No=2
22	If YES, record the specific upper limb tasks used	0 no tasks recorded
		1 Making Tea
		2 Washing and Dressing
		3 Hair brushing
		4 HOLD R HAND ON SARA STEADY AND SENSORY HAND FEEDBACK/ORIENTATION TO WZF
		5 Reach
		6 reaching for hoops
		7 Kitchen activities
		8 washing windows
23	Upper limb functional goals	Yes=1, No=2
24	Overall number of treatment sessions	Number

25	Upper limb treatment delivered	Yes=1, No=2
26	UL treatment delivered	1 UL exercises 2 stretches 3 GRASP 4 Oedema massage 5 sensory work
27	Upper limb pain identified	Yes=1, No=2
28	Technology/adjuncts used	Yes=1, No=2
29	If YES, record the technology/adjuncts used	1= FES 2=Calliper 3=Sling
30	Post session exercises given	Yes=1, No=2
31	Duration of active treatment (	Time (mins)
32	Discharge destination identified	Yes=1, No=2 RIP=3
33	If YES, record location of discharge	Home no FU =1 SPARC =2 Home with CSS=3 Transferred out of region =4 Care Home =5 RIP=6 tx back to acute hospital = 7
34	Discharge date	DDMMYYYY

10.2.7 Data extraction form participant and admission data

Acute		Inpatient Rehabilitation		Community	
ITEM	Date of admission recorded in medical notes (e.g.DDMMYYYY)	ITEM	Date of admission recorded in medical notes (e.g.DDMMYYYY)	ITEM	Date of admission recorded in medical notes (e.g.DDMMYYYY)
Data source	Medical notes	Data source	Medical notes	Data source	Medical notes
P 1	03.01.2019	P 5	SPARC 11.02.19	P 5	10.4.19
P 2	04.01.19	P13	16.1.19	P7	4.2.19
P 3	02.01.19	P15	28.2.19	P13	6.2.19
P 4	04.01.19	P27	5.2.19	P15	26.4.19
P 5	31.12.18	P28	27.2.19	P27	11.2.19
P6	05.01.19	P29	11.3.19	P28	27.5.19
P7	01.01.2019	P33	13.2.19	P29	1.4.19
P8	01/01.19	P34	6.5.19	P33	20.3.19
P9	22.01.2019	P38	5.7.19	P34	13.7.19
P10	28.01.19	P44	29.5.19	P47	21.3.19

P11	26.01.19	P47	7.3.19	P57	30.4.19
P12	23.01.19	P57	24.4.19	P60	2.5.19
P13	10.01.19	P60	17.4.19	P67	28.8.19
P14	22.01.19	P67	12.6.19	P68	22.4.19
P15	29.01.19	P70	24.7.19	P73	14.2.19
P16	14.01.19	P75	8.3.19	P74	17.5.19
P17	17.01.19	P78	16.4.19	P75	27.3.19
P18	17.01.19	P88	6.6.19	P76	4.3.19
P19	09.01.19	P93	1.6.19	P77	14.5.19
P20	19.01.19	P103	3.6.19	P78	20.6.19
P21	15.01.19	P104	15.3.19	P88	1.7.19
P22	10.01.19	P107	6.7.19	P109	25.6.19
P23	13.01.19	P107	27.7.19	P119	31.5.19
P24	20.01.19	P109	9.5.19	P121	21.7.19
P25	19.01.19	P111	12.11.19	P123	7.5.19
P26	13.01.19	P119	2.5.19	P124	17.7.19

P27	28.01.19	P119	7.5.19	P129	22.5.19
P28	16.01.19	P121	7.3.19	P130	10.5.19
P29	28.02.19	P121	8.4.19	P132	28.5.19
P30	20.02.19	P123	10.4.19	P144	7.6.19
P31	07.04.19	P124	19.6.19	P145	2.5.19
P32	14.01.19	P132	28.3.19	P148	27.9.19
P33	31.1.19	P135	16.8.19	P157	16.7.19
P34	03.06.19	P144	26.3.19	P158	7.6.19
P35	24.06.19	P145	2.5.19	P160	3.7.19
P36	14.06.19	P148	12.7.19	P166	7.3.19
P37	12.03.19	P157	14.6.19	P168	18.4.19
P38	26.06.19	P158	20.5.19	P170	13.8.19
P39	25.05.19	P160	19.6.19	P171	12.7.19
P40	23.05.19	P166	26.2.19	P176	22.5.19
P41	25.03.19	P168	2.4.19	P179	25.7.19
P42	16.05.19	P170	18.6.19	P181	27.6.19

P43	06.06.19	P171	6.6.19	P183	7.5.19
P44	05.05.19	P176	15.4.19	P185	13.6.19
P45	01.03.19	P186	9.6.19	P186	24.7.19
P46	05.06.19	P189	26.4.19	P189	28.6.19
P47	01.03.19	P189	28.5.19	P191	11.5.19
P48	21.06.19	P194	13.6.19	P192	4.7.19
P49	15.02.19	P199	23.5.19	P199	27.6.19
P50	20.04.19	P201	8.5.19	P201	6.7.19
P51	14.05.19	P204	4.7.19	P202	22.3.19
P52	14.02.19	P209	9.4.19	P204	8.8.19
P53	23.03.19	P211	5.6.19	P206	6.6.19
P54	29.03.19	P213	21.2.19	P209	22.4.19
P55	06.03.19	P214	20.4.19	P211	13.6.19
P56	30.04.19	P216	7.2.19	P212	14.5.19
P57	20.04.19	P219	28.2.19	P213	21.2.19
P58	04.04.19	P221	9.4.19	P214	23.5.19

P59	01.05.10	P223	30.4.19	P215	29.3.19
P60	12.04.19	P225	25.2.19	P216	18.4.19
P61	22.03.19	P230	21.6.19	P218	24.5.19
P62	19.06.19	P232	28.3.19	P219	26.4.19
P63	05.03.19	P234	22.3.19	P221	16.5.19
P64	01.02.19			P223	31.7.19
P65	20.03.19			P225	10.7.19
P66	30.04.19			P226	11.2.19
P67	05.05.19			P227	5.4.19
P68	21.04.19			P229	16.5.19
P69	10.04.19			P230	20.9.19
P70	29.06.19			P232	25.4.19
P71	26.06.19			P233	5.2.19
P72	10.04.19			P234	22.5.19
P73	12.02.19			P236	28.5.19

P74	13.05.19		
P75	2.3.19		
P76	2.3.19		
P77	3.5.19		
P78	10.04.19		
P79	28.02.19		
P80	21.05.19		
P81	24.02.19		
P82	4.2.19		
P83	29.01.19		
P84	20.05.19		
P85	22.05.19		
P86	7.4.19		
P87	17.02.19		
P88	26.05.19		

P89	28.5.19		
P90	10.06.19		
P91	23.04.19		
P92	16.06.19		
P93	16.04.19		
P93	29.5.19		
P93	13.07.19		
P94	9.5.19		
P95	30.04.19		
P96	6.3.19		
P97	19.2.19		
P98	29.1.19		
P99	11.6.19		
P100	20.1.19		
P101	12.2.19		
P102	6.3.19		

P102	1.5.19		
P103	9.4.19		
P104	6.2.19		
P105	26.6.19		
P106	27.2.19		
P107	29.6.19		
P108	17.5.19		
P109	16.4.19		
P110	14.6.19		
P111	28.1.19		
P111	3.11.19		
P111	2.12.19		
P112	28.3.19		
P113	4.5.19		
P114	10.4.19		
P115	8.5.19		

P116	8.6.19		
P117	25.6.19		
P118	28.5.19		
P119	17.3.19		
P120	8.3.19		
P121	22.2.19		
P122	14.5.19		
P123	7.4.19		
P124	6.6.19		
P125	21.6.19		
P126	12.4.19		
P127	24.4.19		
P128	30.4.19		
P129	16.5.19		
P130	7.5.19		
P131	16.5.19		

P132	18.3.19		
P133	21.2.19		
P134	20.2.19		
P135	8.6.19		
P136	31.5.19		
P137	20.5.19		
P138	5.6.19		
P139	12.2.19		
P140	28.3.19		
P141	27.2.19		
P142	4.2.19		
P143	10.5.19		
P144	10.3.19		
P145	10.4.19		
P146	27.6.19		
P146	14.7.19		

P147	28.3.19		
P148	27.5.19		
P149	19.8.19		
P150	18.4.19		
P151	14.5.19		
P152	26.5.19		
P153	12.3.19		
P154	17.4.19		
P155	12.6.19		
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P157	9.6.19		
P158	10.5.19		
P159	10.5.19		
P160	16.6.19		
P161	14.2.19		
P162	15.3.19		

P163	26.6.19		
P164	9.4.19		
P165	23.4.19		
P166	6.1.19		
P167	14.3.19		
P168	16.3.19		
P169	14.2.19		
P170	17.5.29		
P171	29.5.19		
P172	06.06.19		
P173	15.4.19		
P174	14.6.19		
P175	18.4.19		
P176	15.4.19		
P177	20.6.19		
P178	25.2.19		

P178	15.10.19		
P179	16.6.19		
P180	8.2.19		
P180	14.3.19		
P181	18.6.19		
P182	24.5.19		
P183	24.4.19		
P184	4.5.19		
P185	27.5.19		
P186	3.5.19		
P187	3.6.19		
P189	9.4.19		
P189	13.5.19		
P190	6.2.19		
P191	2.5.19		
P192	25.4.19		

P193	18.2.19		
P194	9.5.19		
P195	14.2.19		
P196	10.5.19		
P197	7.5.19		
P198	25.6.19		
P199	30.4.19		
P200	28.2.19		
P201	17.3.19		
P202	20.3.19		
P203	6.12.19		
P204	25.6.19		
P205	26.6.19		
P206	5.6.19		
P207	18.3.19		
P208	28.2.19		

P209	6.4.19		
P210	11.2.19		
P211	3.6.19		
P212	3.5.19		
P213	17.2.19		
P214	6.4.19		
P215	22.3.19		
P216	1.2.19		
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P220	28.2.19		
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P222	21.2.19		
P223	5.4.19		
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P234	11.3.19		
P235	23.2.19		
P236	20.5.19		
P237	20.5.19		

10.2.8 Full report to clinical effectiveness unit

Clinical Effectiveness Unit

Clinical Effectiveness Project Report

Project Title:	Upper limb clinical management documentation across the NHS Foundation Trust stroke pathway.
CEU Registration Number:	9784
Directorate / Unit:	Integrated Geriatric and Stroke Medicine [Acute Stroke Unit]
Project Priority:	P4 Locally Managed
Report Date:	**Feb 2022**

1. **Project Team:**

Name	Job Title	Roles
Gerry Scott	Senior Physiotherapy Lecturer	PhD student/Senior Physiotherapy Lecturer SHU.
Dr Chris Smith	Head of Department Allied Health Professions, College of Health, Wellbeing and Life Sciences, SHU.	Head of Department AHP SHU

2. **Background:**

It is estimated that, in the UK, there are approximately 1.2 million people living with stroke [1]. The upper limb (UL) is used for a wide variety of functional tasks, which have a direct impact on both quality of life and independence. People with stroke (People with stroke) place significant importance on restoration of UL functional movement [2]. The NICE guidelines for stroke rehabilitation [3] recommend that, following a stroke, the initial treatment duration for those who can actively participate, should be at least 45 minutes per day for a minimum of 5 days per week. It has been documented that people with stroke (People with stroke) might receive as little as 5 hours of physiotherapy whilst in hospital [4]. A national survey of stroke patients [1] and the stroke clinical audit [5] identify that current therapy for the UL post-stroke is falling significantly short of what is required.

People with stroke who have significant UL dysfunctions are far more likely to require higher levels of care post-stroke [6] with a poor outcome of the UL considered a major threat to perceived quality of life in People with stroke [7]. If the UL is treated effectively in the early stages post-stroke it can have a positive impact on UL recovery in the longer term [8]. Therapy should focus on the things most relevant to the individual, particularly functions that are relevant to their participation. Engagement in UL rehabilitation and repetitive practice can improve functional recovery [9]. Recovery of the UL post-stroke varies in time due to the nature of the stroke and the amount of interaction the UL receives as a result of therapy and everyday functional activity.

3. Aims:

The aims of the service evaluation were to:

1) Identify via the clinical documentation, how the post-stroke UL is assessed and managed, including the intensity of clinical interventions within the NHS Foundation Trust stroke pathway. The pathway comprises the Acute Stroke Unit, an in-patient rehabilitation unit and a Community Stroke Service.

2) To identify whether functional electrical stimulation (FES) is utilised as part of the UL treatment interventions.

4. Objectives:

1. To identify the therapist(s) involved in the initial assessment and management of the UL post-stroke.

2. To determine the number of patients who had a UL impairment.

3. To ascertain the number of patients with UL pain post-stroke.

4. To ascertain if specific UL muscles are documented in the clinical notes.

5. To identify the types of outcome measures used in the management of the UL post-stroke.

6. To ascertain the proportion of patients who had the UL identified on a problem list.

7. To determine the proportion and type of patients' UL functional goals.

8. To identify treatment adjuncts applied/utilised as part of the management of the UL post-stroke and how they are used.

9. To ascertain the proportion of patients that have had FES used on their UL post-stroke.

10. To ascertain the frequency of use of FES/therapeutic dose.

11. Identification of the frequency of self-management regimes.

12. To determine the types of UL exercise used.

13. To determine the number and nature of treatment sessions in each clinical setting.

5. Methodology:

Target population:

All patients admitted to the NHS Foundation Trust stroke pathway are automatically referred to the therapy team. During this initial assessment, confirmation of stroke as the diagnosis occurs along with ongoing therapy requirements. In order to Identify via the clinical documentation, how the post-stroke UL is assessed and managed, including the intensity of clinical interventions within the NHS Foundation Trust stroke pathway and identify whether functional electrical stimulation (FES) is utilised as part of the UL treatment interventions the clinical notes of stroke patients admitted to the NHS Foundation Trust Neurological Assessment Unit/Hyper Acute Stroke Unit requiring management of their upper limb during the time period from January 2019–June 2019 were identified and reviewed.

Method of sample selection:

Patients' clinical records up to the point of discharge/transfer out of the NHS Foundation Trust stroke pathway or confirmation of no upper limb impairment between January–June 2019, were used to address the study aims. On discharge from acute/inpatient services, the individual clinical records followed into the community or intermediate care settings within the NHS Foundation Trust stroke care pathway. Individual data collection using the data extraction form was completed in each location until patients had been discharged from therapy services. Based on the Sentinel Stroke National Audit Programme (SSNAP) data from the NHS Foundation Trust during the period from January 2019–June 2019 (Table 1), there were 478 patients directly admitted to STH following a stroke.

Table 1: Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust; January–June 2019.

Sentinel Stroke National Audit Programme (SSNAP) standards data from the NHS Foundation Trust.		
	Jan-March 2019	**April - June 2019**
Number of directly admitted stroke patients	**235**	**243**
% Requiring physio during inpatient stay	**74.2%**	**84.3%**
Transfer post discharge from Sheffield Teaching Hospitals		
Community stroke ESD team	**84**	**76**
In-patient rehabilitation	**52**	**50**
Discharged home	**27**	**37**
Community stroke rehabilitation service	**18**	**24**
Discharged to care home	**8**	**8**
Transferred out of the NHS Foundation Trust pathway	**21**	**12**

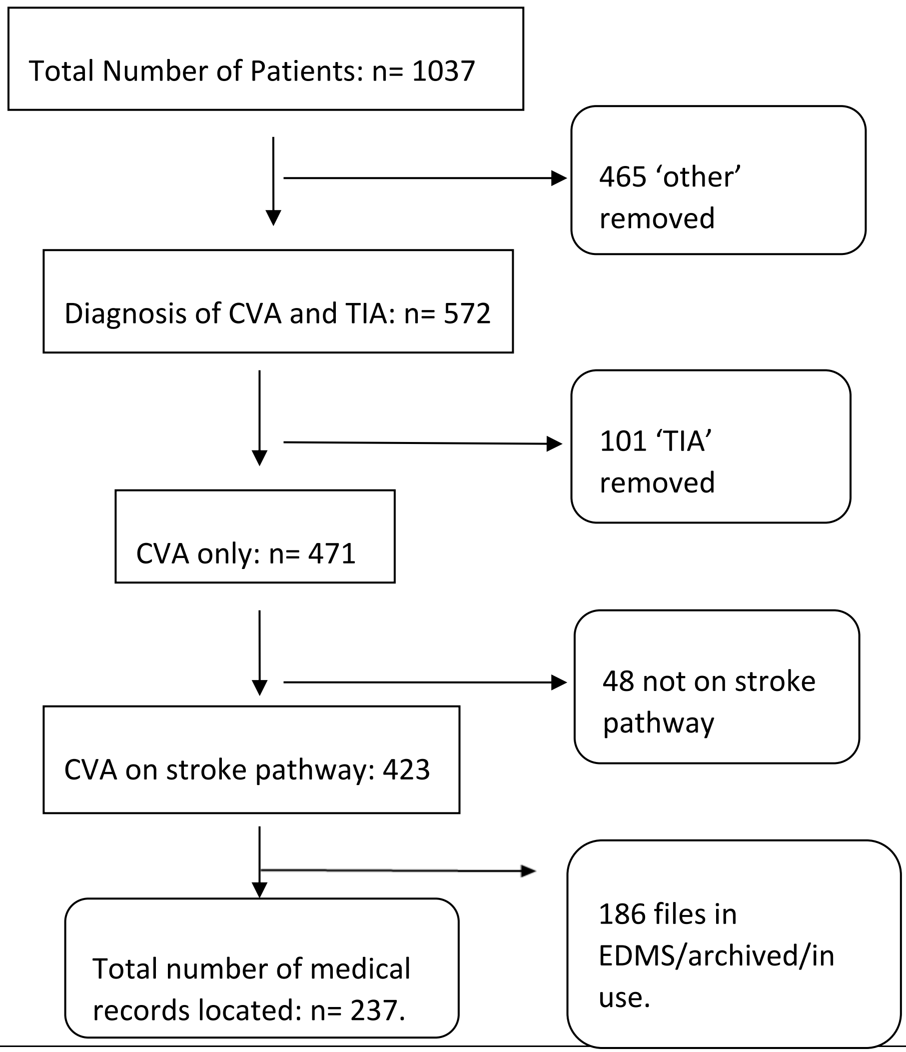
The medical records team, in liaison with the clinical effectiveness team, created a patient list. This identified all admissions to the NHS Foundation Trust with a neurological/stroke acute classification from January 2019 to the end of June 2019. The total number of patients admitted during this six-month period was 1037 (see Figure 1). Following this the inclusion/exclusion criteria was applied to the Excel sheet of total number of admissions.

Table 2: Inclusion/exclusion criteria

Inclusion	**Exclusion**
Confirmed stroke	TIA or other neurology
Adult aged 18 and over	Under 18 years
Admitted to the NHS Foundation Trust	Not directly admitted to the NHS Foundation Trust
Admitted to stroke pathway between Jan 2019 and June 2019	Not on stroke pathway or admitted before or after January 2019–June 2019

The Excel sheet was initially used to identify all patients with a confirmed diagnosis of stroke; any patients with a classification of other neurological presentation were excluded. Following this, any patients with a TIA were also excluded from the original figures and this resulted in the overall number of patients admitted with a confirmed stroke to 471. As the original plan was to identify patients with a confirmed stroke on the stroke pathway, the Excel sheet was further filtered to remove any patients who were not on the stroke pathway and came in via other services. This resulted in the final number of 423 patients admitted to the stroke pathway in the NHS Foundation Trust between January 2019 and June 2019 (see diagram 1). This list was then reviewed by the medical records department as all the original medical notes needed to be sourced/located. During the time when the notes review was in progress, the Covid-19 pandemic had impacted hospital policies. It was approved that the nature of the notes review was safe to continue as there was not any direct patient involvement and, therefore, it was low risk. The pandemic did impact where and when the notes could be reviewed by the main researcher due to social distancing regulations. The medical records team identified the location of the medical notes via the patient's name, date of birth and hospital number. These were collected in batches of 20 sets of notes by the main researcher and reviewed in a private room within the medical records department at the NHS Foundation Trust. Out of the 423 patients identified 237 medical notes were located and manually collected by the researcher for review (see Figure 1).

Figure 1: Flow chart of participant selection process.



Data collection:

A data extraction form was designed using Microsoft Excel. Questions included: background information on the stroke presentation and diagnostic screening; date of stroke, classification of stroke, therapy assessment date, profession of therapist carrying out assessment, UL impairment identified, UL pain identified, hand dominance documented, specific muscle movement documented, outcome measures used, UL identified on problem list, UL treatment delivered, UL tasks used, technology/adjuncts used and frequency of use, UL exercises given post treatment and type of exercise, number of therapy sessions; discharge destination and discharge date. Microsoft Excel and SPSS were used to analyse the data.

Data collection method:

Case note review.

Data analysis:

Sample

- 237 notes located and reviewed across the NHS Foundation Trust stroke pathway (both paper-based, and electronic notes accessed).

Dissemination

The findings of the clinical notes review will be discussed with clinicians across the stroke pathway and the researcher will present the findings of this evaluation at the NHS Foundation Trust Stroke Leadership Team. Focus groups/clinical workshops via Zoom/Teams or face to face are currently being planned for early 2022. These will be voluntary for clinicians across the NHS Foundation Trust stroke pathway and will enable the researcher to gain further understanding of the clinical reasoning and decision-making employed by clinicians in relation to the

management of the post-stroke UL. Reflective practice will be encouraged including any changes/improvements that might need to be made following the findings of the case note review. It is envisaged that this will inform an exploratory study on use of UL FES across the stroke pathway and the service evaluation will also form a chapter in the primary reviewer's PhD thesis.

6. Limitations:

Covid 19 pandemic had a significant impact on the timeframe for the notes review data collection. Subsequently the pandemic will have had implications/ramifications on the current practice within the stroke service including the number of admissions and therapeutic input to those patients during this period. An advantage of the dates used, as this was a 'normal', non-pandemic, time period and, therefore, representative of the stroke service during this timeframe (Jan–June 2019). Furthermore, there were a number of notes in use/archived, however, there was a large enough sample size identified to represent the time period.

7. Action Plan:

Recommendation	Action	Deadline Date	Person Responsible
Focus groups with clinicians in NHS Foundation Trust stroke pathway: These will be voluntary for clinicians across the NHS Foundation Trust stroke pathway and will	To include: • dissemination of service evaluation findings • reflective practice discussion about the management of the post-stroke UL	Feb–March 2022.	Gerry Scott

enable the researcher to gain further understanding of the clinical reasoning and decision-making employed by clinicians in relation to the management of the post-stroke UL. Reflective practice will be encouraged, including any changes/improvements that might need to be made following the findings of the case note review.	• provide information about the current evidence base in the management of the UL, including the place of UL FES		

8. Conclusion:

The service evaluation clearly identified how the UL has been managed in patients admitted to the NHS Foundation Trust stroke pathway between January 2019 and June 2019 through to discharge. When reflecting on the aims of the service evaluation, the clinical documentation highlighted that, on admission, 34% of stroke patients during this time period had a UL impairment documented in their clinical records with the majority of UL assessments initially being conducted across the stroke pathway by a physiotherapist (69% in the acute setting/86% in-patient rehabilitation/57% community stroke services). Specific UL outcome measures were infrequently used across all three sites and there were limited UL-specific patient goals documented.

When considering the management of those with UL impairments identified in the acute setting identification of self-management techniques including UL exercise was not apparent and no UL treatment adjuncts where utilised as part of the overall management of the UL. However, in both in-patient rehabilitation and community stroke services, both exercise and self-management techniques were documented; there was, however, limited specific documentations about what form of UL exercise was used and any rationale for any 'prescriptive' dose. It is clear from the documentation that the UL is not a focus in the acute and even sub-acute settings.

Further to this, the review of the clinical notes highlighted that UL FES as a treatment modality for the management of the UL post-stroke was used infrequently and with limited evidence of justification in the clinical notes. It is, however, important to understand the context from the clinicians involved in the management and treatment of the UL and identify the barriers and enablers to the management of the UL as a whole, including the use of UL FES in the future management of stroke patients within the NHS Foundation Trust Stroke Pathway.

9. References (Harvard or Vancouver)

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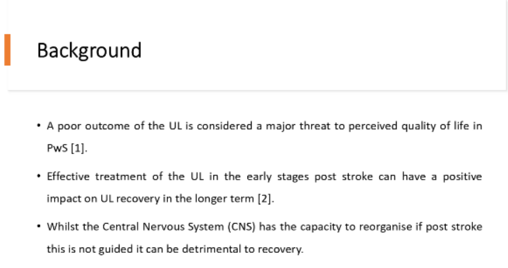
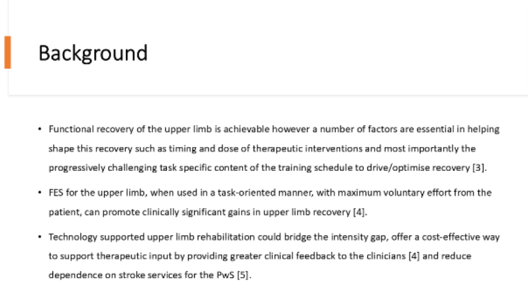
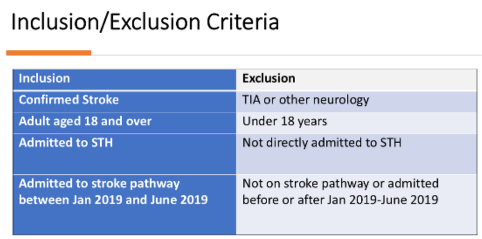
10.2.9 Presentation to Stroke Leadership Team







10.2.10 Example of the presentation delivered to the three key sites across the stroke pathway

Service Evaluation Feedback: Acute Team

G Scott
Sept 2022

Objectives:

1. To identify the therapist(s) involved in the initial assessment and management of the UL post stroke.
2. To determine the number of patients who had an UL impairment.
3. To ascertain the number of patients with UL pain post stroke.
4. To ascertain if specific UL muscles are documented in the clinical notes.
5. To identify the types of outcome measures used in the management of the UL post stroke.
6. To ascertain the proportion of patients who had the UL identified on a problem list.
7. To determine the proportion and type of patients UL functional goals.
8. To identify treatment adjuncts applied/utilised as part of the management of the UL post stroke and how they are used.
9. To ascertain the proportion of patients that have had FES used on their UL post stroke.
10. To ascertain the frequency of use of FES/therapeutic dose.
11. Identification of the frequency of self-management regimes.
12. To determine the types of UL exercise used.
13. To determine the number and nature of treatment sessions in each clinical setting.

Conclusion

- The service evaluation clearly identified how the UL has been managed in patients admitted to the Sheffield Stroke Pathway between Jan 2019 to June 2019 through to discharge.
- When reflecting on the aims of the service evaluation the clinical documentation highlighted that on admission **34%** of stroke patients during this time period had an UL impairment documented in their clinical records with the majority if UL assessments initially being conducted across the stroke pathway by a Physiotherapist.
- Specific UL outcome measures were infrequently used across all three sites and there were limited UL specific patient goals documented.
- In RHH acute services both exercise and self-management techniques were documented; there was however limited specific documentations about what form of UL exercise was used and any rationale for any 'prescriptive' dose.

UL FES as a treatment modality for the management of the UL post stroke was used infrequently and with limited evidence of justification in the clinical notes.

10.3. Chapter 6 appendices

10.3.1 Presented at IFESS conference Sept 2024

Gathering stroke clinicians' views on the use of upper limb functional electrical stimulation in the management of the hemiplegic upper limb.

Gerry Scott[1], George Peat[2], Christine Smith[3], Ben Strafford[4], Mark Collins[5]

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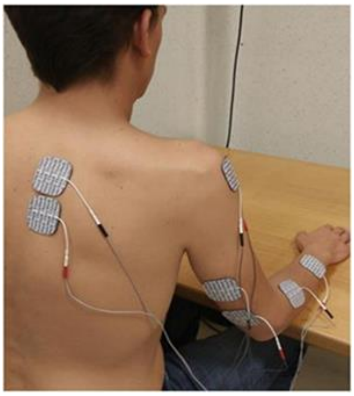
[3] Research Centre for Healthcare & Communities, Coventry University, United Kingdom.

Corresponding author: g.scott@shu.ac.uk

Introduction:

Studies highlight that if the upper limb (UL) is treated effectively in the early stages post-stroke, this can have a positive impact on recovery [1]. A number of studies have shown that functional electrical stimulation (FES) can have a beneficial effect on UL motor recovery [2]. It has been identified that task orientated UL FES promotes clinically significant gains post-stroke [3], and that UL FES combined with conventional therapy improves voluntary reaching and grasp [4]. Recent National Clinical Guidelines for Stroke (2023) [5] recommend consideration of UL FES in people with wrist and finger weakness post-stroke. Despite the growing evidence base to support use of UL FES post-stroke, there is still minimal use within stroke rehabilitation services. This study aimed to explore clinicians' views on the management of the post-stroke hemiplegic upper limb and how UL FES could be used to augment practice to drive sensory-motor recovery.

Methods:



Two NHS Foundation Trusts within South Yorkshire were identified for the focus groups. Six focus groups (total participants n=37) were carried out with clinicians working within acute stroke units (n=13), rehabilitation units (n=10), and in the community (n=13). Focus group recordings were transcribed, and themes were identified in NVivo from the transcripts using thematic analysis [6].

Results:

The findings are in the final stage of analysis and will be ready for presentation at the conference. Emerging themes include: 1) There are a number of barriers to rehabilitation and management of the post-stroke UL; 2) Clinicians find it challenging to apply their clinical reasoning process to the post-stroke UL; 3) Many clinicians lacked confidence in application of UL FES; and 4) there is a need for more clinical-specific guidance and education and training when applying UL FES post-stroke.

Discussion and conclusion:

These findings substantiate those in other studies that the post-stroke UL is not the main priority for therapy in the acute or even sub-acute setting and the intensity of UL intervention is markedly less than what is likely to be effective. [7] This is often due to the emphasis on promoting recovery of mobility and the pace of discharge. Despite the robust RCP [5] and NICE guidelines, [8] stroke clinicians identified they were still unsure how to clinically reason and effectively apply UL FES in the post-stroke population. Confidence in application of UL FES was cited as a significant reason why UL FES was not regularly used by clinicians, in spite of a clear appetite to do so. Clinicians could identify the benefits of UL FES to support sensory-motor recovery post-stroke, and highlighted the need for more clinical practice-based guidelines and further training in the use of UL FES.

References:

[1] Harris, J., et al. (2009). A self-administered Graded Repetitive Arm Supplementary Program (GRASP) improves arm function during inpatient stroke rehabilitation: a multi-site randomized controlled trial. *Stroke*, **40**(6), 2123–2128.

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10.3.2 Poster presented at the IFESS conference Sept 2024

Gathering stroke clinicians' views on the use of upper limb functional electrical stimulation in the management of the hemiplegic upper limb.

Sheffield Hallam University

IFESS International Functional Electrical Stimulation Society

Gerry Scott[1*], George Peat[1], Christine Smith[2], Ben Strafford[3], Mark Collins[1]

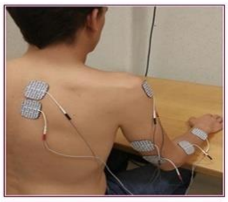
[1] Centre for Applied Health and Social Care Research (CARe), Sheffield Hallam University, Sheffield, UK

[2] Research Centre for Healthcare & Communities, Coventry University, UK

[3] Sport and Physical Activity Research Centre (SPARC), Sheffield Hallam University, Sheffield, UK

Introduction

- Effective treatment in the early stages post-stroke can have a positive impact on upper limb (UL) recovery.[1]
- A number of studies have shown that functional electrical stimulation (FES) can have a beneficial effect on UL motor recovery.[2] Specifically, task-orientated UL FES may promote clinically significant gains post-stroke[3], and UL FES combined with conventional therapy improves voluntary reaching and grasp.[4]
- Recent UK National Clinical Guidelines for Stroke recommend consideration of UL FES in people with wrist and finger weakness post-stroke.[5] Despite the growing evidence base to support use of UL FES post-stroke, there is still minimal use within stroke rehabilitation services.



An example of UL FES application

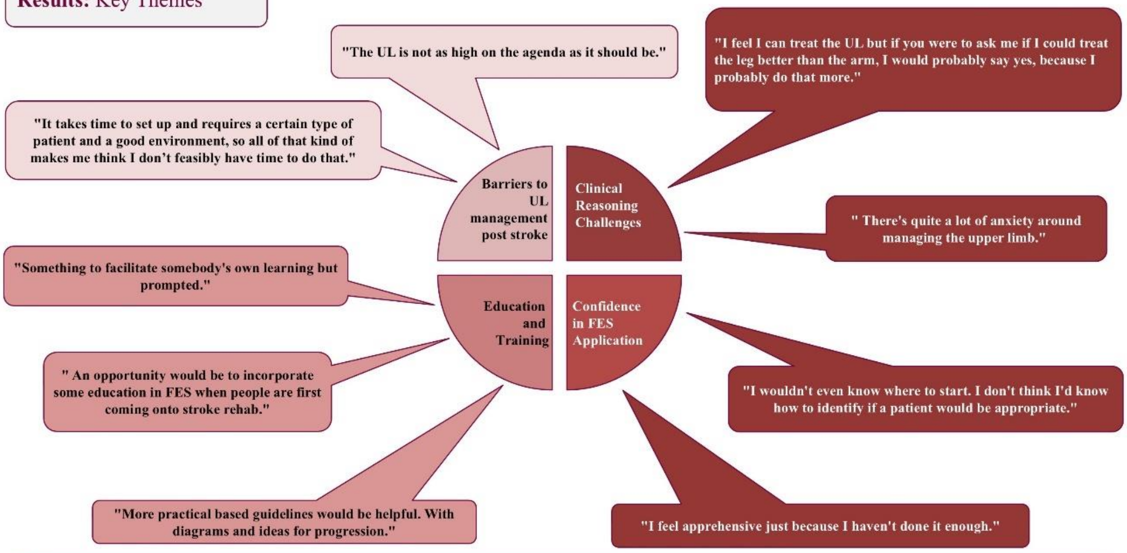
Aim

- To explore clinicians' views on the management of the post-stroke hemiplegic UL and how UL FES could be used to augment practice to drive sensory-motor recovery.

Method

Two NHS Foundation Trusts within South Yorkshire were identified for the focus groups. Institutional ethical approval was granted by the university ethics committee of the lead author (ref: ER44660174), with all participants providing informed written consent prior to the commencement of the study. Six face to face focus groups (total participants n=37) were carried out with clinicians working within acute stroke units (n=13), rehabilitation units (n=11), and in the community (n=13). Focus group recordings were transcribed and themes were identified in NVivo from the transcripts using thematic analysis.[6]

Results: Key Themes



Conclusions

These findings substantiate those in other studies that the post-stroke UL is not the main priority for therapy in the acute or even sub-acute setting and the intensity of UL intervention is markedly less than what is likely to be effective.[7] This is often due to the emphasis on promoting recovery of mobility and the pace of discharge. Despite the robust national clinical practice guidelines,[5,8] stroke clinicians identified they were still unsure how to clinically reason and effectively apply UL FES in the post stroke population. Confidence in application of UL FES was cited as a significant reason why UL FES was not regularly used by clinicians, in spite of a clear appetite to do so. Clinicians could identify the benefits of UL FES to support sensory-motor recovery post stroke and highlighted the need for more clinical practice-based guidelines and further training in the use of UL FES.

References

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Acknowledgements

This project was undertaken as part of a doctoral programme of research by G Scott. The project was approved by Sheffield Hallam University ethics committee ref: ER44660174.

The authors gratefully acknowledge the contributions of staff from STH and DBTH stroke services.

Contact details

* Correspondence to: Gerry Scott, g.scott@shu.ac.uk

10.3.3 Focus group ethical approval (Converis Id: ER44660174)

Gathering clinicians' views on post-stroke hemiplegic upper limb management, including how functional electrical stimulation can augment practice.

Ethics Review Id: ER44660174.

Workflow Status: Approved with advisory comments.

Type of Ethics Review Template: Very low-risk human participants studies.

10.3.4 Focus group topic guide

1.Welcome/introduction and overview of topic.

- No right or wrong answers, only differing points of view
- Recording, one person speaking at a time.
- You don't need to agree with others, but you must listen respectfully as others share their views.
- My role as moderator will be to guide the discussion

2. Current clinical practice

Tell me how an individual with upper limb impairment is currently assessed within ……(insert part of stroke pathway)

- How do you identify the assessment and management of the UL?
- Who does the initial assessment? Is there any rationale behind this?

Tell me about your usual treatments for the upper limb in people with stroke.

- How is the management of the UL captured and measured?
- In patients with UL dysfunction post-stroke how are problems prioritised?
- Patient goal setting – how is this integrated into UL management?
- Are UL specific outcome measures being used? and rationale regarding choice?

Are there other areas of UL post-stroke management that you believe needs to be addressed/further developed within the stroke pathway?

3. Future development/ UL management and where FES sits within that/ technology enhanced upper limb management:

Does technology play a role in the management of the UL?

Are any adjuncts/ technologies used currently in the management of the UL?

- Types
- Justification for use/application
- Application/progression and monitoring of these

What influences your decision to use an adjunct/technology in the management of the UL?

Focusing on the application of UL FES what information would be useful to inform this?

10.3.5 UL focus group participant consent forms

Participant Consent Form

Title of Project: 'Gathering clinicians views on post-stroke hemiplegic upper limb management, including how functional electrical stimulation can augment practice.'

Lead Investigator: Gerry Scott **Please initial box**

I confirm that I have read and understand the information sheet Version 1.0 dated 12.9.22 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my rights being affected. ☐

I understand the information collected will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

I would like to receive information about the project at the end of the study. **Yes/No**

I agree to take part in the above study.

Name of participant…………………………………….Date…………………… Signature…………………………..

10.3.6 UL focus group participant information sheet

'Gathering clinicians views on post-stroke hemiplegic upper limb management, including how functional electrical stimulation can augment practice.'

Participant Information Sheet

Please take the time to read the following information carefully and discuss it with colleagues if you wish. Please ask us if there is anything that is not clear, or if you would like more information. Thank you.

Why have I been given this information? You have been given this information sheet because:

- You are a clinician in the Sheffield stroke pathway.
- You are a clinician who manages/treats the upper limb post-stroke.

You have been invited to participate in a focus group which will be a representative sample of clinicians from a variety of therapeutic backgrounds in the field of upper limb (UL) rehabilitation within the Sheffield stroke pathway. The focus group will take place at your workplace.

Who is doing this research? The research study is being carried out by Sheffield Hallam University. Background to the study An estimated 30–70% of people with stroke (PwS) have reduced or no use of the hemiplegic upper limb (UL). Conventional exercise therapy with a stroke therapist is labour-intensive, so resource limited; new technologies such as Functional

Electrical Stimulation (FES) offer exciting possibilities to increase the dosage of therapy within existing staff resources and promote upper limb recovery where previous interventions have failed. A number of studies have shown that FES can have a beneficial effect on upper limb motor recovery. In spite of this promise there is a current lack of use of FES for the UL within stroke rehabilitation as the advanced nature of these technologies can make them complex to use, which can be a barrier to adoption in clinical practice.

What is the purpose of the research? This research is aimed at gaining your opinions about the assessment and management of the post-stroke UL whilst also gaining your opinions about where the use of UL functional electrical stimulation (FES) sits within the stroke pathway.

Do I have to take part? No, it is up to you to decide whether or not to take part.

How long will I be involved with the study if I take part? The study will take approx. 90 mins for the focus group.

Will I be paid for participating? Your time will be given on a voluntary basis.

What will happen to me if I take part? Discussions from the focus group will be video recorded to aid data analysis. If you consent to participate in this study, this will include permission to be recorded.

Are there any possible disadvantages and risks of taking part? There are no risks to taking part in the study. It will require you to give your time to attend the focus group session.

What are the possible benefits of taking part? Hopefully you will find participating in the study interesting. The research will inform the development of clinical guidelines for the use of upper limb FES therapists following stroke.

What will happen to the results of the research study? The outcomes from this research study will be used to inform the development of upper limb FES clinical guidelines.

Will my taking part in this study be kept confidential? Yes, all information collected about you during the course of the research will be kept strictly confidential and your name will not be used in any publications or research reports.

For how long and where will the data on this study be kept? We will keep the data for up to 5 years after the end of the study. We will keep the data on password protected University computers.

Who has reviewed the study? This study has been reviewed by Sheffield Hallam University research ethics panel and given a favourable opinion.

What if something goes wrong? There are no risks to taking part in the study. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, Sheffield Hallam complaints processes will be available to you.

The contact at Sheffield Hallam University for complaints is:

appealsandcomplaints@shu.ac.uk

10.3.7 Example of NVivo coding from focus groups.

Name: Time Limitations - 20 references coded

Reference 1 - 0.44% Coverage: unfortunately it will determine the pressures of whether…who pushes that along, so it might be, y'know, they're heading to be medically fit…patients medically fir, in terms of the OT, the pressures will be to get them out of the hospital bed, and often I think the physios get a bit more time to do the rehab.

Reference 2 - 0.71% Coverage: I might do printouts but like in assessments to show this week on your own you can do this and then give some functional examples of things that they can do on their own whether they choose to do that or not is…anybody's guess but then also trying to use families to deliver that. But again that takes time…to set up, so as soon as we're pushed then I feel like that is the bit that suffers and then it falls to just the sessions that I facilitate and not the bit where it could be self-managed.

Reference 3 - 0.25% Coverage: I think sometimes harder unless you go through and physically show exercises and sit down with that relative and then hope they can remember and have that carry over of doing…

Reference 4 - 0.41% Coverage: I think it's sometimes challenging though because sometimes we have really keen families, but they only visit in the evenings or at weekends so then you can't almost do that – the teaching sessions or show them because they're never here when we're here so I guess that's a challenge.

Reference 5 - 0.45% Coverage: Yeah. If I've got a more impaired patient it come at the bottom of a list of a lot of things to do like, I might need to give them personal care and then get them to the gym and I know there's a drive to get them out into a chair or to be standing or to be able to mobilise in some way, so my focus would go there.

Reference 6 - 0.74% Coverage: If they're more able and I'm really conscious of…they've got an upper limb problem, I guess I split a session in half, but you end up focusing more on…you've got get them up/get them to the gym and you've got to do a certain amount of work on mobility (because you know that's one of the key drivers). I guess at the end of that comes a period of time where you go, "OK, we've got 20 minutes, let's look at some upper limb stuff". But, y'know, it's an afterthought of the main driver of the session I suppose. Yeah.

Reference 7 - 0.27% Coverage: Even if there were changes to the upper limb it would still be looked at but I don't think it would shift the proportions of the session (or the percentage I guess) of the session spent…

Reference 8 - 0.22% Coverage: I've tried to make efforts to use mirror box therapy in the community but its never been on my radar as feasible to have the time to do that here I suppose.

Reference 9 - 0.41% Coverage: my experience of using it in the community is it needs to be quite personalised and it takes time to set up and requires a certain type of patient and a good environment so all of that kind of makes me think I don't have…feasibly have time to do that I'm going to focus on these other bits.

Reference 10 - 0.25% Coverage: to get someone in a nice quiet environment where they can do some mental imagery in a quiet relaxing space and hopefully prime some motor activity just seems…unrealistic.

Reference 11 - 0.38% Coverage: I think probably there is that element of it takes a lot of thinking about, time to set up, time to do it effectively…so you immediately go "is there another option here?" because that's gonna take a bit of time so you could probably just sum it up as time actually.

Reference 12 - 0.52% Coverage: And I think the pathway thing does come in, if you've just decided "oh yeah, I could…I could do it" and then you get literally told that day, "oh, I've listed them for SPARC" then I do get a little…they're literally going to go to SPARC in a couple of day is there any point in me starting this? When I'm not, I'm not au fait with whether SPARC would continue it…

Reference 13 - 0.24% Coverage: I do think that makes me hold off a bit…well there's no point in me starting something that can't be continued or…they might not justify it in the same way…that I can.

Reference 14 - 0.09% Coverage: it because it takes energy and you just don't have the time

Reference 15 - 0.34% Coverage: we're making compromises and that we're doing it for half an hour because we can't put it on for an hour or we don't have the family available, so you know, is the resource with that or are you just banging your head against a brick wall?

Reference 16 - 0.45% Coverage: But then as soon a someone said "well, yeah it does need to be that" you'd think I can't possibly do that. You could cover with a very engaged family and a very engaged patient but they're few and far between as far as I see…working here. I've done it in community more effectively but yeah, it's hard isn't it? Yeah.

Reference 17 - 0.28% Coverage: There's no capacity on the ward staff, we do have… I mean we have volunteers, but they come for an hour…once a week for the whole ward… 2 of them. I'm just trying to think what other resources…

Reference 18 - 0.23% Coverage: we have a battle to like….can you get this patient out of bed, the patient should sit out every day I think we initiate that for the majority of the patients.

Reference 19 - 0.35% Coverage: But you know, we've got a 45-minute treatment session but a lot of time you're thinking "that patients not been out of bed" so that becomes part of that 45 minute treatment session, is the patient been up and out for a period of time in the day

Reference 20 - 0.22% Coverage: all treatments and evidence we look at is like "good, yeah that's good but it would be time consuming and difficult and there's lots of other pressures".

10.4. Chapter 7 appendices

10.4.1 Delphi Study Ethical Approval (Converis Id: ER61126668)

Consensus of the use of upper limb (UL) functional electrical stimulation (FES) post-stroke: A Delphi study.

Ethics Review Id: ER61126668.

Workflow Status: Approved with advisory comments.

Type of Ethics Review Template: Very low-risk human participants studies.

10.4.2 Delphi Invitation email

Converis ID: ER61126668

Gerry Scott

Sheffield Hallam University

Email: g.scott@shu.ac.uk

Dear Sir/Ms,

Thank you very much for expressing an interest in our study. You have been approached because you are either working with FES both clinically and/or in a research capacity and/or you are an expert in UL rehabilitation. I enclose the Information Sheet that explains the study in detail and encourage you to read this carefully before taking any further action.

If you feel you wish to participate in this Delphi Study, please complete the attached consent form and I will be in contact with details about when the study will commence. If you have any questions about any aspect of the study, please contact me.

Thank you again and we look forward to hearing from you.

Yours sincerely

Gerry Scott

10.4.3 Delphi participant consent form

Converis ID: ER61126668

CONSENSUS OF THE USE OF UPPER LIMB (UL) FUNCTIONAL ELECTRICAL STIMULATION (FES) POST-STROKE: A DELPHI STUDY.

Please answer the following questions by ticking the response that applies.

	YES	NO
1. I have read the Information Sheet for this study and have had details of the study explained to me.		
2. My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point.		
3. I understand that I am free to withdraw from the study within the time limits outlined in the Information Sheet, without giving a reason for my withdrawal or to decline to answer any particular questions in the study without any consequences to my future treatment by the researcher.		
4. I agree to provide information to the researchers under the conditions of confidentiality set out in the Information Sheet.		
5. I wish to participate in the study under the conditions set out in the Information Sheet.		
6. I consent to the information collected for the purposes of this research study, once anonymised (so that I cannot be identified), to be used for any other research purposes.		

Participant’s Signature: **Date:**

Participant’s Name (Printed)………………………………………………………………………… Contact details:

Researcher’s Name (Printed)………………………. Researcher’s Signature…………. Researcher's contact details:

10.4.4 Delphi participant information sheet

Sheffield Hallam University

Converis ID: ER61126668

The following issues should be addressed where relevant. This could be, but does not have to be, in a question-answer format. Use a format that best meets the needs of your research participants, but the list below summarises the areas that need to be addressed to ensure participants are appropriately informed. Plain easily understood language should be used with a minimum of technical or academic terms or jargon. Pay special attention to preparing material for children or adults with limited cognitive capacity - further information on this can be obtained from www.hra-decisiontools.org.uk/consent/

List of Contents Required: They do **not** have to be presented in this order as numbered questions; rather this list provides a checklist of the material that is now required to be in a Participant Information Sheet or equivalent briefing under GDPR.

1. **Title of Project:**

   Consensus of the use of upper limb (UL) functional electrical stimulation (FES) post-stroke: A Delphi study.

2. **Legal basis for research for studies**.

   The University undertakes research as part of its function for the community under its legal status. Data protection allows us to use personal data for research with appropriate safeguards in place under the legal basis of **public tasks that are in the public interest.** A full statement of your rights can be found at: www.shu.ac.uk/about-this-website/privacy-policy/privacy-notices/privacy-notice-for-research. However, all University research is reviewed to ensure that participants are treated appropriately, and their rights respected. This study was approved by the University's Research Ethics Committee with reference number ER61126668. Further information at: www.shu.ac.uk/research/excellence/ethics-and-integrity

3. **Opening statement:**

Please will you take part in a study about the use of functional electrical stimulation (FES) on the upper limb (UL) in people with stroke (People with stroke). The aim of this study will be to build consensus on factors relating to the application of UL FES post-stroke. The focus will be on reaching expert consensus on

(i) Factors that influence application of UL FES in People with stroke.
(ii) Different post-stroke UL presentations and how this impacts UL rehabilitation.
(iii) FES application parameters for the management of a variety of post-stroke UL clinical presentations.
(iv) Adjuncts and/or exercises used alongside FES in the management of the post-stroke UL.

From this consensus study it is anticipated a guideline for the use of UL FES post-stroke will be developed.

4. **Why have you asked me to take part?**

You have been invited to participate in this Delphi study because you are working with FES both clinically and/or in a research capacity, and/or you are an expert in UL rehabilitation.

5. **Do I have to take part?**

It is up to you to decide if you want to take part. A copy of the information provided here is yours to keep, along with the consent form if you do decide to take part. You can still decide to withdraw at any time without giving a reason, or you can decide not to answer a particular question.

6. **What will I be required to do?**

The study will take the form of 3 rounds of e-survey and each round will take approximately 30 minutes to complete.

7. **Where will this take place?**

This study is an e-study, and you will not be required to attend any specific location. You can complete the study on your own computer/laptop from your place of work or home. You will be sent an individual link to the e-survey.

8. **How often will I have to take part, and for how long?**

   If you consent to participate in this study, you will be sent an individual link for an online e-survey at 3 separate points over a 4–6-month period.

9. **If deception is involved in the study**:

   No deception is involved in this study.

10. **Are there any possible risks or disadvantaged in taking part?**

    No

11. **What are the possible benefits of taking part?**

    Hopefully you will find participating in the study interesting. The research will inform the development of clinical guidelines for the use of upper limb FES therapists following stroke.

12. **When will I have the opportunity to discuss my participation?**

    Please take the time to read the following information carefully and please contact g.scott@shu.ac.uk if there is anything that is not clear, or if you would like more information about the study.

13. **Will anyone be able to connect me with what is recorded and reported?**

    All information collected about you during the course of the research will be kept strictly confidential and your name will not be used in any publications or research reports. Nobody other than the doctoral researcher and supervisory team will be able to connect you with what is recorded and reported; as to ensure confidently a preface method will be applied where participants are assigned a number to protect their identity under the jurisdiction outlined in the ICO 'Anonymisation code of practice'.

14. **Who will be responsible for all of the information when this study is over**?

    The doctoral researcher (Gerry Scott: g.scott@shu.ac.uk) and supervisory team (Dr Christine Smith and Dr Mark Collins).

15. **Who will have access to it?**

    Whilst research data is kept within the SHURA system, only the supervisory team will have access to raw research data in order to maintain confidentiality.

16. **What will happen to the information when this study is over?**

    If you consent to participating in this research, data will be stored on Qualtrics (password protected and SHU approved software) until data analysis is complete (approximately three months from the questionnaires closing). The data, once the questionnaire has finished, will be converted to Excel spreadsheets, and will be secured in a password protected and encrypted SHU system folder. Once the study is completed, anonymised research data will be archived as digital files for 7 years, within the SHURA repository. After this time, raw data will be destroyed.

17. **How will you use what you find out?**

Data will be used for academic purposes in the forms such as peer review scientific journals, conference proceedings and a PhD thesis. The research will inform the development of clinical guidelines for the use of upper limb FES following stroke.

18. **How long is the whole study likely to last?**

The study will take the form of 3 rounds of e-survey and each round will take approximately 30 minutes to complete. You will be sent an individual link for an online e-survey at 3 separate points over a 4–6-month period.

19. **How can I find out about the results of the study?**

The outcomes from this research study will be used to inform the development of upper limb FES clinical guidelines.

Participants need to be given the opportunity to ask any further questions or seek clarification.

This information needs to be provided at the end.

Details of who to contact if you have any concerns or if adverse effects occur after the study are given below.

There are no risks to taking part in the study. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, Sheffield Hallam complaints processes will be available to you (please see below):

Researcher/ Research Team Details:

- Gerry Scott: g.scott@shu.ac.uk
- Dr Christine Smith
- Dr Mark Collins

You should contact the Data Protection Officer if:

- you have a query about how your data is used by the University.
- you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately)
- you would like to complain about how the University has used your personal data.

DPO@shu.ac.uk

You should contact the Head of Research Ethics (Dr Mayur Ranchordas) if:

- you have concerns with how the research was undertaken or how you were treated.

ethicssupport@shu.ac.uk

Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT Telephone: 0114 225 5555

10.4.5 Delphi data management plan

Data Management Plan: Consensus of the use of upper limb (UL) functional electrical stimulation (FES) post-stroke: A Delphi study.

What data will you collect or create? How will your data be documented and described?

Digital data will be in the form of participant surveys and consent digitally signed by the participants, held on the Sheffield Hallam University approved platform Qualtrics, and also converted to a password-protected excel document, and an SPSS file in an encrypted file on the SHU Q drive. With participant anonymity retained, the data will be documented in a PhD thesis and a peer-reviewed journal manuscript. Any information will not mention specific questionnaire information and instead the dataset will be kept vague to maintain confidentiality. Raw data files (Meta data from Excel and Qualtrics) will be placed within the thesis methodology and appendices. The ethics documentation will be submitted and reviewed through Converis and the university research ethics committee before data collection may commence. Revisions will be made using the feedback from the independent ethics reviewers.

Relevant ethics forms will be submitted through Converis and the university research ethics committee before data collection takes place. Delphi participants will be given consent and information forms before the study takes place; these will be situated on a landing page of the Qualtrics questionnaire. These are expected to be signed in order for the participant to take part in the survey. In the consent form and information sheet, participants will be reminded of their right to withdraw anytime they wish. Participant contact details will be separated from the questionnaire data. This file will be password protected and kept on an encrypted SHU drive (Q drive). If any sensitive information besides name and email is divulged by the participant, this will be censored or removed from the data collection. A debrief sheet (as a separate page on the Qualtrics questionnaire) will be administered after each Delphi round, containing researcher contact details and details regarding the timing and content of the next Delphi round. Regarding copyright, this study will follow SHU guidelines and suggest that the person who produces the research text, in this case the primary researcher, will have copyright in the work. The researchers have stipulated on the information sheet that in the event of the participant wanting to withdraw their data, they will need to contact the lead researcher via email or telephone, to have their survey data deleted. Withdrawal of data will be allowed within 2 weeks of each round of the Delphi study closing.

How will your data be structured, stored, and backed up?

Data will be stored in the following way. Questionnaire for each Delphi round will be recorded digitally and will be stored on Qualtrics (password protected and SHU approved software). Data will be stored on Qualtrics until data analysis is complete (approximately three months from the questionnaires closing) in case the researcher finds any issue with data corruption in files after moving this to Excel and SPSS. The data, once the questionnaire has finished, will be converted to Excel spreadsheets, and will be secured in a password protected and encrypted SHU system folder on Q drive. Once the study is completed, anonymised research data will be archived as digital files for 7 years, within the SHURA repository. After this time, raw data will be destroyed. Whilst research data is kept within the SHURA system, only the supervisory team will have access to raw research data in order to maintain confidentiality.

Nobody other than the doctoral researcher and supervisory team will be able to connect the participants with what is recorded and reported; as to ensure confidently, we will apply a preface method where participants are assigned a number to protect their identity under the jurisdiction outlined in the ICO 'Anonymisation code of practice'. Data will be used for academic purposes in the forms such as peer review scientific journals, conference proceedings and a PhD thesis.

How will you manage any ethical issues?

Saving the files under the preface P1, P2, P4 will ensure the pseudonymisation of participants.

What are your plans for data sharing after submission of your thesis?

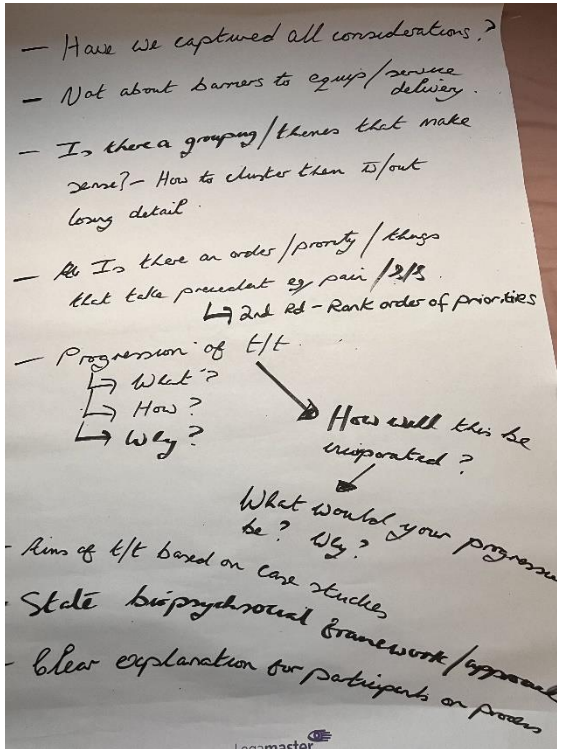
The data generated from this study will not be applicable for data sharing due to the participant grouping.

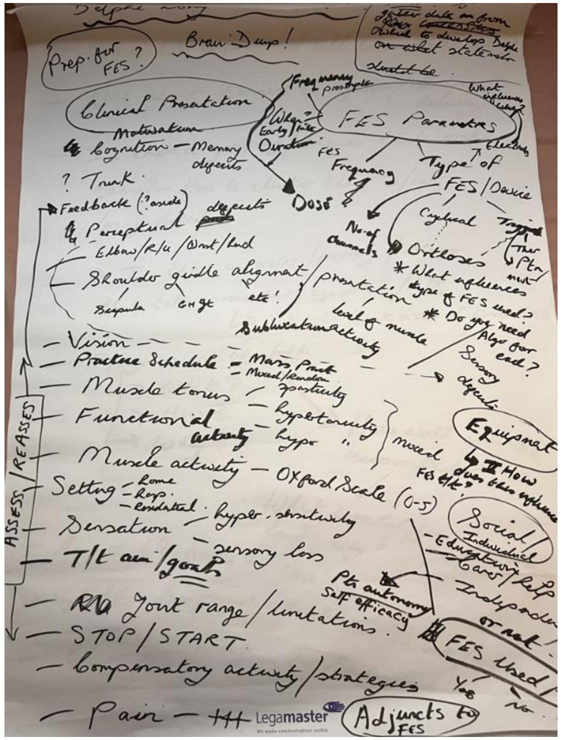
What are your plans for the long-term preservation of data supporting your research?

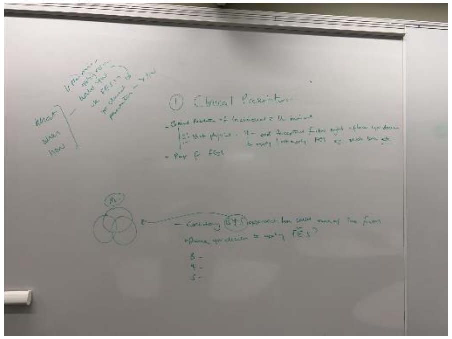
Once the study is completed, anonymised research data will be archived as digital files for 7 years, within the SHU repository. After this time, raw data will be destroyed. Whilst research data is kept within the SHU repository system, only the supervisory team will have access to raw research data in order to maintain confidentiality.

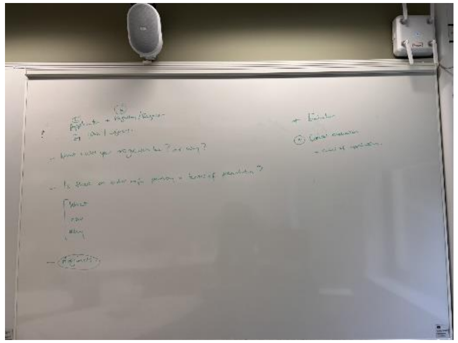
10.4.6 Round one open ended questions

Brainstorm meeting pre-development of round one open ended questions.









Delphi round one open ended questions:

Section 1

Q1: Reflecting on your experiences, could FES to the upper limb be useful post-stroke? Please expand on your answer and provide examples where you feel appropriate.

Q2: What physical, psychological social and perceptual/cognitive factors (if any) could influence your decision to apply/not apply upper limb FES? (e.g. muscle tone, cognition, motivation). Please state as many as apply and order these in terms of priority/precedent.

Q3: What preparation (if any) of the individual might you need to consider before applying FES? (e.g. upper limb mobilisation, trunk alignment). Please expand your answer with specific aspects of individual preparation you might need to consider to formulate your clinical decision.

Q4: Other than the known contraindications, are there any other reasons you would not consider an individual for upper limb FES? Please state as many that may apply.

Section 2

Q1: What type of FES (if any) do you use (e.g. triggered, cyclical)? Please state as many as apply. Please expand on the reasons for why or why not, providing examples where you feel it appropriate.

Q2: Do you use any adjuncts to treatment or equipment alongside FES? (Yes, No).

If Yes: Please list the adjuncts to treatment or equipment you might use. Please also expand on your reasons for using adjuncts to treatment or equipment alongside FES. Please provide examples where you feel it appropriate (e.g. does the use of equipment/adjuncts influence FES treatment?)

If No: Please expand on your reasons for not using adjuncts to treatment or equipment alongside FES.

Q3: If you use FES, what variables do you use to decide the dosage? Please state as many as apply and order these in terms of priority/precedent. Please provide examples where you feel it appropriate, addressing What, How and Why.

Q4: Would you enable the FES user to independently use the FES equipment?

If Yes: What factors might need to be considered? Please state as many as apply and order these in terms of priority.

If No: What factors did you use to formulate your decision to not allow the user to use FES equipment independently. Please state as many as apply and order them in terms of priority.

Section 3

Q1: In terms of FES treatment progression, what factors would inform your clinical decision to progress the use of FES? Please expand on your answer, providing examples where you feel these are appropriate.

Q2: When and why might you discontinue using FES? Please expand your answer with specific aspects you might need to consider to formulate your clinical decision.

Section 4

Q1: How would you evaluate/measure the use of FES? Please state as many as apply.

10.4.7 Round two and three short answer questions

Section 1: Clinical presentation

- UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation.
- UL FES can improve motor control and decrease spasticity in subacute and chronic stroke.
- Application of FES on the shoulder complex has a positive impact on the management of post-stroke hemiplegic shoulder pain.
- FES can be used to stimulate muscles stabilisers of the shoulder.
- UL co-ordination can be improved if UL FES is used to stimulate the correct sequence and timing of muscles.
- UL FES can be used as a tool to motivate patients in the early stages of recovery post-stroke.
- Application of UL FES can prevent muscle atrophy.
- UL FES can be applied to increase joint range of motion in patients with UL hypertonicity.
- UL FES can be effective in the management of learnt non-use.
- UL FES can reduce sensory inattention of the hemiplegic UL.
- A painful shoulder would be the main reason for applying UL FES to hemiplegic subluxed shoulder.
- UL FES can be used where there is no residual movement or function.
- Sufficient cognitive ability is required to understand the aims of UL FES treatment.
- Severe cognitive impairment would inhibit the use of UL FES.
- The patient must be able to give informed consent to apply UL FES
- Patient motivation to engage with UL FES needs to be established prior to application.
- Patient commitment to an UL FES treatment plan is required. The patient should be able to apply regularly (either independently or with aid of carers, family, therapists)
- Patient compliance with an UL FES treatment plan is required.
- To gain maximum benefit from UL FES the patient needs to be able to see progress
- Affordability of FES equipment might impact the decision to commence with UL FES as a treatment option.
- The practice environment for application of UL FES should be considered as this could impact the treatment application.
- A cognitive impairment that inhibits the patient from engaging with UL FES would inhibit application.
- A patient presenting with severe anxiety, agitation and/or confusion should not be considered for UL FES.
- If a patient is unable to engage in functional tasks, even when postural support is provided, UL FES should not be applied.

- Patient engagement with UL FES is essential when considering application.
- Poor adherence to application would influence the decision to apply UL FES.
- UL FES can be suitable for UL oedema management and prevention of UL muscle atrophy.

Section 2: Application

- Appropriate measures need to be taken prior and post UL FES application to measure progress.
- Tolerance for UL FES should be assessed prior to application UL.
- UL FES should not cause any discomfort.
- Individual patient centred goals need to be established prior to use of UL FES and monitored to identify the impact of UL FES application.
- Patients should be educated in the use of UL FES.
- Posture of the trunk and neck are important to consider and assess pre UL FES application.
- Active UL movement should be assessed prior to application of UL FES.
- Passive and active joint ROM should be assessed prior to UL FES application.
- UL alignment including the glenohumeral joint and scapula should be assessed pre application of UL FES.
- Skin integrity must be assessed prior to decision to apply UL FES.
- UL sensation should be assessed prior to UL FES application.
- Priming activities such as UL stretching and joint mobilisations should be considered prior to application of UL FES.
- Treatment goals should be agreed prior to commencing UL FES.
- Goals of UL FES treatment should be regularly reviewed and clearly documented.
- UL FES should be used in conjunction with conventional UL treatment.
- UL FES where possible should be used in conjunction with task specific training/ exercise.
- A clear UL FES practice schedule should be documented and communicated to the patient.
- The patient should be in a well-supported appropriate position during UL FES application.
- A rationale for UL FES use should be agreed and documented.
- Adverse effects to UL FES must be regularly monitored and documented.
- Cyclical UL FES can be used prior to task orientated activity with or without FES.
- Patient triggered UL FES can help with motivation and engagement in upper limb recovery.
- When applying UL FES the user should always be taught self-passive movements.
- UL FES should always be applied at a comfortable level for the patient and then built up whilst remaining within tolerance levels.

- UL FES programme intensity should be increased gradually to a level where a functional outcome is achieved.
- UL FES stimulation frequency of between 20-35Hz should be used so as to not fatigue the stimulated muscle(s).
- Dosage of stimulation of UL FES should be incrementally increased over time to ensure no adverse responses and to minimise the chance of muscle fatigue.
- Intensity of stimulation of UL FES should be dependent on what is required to achieve the necessary muscle contraction.
- Lower FES frequencies should be used when the target muscle is presenting with high levels of spasticity.
- Dose of training of UL FES should be quantified by the number of repetitions of a task or tasks.
- UL FES training needs to take account of the amount of training time the patient can commit to.
- UL FES dose of training should be dependent on individual patient existing ability and muscle fatigue.
- UL FES dose of training should consider individual patient motivation to engage with the training schedule.
- Patients with good cognition should be given a home program for UL FES use.
- All UL FES patients should have a good understanding of usage and application if using independently.
- Safety of UL FES application should always be assessed prior to decision about independent use.
- If support is needed to use UL FES then family/carer support should be taken into consideration when making a decision about independent use.
- User expectation of UL FES should be taken into consideration and discussed pre-treatment.
- Triggered UL FES should be used in combination with task based UL practice.
- Cyclical UL FES can be useful when functional movement is limited.

Section 3: Treatment Progression

- Improvement in UL muscle strength could justify a progression of FES usage.
- Improvement in consistency and quality of UL movements could justify a progression of UL FES usage.
- Increased functional use of the hemiplegic UL could justify a progression of UL FES usage.
- Meaningful benefits to the user of UL FES should be taken into consideration when deciding on treatment progression.
- Variability of UL FES usage could be important to maintaining user interest and motivation.

- UL FES progression could include increasing number of movement repetitions, duration of movement practice or complexity of movement.
- A lack of measurable improvement could justify discontinuing the use of UL FES.
- UL FES should be discontinued when the patient is able to perform the task/movement independently.
- UL FES should be discontinued when comorbid medical diagnosis requires UL FES discontinuation.
- UL FES should be discontinued when the patient shows signs of notable adverse effects/reaction.
- UL FES could be discontinued if the patient is not achieving their goals.
- Upper limb FES should be discontinued if the individual user does not want to continue with FES application/use.
- UL FES should be discontinued when a patient is demotivated and perceived no benefit in UL FES application.
- UL FES could be discontinued when a patient has accepted their level of UL functional movement.
- UL FES could be discontinued if the patient is facing application issues due to lack of family/carer support in the community/home environment.
- UL FES could be discontinued when the patient has improved quality of life and no longer sees the benefit of continued UL FES application.
- UL FES could be discontinued when the patient is able to fully perform the specific task without UL FES.

Section 4: Treatment evaluation

- UL FES use should be evaluated using appropriate standardised, evidence based outcome measures.
- Goal attainment scales/measures should be used when evaluating the use of UL FES.
- A combination of functional and patient reported measures should be used when evaluating the use of UL FES.
- Assessment tools that contribute to the ICF assessment should be used to evaluate the use of UL FES.
- Patient feedback about UL FES should be taken into consideration when evaluating treatment.
- Patient reported outcome measures should be used when evaluating the use of UL FES.
- Carer feedback should be considered when evaluating/measuring the use of UL FES.
- Activity monitors should be used to evaluate/measure the use of UL FES.

- Use of motion capture and video should be used to evaluate/ measure the use of UL FES.
- Understanding individual patient goals should be established to direct the application of UL FES.

10.4.8 Final Delphi statements

Section 1: Clinical presentation

- UL FES should be used in the early stages (first 6 weeks) of post-stroke rehabilitation.
- UL FES can improve motor control and decrease spasticity in subacute and chronic stroke.
- Application of FES on the shoulder complex has a positive impact on the management of post-stroke hemiplegic shoulder pain.
- FES can be used to stimulate muscles stabilisers of the shoulder.
- UL co-ordination can be improved if UL FES is used to stimulate the correct sequence and timing of muscles.
- UL FES can be used as a tool to motivate patients in the early stages of recovery post-stroke.
- Application of UL FES can prevent muscle atrophy.
- UL FES can be applied to increase joint range of motion in patients with UL hypertonicity.
- UL FES can be effective in the management of learnt non-use.
- UL FES can reduce sensory inattention of the hemiplegic UL.
- A painful shoulder would be the main reason for applying UL FES to hemiplegic subluxed shoulder.
- UL FES can be used where there is no residual movement or function.

- Sufficient cognitive ability is required to understand the aims of UL FES treatment.
- Severe cognitive impairment would inhibit the use of UL FES.
- The patient must be able to give informed consent to apply UL FES.
- Patient motivation to engage with UL FES needs to be established prior to application.
- Patient commitment to a UL FES treatment plan is required. The patient should be able to apply regularly (either independently or with aid of carers, family, therapists).
- Patient compliance with a UL FES treatment plan is required.
- To gain maximum benefit from UL FES, the patient needs to be able to see progress.
- Affordability of FES equipment might impact the decision to commence with UL FES as a treatment option.
- The practice environment for application of UL FES should be considered as this could impact the treatment application.
- A cognitive impairment that inhibits the patient from engaging with UL FES would inhibit application.
- A patient presenting with severe anxiety, agitation and/or confusion should not be considered for UL FES.
- If a patient is unable to engage in functional tasks, even when postural support is provided, UL FES should not be applied.
- Patient engagement with UL FES is essential when considering application.
- Poor adherence to application would influence the decision to apply UL FES.
- UL FES can be suitable for UL oedema management and prevention of UL muscle atrophy.

Section 2: Application

- Appropriate measures need to be taken pre- and post-UL FES application to measure progress.
- Tolerance for UL FES should be assessed prior to application.
- UL FES should not cause any discomfort.
- Individual patient-centred goals need to be established prior to use of UL FES and monitored to identify the impact of UL FES application.
- Patients should be educated in the use of UL FES.
- Posture of the trunk and neck are important to consider and assess pre-UL FES application.
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- UL alignment including the glenohumeral joint and scapula should be assessed pre application of UL FES.
- Skin integrity must be assessed prior to decision to apply UL FES.
- UL sensation should be assessed prior to UL FES application.
- Priming activities such as UL stretching, and joint mobilisations should be considered prior to application of UL FES.
- Treatment goals should be agreed prior to commencing UL FES.
- Goals of UL FES treatment should be regularly reviewed and clearly documented.
- UL FES should be used in conjunction with conventional UL treatment.

- UL FES where possible should be used in conjunction with task specific training/ exercise.
- A clear UL FES practice schedule should be documented and communicated to the patient.
- The patient should be in a well-supported appropriate position during UL FES application.
- A rationale for UL FES use should be agreed and documented.
- Adverse effects to UL FES must be regularly monitored and documented.
- Cyclical UL FES can be used prior to task-orientated activity with or without FES.
- Patient-triggered UL FES can help with motivation and engagement in upper limb recovery.
- When applying UL FES, the patient should always be taught self-passive movements.
- UL FES should always be applied at a comfortable level for the patient and then built up whilst remaining within tolerance levels.
- UL FES programme intensity should be increased gradually to a level where a functional outcome is achieved.
- UL FES stimulation frequency of between 20–35Hz should be used so as to not fatigue the stimulated muscle(s).
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